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Sutezolid external deck Oct 2012 conf unprotected.pptx
PNU-0100480 IB 2012.pdf
ResearchSolidFormNomination2341272 final.pdf
PF02341272SaltScreen Memo03Sept09.pdf
BR Reblinded CTSUR 22-JAN-2013 21-JUL-2013 PNU-100480.pdf
PF-02341272 PNU-0100480 IB 2012.pdf
PC29228Report.pdf
SimCYP Model Development and Simulation for PNU-100480 - 04-11-11.pptx
PNU DDI DiscussionMay2012.ppt
FaceToFaceMeetingRequestTracker.xlsx
PNU-100480Drug Product Design Risk AssessmentREDACTED.pdf
Universal PbO Oval Tablet 21 MCCLactose CM-1521009 09-080751 CSM Groton 11Jan2010.pdf
Taurus SQ Files for Transfer.msg
00216pfizersutezolidpkpdsigned21aug13corrected.docx
00216pfizersutezolidpkpdsigned21aug13corrected.pdf
DAWSON Results1.tif
DAWSON Results.tif
DIACON results1.zip
DIACON Results.zip
Sutezolid MSDS.pdf
PF02341272SaltScreen Memo03Sept09.pdf
ResearchSolidFormNomination2341272 final.pdf
PNU-100480 July 2013 SUSAR LL.pdf
Vendor ListsutezolidAug2013.xlsx

00216pfizersutezolidpkpdfinal21aug13.pdf

DRAFTAnnual report EU-3-11-897.pdf

Sutezolid Annual Report Filings.docx

Study B1171003 - PMAR00318.doc

Memo TB2 MS 130723[1].pdf

PRES Pfizer TB2 130109 with questions[1].ppt

PRES Pfizer TB2 130301[1].ppt

PRES Pfizer TB2 130403[1].ppt

PRES Pfizer TB2 130624[1].ppt

PF-02341272 initial and stability_01_09 JUL2008.xls

PF-02341272Validation_Jul2008.xls

Processing method_Jul2008.pdf

Stability standard after 7 days_instrmeth_18Aug2008.pdf

Stability standard after 7 days_Jul2008.pdf

Stability standard after 7 days_LOQ_18Aug2008.pdf

Stability standard after 7 days_procmeth_18Aug2008.pdf

Stability standard after 7 days_sequence_18Aug2008.pdf

TM100000957.doc.pdf

TM000004394.doc.pdf

Andy CEN entry 00701319-0001v3_1565710358483.pdf

Doug's CEN 00700247-0016v1_1565710458562.pdf

instrument method_Jul2008.pdf

LOQ_Jul2008.pdf

method sequence_Jul2008.pdf

PF-02341272 (Achiral Purity mthd).doc

INX000071988.pdf

PNU-0100480 Campaign Summary Report from SAFC R2 Campaign (Pfizer lots GR03496, GR03497, GR03498)_1.pdf

CSR-038_(P72-005_OKO_Report).pdf.pdf

HA Incoming Corrspd Archival Form.doc.pdf

08 09 13 FDA Comments on 07 03 13 Submission.pdf

allformats.xpt

IND 104806Diff28Aug2013.xls

HA Incoming Corrspd Archival Form.doc.pdf

B1171003datav9.xpt

B1171003datavaiv9.xpt

Annual report EU-3-11-897.pdf

EU ROC 537576.Report.pdf

CL ODD.pdf

HA Incoming Corrspd Archival Form.doc.pdf

08 09 13 FDA Comments on 07 03 13 Submission.pdf

B1171002datav9.xpt

B1171002datavaiv9.xpt

B1171001datav9.xpt

B1171001datavaiv9.xpt

B1171003AnnotatedeCRFs31JUL2013.pdf

index-md5.txt

index.xml

index-md5.txt

index.xml

Notice Of Grant-033817A-RUSS-2011108026-G-493933-Granted Patent and Claims.msg

PC33817 Family and Due Date Report.xlsx

US-OrphanPNU 10048029May2013.xls

PC033817Annuities.xls

ectd-2-0.xsl

us-regional.xsl

ectd-2-0.xsl

ich-stf-stylesheet-2-2a.xsl

us-regional.xsl

valid-values.xml

B117B1171003100310031001null.pdf

B117B1171003100310031002null.pdf

B117B1171003100310031003null.pdf

B117B1171003100310031004null.pdf

B117B1171003100310031005null.pdf

B117B1171003100310031006null.pdf

B117B1171003100310031008null.pdf

B117B1171003100310031009null.pdf

B117B1171003100310031011null.pdf

B117B1171003100310031013null.pdf

B117B1171003100310031012null.pdf

B117B1171003100310031014null.pdf

B117B1171003100310031015null.pdf

B117B1171003100310031016null.pdf

B117B1171003100310031017null.pdf

B117B1171003100310031018null.pdf

B117B1171003100310031019null.pdf

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B117B1171003100310031021null.pdf

B117B1171003100310031022null.pdf

B117B1171003100310031025null.pdf

B117B1171003100310031026null.pdf

B117B1171003100310031027null.pdf

B117B1171003100310031028null.pdf

ich-ectd-3-2.dtd

ich-stf-v2-2.dtd

us-regional-v2-01.dtd

B117B1171003100210021001null.pdf

B117B1171003100210021002null.pdf

B117B1171003100210021004null.pdf

B117B1171003100210021005null.pdf

B117B1171003100210021006null.pdf

B117B1171003100210021008null.pdf

B117B1171003100210021007null.pdf

B117B1171003100210021009null.pdf

B117B1171003100210021010null.pdf

B117B1171003100210021012null.pdf

B117B1171003100210021013null.pdf

B117B1171003100210021014null.pdf

B117B1171003100210021015null.pdf

B117B1171003100210021016null.pdf

B117B1171003100210021017null.pdf

B117B1171003100210021018null.pdf

B117B1171003100210021019null.pdf

B117B1171003100210021020null.pdf

B117B1171003100210021021null.pdf

B117B1171003100210021023null.pdf

B117B1171003100210021024null.pdf

B117B1171003100210021025null.pdf

B117B1171003100210021026null.pdf

B117B1171003100210021027null.pdf

B117B1171003100210021028null.pdf

B117B1171003100210021029null.pdf

B117B1171003100210021031null.pdf

B117B1171003100210021032null.pdf

B117B1171003100210021034null.pdf

B117B1171003100210021033null.pdf

B117B1171003100210021035null.pdf

B117B1171003100210021037null.pdf

B117B1171003100210021038null.pdf

B117B1171003100210021039null.pdf

HA Incoming Corrspd Archival Form.doc.pdf

Orphan Drug AR 2013.pdf

FDA CorrespPNU100480021411.pdf

ich-ectd-3-2.dtd

us-regional-v2-01.dtd

PNU-100480 ODD Request.pdf

References.pdf

Cover Letter.pdf

033817A-CANA-2735229-F-493922-EFRFileWrapper.pdf

IND 10480628May2013.xls

IND 104806diff09Jul2013.xls

IND 104806diff24Jun2013.xls

CCLRATaurusR1.xls

DEATaurusPFEARGStudyR1.pdf

ROCUSPNU 10048028May2013.xls

cover.pdf

1571.pdf

us-regional.xml

1571.pdf

us-regional.xml

cover.pdf

ROC 121464.Report.pdf

ROC 120103.Report.pdf

Division Comments email 01-28-2010.pdf

01 28 2010 Comments to Sponsor for 12 23 09 submission.pdf

ROC 121022.Report.pdf

HA Incoming Corrspd Archival Form.doc.pdf

1.ROC 121464.Report.pdf

1.ROC 120103.Report.pdf

3.10 23 09 Fax Clinical Comments.pdf

2.10 23 09 Fax Clinical Comments Email.pdf

1.ROC 121022.Report.pdf

2.Division Comments email 01-28-2010.pdf

3.01 28 2010 Comments to Sponsor for 12 23 09 submission.pdf

10 23 09 Fax Clinical Comments Email.pdf

10 23 09 Fax Clinical Comments.pdf

2011-06-28-ClinicalTrialAgreementConfirmation-NotetoFile194671758.pdf

2009-10-08-IIPLetters-Approval177206400.pdf

2010-05-22-CorrspdwithSite179122003.pdf

2009-11-09-CorrspdwithSite174528783.pdf

2010-05-26-CorrspdwithSite179263319.pdf

2011-04-15-Affidavit190650349.pdf

2011-06-17-CSR-PIAcknowledgmentofReceipt201104334.pdf

2010-05-10-ProtocolDeviationsLog179122351.pdf

2009-08-10-CV-SubInvestigator-OnePage-UDERMAN,HOWARDD173273956.pdf

2009-08-14-CV-SubInvestigator-OnePage-HANSSON,ARNEG173274286.pdf

2009-09-02-CV-SubInvestigator-OnePage-PAWLAK,SYLVESTERS173274102.pdf

2009-09-06-CV-PrincipalInvestigator-OnePage-BEDARIDA,GABRIELLA173273953.pdf

2009-09-11-IRBIECCorrspd173274199.pdf

2009-08-17-IRBIECPanelMembershipNon-VotingStatus173484063.pdf

2009-09-21-IRBIECSubmissionFilingPackage173418605.pdf

2009-09-29-IRBIECApproval-1572ProtICDIBSafety173484296.pdf

2009-12-21-IRBIECApproval-ProtAmendICD175790225.pdf

2010-03-01-IRBIECCorrspd-SAE177120460.pdf

2010-03-02-IRBIECAApproval-ICD177097581.pdf

2010-03-02-IRBIECSafetySAENotification-SAE177203949.pdf

2010-03-25-IRBIECSafetySAENotification-IBSafety177741537.pdf

2010-04-19-IRBIECAckofReceipt-IBSafety178196752.pdf

2010-04-01-IRBIECAApproval-ICDProtAmend177899605.pdf

2010-06-28-IRBIECStudyCloseOutCommunications181069171.pdf

2009-09-21-FDA1572173274378.pdf

2009-10-05-IIPTransmittal173517298.pdf

2008-12-21-InformedConsentFormsChklstApprDRF-Center175916087.pdf

2009-09-28-InformedConsentFormsChklstApprDRF-Center173515789.pdf

2009-09-29-LocalAdvertApprovalDRF(2)173484107.pdf

2009-09-29-InformedConsentForms173483855.pdf

2009-09-29-LocalAdvertApprovalDRF173483968.pdf

2009-12-21-InformedConsentForms175789987.pdf

2010-03-02-InformedConsentForms177097642.pdf

2010-03-02-InformedConsentFormsChklstApprDRF-Center177097403.pdf

2010-04-01-InformedConsentForms177899949.pdf

2010-04-01-InformedConsentFormsChklstApprDRF-Center177899854.pdf

b1171003-adverse-events.pdf

b1171003-analytical-reports.pdf

b1171003-compliance.pdf

b1171003-discontinued-patients.pdf

b1171003-demographics.pdf

b1171003-efficacy-response.pdf

b1171003-invest-signature.pdf

b1171003-informed-consent.pdf

b1171003-investigators.pdf

b1171003-lab-measurements.pdf

b1171003-patient-batches.pdf

b1171003-protocol-deviations.pdf

b1171003-protocol.pdf

b1171003-report-body.pdf

b1171003-randomization.pdf

b1171003-sample-crf.pdf

b1171003-sap.pdf

b1171003-sponsor-signature.pdf

b1171003-synopsis.pdf

b1171003-summary-of-changes.pdf

stf-b1171003.xml

2009-09-15-InvestigatorProtocolAcceptanceForm173274099.pdf

2010-03-23-InvestigatorProtocolAcceptanceForm177852362.pdf

2009-12-16-InvestigatorProtocolAcceptanceForm175767259.pdf

2009-12-17-InvestigationalProductAccountabilityLog-MultipleSubjects183583275.pdf

2010-01-15-InvestigationalProductAccountabilityLog-MultipleSubjects183583566.pdf

2009-12-23-ClinicalSupplyCorrspd175916021.pdf

2010-10-06-InvestigationalProductAccountabilityLog-MultipleSubjects(2)183583779.pdf

2010-10-06-InvestigationalProductAccountabilityLog-MultipleSubjects(4)183583521.pdf

2010-10-06-InvestigationalProductAccountabilityLog-MultipleSubjects(7)183583276.pdf

2010-10-06-InvestigationalProductAccountabilityLog-MultipleSubjects(9)183583525.pdf

2010-10-06-InvestigationalProductAccountabilityLog-MultipleSubjects(8)183583571.pdf

2009-04-24-LocalLabNormalRanges173274383.pdf

FDA Communication IND 104806-PNU100480-Pfizer-Response to 52913 Submission.pdf

2010-08-20-CriticalInformationSheet183482342.pdf

2010-09-15-Pre-TrialAssessmentReport183257244.pdf

2011-02-08-SiteVisitLog204508868.pdf

2011-02-22-SiteTrainingCertification199590678.pdf

2011-02-23-SiteTrainingCertification-GCPTTraining191973846.pdf

2011-03-23-SiteTrainingCertification-GCPTTraining191966611.pdf

2011-04-01-SiteTraining-GCP-None199779379.pdf

2011-04-14-SiteTrainingCertification-GCPTTraining(2)191966353.pdf

2011-04-14-SiteTrainingCertification-GCPTTraining191966449.pdf

2011-04-27-SiteTrainingCertification-GCPTTraining191975478.pdf

2011-05-11-EDCComplianceDocumentation204508580.pdf

2011-05-15-SiteTrainingCertification-GCPTTraining191974628.pdf

2011-06-27-SiteTrainingCertification197227028.pdf

2011-06-27-SiteTrainingCertification(2)197831905.pdf

2011-06-29-ContactReport195335762.pdf

2011-07-01-SiteTrainingCertification(2)198027066.pdf

2011-07-01-SiteTrainingCertification198021079.pdf

2011-07-19-SiteTrainingCertification-EDCTTraining197896426.pdf

2011-07-21-SiteTrainingCertification-EDCTTraining197901569.pdf

2011-07-26-SiteTrainingCertification-EDCTTraining(2)197896408.pdf

2011-07-28-SiteTrainingCertification-EDCTTraining197890546.pdf

2011-07-26-SiteTrainingCertification-EDCTTraining197896301.pdf

2011-07-29-SiteTrainingCertification-EDCTTraining197891566.pdf

2011-08-16-MonitoringVisitActionFollowupForm196671342.pdf

2011-08-02-SiteTrainingCertification-EDCTraining197895045.pdf

2011-08-16-SiteInitiationReport195594123.pdf

2011-08-19-SiteTrainingCertification198022731.pdf

2011-08-28-SiteTrainingCertification-EDCTraining197891535.pdf

2011-09-16-MonitoringVisitActionFollowupForm(2)197804611.pdf

2011-09-16-MonitoringVisitActionFollowupForm196671174.pdf

2011-09-16-MonitoringVisitReport196321847.pdf

2011-10-06-MonitoringVisitActionFollowupForm(2)197804434.pdf

2011-10-06-MonitoringVisitActionFollowupForm197804337.pdf

2011-10-06-MonitoringVisitReport196863991.pdf

2011-10-06-SiteTrainingCertification-OtherTraining198021926.pdf

2011-10-18-MonitoringVisitActionFollowupForm197804521.pdf

2011-10-14-SiteTrainingCertification-EDCTraining197470376.pdf

2011-10-18-MonitoringVisitReport197123447.pdf

2011-10-18-SiteTrainingCertification200695122.pdf

2011-10-24-SiteTrainingCertification-EDCTraining197900117.pdf

2011-11-08-MonitoringVisitActionFollowupForm197804186.pdf

2011-10-31-SiteTrainingCertification-OtherTraining197894503.pdf

2011-11-08-MonitoringVisitReport197693865.pdf

2011-12-06-MonitoringVisitReport198941500.pdf

2011-12-06-MonitoringVisitActionFollowupForm201886282.pdf

2012-01-13-MonitoringVisitActionFollowupForm201885335.pdf

2012-01-13-MonitoringVisitReport199939340.pdf

2012-01-26-MonitoringVisitActionFollowupForm201885696.pdf

2012-01-26-MonitoringVisitReport200303149.pdf

2012-02-29-SiteTraining-GCP-DAWSON,RODNEY204812053.pdf

2012-02-29-SiteTraining-GCP-None(10)204809901.pdf

2012-02-29-SiteTraining-GCP-NARUNSKY,KIM204811465.pdf

2012-02-29-SiteTraining-GCP-None(2)204811456.pdf

2012-02-29-SiteTraining-GCP-None(3)204810289.pdf

2012-02-29-SiteTraining-GCP-None(4)204809892.pdf

2012-02-29-SiteTraining-GCP-None(5)204812050.pdf

2012-02-29-SiteTraining-GCP-None(6)204811462.pdf

2012-02-29-SiteTraining-GCP-None(7)204810496.pdf

2012-02-29-SiteTraining-GCP-None(8)204810295.pdf

2012-02-29-SiteTraining-GCP-None(9)204812056.pdf

2012-02-29-SiteTraining-GCP-None204812047.pdf

2012-02-29-SiteTraining-GCP-SMIT,TANYA204811459.pdf

2012-02-29-SiteTraining-GCP-SYMONS,GREGORYJOHN204810292.pdf

2012-02-29-SiteTraining-GCP-WHALE,CAROLYNANNE204810490.pdf

2012-03-09-ProtocolDeviationsLog201204739.pdf

2012-07-16-SiteClose-OutLetter204508962.pdf

2012-07-17-SiteCloseOutReport204598914.pdf

2012-07-17-SiteVisitLog204508965.pdf

2012-08-14-DataHandlingConventionInvestigatorEndorsement205201482.pdf

2012-07-25-InformedConsentTrackingLog204557928.pdf

2012-12-12-ScreenandEnrollmentLog204508571.pdf

2011-05-13-CV-SubInvestigator-OnePage-SYMONS,GREGORYJOHN191974232.pdf

2011-05-13-CV-SubInvestigator-OnePage-WHALE,CAROLYNANNE198021360.pdf

2011-05-16-CV-PrincipalInvestigator-OnePage-DAWSON,RODNEY191966959.pdf

2011-05-16-CV-SubInvestigator-OnePage-SMIT,TANYA191970194.pdf

2011-06-02-CV-SubInvestigator-OnePage-Narunsky,Kim192272762.pdf

2011-06-02-FinancialDisclosureForm-Dawson,Rodney192272304.pdf

2011-06-02-FinancialDisclosureForm-Narunsky,Kim192272964.pdf

2011-06-02-FinancialDisclosureForm-Smit,Tanya192272766.pdf

2011-06-02-FinancialDisclosureForm-WHALE,CAROLYNANNE201826186.pdf

2011-06-02-PersonalDataConsentForm-Other192272492.pdf

2011-06-02-PersonalDataConsentForm-PI-DAWSON,RODNEY192273072.pdf

2011-06-02-PersonalDataConsentForm-Sub-Inv-Narunsky,Kim192272861.pdf

2011-06-02-PersonalDataConsentForm-Sub-Inv-Smit,Tanya192271606.pdf

2011-06-02-PersonalDataConsentForm-Sub-Inv-WHALE,CAROLYNANNE198022100.pdf

2011-06-03-FinancialDisclosureForm-VanZyl-Smit,RichardNellis192272980.pdf

2011-06-03-FinancialDisclosureForm-Symons,GregoryJohn192272389.pdf

2011-06-03-PersonalDataConsentForm-Other(10)192273069.pdf

2011-06-03-PersonalDataConsentForm-Other(11)204594927.pdf

2011-06-03-PersonalDataConsentForm-Other(2)192272858.pdf

2011-06-03-PersonalDataConsentForm-Other(3)192272386.pdf

2011-06-03-PersonalDataConsentForm-Other(4)192272282.pdf

2011-06-03-PersonalDataConsentForm-Other(5)192271322.pdf

2011-06-03-PersonalDataConsentForm-Other(6)192272965.pdf

2011-06-03-PersonalDataConsentForm-Other(7)192272673.pdf

2011-06-03-PersonalDataConsentForm-Other(8)192272765.pdf

2011-06-03-PersonalDataConsentForm-Other(9)192272590.pdf

2011-06-03-PersonalDataConsentForm-Other192272587.pdf

2011-06-03-PersonalDataConsentForm-Sub-Inv-VanZyl-Smit,RichardNellis192272285.pdf

2011-06-03-PersonalDataConsentForm-Sub-Inv-Symons,GregoryJohn192271607.pdf

2011-06-06-CV-SubInvestigator-OnePage-VanZyl-Smit,RichardNellis192273055.pdf

2011-06-06-PersonalDataConsentForm-Other(2)192272776.pdf

2011-06-06-PersonalDataConsentForm-Other(3)196671087.pdf

2011-06-06-PersonalDataConsentForm-Other192271612.pdf

2011-08-15-SignatureSheetandDelegationofDutiesLog-Ongoing199631545.pdf

2011-08-16-SignatureSheetandDelegationofDutiesLog(2)198022115.pdf

2011-08-16-SignatureSheetandDelegationofDutiesLog197191557.pdf

2011-08-23-CV-Other(2)197470048.pdf

2011-08-23-CV-Other197469961.pdf

2011-09-10-MedicalLicenses198022710.pdf

2011-10-18-PersonalDataConsentForm-Other197470042.pdf

2011-11-14-SignatureSheetandDelegationofDutiesLog197894115.pdf

2011-12-12-CV-Other199780063.pdf

2011-12-12-SignatureSheetandDelegationofDutiesLog-Ongoing199122232.pdf

2012-07-17-SignatureSheetandDelegationofDutiesLog204509148.pdf

2011-07-27-IIPTransmittal194971451.pdf

2011-06-06-FDA1572192273054.pdf

2011-08-03-IIPApproval194812152.pdf

2011-10-04-FDA1572201826659.pdf

2011-10-04-FDA1572RevisionsCoverSheet(2)201826844.pdf

2011-10-04-FDA1572RevisionsCoverSheet197224874.pdf

2011-12-12-OtherSignedAgreementwauthorities199779872.pdf

2009-12-23-RegulatoryAgenciesApplSubCoverletter-ProtocolAmend176387040.pdf

2009-09-17-RegulatoryAgenciesApplSubCoverletter-Protocol173166586.pdf

2010-04-01-RegulatoryAgenciesApplSubCoverletter-ProtocolAmend177854270.pdf

2009-11-19-CountryRegionalCorrspd-minutes175392855.pdf

2010-01-04-CountryRegionalCorrspd-minutes176122942.pdf

2010-02-03-CountryRegionalCorrspd-minutes176702905.pdf

2010-04-27-RTIStudyTreatmentSignoff189267862.pdf

2011-06-17-TMFCompletionForm193306607.pdf

2010-10-04-RTIStudyTreatmentSignoff189262183.pdf

2011-09-14-SuspectedSignificantDeviationsFindingsandConclusionsReport-SiteLevel198026856.pdf

2011-09-21-CountryRegionalCorrspd-proceduresRecruitmentRetention197165361.pdf

2011-12-02-SuspectedSignificantDeviationsFindingsandConclusionsReport-SiteLevel197932719.pdf

2011-11-17-SuspectedSignificantDeviationsFindingsandConclusionsReport197601409.pdf

2011-12-15-InternalReviewCommittee199122514.pdf

2011-12-15-SuspectedSignificantDeviationsFindingsandConclusionsReport-SiteLevel199632225.pdf

2012-03-13-CountryRegionalCorrspd201826753.pdf

2010-08-06-DataManagementPlan-DataManagementOversightPlan182383438.pdf

2010-08-27-DataManagementPlan-DataQualityControlPlanDQCP185027622.pdf

2010-08-27-DataManagementPlan-DQCPSummaryandApprovalReportforSystemRecon185027705.pdf

2010-08-27-DataManagementPlan-Study-SpecificDataEntryGuidelines185028116.pdf

2010-08-27-DataManagementPlan-DQCPSummaryandApprovalReportforDCTtoDB185027524.pdf

2010-11-12-RandomizationScheduleRequestForm202212053.pdf

2010-12-10-RandomizationScheduleRequestForm202211968.pdf

2010-12-10-TestRandomizationList-Approval197701696.pdf

2010-12-21-SampleSizeReviewForm185601574.pdf

2011-02-28-DataManagementActionFollowUp-NotetoFile190071878.pdf

2011-03-24-RandomizationScheduleRequestForm202212372.pdf

2011-03-24-TestRandomizationList-Approval197701588.pdf

2011-05-24-DataListingDocument191823799.pdf

2011-05-03-DataManagementPlan-DataFlowActivities192881540.pdf

2011-05-26-DataManagementPlan-DataQualitySpecificationsApprovalForm(2)191897624.pdf

2011-05-25-DataManagementPlan-CRFeCRFCompletionRequirements191863749.pdf

2011-05-26-DataManagementPlan-DataQualitySpecificationsApprovalForm191897809.pdf

2011-05-26-DataQualityReport(DQR)192881264.pdf

2011-06-09-StudyMonitoringPlan201664606.pdf

2011-06-16-ProtocolRecruitmentPlan201664793.pdf

2011-06-17-DataManagementPlan-DataQualitySpecificationsApprovalForm(2)192894684.pdf

2011-06-17-DataManagementPlan-DataQualitySpecificationsApprovalForm192894289.pdf

2011-06-20-DataQualityReport(DQR)193567018.pdf

2011-10-24-DataQualityReport(DQR)196989557.pdf

2011-06-21-DataManagementPlan-CRFeCRFCompletionRequirements193567498.pdf

2011-09-14-DataListingDocument196027259.pdf

2011-10-26-DataManagementPlan-DataQualitySpecificationsApprovalForm(2)197019293.pdf

2011-11-10-ExemptDataForm(2)197412775.pdf

2011-11-10-ExemptDataForm197412504.pdf

2011-10-26-DataManagementPlan-DataQualitySpecificationsApprovalForm197019200.pdf

2011-12-12-DataManagementPlan-DataQualitySpecificationsApprovalForm(2)198415143.pdf

2011-12-12-DataManagementPlan-DataQualitySpecificationsApprovalForm198415140.pdf

2012-01-23-DatabaseReleaseForm(2)199929906.pdf

2011-12-12-DataQualityReport(DQR)198464922.pdf

2012-01-23-DatabaseReleaseForm199929654.pdf

2012-02-07-DatabaseReleaseForm200314472.pdf

2012-02-07-DatabaseReleaseForm(2)200313969.pdf

2012-01-23-DataReviewTrackingLog199978534.pdf

2012-02-07-DataReviewTrackingLog200314650.pdf

2012-02-07-SubjectEvaluabilityList-Approval203704221.pdf

2012-03-01-DataListingDocument201684488.pdf

2012-04-03-DataManagementActionFollowUp-NotetoFile201917316.pdf

2012-04-18-ConfirmationofTreatmentCodeAppliedCorrectly203395711.pdf

2012-04-18-DatabaseChangeReport203395798.pdf

2012-04-18-DatabaseReleaseEmailNotification202875938.pdf

2010-10-01-CROVendorOversightPlanTransferofObligations-CROOversightPlan183605196.pdf

2012-04-18-DatabaseReleaseForm(2)202875449.pdf

2012-04-18-DatabaseReleaseForm-LimitedWriteAccessEmailNotification202875935.pdf

2012-04-18-RandomizationCodeReleaseRequestForm-Completed202212046.pdf

2011-05-31-CROUserManualProcedures-StudySpecificConsultingVendor(2)201873608.pdf

2012-04-18-MasterRandomizationList203704108.pdf

2012-04-18-DatabaseReleaseForm202875741.pdf

2011-05-31-CROUserManualProcedures-StudySpecificConsultingVendor(3)201872644.pdf

2012-04-18-RandomizationCodeReleaseRequestForm-Approval203530649.pdf

2012-04-18-DataReviewTrackingLog202875648.pdf

2011-05-31-CROUserManualProcedures-StudySpecificConsultingVendor(4)201873609.pdf

2012-04-18-SubjectEvaluabilityList203704012.pdf

2012-05-02-DatabaseReleaseChecklist202876590.pdf

2011-05-31-CROUserManualProcedures-StudySpecificConsultingVendor201872643.pdf

2012-06-14-DatabaseChangeRequestForm(2)203762542.pdf

2012-06-14-DatabaseChangeRequestForm203762439.pdf

2011-06-01-CROVendorOversightPlanTransferofObligations-
ClinicalStudyVendorOversightPlanSummary192999321.pdf

2012-06-18-DatabaseChangeRequestForm(2)203763206.pdf

2012-06-18-DatabaseChangeRequestForm203763397.pdf

2011-06-27-CROVendorOversightPlanTransferofObligations-CROOversightPlan203274344.pdf

2012-07-30-DatabaseChangeReport204812945.pdf

2012-07-30-DatabaseReleaseChecklist204815084.pdf

2011-09-26-CROVendorOversightPlanTransferofObligations-CROOversightPlan203392391.pdf

2012-07-30-DatabaseReleaseForm204815181.pdf

2012-07-30-DatabaseReleaseEmailNotification204813742.pdf

2011-09-26-CROVendorOversightPlanTransferofObligations-CROOversightPlan(2)203392692.pdf

2012-07-30-DatabaseReleaseForm(2)204814529.pdf

2011-09-26-CROVendorOversightPlanTransferofObligations-CROOversightPlan(3)203392484.pdf

2012-07-30-DataReviewTrackingLog204813739.pdf

2012-03-01-CROUserManualProcedures203065922.pdf

2012-04-02-CROVendorOversightPlanTransferofObligations-
ClinicalStudyVendorOversightPlanSummary203392292.pdf

2011-06-15-ClinicalTrialAgreementConfirmation193440603.pdf

2011-06-29-ClinicalTrialAgreementConfirmation-NotetoFile193480721.pdf

2011-05-05-InvestigatorMtgDocuments-Agenda201439637.pdf

2011-05-05-InvestigatorMtgDocuments-Attendancelist196246129.pdf

2011-05-06-InvestigatorMtgDocuments-Attendancelist196245951.pdf

2011-05-06-InvestigatorMtgDocuments-InitiationReport(2)196245915.pdf

2011-05-06-InvestigatorMtgDocuments-InitiationReport196246003.pdf

2011-05-06-InvestigatorMtgDocuments-Presentation(10)201440195.pdf

2011-05-06-InvestigatorMtgDocuments-Presentation(2)201436307.pdf

2011-05-06-InvestigatorMtgDocuments-Presentation(3)201436208.pdf

2011-05-06-InvestigatorMtgDocuments-Presentation(4)201435714.pdf

2011-05-06-InvestigatorMtgDocuments-Presentation(5)201440192.pdf

2011-05-06-InvestigatorMtgDocuments-Presentation(6)201435814.pdf

2011-05-06-InvestigatorMtgDocuments-Presentation(7)201436310.pdf

2011-05-06-InvestigatorMtgDocuments-Presentation(8)201436211.pdf

2011-05-06-InvestigatorMtgDocuments-Presentation(9)201440490.pdf

2011-05-06-InvestigatorMtgDocuments-Presentation201435811.pdf

2011-06-12-TranslationCertificate195503861.pdf

2011-06-27-NotetoFile193489977.pdf

2011-07-11-NotetoFile193771217.pdf

2010-04-14-ShipmentofHazardousMaterials191384565.pdf

2011-08-05-InvestigatorMtgDocuments-Agenda201434942.pdf

2011-08-05-InvestigatorMtgDocuments-Attendancelist201435326.pdf

2011-05-31-DrugNon-DrugSupplyCorrspd192270655.pdf

2011-08-05-InvestigatorMtgDocuments-Presentation(10)201434567.pdf

2011-05-12-ImportExportLicense193295203.pdf

2011-08-05-InvestigatorMtgDocuments-Presentation(11)201435351.pdf

2011-07-11-DrugNon-DrugSupplyCorrspd195253796.pdf

2011-08-26-SampleDrugLabels197223325.pdf

2011-08-05-InvestigatorMtgDocuments-Presentation(12)201435338.pdf

2011-10-03-DrugNon-DrugSupplyCorrspd196462904.pdf

2011-08-05-InvestigatorMtgDocuments-Presentation(2)201434555.pdf

2011-08-05-InvestigatorMtgDocuments-Presentation(3)201434964.pdf

2011-08-05-InvestigatorMtgDocuments-Presentation(4)201435065.pdf

2011-08-05-InvestigatorMtgDocuments-Presentation(5)201434477.pdf

2011-08-05-InvestigatorMtgDocuments-Presentation(6)201434575.pdf

2011-08-16-NotetoFile200694173.pdf

2011-08-05-InvestigatorMtgDocuments-Presentation(7)201434957.pdf

2011-08-05-InvestigatorMtgDocuments-Presentation(8)201435054.pdf

2011-08-05-InvestigatorMtgDocuments-Presentation(9)201434468.pdf

2011-08-05-InvestigatorMtgDocuments-Presentation201435039.pdf

2011-09-01-InvestigatorMtgDocuments-InitiationReportAttendanceList195705001.pdf

2012-07-18-Corrspd-General205013507.pdf

2011-02-15-CaseReportForm-Approval(2)186619287.pdf

2011-04-30-CaseReportForm-Approval(2)191006403.pdf

2011-04-30-CaseReportForm-Approval191006109.pdf

2011-05-24-CaseReportForm-Approval(2)191703674.pdf

2011-05-24-CaseReportForm-Approval191706670.pdf

2011-05-26-CaseReportForm-Approval(2)191895687.pdf

2011-05-26-CaseReportForm-Approval191895546.pdf

2011-05-26-CaseReportForm-Blank192894351.pdf

2011-06-17-CaseReportForm-Blank192895541.pdf

2011-06-19-CaseReportForm-Approval(2)192895628.pdf

2011-06-19-CaseReportForm-Approval192894989.pdf

2010-08-05-CorrspdwithSite(2)183051721.pdf

2010-08-05-CorrspdwithSite183051546.pdf

2010-09-02-CorrspdwithSite-SiteVisits183946431.pdf

2010-11-10-CorrspdwithSite185172548.pdf

2010-11-11-IIPLetters-PrefilingCover185172471.pdf

2011-02-07-CorrspdwithSite-IBSafetyICFProtocol189798292.pdf

2011-02-07-CorrspdwithSite189797844.pdf

2011-02-10-CorrspdwithSite189798385.pdf

2011-02-16-CorrspdwithSite190009232.pdf

2011-03-25-CorrspdwithSite192054453.pdf

2011-03-25-IIPLetters-PrefilingCover(BOTH)190858520.pdf

2011-04-13-CorrspdwithSite191473544.pdf

2011-04-15-CorrspdwithSite-Training191363249.pdf

2011-05-09-CorrspdwithSite192054087.pdf

2011-05-11-CorrspdwithSite191487743.pdf

2011-06-29-CorrspdwithSite-ICF195013809.pdf

2011-07-19-CorrspdwithSite-Contract195540283.pdf

2011-09-19-CorrspdwithSite-Contract197305790.pdf

2011-09-26-CorrspdwithSite-Ethics197305990.pdf

2011-10-03-Corrspd-Internal-Ethics197305695.pdf

2011-10-18-CorrspdwithSite197305893.pdf

2010-09-02-Pre-TrialAssessmentReport182645230.pdf

2011-01-27-SiteTrainingCertification-OtherTraining195442304.pdf

2011-04-27-SiteTrainingCertification-GCPTTraining191879997.pdf

2011-06-01-FinalSiteSelectionForm192054182.pdf

2011-06-09-SiteTrainingCertification-GCPTTraining193782769.pdf

2011-07-25-SiteTrainingCertification-EDCTTraining195443435.pdf

2011-07-26-SiteTrainingCertification-EDCTTraining195443242.pdf

2011-07-28-SiteTraining-GCP-PALACI,MOISES195443136.pdf

2011-08-08-SiteTrainingCertification-GCPTTraining195145802.pdf

2011-08-09-SiteTraining-GCP-DIETZE,REYNALDO195442941.pdf

2011-02-23-CentralLabCVs193054986.pdf

2011-03-10-CentralLabNormalRanges203756666.pdf

2011-04-02-CentralLabNormalRanges193056791.pdf

2011-04-12-CentralLabNormalRanges193432133.pdf

2011-04-13-CentralLabManualProcedures201664699.pdf

2011-04-14-CentralLabAccreditation-QC-Cert193432321.pdf

2011-06-21-CentralLabCVs193056540.pdf

2011-08-31-DrugShipmentAddress-Form195750083.pdf

2011-07-27-CentralLabManualProcedures201664339.pdf

2011-10-10-CentralLabCorrspd197225062.pdf

2013-02-28-CentralLabAccreditation-QC-Cert193056641.pdf

2009-09-01-ProtocolSynopsisApproval172872144.pdf

2009-09-15-ApprovedProtocolAmend173184813.pdf

2009-12-16-ApprovedProtocolAmend176386835.pdf

2009-09-15-ProtocolSignatureFormDRF173169644.pdf

2009-12-16-ProtocolSignatureFormDRF175663433.pdf

1994-08-01-InvestigatorBrochure(2)178108118.pdf

2010-03-23-ApprovedProtocolAmend177854502.pdf

2010-05-21-FinancialDisclosureAssessmentForm179095529.pdf

2010-03-23-ProtocolSignatureFormDRF177755054.pdf

2009-07-01-DataManagementPlan-DataHandlingConventions(DHC)178687920.pdf

2009-10-23-DataManagementPlan-DataFlowActivities178688017.pdf

2009-10-23-DataManagementPlan-DataManagementOversightPlan178688236.pdf

2009-11-10-DataManagementPlan-DataManagementOversightPlan178688200.pdf

[2009-10-27-DataManagementPlan-DataQualitySpecificationsApprovalForm174065164.pdf](#)

[2010-01-12-DataManagementPlan-DataFlowActivities176084184.pdf](#)

[2010-01-29-DataManagementPlan-DataQualitySpecificationsApprovalForm\(2\)177687484.pdf](#)

[2010-01-29-DataManagementPlan-DataQualitySpecificationsApprovalForm176453486.pdf](#)

[2010-05-10-ExemptDataForm178688456.pdf](#)

[2010-04-01-DataManagementPlan-DataQualitySpecificationsApprovalForm\(2\)177836376.pdf](#)

[2010-03-31-DataManagementPlan-DataHandlingConventions\(DHC\)178688095.pdf](#)

[2010-04-01-DataManagementPlan-DataQualitySpecificationsApprovalForm177836187.pdf](#)

[2010-05-10-DataManagementPlan-DataQualityControlPlanDQCP178688584.pdf](#)

[2010-05-10-DataManagementPlan-CRFeCRFCompletionRequirements178688482.pdf](#)

[2010-05-10-DataManagementPlan-DQCPSummaryandApprovalReportforDCTtoDB178688773.pdf](#)

[2010-05-10-DataManagementPlan-DQCPSummaryandApprovalReportforSystemRecon178688677.pdf](#)

[2010-05-10-DataManagementPlan-Study-SpecificDataEntryGuidelines178688588.pdf](#)

[2010-05-21-RandomizationCodeReleaseRequestForm179592388.pdf](#)

[2010-05-19-BlindedDataReviewForm179019141.pdf](#)

[2010-05-25-DatabaseChangeRequestForm179203474.pdf](#)

[2010-05-26-MasterRandomizationList179236277.pdf](#)

[2010-05-26-RandomizationCodeReleaseRequestForm180433691.pdf](#)

[2010-06-02-DatabaseReleaseForm-LimitedWriteAccessEmailNotification179544619.pdf](#)

[2010-06-23-DatabaseReleaseForm180707365.pdf](#)

[2010-06-23-DatabaseReleaseForm\(2\)180707368.pdf](#)

[2011-05-18-FDA1572193783818.pdf](#)

[2010-08-11-PersonalDataConsentForm-Other\(2\)183051543.pdf](#)

[2010-08-11-PersonalDataConsentForm-Other\(3\)183051638.pdf](#)

[2010-11-17-FDA1572192884740.pdf](#)

2010-08-11-PersonalDataConsentForm-Other183051717.pdf

2010-08-11-PersonalDataConsentForm-PI-DIETZE,REYNALDO183051632.pdf

2011-08-15-FDA1572195749705.pdf

2010-08-11-PersonalDataConsentForm-Sub-Inv-HADAD,DAVIDJAMIL183051714.pdf

2010-08-12-PersonalDataConsentForm-Sub-Inv-ANDRADE,MELISSAFONSECA183051635.pdf

2010-08-11-PersonalDataConsentForm-Sub-Inv-MOLINO,LUCILIAPEREIRADUTRA183051540.pdf

2010-11-17-FinancialDisclosureForm-ANDRADE,MELISSAFONSECA191879993.pdf

2010-11-17-FinancialDisclosureForm-DIETZE,REYNALDO191879720.pdf

2010-11-17-FinancialDisclosureForm-HADAD,DAVIDJAMIL191879992.pdf

2010-11-17-FinancialDisclosureForm-MOLINO,LUCILIAPEREIRADUTRA191879721.pdf

2010-12-14-CV-SubInvestigator-OnePage-HADAD,DAVIDJAMIL190025610.pdf

2011-01-06-CV-Other-OnePage190025398.pdf

2011-01-10-CV-Other-OnePage190025397.pdf

2011-01-11-CV-SubInvestigator-OnePage-MOLINO,LUCILIAPEREIRADUTRA190025441.pdf

2011-01-12-CV-PrincipalInvestigator-OnePage-DIETZE,REYNALDO(2)195443142.pdf

2011-02-11-CV-Other-OnePage190025613.pdf

2011-05-18-FinancialDisclosureForm-Palaci,Moisés193784042.pdf

2011-05-18-PersonalDataConsentForm-Sub-Inv-Palaci,Moisés193783560.pdf

2011-05-24-CV-SubInvestigator-OnePage-ANDRADE,MELISSAFONSECA193411916.pdf

2011-07-25-CV-Other-OnePage(2)195443245.pdf

2011-07-25-CV-Other-OnePage(3)195442310.pdf

2011-07-25-CV-Other-OnePage195443139.pdf

2011-07-25-PersonalDataConsentForm-Other(2)195443438.pdf

2011-07-25-PersonalDataConsentForm-Other195442944.pdf

2011-07-26-CV-SubInvestigator-OnePage-PALACI,MOISES195442307.pdf

2011-08-05-CV-Other-OnePage(2)195145573.pdf

2011-08-05-CV-Other-OnePage195145799.pdf

2011-08-05-PersonalDataConsentForm-Other(2)195145898.pdf

2011-08-05-PersonalDataConsentForm-Other(3)195145415.pdf

2011-08-05-PersonalDataConsentForm-Other195145318.pdf

2011-08-17-FinancialDisclosureForm-MIRANDA,MAYKEARMANI195749534.pdf

2011-08-17-PersonalDataConsentForm-Sub-Inv-MIRANDA,MAYKEARMANI195749537.pdf

2011-08-18-CV-SubInvestigator-OnePage-MIRANDA,MAYKEARMANI195749820.pdf

2008-03-26-IRBIECCorrspd(BOTH)191473445.pdf

2010-04-08-IRBIECGCPComplianceStatement(BOTH)191473442.pdf

2010-11-17-IRBIECAckofReceipt-ICDProt185341734.pdf

2010-11-17-IRBIECCorrspd190099189.pdf

2011-02-10-IRBIECAckofReceipt190099108.pdf

2011-02-17-IRBIECAckofReceipt191421645.pdf

2011-03-17-IRBIECPanelMembershipNon-VotingStatus-PanelMembership(BOTH)191473357.pdf

2011-03-21-IRBIECCorrspd191879723.pdf

2011-03-30-IRBIECApproval-ICDProtAmend(BOTH)191879994.pdf

2011-03-30-IRBIECApproval-IBSafetyICDProtAmend(BOTH)191879722.pdf

IRBIECCorrspd191879995.pdf

2011-04-14-IRBIECCorrspd(BOTH)195013098.pdf

2011-04-25-IRBIECAckofReceipt-ProtAmendICDIBSafety(BOTH)191879724.pdf

2011-05-04-IRBIECCorrspd(2)199158339.pdf

2011-07-04-IRBIECAckofReceipt-ICD195142238.pdf

2011-07-06-IRBIECCorrspd195142402.pdf

2011-08-03-IRBIECApproval(BOTH)195750229.pdf

2011-08-26-IRBIECCorrspd197172005.pdf

2011-10-24-IRBIECStudyCloseOutCommunications199169533.pdf

2011-05-25-InvestigatorReceipt192646091.pdf

2011-05-27-InvestigatorReceipt192646181.pdf

2011-06-01-IIPLetters193055798.pdf

2011-06-01-InvestigatorReceipt-IB192016543.pdf

2011-06-12-TranslationCertificate-Centre(2)197195133.pdf

2011-06-30-InvestigatorReceipt193440506.pdf

2011-07-18-CorrspdwithSite-SiteVisits195503852.pdf

2011-08-11-CorrspdwithSite-SiteVisits197194946.pdf

2011-08-16-CorrspdwithSite197165797.pdf

2011-09-13-Corrspd-Internal197191458.pdf

2011-09-20-CorrspdwithSite-Labs196159000.pdf

2011-10-10-CorrspdwithSite198029100.pdf

2011-10-14-CorrspdwithSite196984408.pdf

2011-10-17-CorrspdwithSite-SiteVisits198027228.pdf

2011-10-21-InvestigatorReceipt198026959.pdf

2012-01-23-CorrspdwithSite-SiteVisits201121773.pdf

2011-10-28-Corrspd-Internal198027063.pdf

2009-09-03-MedicalLicenses197202264.pdf

2010-09-09-PersonalDataConsentForm-Other201051606.pdf

2011-01-07-CV-Other201194779.pdf

2011-01-12-CV-Other201051920.pdf

2011-03-31-CV-SubInvestigator-OnePage-SIWENDU,SWEETNESSNONZWAKAZI201051852.pdf

2011-05-12-PersonalDataConsentForm-Other(2)191946619.pdf

2011-05-12-PersonalDataConsentForm-Other(3)191946241.pdf

2011-05-12-PersonalDataConsentForm-Other191946152.pdf

2011-05-12-PersonalDataConsentForm-Sub-Inv-DuBois,Jeannine191944986.pdf

2011-05-13-CV-Other(2)197227289.pdf

2011-05-13-CV-Other(3)197227031.pdf

2011-05-13-CV-Other(4)197227383.pdf

2011-05-13-CV-Other(5)197227468.pdf

2011-05-13-CV-Other(6)201051684.pdf

2011-05-13-CV-Other197224875.pdf

2011-05-13-PersonalDataConsentForm-Other(2)191946155.pdf

2011-05-13-PersonalDataConsentForm-Other(4)201051597.pdf

2011-05-13-PersonalDataConsentForm-Other(3)191946242.pdf

2011-05-13-PersonalDataConsentForm-Other191945383.pdf

2011-05-15-PersonalDataConsentForm-Other191946238.pdf

2011-05-30-PersonalDataConsentForm-Other(2)192272778.pdf

2011-05-30-PersonalDataConsentForm-Other(3)192272295.pdf

2011-05-30-PersonalDataConsentForm-Other(4)201051507.pdf

2011-05-30-PersonalDataConsentForm-Other192271616.pdf

2011-05-30-PersonalDataConsentForm-Sub-Inv-Noveljic,Zoja192271619.pdf

2011-05-31-CV-PrincipalInvestigator-OnePage-Diacon,AndreasHenri193488670.pdf

2011-05-31-CV-SubInvestigator-OnePage-DUBOIS,JEANNINE(2)193648562.pdf

2011-05-31-CV-SubInvestigator-OnePage-DuBois,Jeannine193055704.pdf

2011-05-31-CV-SubInvestigator-OnePage-Noveljic,Zoja192271624.pdf

2011-05-31-CV-SubInvestigator-OnePage-SIWENDU,SWEETNESSNONZWAKAZI193648981.pdf

2011-05-31-FinancialDisclosureForm-DIACON,ANDREASHENRI193055953.pdf

2011-05-31-FinancialDisclosureForm-DUBOIS,JEANNINE193055795.pdf

2011-05-31-FinancialDisclosureForm-Noveljic,Zoja192273066.pdf

2011-05-31-FinancialDisclosureForm-Siwendu,SweetnessNonzwakazi192272499.pdf

2011-05-31-PersonalDataConsentForm-Other192272985.pdf

2011-05-31-PersonalDataConsentForm-Other(2)192272786.pdf

2011-05-31-PersonalDataConsentForm-PI-DIACON,ANDREASHENRI192273061.pdf

2011-05-31-PersonalDataConsentForm-Sub-Inv-Siwendu,SweetnessNonzwakazi192272299.pdf

2011-06-01-CV-SubInvestigator-OnePage-VonGroote-Bidlingmaier,FlorianTill192272682.pdf

2011-06-01-CV-SubInvestigator-OnePage-VONGROOTE-BIDLINGMAIER,FLORIAN TILL193652372.pdf

2011-06-01-FinancialDisclosureForm-VonGroote-Bidlingmaier,FlorianTill192272681.pdf

2011-06-01-PersonalDataConsentForm-Sub-Inv-VonGroote-Bidlingmaier,FlorianTill192271621.pdf

2011-06-22-CV-SubInvestigator-PATIENTIA, RAMONDEFIONA197195956.pdf

2011-06-14-CV-SubInvestigator-OnePage-Siwendu,SweetnessNonzwakazi193319085.pdf

2011-06-27-CV-Other201051603.pdf

2011-06-30-CV-Other201051773.pdf

2011-07-12-CV-SubInvestigator-OnePage-NOVELJIC,ZOJA193647895.pdf

2011-07-21-SignatureSheetandDelegationofDutiesLog-Ongoing195504026.pdf

2011-07-21-SignatureSheetandDelegationofDutiesLog197201032.pdf

2011-08-30-CV-Other201051861.pdf

2011-09-05-CV-Other201051687.pdf

2011-09-09-CV-Other201051770.pdf

2011-09-10-CV-Other201051858.pdf

2011-10-27-PersonalDataConsentForm-Other201051917.pdf

2011-10-30-PersonalDataConsentForm-Other201051681.pdf

2011-11-18-PersonalDataConsentForm-Other(2)201051767.pdf

2011-11-18-PersonalDataConsentForm-Other(3)201051600.pdf

2011-11-18-PersonalDataConsentForm-Other201051855.pdf

2011-12-31-MedicalLicenses197227469.pdf

2012-01-24-PersonalDataConsentForm-Other201051923.pdf

2012-01-26-CV-SubInvestigator-OnePage-None201119279.pdf

2012-01-26-CV-SubInvestigator-OnePage-PATIENTIA,RAMONDEFIONA200622577.pdf

2012-01-26-FinancialDisclosureForm-PATIENTIA,RAMONDEFIONA200621514.pdf

2012-01-26-PersonalDataConsentForm-Sub-Inv-PATIENTIA,RAMONDEFIONA200622484.pdf

2012-01-27-FinancialDisclosureForm-None200621039.pdf

2012-01-27-CV-SubInvestigator-OnePage-HANEKOM,MADELEINE200621498.pdf

2012-01-27-PersonalDataConsentForm-Sub-Inv-HANEKOM,MADELEINE200621980.pdf

2012-03-31-MedicalLicenses197195896.pdf

2012-04-01-MedicalLicenses197227033.pdf

2012-04-30-MedicalLicenses(2)197227460.pdf

2012-04-30-MedicalLicenses197225326.pdf

2012-05-07-MedicalLicenses197227124.pdf

2012-05-31-CV-PrincipalInvestigator-OnePage-None201119658.pdf

2012-07-27-SignatureSheetandDelegationofDutiesLog-Close-Out204810499.pdf

2012-08-31-MedicalLicenses197196050.pdf

2009-08-21-SiteTraining-GCP-None200622369.pdf

2009-08-24-SiteTrainingCertification-EDCTraining193056046.pdf

2009-09-03-SiteTraining-GCP-None(2)200621977.pdf

2009-09-03-SiteTraining-GCP-None(3)200622278.pdf

2009-09-03-SiteTrainingCertification-OtherTraining200621651.pdf

2009-09-09-SiteTraining-GCP-None200621326.pdf

2009-11-06-SiteTraining-GCP-None200621877.pdf

2010-03-31-SiteTraining-GCP-None(2)200621495.pdf

2010-03-31-SiteTraining-GCP-None(3)200621034.pdf

2010-03-31-SiteTraining-GCP-None(4)200620723.pdf

2010-03-31-SiteTraining-GCP-None200621323.pdf

2010-06-11-SiteTraining-GCP-None(2)200621786.pdf

2010-09-28-Pre-TrialAssessmentReport183378822.pdf

2011-01-06-SiteTrainingCertification-EDCTraining192272977.pdf

2011-02-04-SiteTraining-GCP-None(2)200621787.pdf

2011-02-04-SiteTraining-GCP-None(4)200622281.pdf

2011-02-04-SiteTraining-GCP-None200621517.pdf

2011-02-04-SiteTrainingCertification-GCPTraining(2)197227374.pdf

2011-02-04-SiteTrainingCertification-GCPTraining(3)197227463.pdf

2011-02-04-SiteTrainingCertification-GCPTraining(4)197227127.pdf

2011-02-04-SiteTrainingCertification-GCPTraining197224971.pdf

2011-03-16-SiteTrainingCertification-GCPTraining(3)191970182.pdf

2011-03-16-SiteTrainingCertification-GCPTraining(2)191969807.pdf

2011-03-16-SiteTrainingCertification-GCPTraining191969974.pdf

2011-04-05-SiteTrainingCertification-GCPTraining191973436.pdf

2011-04-18-SiteTrainingCertification-GCPTraining191965891.pdf

2011-05-10-SiteTrainingCertification-GCPTraining197227380.pdf

2011-05-27-SiteTrainingCertification-EDCTraining(2)192270799.pdf

2011-05-27-SiteTrainingCertification-EDCTraining192270983.pdf

2011-06-01-SiteTrainingCertification-EDCTraining197804695.pdf

2011-07-21-SiteInitiationReport195048263.pdf

2011-07-15-SiteTrainingCertification200621331.pdf

2011-07-18-SiteTrainingCertification(2)200622468.pdf

2011-07-18-SiteTrainingCertification(3)200622481.pdf

2011-07-18-SiteTrainingCertification(4)200621511.pdf

2011-07-18-SiteTrainingCertification200621790.pdf

2011-07-21-MonitoringVisitActionFollowupForm195503959.pdf

2011-07-21-SiteTrainingCertification(2)197201157.pdf

2011-07-21-SiteTrainingCertification-OtherTraining195968304.pdf

2011-07-21-SiteTrainingCertification197200975.pdf

2011-08-12-MonitoringVisitActionFollowupForm195969006.pdf

2012-07-26-SiteVisitLog204810493.pdf

2011-08-12-MonitoringVisitReport195452956.pdf

2011-09-09-ScreenandEnrollmentLog205179167.pdf

2011-09-21-MonitoringVisitActionFollowupForm197165601.pdf

2011-09-21-MonitoringVisitReport196399429.pdf

2011-09-29-ScreenandEnrollmentLog205179734.pdf

2011-10-11-ScreenandEnrollmentLog205179615.pdf

2011-10-13-MonitoringVisitReport197044857.pdf

2011-10-13-SiteTrainingCertification200622574.pdf

2011-10-20-MonitoringVisitActionFollowupForm199357426.pdf

2011-10-26-MonitoringVisitReport197343099.pdf

2011-10-28-SiteTrainingCertification200621783.pdf

2011-11-02-MonitoringVisitActionFollowupForm(2)198026847.pdf

2011-11-02-MonitoringVisitActionFollowupForm199357522.pdf

2011-11-03-ScreenandEnrollmentLog205177989.pdf

2011-11-03-SiteTraining-GCP-None(2)201120230.pdf

2011-11-03-SiteTraining-GCP-None200620720.pdf

2011-11-15-MonitoringVisitReport(2)200202984.pdf

2011-11-15-MonitoringVisitReport197693868.pdf

2011-11-22-MonitoringVisitActionFollowupForm199356482.pdf

2011-12-21-MonitoringVisitReport199122667.pdf

2011-12-23-MonitoringVisitActionFollowupForm199357622.pdf

2012-01-26-MonitoringVisitReport200302536.pdf

2012-02-03-MonitoringVisitActionFollowupForm201121115.pdf

2012-07-25-SiteClose-OutLetter204809895.pdf

2012-07-26-SiteCloseOutReport204970368.pdf

2012-07-27-EDCComplianceDocumentation-CloseOutForm204810298.pdf

2012-08-31-EDCComplianceDocumentation-CloseOutForm205621415.pdf

2011-01-26-InvestigationalProductAccountabilityLog-MultipleSubjects205176388.pdf

2011-05-30-DrugShipmentAddress-Form191934838.pdf

2011-06-01-DrugShipmentAddress-CSDSScreenCapture192311126.pdf

2011-06-02-TransferofInvestigationalProduct-Center195253463.pdf

2011-06-03-DrugNon-DrugReceiptForm197225068.pdf

2011-09-01-InvestigationalProductAccountabilityLog-MultipleSubjects205176988.pdf

2011-09-01-InvestigationalProductAccountabilityLog-SingleSubject205177614.pdf

2011-09-06-InvestigationalProductAccountabilityLog-SingleSubject205176394.pdf

2011-09-08-InvestigationalProductAccountabilityLog-SingleSubject205176982.pdf

2011-09-13-InvestigationalProductAccountabilityLog-SingleSubject205177611.pdf

2011-09-14-InvestigationalProductAccountabilityLog-SingleSubject205177872.pdf

2011-09-19-InvestigationalProductAccountabilityLog-SingleSubject205176925.pdf

2011-09-23-InvestigationalProductAccountabilityLog-SingleSubject205621147.pdf

2011-09-29-InvestigationalProductAccountabilityLog-SingleSubject205621066.pdf

2011-10-03-InvestigationalProductAccountabilityLog-SingleSubject205177203.pdf

2011-10-05-InvestigationalProductAccountabilityLog-SingleSubject205176385.pdf

2011-10-06-InvestigationalProductAccountabilityLog-SingleSubject205177377.pdf

2011-10-11-InvestigationalProductAccountabilityLog-SingleSubject(2)205177475.pdf

2011-10-11-InvestigationalProductAccountabilityLog-SingleSubject(3)205177102.pdf

2011-10-11-InvestigationalProductAccountabilityLog-SingleSubject205176119.pdf

2011-10-12-InvestigationalProductAccountabilityLog-SingleSubject(2)205177620.pdf

2011-10-12-InvestigationalProductAccountabilityLog-SingleSubject205176979.pdf

2011-10-19-InvestigationalProductAccountabilityLog-SingleSubject205177610.pdf

2011-10-21-InvestigationalProductAccountabilityLog-SingleSubject205177878.pdf

2011-10-25-InvestigationalProductAccountabilityLog-SingleSubject(2)205177962.pdf

2011-10-25-InvestigationalProductAccountabilityLog-SingleSubject(4)205176991.pdf

2011-10-25-InvestigationalProductAccountabilityLog-SingleSubject(3)205177965.pdf

2011-10-25-InvestigationalProductAccountabilityLog-SingleSubject205177875.pdf

2011-10-27-InvestigationalProductAccountabilityLog-SingleSubject(2)205179728.pdf

2011-10-27-InvestigationalProductAccountabilityLog-SingleSubject205179604.pdf

2011-10-31-InvestigationalProductAccountabilityLog-SingleSubject205177953.pdf

2011-11-02-InvestigationalProductAccountabilityLog-SingleSubject205178718.pdf

2011-11-04-InvestigationalProductAccountabilityLog-SingleSubject(2)205179729.pdf

2011-11-04-InvestigationalProductAccountabilityLog-SingleSubject205179607.pdf

2011-11-07-InvestigationalProductAccountabilityLog-SingleSubject205179612.pdf

2011-11-10-InvestigationalProductAccountabilityLog-SingleSubject205177617.pdf

2011-11-15-InvestigationalProductAccountabilityLog-SingleSubject(2)205177984.pdf

2011-11-15-InvestigationalProductAccountabilityLog-SingleSubject205177869.pdf

2012-01-26-InvestigationalProductAccountabilityLog-MultipleSubjects(2)201119651.pdf

2012-01-26-InvestigationalProductAccountabilityLog-MultipleSubjects(3)201119284.pdf

2012-01-26-InvestigationalProductAccountabilityLog-MultipleSubjects(4)201119652.pdf

2012-01-26-InvestigationalProductAccountabilityLog-MultipleSubjects(5)201120133.pdf

2012-01-26-InvestigationalProductAccountabilityLog-MultipleSubjects(6)201120234.pdf

2012-01-26-InvestigationalProductAccountabilityLog-MultipleSubjects(7)205177959.pdf

2012-01-26-InvestigationalProductAccountabilityLog-MultipleSubjects(8)205176985.pdf

2012-01-26-InvestigationalProductAccountabilityLog-MultipleSubjects(9)205176391.pdf

2012-01-26-InvestigationalProductAccountabilityLog-MultipleSubjects201120130.pdf

2012-01-26-InvestigationalProductReconciliationReport(2)201120231.pdf

2012-01-26-InvestigationalProductReconciliationReport201120129.pdf

2012-02-02-DrugNonDrugDestructionofInvestigationalProduct200694966.pdf

2012-08-18-InvestigationalProductAccountabilityLog-MultipleSubjects205177099.pdf

2010-10-27-IRBIECAApproval-ConditionalApproval193632154.pdf

2011-01-10-IRBIECCorrspd197224974.pdf

2011-03-08-IRBIECAApproval-ProtAmend189723543.pdf

2011-08-07-IRBIECCorrspd-ProtAmend197200838.pdf

2011-08-11-IRBIECCorrspd197201297.pdf

2011-08-12-IRBIECCorrspd195504194.pdf

2011-08-16-IRBIECCorrspd195504032.pdf

2011-09-16-IRBIECAckofReceipt-NotificationofSiteStaff(2)197201037.pdf

2009-10-05-NotetoFile-Protocol173562650.pdf

2011-09-16-IRBIECAckofReceipt-NotificationofSiteStaff197227327.pdf

2010-02-03-NotetoFile176702668.pdf

2011-09-16-IRBIECCorrspd197165515.pdf

2010-02-16-NotetoFile-Protocol176833560.pdf

2011-11-24-IRBIECCorrspd197225095.pdf

2010-06-03-NotetoFile-PKPGPD181369584.pdf

2012-05-15-Corrspd-General203736871.pdf

2010-11-10-InformedConsentForms-ClinicalTrialICD(BOTH)185416617.pdf

2010-11-10-InformedConsentFormsChklstApprDRF-Center-ClinicalTrialICD185172370.pdf

2011-02-07-InformedConsentForms-ClinicalTrialICD(BOTH)189798022.pdf

2011-02-07-InformedConsentFormsChklstApprDRF-Center-ClinicalTrialICD189798289.pdf

2011-03-23-InformedConsentForms-ClinicalTrialICD(BOTH)190858697.pdf

2011-03-23-InformedConsentFormsChklstApprDRF-Center-ClinicalTrialICD190858781.pdf

2011-06-28-InformedConsentForms-ClinicalTrialICD(BOTH)195014060.pdf

2011-06-28-InformedConsentFormsChklstApprDRF-Center-ClinicalTrialICD195013062.pdf

2011-05-31-FDA1572193497572.pdf

2011-06-22-OtherSignedAgreementwauthorities197195782.pdf

2011-06-27-IIPTransmittal193802228.pdf

2011-07-01-FDA1572(2)193659574.pdf

2011-07-14-IIPApproval201454675.pdf

2010-04-30-Confident-SecrecyAgreement185965402.pdf

2010-07-20-InvestigatorProtocolAcceptanceForm186127616.pdf

2011-01-26-InvestigatorProtocolAcceptanceForm201051678.pdf

2010-12-07-InvestigatorProtocolAcceptanceForm193432228.pdf

2011-03-21-InvestigatorProtocolAcceptanceForm192273074.pdf

2011-05-31-InvestigatorProtocolAcceptanceForm201051764.pdf

2011-06-01-FinDisc-InvestigatorLetter(2)193055794.pdf

2011-07-01-InvestigatorProtocolAcceptanceForm201051504.pdf

2011-01-12-InformedConsentForms(TR)(2)197191128.pdf

2011-01-12-InformedConsentForms(TR)197165702.pdf

2011-01-12-InformedConsentForms-ClinicalTrialICD193633090.pdf

2011-01-20-InformedConsentForms-ClinicalTrialICD193481173.pdf

2011-01-20-InformedConsentFormsChklstApprDRF-Center193480632.pdf

2011-03-21-InformedConsentFormsChklstApprDRF-Center(2)197470281.pdf

2011-03-21-InformedConsentFormsChklstApprDRF-Center197227283.pdf

2011-03-28-InformedConsentForms(2)197191455.pdf

2011-03-28-InformedConsentForms(TR)197191217.pdf

2011-03-28-InformedConsentForms-NotetoFile195253466.pdf

2011-03-28-InformedConsentForms192272775.pdf

2011-03-28-InformedConsentFormsChklstApprDRF-Center-ClinicalTrialICD195253607.pdf

2011-03-28-InformedConsentFormsChklstApprDRF-Center-
ClinicalTrialICDCombinedInformationSheet193763470.pdf

2011-03-28-InformedConsentFormsChklstApprDRF-Center195238694.pdf

2010-04-28-Confident-SecrecyAgreement-Investigator191879996.pdf

2010-07-20-InvestigatorProtocolAcceptanceForm195442947.pdf

2009-11-10-CROVendorOversightPlanTransferofObligations-CROOversightPlan189267902.pdf

2010-11-10-FinDisc-InvestigatorLetter185172301.pdf

2010-12-07-InvestigatorProtocolAcceptanceForm191879991.pdf

2011-03-21-InvestigatorProtocolAcceptanceForm191879719.pdf

2010-05-10-CaseReportForm-Approval178676882.pdf

2010-05-11-CaseReportForm-Blank178690415.pdf

2009-11-01-DrugNon-DrugLabelsApproval174297586.pdf

2009-11-04-DrugNon-DrugLabelsApproval174446022.pdf

[2009-11-06-DrugNon-DrugLabelsApproval174495964.pdf](#)

[2009-11-08-DrugNon-DrugLabelsApproval174496117.pdf](#)

[2009-11-11-DrugNon-DrugLabelsApproval174603251.pdf](#)

[2009-11-13-DrugNon-DrugLabelsApproval174718656.pdf](#)

[2009-11-16-DrugNon-DrugLabelsApproval174794723.pdf](#)

[2009-12-07-DrugNon-DrugLabelsApproval175495788.pdf](#)

[2009-12-09-DrugNon-DrugLabelsApproval175495852.pdf](#)

[2009-12-16-DrugNon-DrugLabelsApproval175663618.pdf](#)

[2009-12-11-DrugNon-DrugLabelsApproval175579275.pdf](#)

[2009-12-14-DrugNon-DrugLabelsApproval175599150.pdf](#)

[2009-12-17-DrugNon-DrugLabelsApproval175692914.pdf](#)

[2009-12-18-DrugNon-DrugLabelsApproval175767086.pdf](#)

[2009-12-21-DrugNon-DrugLabelsApproval175767168.pdf](#)

[2010-01-11-DrugNon-DrugLabelsApproval176060643.pdf](#)

[2010-01-12-DrugNon-DrugLabelsApproval176091973.pdf](#)

[2010-01-15-DrugNon-DrugLabelsApproval176151887.pdf](#)

[2010-01-18-DrugNon-DrugLabelsApproval176198063.pdf](#)

[2010-01-19-DrugNon-DrugLabelsApproval176237012.pdf](#)

[2010-01-22-DrugNon-DrugLabelsApproval176315080.pdf](#)

[2010-01-25-DrugNon-DrugLabelsApproval176356709.pdf](#)

[2010-02-08-DrugNon-DrugLabelsApproval\(2\)176671295.pdf](#)

[2010-02-08-DrugNon-DrugLabelsApproval176671387.pdf](#)

[2010-02-10-DrugNon-DrugLabelsApproval176731282.pdf](#)

[2010-02-12-DrugNon-DrugLabelsApproval176788409.pdf](#)

[2010-02-15-DrugNon-DrugLabelsApproval176788767.pdf](#)

2010-02-16-DrugNon-DrugLabelsApproval176839755.pdf

2010-02-19-DrugNon-DrugLabelsApproval176912980.pdf

2010-02-22-DrugNon-DrugLabelsApproval(2)176916602.pdf

2010-02-22-DrugNon-DrugLabelsApproval176916669.pdf

2010-02-23-DrugNon-DrugLabelsApproval176982285.pdf

2010-02-23-DrugNon-DrugLabelsApproval(2)176982367.pdf

2010-02-26-DrugNon-DrugLabelsApproval(2)177045014.pdf

2010-02-26-DrugNon-DrugLabelsApproval177044758.pdf

2010-03-01-BlindBreakingInstructionsDocumentation177072581.pdf

2010-03-01-DrugNon-DrugLabelsApproval177051947.pdf

2010-03-04-DrugNon-DrugLabelsApproval177204286.pdf

2010-03-05-DrugNon-DrugLabelsApproval177204204.pdf

2010-04-08-DrugNon-DrugLabelsApproval178032099.pdf

2010-04-13-DrugNon-DrugLabelsApproval178102927.pdf

2010-04-20-DrugNon-DrugLabelsApproval(2)178228979.pdf

2010-04-20-DrugNon-DrugLabelsApproval178228738.pdf

2010-04-27-DrugNon-DrugLabelsApproval178403224.pdf

2010-10-01-EOSNotificationtoSupplyChainOrganization183452979.pdf

2010-09-21-InformedConsentForms-ClinicalTrialICD193481977.pdf

2010-09-21-InformedConsentFormsChklstApprDRF-Center193481094.pdf

2011-03-28-InformedConsentForms(10)197191560.pdf

2011-03-28-InformedConsentForms(11)197191313.pdf

2011-03-28-InformedConsentForms(2)194671796.pdf

2011-03-28-InformedConsentForms(5)197191131.pdf

2011-03-28-InformedConsentForms(TR)(2)195504191.pdf

2011-03-28-InformedConsentForms(TR)(3)195503855.pdf

2011-03-28-InformedConsentForms(TR)(4)195504029.pdf

2011-03-28-InformedConsentForms(TR)(5)195504108.pdf

2011-03-28-InformedConsentForms(TR)(6)195504105.pdf

2011-03-28-InformedConsentForms(TR)(7)198027147.pdf

2011-03-28-InformedConsentForms(TR)(8)198027238.pdf

2011-03-28-InformedConsentForms(TR)195503953.pdf

2011-03-28-InformedConsentFormsChklstApprDRF-Center(2)198021385.pdf

2011-03-28-InformedConsentForms194672442.pdf

2011-03-28-InformedConsentFormsChklstApprDRF-Center(3)198026853.pdf

2011-03-28-InformedConsentFormsChklstApprDRF-Center-ClinicalTrialICD194671760.pdf

2011-03-28-InformedConsentFormsChklstApprDRF-Center193481978.pdf

2011-07-12-InformedConsentForms-NotetoFile194672742.pdf

2010-11-04-IRBIECCorrspd189915135.pdf

2011-02-01-IRBIECCorrspd-ProtAmend193480993.pdf

2010-11-04-IRBIECRejectionRescind-Suspension184733836.pdf

2011-02-01-IRBIECCorrspd-Protocol193481093.pdf

2011-02-02-IRBIECAckofReceipt198021914.pdf

2011-02-02-IRBIECSubmissionFilingPackage198023129.pdf

2011-02-28-IRBIECCorrspd189591025.pdf

2011-03-30-IRBIECSubmissionFilingPackage-ICDProtocolAmend191894294.pdf

2011-05-03-IRBIECCorrspd-IBSafetyProtAmend197470476.pdf

2011-05-11-IRBIECApproval-CVICDProtAmend192016410.pdf

2011-09-08-IRBIECCorrspd197470379.pdf

2011-06-09-IRBIECCorrspd-NotificationofSiteStaff197470045.pdf

2011-07-20-IRBIECCorrspd-NotificationofSiteStaff197469958.pdf

2010-07-20-InvestigatorProtocolAcceptanceForm194672258.pdf

2011-09-09-IRBIECApapproval-InformationSheet197470473.pdf

2011-09-28-IRBIECSubmissionFilingPackage-WrittenInfoforsubject196671413.pdf

2011-03-21-InvestigatorProtocolAcceptanceForm192271626.pdf

2010-12-07-InvestigatorProtocolAcceptanceForm193763567.pdf

2011-06-01-FinDisc-InvestigatorLetter(2)193056561.pdf

2011-09-09-IRBIECCorrspd-ICD197191220.pdf

2011-09-29-IRBIECAckofReceipt-LogAdminChangeWrittenInfotoSubject196671284.pdf

2012-07-23-IRBIECSiteCloseOutCommunications205141693.pdf

2012-07-26-IRBIECSiteCloseOutCommunications(2)205202636.pdf

2012-07-26-IRBIECSiteCloseOutCommunications205142266.pdf

2010-09-20-CorrspdwithSite-Ethics183774858.pdf

2010-09-20-CorrspdwithSite-ICFProtocol183230308.pdf

2011-02-21-SubjectEligibilityRandomizationApproval195253588.pdf

2011-05-31-InvestigatorReceipt-IB196671339.pdf

2011-06-01-IIPLetters192646257.pdf

2011-06-12-TranslationCertificate-Centre197165794.pdf

2011-06-01-InvestigatorReceipt-IB193056365.pdf

2011-07-01-InvestigatorReceipt193440432.pdf

2011-07-19-CorrspdwithSite195253364.pdf

2011-08-01-CorrspdwithSite-ICF195253705.pdf

2011-08-02-CorrspdwithSite-IBSafety195253690.pdf

2011-08-12-InvestigatorReceipt197223219.pdf

2011-09-14-CorrspdwithSite-SiteVisits197804518.pdf

2011-09-14-CorrspdwithSite-Protocol196671416.pdf

2011-09-15-InvestigatorReceipt198027677.pdf

2011-09-29-CorrspdwithSite-SiteVisits197804608.pdf

2011-10-06-CorrspdwithSite197191310.pdf

2011-10-04-CorrspdwithSite197225321.pdf

2011-10-13-CorrspdwithSite-SiteVisits197804183.pdf

2011-10-14-CorrspdwithSite196984411.pdf

2011-10-18-InvestigatorReceipt198021351.pdf

2011-11-03-CorrspdwithSite-SiteVisits(2)197804334.pdf

2011-11-03-CorrspdwithSite-SiteVisits197804425.pdf

2011-12-02-CorrspdwithSite-SiteVisits201885332.pdf

2012-01-09-CorrspdwithSite-SiteVisits201886181.pdf

2012-01-20-CorrspdwithSite-SiteVisits201885792.pdf

2012-07-13-CorrspdwithSite-SiteVisits205012627.pdf

2012-07-23-CorrspdwithSite-Protocol205013320.pdf

2012-09-14-CorrspdwithSite206031299.pdf

2011-03-10-LocalLabNormalRanges205012309.pdf

2011-04-14-LocalLabAgreement204509152.pdf

2011-05-03-DrugNon-DrugHandlingInstructions-Center195253687.pdf

2011-05-09-DrugNon-DrugHandlingInstructions-Center(2)195253349.pdf

2011-05-09-DrugNon-DrugHandlingInstructions-Center195253576.pdf

2011-05-26-DrugNonDrugNoticeofShipmenttoInvestigator-ProofofReceipt192646419.pdf

2011-05-30-DrugShipmentAddress-Form191936718.pdf

2011-06-02-TransferofInvestigationalProduct-Center195253448.pdf

2011-06-01-DrugShipmentAddress-CSDSScreenCapture192317530.pdf

2011-06-03-DrugNonDrugNoticeofShipmenttoInvestigator-ProofofReceipt200694450.pdf

2011-06-03-DrugNon-DrugReceiptForm197227388.pdf

2011-08-15-DrugNonDrugNoticeofShipmenttoInvestigator-ProofofReceipt200694066.pdf

2011-09-13-DrugNonDrugNoticeofShipmenttoInvestigator-ProofofReceipt(2)200694449.pdf

2011-09-13-DrugNonDrugNoticeofShipmenttoInvestigator-ProofofReceipt200694065.pdf

2011-10-19-DrugNonDrugNoticeofShipmenttoInvestigator-ProofofReceipt197804524.pdf

2011-10-19-DrugNonDrugNoticeofShipmenttoInvestigator200694167.pdf

2011-11-14-InvestigationalProductAccountabilityLog-MultipleSubjects204594639.pdf

2012-01-09-TemperatureExcursionApproval201051864.pdf

2012-01-26-InvestigationalProductAccountabilityLog-SingleSubject(10)200775507.pdf

2012-01-26-InvestigationalProductAccountabilityLog-SingleSubject(11)200775246.pdf

2012-01-26-InvestigationalProductAccountabilityLog-SingleSubject(12)200774927.pdf

2012-01-26-InvestigationalProductAccountabilityLog-SingleSubject(14)200775322.pdf

2012-01-26-InvestigationalProductAccountabilityLog-SingleSubject(13)200774435.pdf

2012-01-26-InvestigationalProductAccountabilityLog-SingleSubject(15)200774838.pdf

2012-01-26-InvestigationalProductAccountabilityLog-SingleSubject(16)200775577.pdf

2012-01-26-InvestigationalProductAccountabilityLog-SingleSubject(17)200774839.pdf

2012-01-26-InvestigationalProductAccountabilityLog-SingleSubject(18)200775431.pdf

2012-01-26-InvestigationalProductAccountabilityLog-SingleSubject(19)200774436.pdf

2012-01-26-InvestigationalProductAccountabilityLog-SingleSubject(2)200694972.pdf

2012-01-26-InvestigationalProductAccountabilityLog-SingleSubject(20)200775249.pdf

2012-01-26-InvestigationalProductAccountabilityLog-SingleSubject(21)200774930.pdf

2012-01-26-InvestigationalProductAccountabilityLog-SingleSubject(22)200774437.pdf

2012-01-26-InvestigationalProductAccountabilityLog-SingleSubject(24)200774841.pdf

2012-01-26-InvestigationalProductAccountabilityLog-SingleSubject(23)200775325.pdf

2012-01-26-InvestigationalProductAccountabilityLog-SingleSubject(25)200775580.pdf

2012-01-26-InvestigationalProductAccountabilityLog-SingleSubject(3)200694073.pdf

2012-01-26-InvestigationalProductAccountabilityLog-SingleSubject(4)200694457.pdf

2012-01-26-InvestigationalProductAccountabilityLog-SingleSubject(5)200695135.pdf

2012-01-26-InvestigationalProductAccountabilityLog-SingleSubject(6)200696719.pdf

2012-01-26-InvestigationalProductAccountabilityLog-SingleSubject(7)200694975.pdf

2012-01-26-InvestigationalProductAccountabilityLog-SingleSubject(8)200696819.pdf

2012-01-26-InvestigationalProductAccountabilityLog-SingleSubject(9)200775428.pdf

2012-01-26-InvestigationalProductAccountabilityLog-SingleSubject200694072.pdf

2012-02-02-DrugNonDrugDestructionofInvestigationalProduct200695127.pdf

2012-02-26-InvestigationalProductAccountabilityLog-SingleSubject200774741.pdf

2012-06-20-DrugNonDrugDestructionofInvestigationalProduct-ConfirmationofDestruction204508865.pdf

2012-07-16-InvestigationalProductReconciliationReport(2)204508968.pdf

2012-07-16-InvestigationalProductReconciliationReport204509058.pdf

2012-10-28-InvestigationalProductAccountabilityLog-MultipleSubjects204594703.pdf

2012-11-03-InvestigationalProductAccountabilityLog-MultipleSubjects204809898.pdf

IND 104806 FDA Corrspd 14Feb2011.pdf

PNU-100480 FDA CorrspdOrphanDesignation29Nov2010.pdf

PNU-100480S. Africa Corrspd10Nov2010.pdf

Machado, Peter PFE.pdf

HA Incoming Corrspd Archival Form.doc

11 16 12 Meeting Request Granted (COR-MEET-01)(COR-BLAMEET-01).pdf

Form.pdf

2013-01-30-CSRAcknowledgmentofReceiptSummary210485229.pdf

HA Incoming Corrspd Archival Form.doc

2010-11-10-RegulatoryAgenciesCorrspd184362649.pdf

2010-11-17-RegulatoryAgenciesCorrspd184733680.pdf

2011-01-18-RegulatoryAgenciesApproval-Prot(2)189934995.pdf

2011-01-18-RegulatoryAgenciesApproval-Prot185965039.pdf

2011-01-28-RegulatoryAgenciesCorrspd-ProtAmend189723696.pdf

2011-02-10-RegulatoryAgenciesCorrspd204508574.pdf

2011-03-30-RegulatoryAgenciesAckReceipt-ProtocolAmendIBSafety191894012.pdf

2011-04-19-RegulatoryAgenciesApplSubCoverletter192075212.pdf

2011-04-19-RegulatoryAgenciesCorrspd-NotificationofNewInvestigator192076787.pdf

2011-05-09-RegulatoryAgenciesAckReceipt191582923.pdf

2011-06-01-OtherSignedAgreementwauthorities197804343.pdf

2011-06-02-RegulatoryAgenciesCorrspd-ProtAmend192672170.pdf

2011-06-15-RegulatoryAgenciesAckReceipt-CV196671090.pdf

2011-06-15-RegulatoryAgenciesApplSubCoverletter193056668.pdf

2011-07-05-RegulatoryAgenciesAckReceipt-ProtocolAmend193480990.pdf

2011-07-05-RegulatoryAgenciesApproval-ProtAmend193480345.pdf

2011-07-08-RegulatoryAgenciesAckReceipt199145381.pdf

2011-07-12-RegulatoryAgenciesApproval197227757.pdf

2011-07-12-RegulatoryAgenciesCorrspd198020983.pdf

2011-08-08-RegulatoryAgenciesApproval195503946.pdf

HOSHB00.pdf

2011-08-08-RegulatoryAgenciesCorrspd(2)195503948.pdf

2011-08-08-RegulatoryAgenciesCorrspd(3)195504102.pdf

2011-08-08-RegulatoryAgenciesCorrspd(4)195504188.pdf

2011-08-08-RegulatoryAgenciesCorrspd(5)197200765.pdf

2011-08-08-RegulatoryAgenciesCorrspd(7)197200771.pdf

2011-08-15-RegulatoryAgenciesAckReceipt198932479.pdf

2011-08-08-RegulatoryAgenciesCorrspd195503947.pdf

2011-08-22-RegulatoryAgenciesApproval-Prot(BOTH)195478593.pdf

2011-08-26-RegulatoryAgenciesProtocolImportPermit-ImportExportLicense(2)197378650.pdf

2011-08-26-RegulatoryAgenciesProtocolImportPermit-ImportExportLicense197378989.pdf

2011-08-29-RegulatoryAgenciesProtocolImportPermit-Application(2)197378793.pdf

2011-08-29-RegulatoryAgenciesProtocolImportPermit-Application197379089.pdf

2011-09-16-RegulatoryAgenciesCorrspd197165699.pdf

2011-09-22-RegulatoryAgenciesProtocolImportPermit-ImportExportLicense(2)197379095.pdf

2011-09-22-RegulatoryAgenciesProtocolImportPermit-ImportExportLicense197378992.pdf

2011-09-23-RegulatoryAgenciesProtocolImportPermit-Application(2)197378796.pdf

2011-09-23-RegulatoryAgenciesProtocolImportPermit-Application197379092.pdf

2011-10-13-RegulatoryAgenciesInterimAnnualFinalReport197164533.pdf

2011-11-02-RegulatoryAgenciesCorrspd200307733.pdf

2011-11-01-RegulatoryAgenciesProtocolImportPermit-Application200353347.pdf

2011-11-04-RegulatoryAgenciesCorrspd198016459.pdf

2011-11-04-RegulatoryAgenciesSafetyAENotification198016438.pdf

2011-11-08-RegulatoryAgenciesAckReceipt-SAE198027140.pdf

2011-11-21-RegulatoryAgenciesApproval198027059.pdf

2011-12-12-RegulatoryAgenciesCorrspd204508871.pdf

2011-12-19-RegulatoryAgenciesAckReceipt199628797.pdf

2011-12-19-RegulatoryAgenciesCorrspd-AckofReceipt199631728.pdf

2011-12-19-RegulatoryAgenciesCorrspd199121577.pdf

2012-02-10-RegulatoryAgenciesAckReceipt204509158.pdf

2012-03-30-RegulatoryAgenciesInterimAnnualFinalReport202534433.pdf

2012-07-13-RegulatoryAgenciesCorrspd(2)204508980.pdf

2012-07-13-RegulatoryAgenciesCorrspd204509067.pdf

2012-08-06-RegulatoryAuthorityStudyCloseOutCommunication-CountryEndofTrialNotification205177956.pdf

2010-01-02-NatRegionalECPanelMembershipNon-VotingStatus200694456.pdf

2010-10-27-NatRegionalECApproval-Conditionalapproval193635557.pdf

2010-11-24-NatRegionalECCorrspd-ICDProtocol184819213.pdf

2011-01-02-NatRegionalECPanelMembershipNon-VotingStatus-MembershipListandNonVotingStatus204594938.pdf

2011-01-21-NatRegionalECApproval-ICD186000895.pdf

2011-02-02-NatRegionalECAckofReceipt198026962.pdf

2011-02-02-NatRegionalECCorrspd-NotificationofSiteStaff198027150.pdf

2011-02-10-NatRegionalECCorrspd-IBSafety198027235.pdf

2011-02-23-NatRegionalECApproval-ProtAmend195240852.pdf

2011-02-11-NatRegionalECAckofReceipt198027232.pdf

2011-02-28-NatRegionalECCorrspd198022722.pdf

2011-03-03-NatRegionalECCorrspd198016893.pdf

2011-05-11-NatRegionalECCorrspd198021370.pdf

2011-05-13-NatRegionalECAckofReceipt198026850.pdf

2011-05-27-NatRegionalECCorrspd193951573.pdf

2011-05-31-NatRegionalECApproval-IBSafetyICDProtAmend192016448.pdf

2011-05-31-NatRegionalECApproval-ProtAmend192646184.pdf

2011-06-07-NatRegionalECAckofReceipt-LogAdminChange198021280.pdf

2011-06-20-NatRegionalECAckofReceipt-LogAdminChange198021336.pdf

2011-10-17-NatRegionalECCorrspd198021076.pdf

2011-08-17-NatRegionalECApproval-NotificationofSiteStaff195503858.pdf

2011-10-17-NatRegionalECAckofReceipt200695130.pdf

2011-08-16-NatRegionalECAckofReceipt195503956.pdf

2011-10-19-NatRegionalECAckofReceipt198022633.pdf

2011-11-04-NatRegionalECCorrspd(2)198027144.pdf

2011-11-04-NatRegionalECCorrspd(3)198026965.pdf

2011-11-04-NatRegionalECCorrspd198016727.pdf

2011-11-04-NatRegionalECSafetySAENotification198015769.pdf

2011-11-08-NatRegionalECAckofReceipt-SAE199122421.pdf

2011-11-22-NatRegionalECCorrspd-Protocol201857354.pdf

2011-11-22-NatRegionalECCorrspd201857351.pdf

2011-12-14-NatRegionalECAckofReceipt200694969.pdf

2011-12-12-NatRegionalECCorrspd-NotificationofSiteStaff199778540.pdf

2011-12-02-NatRegionalECCorrspd198028256.pdf

2011-12-14-NatRegionalECApproval-NotificationofSiteStaff199778741.pdf

2011-12-14-NatRegionalECCorrspd200694069.pdf

2011-12-31-NatRegionalECPanelMembershipNon-VotingStatus-MembershipListandNonVotingStatus204508883.pdf

2012-01-13-NatRegionalECAckofReceipt-NotificationofSiteStaff200694453.pdf

2012-01-13-NatRegionalECCorrspd-NotificationofSiteStaff200694170.pdf

2012-01-20-NatRegionalECCorrspd201049454.pdf

2012-02-15-NatRegionalECApproval201119752.pdf

2012-02-15-NatRegionalECApproval-Annual(re)approval200621031.pdf

2012-03-07-NatRegionalECAckofReceipt-NotificationofSiteStaff204508568.pdf

2012-03-28-NatRegionalECCorrspd-SAE202534698.pdf

2012-03-30-NatRegionalECAckofReceipt204594266.pdf

2012-03-30-NatRegionalECCorrspd204594557.pdf

2012-04-02-NatRegionalECCorrspd202062834.pdf

2012-04-04-NatRegionalECCorrspd202534521.pdf

2012-04-25-NatRegionalECCorrspd204509145.pdf

2012-04-25-NatRegionalInterimAnnualFinalReport-InterimReport203065823.pdf

2012-05-02-NatRegionalECAckofReceipt204509055.pdf

2012-05-02-NatRegionalECApproval-Annual(re)approval203066017.pdf

2012-07-13-NatRegionalECCorrspd-NotificationofSiteStaff204810241.pdf

2012-07-17-NatRegionalECAckofReceipt204809481.pdf

2012-08-23-NatRegionalECAckofReceipt(2)205311596.pdf

2012-08-23-NatRegionalECAckofReceipt205307367.pdf

2010-09-13-InformedConsentForms-CountryRegional183229899.pdf

2010-09-13-InformedConsentFormsChklstApprovalDRF-Protocol182906989.pdf

2010-11-08-InformedConsentForms-CountryRegional184818889.pdf

2010-11-08-InformedConsentFormsChklstApprovalDRF-Protocol184819059.pdf

2010-11-10-InformedConsentForms-CountryRegional(BOTH)185872783.pdf

2010-11-10-InformedConsentFormsChklstApprovalDRF-Protocol-ClinicalTrialICD185172621.pdf

2011-01-12-InformedConsentForms-CountryRegional-ClinicalTrialICD193633195.pdf

2010-12-30-InsuranceStatement189798115.pdf

2010-12-31-InsuranceStatement185237264.pdf

2011-01-20-InformedConsentForms-CountryRegional-ClinicalTrialICD(2)193482834.pdf

2011-01-20-InformedConsentForms-CountryRegional-ClinicalTrialICD193480830.pdf

2011-01-20-InformedConsentForms-CountryRegional-CombinedInformationSheet194671764.pdf

2011-02-07-InformedConsentForms-CountryRegional(BOTH)189798112.pdf

2011-01-20-InformedConsentFormsChklstApprovalDRF-Protocol(2)193482660.pdf

2011-01-20-InformedConsentFormsChklstApprovalDRF-Protocol193480039.pdf

2011-02-07-InformedConsentFormsChklstApprovalDRF-Protocol-ClinicalTrialICD189797467.pdf

2011-03-23-InformedConsentForms-CountryRegional-ClinicalTrialICD(BOTH)190826155.pdf

2011-03-23-InformedConsentForms-Prototype192857374.pdf

2011-03-23-InformedConsentFormsChklstApprovalDRF-Protocol-ClinicalTrialICD190826223.pdf

2011-03-23-InformedConsentFormsChklstApprovalDRF-Protocol192856704.pdf

2011-03-28-InformedConsentForms-CountryRegional(2)197201140.pdf

2011-03-28-InformedConsentForms-CountryRegional-ClinicalTrialICD193480998.pdf

2011-03-28-InformedConsentForms-CountryRegional-ClinicalTrialICDCombinedInformationSheet193763471.pdf

2011-03-28-InformedConsentForms-CountryRegional-NotetoFile193763329.pdf

2011-03-28-InformedConsentForms-CountryRegional194671759.pdf

2012-01-01-InsuranceStatement(BOTH)191131838.pdf

2011-03-28-InformedConsentFormsChklstApprovalDRF-
ProtoClinTrialICDCombinedInfoSheetCountryReg193482380.pdf

2011-03-28-InformedConsentFormsChklstApprovalDRF-Protocol-
ClinicalTrialICDCombinedInformationSheet(2)193763657.pdf

2011-03-28-InformedConsentFormsChklstApprovalDRF-Protocol194671614.pdf

2011-06-28-InformedConsentForms-CountryRegional-ClinicalTrialICD(BOTH)193951472.pdf

2011-06-28-InformedConsentFormsChklstApprovalDRF-Protocol-CountryRegionalClinicalTrialICD193951740.pdf

2004-03-23-FinancialDisclosureSynopsis191384468.pdf

2010-04-01-FeasibilityQuestionnaire-Blank201664510.pdf

2010-06-01-ProtocolLaunchMeeting197326411.pdf

2010-06-01-ProtocolLaunchMeeting-Agenda197326510.pdf

2010-07-20-ApprovedProtocolAmend(TR)182843411.pdf

2010-07-20-ApprovedProtocolAmend185638495.pdf

2010-07-20-ProtocolSignatureFormDRF181460029.pdf

2010-12-06-RiskAssessmentForm186158868.pdf

2010-10-08-LogisticalorAdminChange183666683.pdf

2010-12-07-ApprovedProtocolAmend-NotetoFile192224496.pdf

2010-12-07-ProtocolSignatureFormDRF185010295.pdf

2011-03-21-ApprovedProtocolAmend-NotetoFile192224838.pdf

2011-03-21-ApprovedProtocolAmend(TR)190535079.pdf

2011-03-21-ApprovedProtocolAmend192224945.pdf

2011-03-21-ProtocolSignatureFormDRF190047652.pdf

2011-04-06-LogisticalorAdminChange(TR)191198140.pdf

2011-05-10-LogisticalorAdminChange191710008.pdf

2011-05-10-LogisticalorAdminChange(TR)193951320.pdf

2011-05-16-LogisticalorAdminChange191709828.pdf

2011-06-08-ApprovedProtocolAmend-NotetoFile192224835.pdf

2011-08-19-LogisticalorAdminChange195705220.pdf

2011-09-21-LogisticalorAdminChange196158835.pdf

2011-08-08-AnnualSafetyReports(BOTH)199004131.pdf

2012-03-14-SpecialSafetyConcerns201455197.pdf

Incoming Corrspd.pdf

02.06.13 FINAL IND Preliminary Meeting Comments.pdf

index-md5.txt

index.xml

ROC 118393.Report.pdf

index-md5.txt

index.xml

index-md5.txt

index.xml

ROC 118261.Report.pdf

ROC 118211.Report.pdf

PNU-100480 ODD Request.pdf

References.pdf

1.ROC 118393.Report.pdf

2.04.21.09 104,806 Study May Proceed.pdf

3.04 24 09 Comments to Sponsor for 3 23 09 submission.pdf

4.Study May Proceed email 4-21-2009.pdf

5.Division Comments email 4-24-2009.pdf

1.ROC 118261.Report.pdf

2.April 08 Information Request.pdf

1.ROC 118211.Report.pdf

2.Acknowledgement Email.pdf

3.IND 104,806 Acknowledgement Letter.pdf

ectd-2-0.xsl

us-regional.xsl

ich-ectd-3-2.dtd

us-regional-v2-01.dtd

ectd-2-0.xsl

us-regional.xsl

ich-ectd-3-2.dtd

us-regional-v2-01.dtd

ectd-2-0.xsl

us-regional.xsl

ich-ectd-3-2.dtd

us-regional-v2-01.dtd

2009-04-09-IIPLetters-Approval177206500.pdf

2009-07-15-CorrspdwithSite171357772.pdf

2009-08-19-CorrspdwithSite172614916.pdf

2009-09-16-CorrspdwithSite173246869.pdf

2009-08-20-CorrspdwithSite172651668.pdf

2010-05-21-Affidavit179087539.pdf

2007-03-02-CV-SubInvestigator-OnePage-UDERMAN,HOWARDD168082115.pdf

2007-04-17-CV-SubInvestigator-OnePage-BEDARIDA,GABRIELLA168082039.pdf

2008-01-29-CV-SubInvestigator-OnePage-HANSSON,ARNEG168082186.pdf

2008-05-16-CV-SubInvestigator-OnePage-BANERJEE,SUBHASHIS168082112.pdf

2008-09-10-CV-PrincipalInvestigator-OnePage-DIMITROVA,DESSISLAVAI168082276.pdf

2008-09-11-CV-SubInvestigator-OnePage-PAWLAK,SYLVESTERS168082366.pdf

2009-03-16-FDA1572168255580.pdf

2009-04-06-IIPTransmittal168859663.pdf

2009-02-16-IRBIECPanelMembershipNon-VotingStatus168820845.pdf

2009-03-16-IRBIECSubmissionFilingPackage168514059.pdf

2009-03-31-IRBIECApproval-1572AdvertICDProt168820588.pdf

2009-03-23-IRBIECCorrspd-IBSafety168435436.pdf

2009-03-31-IRBIECApproval-Advert168820506.pdf

2009-04-14-IRBIECApproval-Advert169105111.pdf

2009-04-14-IRBIECApproval169105287.pdf

2009-05-07-IRBIECApproval-ProtAmendICD169717002.pdf

2009-07-02-IRBIECApproval-ICD171125962.pdf

2009-08-19-IRBIECStudyCloseOutCommunications172762536.pdf

2009-03-12-InvestigatorProtocolAcceptanceForm168255754.pdf

2009-03-31-InformedConsentForms168820844.pdf

2009-08-18-ProtocolDeviationsLog172615738.pdf

2009-05-06-InvestigatorProtocolAcceptanceForm169701723.pdf

2009-03-31-InformedConsentFormsChklstApprDRF-Center168824510.pdf

2009-05-07-InformedConsentForms169716646.pdf

2009-05-07-InformedConsentFormsChklstApprDRF-Center169716682.pdf

2009-07-02-InformedConsentForms171126251.pdf

2009-07-02-InformedConsentFormsChklstApprDRF-Center171125853.pdf

2008-09-18-LocalLabNormalRanges168119695.pdf

2009-07-29-LocalLabCorrspd171903381.pdf

2009-07-13-ClinicalSupplyCorrspd171311793.pdf

2010-05-18-DrugNonDrugDestructionofInvestigationalProduct178951327.pdf

2010-05-18-InvestigationalProductAccountabilityLog-MultipleSubjects(3)178951564.pdf

2010-05-18-InvestigationalProductAccountabilityLog-MultipleSubjects(2)178951470.pdf

2010-05-18-InvestigationalProductAccountabilityLog-MultipleSubjects(4)178951375.pdf

2010-05-18-InvestigationalProductAccountabilityLog-MultipleSubjects178951233.pdf

Acknowledgement Email.pdf

IND 104,806 Acknowledgement Letter.pdf

April 08 Information Request.pdf

Study May Proceed email 4-21-2009.pdf

Division Comments email 4-24-2009.pdf

04.21.09 104,806 Study May Proceed.pdf

04 24 09 Comments to Sponsor for 3 23 09 submission.pdf

Cover Letter.pdf

index-md5.txt

1571.pdf

index.xml

cover.pdf

gen-invest-plan.pdf

ind-stud-infor.pdf

sum-clinpharm-info-pub.pdf

sum-nonclin-stud-tox.pdf

sum-safety-info.pdf

us-regional.xml

index-md5.txt

index.xml

1571.pdf

cover.pdf

us-regional.xml

index-md5.txt

index.xml

1571.pdf

cover.pdf

us-regional.xml

2010-05-11-StudyReport-DRF178961194.pdf

2009-03-18-MasterRandomizationList(2)179095431.pdf

2009-03-18-MasterRandomizationList(3)179095526.pdf

2009-03-18-MasterRandomizationList(4)179095873.pdf

2009-03-18-MasterRandomizationList179095870.pdf

2009-09-11-DatabaseChangeRequestForm173085858.pdf

2010-05-20-RandomizationCodeReleaseRequestForm179590808.pdf

2009-06-05-CROVendorOversightPlanTransferofObligations178976124.pdf

ectd-2-0.xsl

us-regional.xsl

1571.pdf

appendix-type-c-meeting-minutes-11-feb-2013.pdf

cover.pdf

type-c-meeting-minutes-11-feb-2013.pdf

us-regional.xml

1571.pdf

cover.pdf

mtg-bkgrd-material-11-feb-2013.pdf

us-regional.xml

ectd-2-0.xsl

us-regional.xsl

ectd-2-0.xsl

ich-stf-styleSheet-2-2a.xsl

us-regional.xsl

valid-values.xml

1571.pdf

cover.pdf

us-regional.xml

ich-ectd-3-2.dtd

ich-stf-v2-2.dtd

us-regional-v2-01.dtd

ich-ectd-3-2.dtd

us-regional-v2-01.dtd

ich-ectd-3-2.dtd

us-regional-v2-01.dtd

2009-05-06-DrugNon-DrugLabelsApproval169668328.pdf

2009-05-20-DrugNon-DrugLabelsApproval170012601.pdf

2009-05-30-DrugNon-DrugLabelsApproval170283505.pdf

2009-06-14-DrugNon-DrugLabelsApproval(2)170649097.pdf

2009-06-14-DrugNon-DrugLabelsApproval(3)170648928.pdf

2009-06-14-DrugNon-DrugLabelsApproval170649008.pdf

2009-06-28-DrugNon-DrugLabelsApproval(2)171095568.pdf

2009-06-28-DrugNon-DrugLabelsApproval171095645.pdf

2009-07-12-DrugNon-DrugLabelsApproval(2)171286490.pdf

2009-07-12-DrugNon-DrugLabelsApproval(3)171286562.pdf

2009-07-12-DrugNon-DrugLabelsApproval171286827.pdf

2009-07-26-DrugNon-DrugLabelsApproval(2)172071094.pdf

2009-08-09-DrugNon-DrugLabelsApproval172425697.pdf

2009-07-26-DrugNon-DrugLabelsApproval172071193.pdf

2010-05-10-EOSNotificationtoSupplyChainOrganization178727861.pdf

2008-01-22-NotetoFile167430428.pdf

2009-03-31-NotetoFile169140812.pdf

2009-04-09-NotetoFile174045952.pdf

2009-04-15-NotetoFile169140811.pdf

2009-05-01-Corrspd-General169711025.pdf

2009-05-05-NotetoFile-Regulatory169543760.pdf

2009-05-13-NotetoFile-Protocol172952299.pdf

2009-05-18-Corrspd-General-IBSafetyPKPGPD169917680.pdf

2009-05-18-Corrspd-General-PKPGPDIBSafety169918021.pdf

2009-05-18-NotetoFile-PKPGPDProtocol169917918.pdf

2009-05-18-NotetoFile-Protocol169917771.pdf

2009-05-29-NotetoFile171199163.pdf

2009-05-29-NotetoFile(3)171198949.pdf

2009-05-29-NotetoFile(2)171198946.pdf

2009-06-04-NotetoFile171198847.pdf

2009-06-12-NotetoFile(2)171198789.pdf

2009-06-12-NotetoFile(3)171199047.pdf

2009-06-12-NotetoFile(4)171198792.pdf

2009-06-12-NotetoFile(5)171199169.pdf

2009-06-12-NotetoFile171199044.pdf

2009-06-26-NotetoFile171198786.pdf

2009-06-26-NotetoFile(2)171198850.pdf

2009-07-02-NotetoFile(2)171198844.pdf

2009-07-02-NotetoFile171199041.pdf

2009-07-10-NotetoFile171292404.pdf

2009-07-10-Corrspd-General171292245.pdf

2009-07-15-NotetoFile171380623.pdf

2010-05-19-PfizerCROPersonnelLog178856348.pdf

2009-03-23-RegulatoryAgenciesApplSubCoverletter-InitialINDProtocol168490597.pdf

2009-05-11-RegulatoryAgenciesApplSubCoverletter-ProtocolAmend169764170.pdf

index-md5.txt

index.xml

2009-03-12-ApprovedProtocolAmend168489677.pdf

2009-03-12-ProtocolSignatureFormDRF(2)168170431.pdf

2009-03-12-ProtocolSignatureFormDRF168170293.pdf

2009-05-06-ApprovedProtocolAmend169764167.pdf

2009-05-06-ProtocolSignatureFormDRF169633734.pdf

2010-05-21-FinancialDisclosureAssessmentForm179095876.pdf

index-md5.txt

index.xml

index-md5.txt

index.xml

index-md5.txt

index.xml

index-md5.txt

index.xml

index-md5.txt

index.xml

1571.pdf

cover.pdf

ib-track-changes.pdf

ib.pdf

us-regional.xml

ectd-2-0.xsl

us-regional.xsl

ectd-2-0.xsl

ich-stf-stylesheet-2-2a.xsl

us-regional.xsl

valid-values.xml

ectd-2-0.xsl

us-regional.xsl

cover.pdf

1571.pdf

us-regional.xml

ectd-2-0.xsl

us-regional.xsl

b1171003-adverse-events.pdf

b1171003-analytical-reports.pdf

b1171003-compliance.pdf

b1171003-demographics.pdf

b1171003-informed-consent.pdf

b1171003-discontinued-patients.pdf

b1171003-efficacy-response.pdf

b1171003-invest-signature.pdf

b1171003-investigators.pdf

b1171003-lab-measurements.pdf

b1171003-patient-batches.pdf

b1171003-protocol-deviations.pdf

b1171003-randomization.pdf

b1171003-protocol.pdf

b1171003-report-body.pdf

b1171003-sap.pdf

b1171003-sample-crf.pdf

b1171003-sponsor-signature.pdf

b1171003-synopsis.pdf

stf-b1171003.xml

ectd-2-0.xsl

us-regional.xsl

ich-ectd-3-2.dtd

us-regional-v2-01.dtd

ich-ectd-3-2.dtd

us-regional-v2-01.dtd

ich-ectd-3-2.dtd

us-regional-v2-01.dtd

ich-ectd-3-2.dtd

ich-stf-v2-2.dtd

us-regional-v2-01.dtd

ich-ectd-3-2.dtd

us-regional-v2-01.dtd

index-md5.txt

index.xml

1571.pdf

cover.pdf

general-investigational-plan.pdf

indiv-study-info.pdf

summary-clinpharm-info-pub.pdf

summary-manufacturing-changes.pdf

summary-nonclin-study-pub.pdf

summary-safety-info.pdf

us-regional.xml

ectd-2-0.xsl

us-regional.xsl

1571.pdf

cover.pdf

mtg-request-02-oct-2012.pdf

us-regional.xml

1571.pdf

cover.pdf

general-invest-plan.pdf

1571.pdf

cover.pdf

individual-study-info.pdf

us-regional.xml

sum-manu-chan.pdf

sum-clin-pham-info.pdf

sum-safety-info.pdf

summary-nonclin-studies-toxicology.pdf

us-regional.xml

ich-ectd-3-2.dtd

us-regional-v2-01.dtd

index-md5.txt

index.xml

ectd-2-0.xsl

ich-stf-stylesheet-2-2a.xsl

us-regional.xsl

valid-values.xml

3674.pdf

1571.pdf

cover.pdf

us-regional.xml

ich-ectd-3-2.dtd

ich-stf-v2-2.dtd

us-regional-v2-01.dtd

index-md5.txt

index.xml

stability-data.pdf

stability-summary.pdf

stf-10ca010.xml

study-10ca010-amend-1.pdf

study-10ca010.pdf

stability-data.pdf

stability-summary.pdf

ich-ectd-3-2.dtd

us-regional-v2-01.dtd

ectd-2-0.xsl

us-regional.xsl

1571.pdf

investigational-brochure.pdf

cover.pdf

summary-changes.pdf

us-regional.xml

stf-10ca009.xml

study-10ca009.pdf

index.xml

index-md5.txt

index-md5.txt

index.xml

ectd-2-0.xsl

us-regional.xsl

introduction.pdf

1571.pdf

cover.pdf

us-regional.xml

b1171002-adverse-events.pdf

b1171002-analytical-reports.pdf

b1171002-compliance.pdf

b1171002-demographics.pdf

b1171002-discontinued-patients.pdf

b1171002-efficacy-response.pdf

b1171002-iec-irb-list.pdf

b1171002-invest-signature.pdf

b1171002-investigators.pdf

b1171002-measurements.pdf

b1171002-protocol.pdf

b1171002-patient-batches.pdf

b1171002-publications.pdf

b1171002-protocol-deviations.pdf

b1171002-randomization.pdf

b1171002-report-body.pdf

b1171002-sap.pdf

b1171002-sponsor-signature.pdf

b1171002-synopsis.pdf

stf-b1171002.xml

cover-letter.pdf

fda-form-1571.pdf

pnu-100480-odd-request.pdf

us-regional.xml

ectd-2-0.xsl

us-regional.xsl

us-regional.xsl

ectd-2-0.xsl

ich-ectd-3-2.dtd

us-regional-v2-01.dtd

introduction.pdf

ich-ectd-3-2.dtd

us-regional-v2-01.dtd

ich-ectd-3-2.dtd

us-regional-v2-01.dtd

stability-data.pdf

stability-summary.pdf

reference-standards.pdf

manufacturer.pdf

cover-letter.pdf

fda-form-1571.pdf

us-regional.xml

index-md5.txt

index.xml

index-md5.txt

index.xml

batch-analyses.pdf

placebo-for-pnu-100480.pdf

index-md5.txt

index.xml

justification-of-specifications.pdf

stability-data.pdf

stability-summary.pdf

stability-data.pdf

stability-summary.pdf

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us-regional-v2-01.dtd

cover-letter.pdf

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us-regional.xsl

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ich-ectd-3-2.dtd

us-regional-v2-01.dtd

impurities.pdf

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justification-of-specification.pdf

batch-analyses.pdf

specification.pdf

cover-letter.pdf

fda-form-1571.pdf

fda-form-3674.pdf

us-regional.xml

characterisation-impurities.pdf

stf-b1171001.xml

b1171001-investigator-declaration.pdf

study-b1171001-additional-data-listings.pdf

study-b1171001.pdf

analytical-procedures.pdf

specifications.pdf

fda-1571-form.pdf

cover-letter.pdf

us-regional.xml

index.xml

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ich-stf-stylesheet-2-2a.xsl

us-regional.xsl

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valid-values.xml

medwatch-2010026268-fu2.pdf

stf-b1171002.xml

ich-ectd-3-2.dtd

ich-stf-v2-2.dtd

us-regional-v2-01.dtd

ich-ectd-3-2.dtd

us-regional-v2-01.dtd

ich-ectd-3-2.dtd

ich-stf-v2-2.dtd

us-regional-v2-01.dtd

ich-ectd-3-2.dtd

ich-stf-v2-2.dtd

us-regional-v2-01.dtd

ich-ectd-3-2.dtd

ich-stf-v2-2.dtd

us-regional-v2-01.dtd

ich-ectd-3-2.dtd

ich-stf-v2-2.dtd

us-regional-v2-01.dtd

cover-letter.pdf

fda-form-1571.pdf

us-regional.xml

waterman2007.pdf

introduction.pdf

cover-letter.pdf

cover-letter.pdf

fda-form-1571.pdf

fda-form-1571.pdf

general-investigational-plan.pdf

indiv-study-info.pdf

summary-clinpharm-info.pdf

summary-manufacturing-changes.pdf

summary-nonclin-study.pdf

fda-form-3674.pdf

summary-safety-info.pdf

investigational-brochure-summary-of-changes.pdf

us-regional.xml

investigational-brochure.pdf

us-regional.xml

b1171002-1001-fda-1572-form-21-sep-2009.pdf

bedarida-gabriella.pdf

stf-b1171002.xml

cover-letter.pdf

us-regional.xml

fda-form-1571.pdf

cover-letter.pdf

us-regional.xml

fda-form-1571.pdf

pk-and-wba-of-pnu-100480.pdf

stf-b1171001.xml

wba-mgit-protocol.pdf

protocol-b1171002.pdf

stf-b1171002.xml

fda-form-1571.pdf

cover-letter.pdf

us-regional.xml

stability-data.pdf

stability-summary.pdf

batch-analyses.pdf

validation-analytical-procedures.pdf

container-closure-system.pdf

pnu-100480-30nov09-16346.pdf

stf-pnu-100480-30nov09-163646.xml

stability-data.pdf

stability-summary.pdf

-pnu-100480-30nov09-163108.pdf

stf-pnu-100480-30nov09-163108.xml

pnu-100480-30nov09-162538.pdf

stf-pnu-100480-30nov09-162538.xml

reference-standards.pdf

medwatch-2010026268.pdf

stf-b1171002.xml

batch-formula.pdf

controls-critical-steps.pdf

manuf-process-and-controls.pdf

manufacturers.pdf

pharmaceutical-development.pdf

description-and-composition.pdf

placebo-for-pnu-100480.pdf

stability-data.pdf

stability-summary.pdf

justification-of-specifications.pdf

control-excipients-compendial.pdf

characterisation-impurities.pdf

batch-analyses.pdf

analytical-procedures.pdf

validation-analytical-procedures.pdf

specification.pdf

index-md5.txt

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manuf-process-and-controls.pdf

manuf-process-development.pdf

medwatch-2010026268-fu1.pdf

stf-b1171002.xml

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cover-letter.pdf

fda-form-1571.pdf

us-regional.xml

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ich-stf-stylesheet-2-2.xsl

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ich-stf-stylesheet-2-2.xsl

us-regional.xsl

valid-values.xml

ich-ectd-3-2.dtd

ich-stf-v2-2.dtd

us-regional-v2-01.dtd

ectd-2-0.xsl

ich-stf-stylesheet-2-2.xsl

us-regional.xsl

valid-values.xml

M0030423111865227300 (2).pdf

M0030410111865238900.pdf

ROC 515906.Report.pdf

ich-ectd-3-2.dtd

ich-stf-v2-2.dtd

us-regional-v2-01.dtd

b1171001-1001-fda-1572-form-16-mar-2009.pdf

b1171001-protocol-12-march-2009-.pdf

dimitrova-dessislava-i.pdf

stf-b1171001.xml

ich-ectd-3-2.dtd

ich-stf-v2-2.dtd

us-regional-v2-01.dtd

ich-ectd-3-2.dtd

ich-stf-v2-2.dtd

us-regional-v2-01.dtd

ich-ectd-3-2.dtd

ich-stf-v2-2.dtd

us-regional-v2-01.dtd

ich-ectd-3-2.dtd

ich-stf-v2-2.dtd

us-regional-v2-01.dtd

B1171003 - Regulatory Authority Approval (MCC) (2).pdf

ROC 500478.Report.pdf

cover-letter.pdf

fda-1571-form.pdf

us-regional.xml

2-6-1--introduction.pdf

2-6-2--pharmacology-written-summary.pdf

2-6-3-3--secondary-pharmacodynamics.pdf

2-6-3-1--pharmacology-overview.pdf

2-6-3-4--safety-pharmacology.pdf

2-6-4--pharmacokinetics-written-summary.pdf

2-6-5-1--pharmacokinetics---overview.pdf

2-6-5-10--pharmacokinetics---Metab-in-vitro.pdf

2-6-5-12--pharmacokinetics---induction-inhibition-of-drug-me.pdf

2-6-5-13--pharmacokinetics---excretion.pdf

2-6-5-3--pharmacokinetics---absorption-after-a-single-dose.pdf

2-6-7-1--toxicology-overview.pdf

2-6-5-6--pharmacokinetics---plasma-protein-binding.pdf

2-6-5-8--pharmacokinetics---other-Distrb-study.pdf

2-6-5-9--pharmacokinetics---Metab-in-vivo.pdf

2-6-7-5-single-dose-toxicity.pdf

2-6-7-6a-repeat-dose-toxicity.pdf

2-6-7-6c-repeat-dose-toxicity.pdf

2-6-7-6b-repeat-dose-toxicity.pdf

2-6-7-6d-repeat-dose-toxicity-nonpivotal-studies.pdf

2-6-7-7a-repeat-dose-toxicity.pdf

2-6-7-7b-repeat-dose-toxicity.pdf

2-6-7-8a-genotoxicity-in-vitro--bacterial-reverse-mutation-a.pdf

2-6-7-8b-genotoxicity-in-vitro--cytogenetic-assay-.pdf

2-6-7-9-genotoxicity-in-vivo--micronucleus-assay-.pdf

2-4-nonclinical-overview.pdf

-investigator-s-brochure--march-2009--pnu-100480--pf-0234127.pdf

1-13-9--pnu-100480-general-investigational-plan-.pdf

1-9-6-other-correspondence-regarding-pediatric-exclusivity-o.pdf

cover-letter.pdf

environmental-assessment.pdf

fda-1571-form.pdf

fda-3674-form.pdf

labelling.pdf

us-regional.xml

cheon-sh--kampmann-b--hise-ag--et-al-.pdf

wallis-brs--palaci-m--vinhas-s--et-al-.pdf

wallis-rs--vinhas-s--janulionis-e-.pdf

wallis-rs--vinhas-sa--johnson-jl--et-al-.pdf

pnu-100480--pf-02341272--22dec08-123524.pdf

stf-pnu-100480-pf-02341272-22dec08-123524.xml

pnu-100480--pf-02341272--19nov08-113708-.pdf

stf-pnu-100480--pf-02341272--19nov08-113708.xml

b1171001-1001-fda-1572-form-16-mar-2009.pdf

b1171001-protocol-12-march-2009-.pdf

dimitrova-dessislava-i.pdf

stf-b1171001.xml

wallis-robert-s.pdf

08gr343.pdf

stf-08gr343.xml

stability-data.pdf

stability-summary.pdf

container-closure-system.pdf

stability-data.pdf

stability-summary.pdf

stf-pf04918975herg.xml

pf-04918975herg.pdf

pf04685698herg.pdf

stf-pf04685698herg.xml

08gr365.pdf

stf-08gr365.xml

pf02341272herg.pdf

stf-pf02341272herg.xml

pf-02341272na15.pdf

stf-pf002341272na15.xml

08gr370.pdf

stf-08gr370.xml

control-excipients-compendial.pdf

08gr360.pdf

stf-08gr360.xml

08gr364.pdf

stf-08gr364.xml

stf-08gr310.xml

08gr310.pdf

description-and-composition.pdf

reference-standards.pdf

elucidation-of-structure.pdf

impurities.pdf

control-of-materials.pdf

manuf-process-and-controls.pdf

manuf-process-development.pdf

manufacturer.pdf

general-properties.pdf

nomenclature.pdf

structure.pdf

08gr312-report-amendment-1.pdf

08gr312.pdf

stf-08gr312.xml

08gr338.pdf

stf-08gr338.xml

08gr188.pdf

stf-08gr188.xml

08gr104.pdf

stf-08gr104.xml

justification-of-specification.pdf

batch-analyses.pdf

validation-analytical-procedures.pdf

specification.pdf

analytical-procedures.pdf

07gr384.pdf

stf-07gr384.xml

pnu-100480--pf-02341272--06nov08-125730-final-format-.pdf

stf-pnu-100480--pf-02341272--06nov08-125730.xml

pnu-100480--pf-02341272--06nov08-125636-final-format.pdf

stf-pnu-100480--pf-02341272--06nov08-125636.xml

pnu-100480--pf-02341272--05jan09-132137-final-format.pdf

stf-pnu-100480--pf-02341272--05jan09-132137.xml

pf-02341272-25nov08-110229--final-format-.pdf

stf-pf-02341272-25nov08-110229.xml

placebo-for-pnu-100480.pdf

stf-08gr351.xml

08gr351.pdf

08gr349.pdf

stf-08gr349.xml

2-2-introduction.pdf

introduction.pdf

07gr383.pdf

stf-07gr383.xml

pnu-100480--pf-02341272--06nov08-134939.pdf

stf-pnu-100480--pf-02341272--06nov08-134939--.xml

pnu-100480--pf-02341272--06nov08-133910.pdf

stf-pnu-100480--pf-02341272--06nov08-133910--.xml

cover-letter.pdf

fda-1571-form.pdf

qqr.pdf

us-regional.xml

2-6-2--pharmacology-written-summary.pdf

ROCEUPNU 10048029May2013.xls

0003---cover-letter-1-.pdf

0003---fda-1571-form-1-.pdf

0003---fda-3674-form-1-.pdf

us-regional.xml

cover-letter.pdf

fda-form-1571.pdf

us-regional.xml

fda-form-3674.pdf

ROCBPNU 10048029May2013.xls

PNU-100480 EU ODDEMA Documents - 12 July 2011.zip

ROC 515982.Report.pdf

stability-data.pdf

stability-summary.pdf

PNU-100480Outcome of COMP - Positive OpinionEMAOD02911 - 10 Jun 2011.pdf

ROC 515520.Report.pdf

EMA Timetable - Received 8 Apr 2011.pdf

ROC 501288.Report.pdf

b1171001-protocol-amendment-1-06-may-2009.pdf

stf-b1171001.xml

pnu-100480-05jan09-135656.pdf

stf-pnu-100480-05jan09-135656.xml

pnu-100480-tb-mic90s.pdf

stf-pnu-100480.xml

rr-pnu-10048005dec08121656-.pdf

stf-pnu-100480-05dec08-121656.xml

BR ROC 518786.Report.pdf

CE B1171003.pdf

rr-7246-94-077-.pdf

stf-7246-94-077.xml

BR ROC 518632.Report.pdf

b1171002-protocol-15-september-2009-.pdf

stf-b1171002.xml

ROC 501221.Report.pdf

ROC 501072.Report.pdf

EU - 1.0 Cover Letter - ODD Letter of IntentUpdate.pdf

ROC 500762.Report.pdf

ROC 500593.Report.pdf

Draft MinutesPre-Submission Meeting 21 Jan 2011 - 27 Jan 2011.doc

ROC 500559.Report.pdf

ROC 500532.Report.pdf

02EMA FDAApplication Form - ODD - PNU-100480.doc

Sutezolid Core Plan final.docx

Sutezolid Core Plan final.pdf

bvoordouwCV.pdf

ROC 500371.Report.pdf

ROC 500245.Report.pdf

EU - 1.0 Cover Letter - ODD Letter of Intent.pdf

ROC 500246.Report.pdf

20110830PNU-100480 ODD EU Commission Decision.pdf

EU ROC 521620.Report.pdf

Annual report EU-3-11-897.pdf

EU ROC 530223.Report.pdf

EU ROC 516743.Report.pdf

PNU-100480 EU ODDEMA Documents - 4 Aug 2011.zip

01EU - 1.0 Cover Letter - Package for Pre-Submission Meeting.pdf

ROC 500467.Report.pdf

FinancialDisclosures.xlsx

033817-USA-61093879-I-298047-EFRFileWrapper.pdf

033817A-ASTL-2009288820-F-493920-EFRFileWrapper.pdf

033817A-BRAZ-PI0918802-9-F-493921-EFRFileWrapper.pdf

033817A-CANA-2735229-F-493922-EFRFileWrapper.pdf

033817A-CHIN-200980134310.X-F-493923-EFRFileWrapper.pdf

033817A-EPC-09787058.8-F-493917-EFRFileWrapper.pdf

033817A-HONG-11110319.0-F-493924-EFRFileWrapper.pdf

033817A-INDI-PCTIB2009053796-I-493927-EFRFileWrapper.pdf

033817A-ISRA-211293-F-493928-EFRFileWrapper.pdf

033817A-KORS-2011-7007672-F-493930-EFRFileWrapper.pdf

033817A-MACA-D-493926-EFRFileWrapper.pdf

033817A-JAPA-2011-525657-F-493929-EFRFileWrapper.pdf

033817A-MEXI-MXA2011002348-F-493931-EFRFileWrapper.pdf

033817A-PCT-PCTIB2009053796-I-305070-EFRFileWrapper.pdf

033817A-NEWZ-591169-F-493932-EFRFileWrapper.pdf

033817A-RUSS-2011108026-F-493933-EFRFileWrapper.pdf

033817A-SAFR-201101742-F-493936-EFRFileWrapper.pdf

033817A-SING-201101113-7-F-493934-EFRFileWrapper.pdf

033817A-USA-13061233-F-298936-EFRFileWrapper.pdf

Copies of the claims-P51483ZA00.pdf

P610 - P51483ZA00 - certificate of grant letter to client.pdf

Office Action-033817A-USA-13061233-F-298936-Prosecution.pdf

PC33817A-RestrictionReqAsFiled-2-18-13.pdf

PC33817AmendedclaimsMX.pdf

A1ad0b3aa-252d-44f2-9b7e-d55d6f327a8d.pdf

M0180461092305947400.pdf

TBOxie Letter to Investigators 02 Oct 13.docx

Sutezolid PNU-100480 PF-02341272 IB 2012.docx

2011-05-31-FinancialDisclosureForm-DUBOIS,JEANNINE.pdf

2011-05-31-FinancialDisclosureForm-DIACON,ANDREASHENRI.pdf

2011-05-31-FinancialDisclosureForm-Noveljic,Zoja.pdf

2011-05-31-FinancialDisclosureForm-Siwendu,SweetnessNonzwakazi.pdf

2011-06-01-FinancialDisclosureForm-VonGroote-Bidlingmaier,FlorianTill.pdf

2012-01-27-FinancialDisclosureForm-None.pdf

2012-01-26-FinancialDisclosureForm-PATIENTIA,RAMONDEFIONA.pdf

2011-06-02-FinancialDisclosureForm-Narunsky, Kim.pdf

2011-06-02-FinancialDisclosureForm-Dawson,Rodney.pdf

2011-06-02-FinancialDisclosureForm-Smit,Tanya.pdf

2011-06-02-FinancialDisclosureForm-WHALE,CAROLYNANNE.pdf

2011-06-03-FinancialDisclosureForm-Symons,GregoryJohn.pdf

2011-06-03-FinancialDisclosureForm-VanZyl-Smit,RichardNellis.pdf

033817A-ASTL-2009288820-F-493920-EFRFileWrapper.pdf

033817A-CANA-2735229-F-493922-EFRFileWrapper.pdf

033817A-CHIN-200980134310.X-F-493923-EFRFileWrapper.pdf

033817A-EPC-09787058.8-F-493917-EFRFileWrapper.pdf

033817A-ISRA-211293-F-493928-EFRFileWrapper.pdf

033817A-MEXI-MXA2011002348-G-493931-EFRFileWrapper.pdf

033817A-NEWZ-591169-G-493932-EFRFileWrapper.pdf

033817A-NEWZ-604044-F-505410-EFRFileWrapper.pdf

033817A-RUSS-2011108026-F-493933-EFRFileWrapper.pdf

033817A-SAFR-201101742-G-493936-EFRFileWrapper.pdf

033817A-SING-201101113-7-F-493934-EFRFileWrapper.pdf

033817A-USA-13061233-F-298936-EFRFileWrapper.pdf

2010-11-17-FinancialDisclosureForm-ANDRADE,MELISSAFONSECA.pdf

2010-11-17-FinancialDisclosureForm-DIETZE,REYNALDO.pdf

2010-11-17-FinancialDisclosureForm-HADAD,DAVIDJAMIL.pdf

2010-11-17-FinancialDisclosureForm-MOLINO,LUCILIAPEREIRADUTRA.pdf

2011-08-17-FinancialDisclosureForm-MIRANDA,MAYKEARMANI.pdf

2011-05-18-FinancialDisclosureForm-Palaci,Moises.pdf

Sutezolidreport02-20-2013-Final.docx

NonClinical Tox Studies for PF 02341272.pdf

PNU-0100480 Native.xlsx

PNU-0100480 PDF w-Overlay.xlsx

BR-PNU-100480(PF-02341272)-CTSUR-22-JAN-2011-21-JUL-2011.pdf

LL-PNU-100480(PF-02341272)-CTSUR-22JAN2011-21JUL2011.pdf

CSA for B1171003 -- CSP07435.pdf

CSA for B1171003 -- CSP07435.xml

CSP07474.doc

CSP07474.pdf

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CSP4857 New Haven CRU.doc.pdf

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CSP4857.doc.pdf

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CSP6541.doc

CSP65411.doc

CSP65411.pdf

CSP65412.pdf

CSP65412.doc

CSP65413.doc

CSP65413.pdf

CSP6542.doc

CSP6542.pdf

CSP65421.doc

CSP65421.pdf

PD for B1171003.pdf

PD for B1171003.pptx

PD for CSP07846.pdf

PD for CSP07846.ppt

PD for CSP09649.pdf

PD for CSP09649.ppt

PNU-10048031Mar11143553.pdf

PNU-10048030Nov0916346.pdf

PF-04918975HERG.doc

PF-04918975HERG1.pdf

SPR for Zyvox B1171003CSP099656Jan11.pdf

SPR for Zyvox B1171003CSP099656Jan11.doc

Figure 14.2.1.7.3 Plot of Individual Absolute Value for WBA by Subject.pdf

Figure 14.2.1.7.2 Plot of Mean Absolute Value with Standard Error for WBA by Treatment.pdf

Figure 14.2.1.8.3 Plot of Individual ChngBase for WBA by Subject.pdf

Figure 14.2.1.7.4 Plot of Individual Absolute Value for WBA by Treatment.pdf

Figure 14.2.1.8.4 Plot of Individual ChngBase for WBA by Treatment.pdf

Figure 14.2.1.8.2 Plot of Mean ChngBase with Standard Error for WBA by Treatment.pdf

Figure 14.2.1.9.2 Plot of Individual Base 24-hour AUC WBA and Cumulative WBA with Mean by Treatment.pdf

Table 14.2.1.7.1 Dscrp Sum Absolute Values for WBA.pdf

Figure 14.2.1.9.3 Plot of Mean Cumulative WBA over 24-hour Time Post Dose with Standard Error.pdf

Table 14.2.1.8.1 Dscrp Sum ChngBase for WBA.pdf

Table 14.2.1.9.1 Dscrp Sum Base 24-hour AUC WBA and Cumulative WBA.pdf

Table 14.2.2.6.1 Sum Stats ANCOVA Cumulative WBA - FAS.pdf

Table 16.2.6.4.1 Listing of Individual WBA.pdf

Table 16.1.9.2.6.1 Statistical Output ANCOVA Cumulative WBA - FAS.pdf

Table 16.2.6.4.2 Listing of Base 24-hour AUC WBA and Cumulative WBA.pdf

B1171003-Center-1002-rando.pdf

B1171003-Center-1003-rando.pdf

(CL) Orphan Drug AR 2013.doc

1.1.2 FDA Form 356h-Change to Sterilization of Filling Pumps.pdf

(CL) Orphan Drug AR 2013.doc.pdf

1.2 Cover Letter-Change to Sterilization of Filling Pumps.doc

1.2 Cover Letter-Change to Sterilization of Filling Pumps.pdf

PNU-100480 Orphan Drug Annual Rpt 2013.docx

PNU-100480 Orphan Drug Annual Rpt 2013.docx.pdf

Sutezolid - Pfizer minutes final.pdf

Sutezolid FDA type C mtg 11 FEB slides.pdf

B117Finaldeliverables20131.pdf

Table 1.13.3-6.2-104806-B117-20131.pdf

Table 1.13.8-1-104806-B117-20131.pdf

Table 1.13.8-2-104806-B117-20131.pdf

Table 1.13.8-3-104806-B117-20131.pdf

1.13.2 Sum Clinical PharmaC1.pdf

1.13.3 - Summary Page1.pdf

1.13.3 - TOC1.pdf

1.13.3 Sum SI.1.pdf

1.13.8 - Summary Page1.pdf

1.13.8 - TOC1.pdf

1.13.8 Individual study Info1.pdf

1.13.9 General Investigational Plan1.pdf

B117Finaldeliverables20131.pdf

1.14.4.1 IB (paper submission only)1.pdf

IND Annual Rpt carboprost tromethamine PNU-0100480 22 Jan 2012 - 21 Jan 20131.pdf

Table 1.13.1-1 Sum Non-Clinical Studies - Tox1.pdf

Table 1.13.3-6.2-104806-B117-20131.pdf

Table 1.13.8-1-104806-B117-20131.pdf

Table 1.13.8-2-104806-B117-20131.pdf

Table 1.13.8-3-104806-B117-20131.pdf

5.1 NoCln PharmaC1.pdf

2.5 Clinical Overview1.pdf

1.13.2 Sum Clinical PharmaC1.pdf

1.13.3 - Summary Page1.pdf

1.13.3 - TOC1.pdf

1.13.3 Sum SI.1.pdf

1.13.8 - TOC1.pdf

1.13.8 - Summary Page1.pdf

1.13.8 Individual study Info1.pdf

1.13.9 General Investigational Plan1.pdf

1.14.4.1 IB (paper submission only)1.pdf

Table 1.13.1-1 Sum Non-Clinical Studies - Tox1.pdf

Figure 14.2.1.1.1.2 Plot of Mean Absolute Value for Sputum Log CFU/ml with Standard Error over Time.pdf

Figure 14.2.1.1.2.2 Plot of Mean ChngBase for Sputum Log CFU/ml with Standard Error over Time.pdf

Figure 14.2.1.2.1.2 Plot of Individual Rate of Change in Sputum Log CFU/ml with Mean from Day 0 to Day 2 by Treatment.pdf

Figure 14.2.1.3.1.2 Plot of Mean Absolute Value for TTP with Standard Error over Time.pdf

Figure 14.2.1.3.2.2 Plot of Mean ChngBase for TTP with Standard Error over Time.pdf

Figure 14.2.1.4.1.2 Plot of Individual Rate of Change in TTP with Mean from Day 0 to Day 2 by Treatment.pdf

Figure 14.2.1.4.2.2 Plot of Individual Rate of Change in TTP with Mean from Day 0 to Day 14 by Treatment.pdf

Figure 14.2.1.2.2.2 Plot of Individual Rate of Change in Sputum Log CFU/ml with Mean from Day 0 to Day 14 by Treatment.pdf

Figure 14.2.1.2.3.2 Plot of Individual Rate of Change in Sputum Log CFU/ml with Mean from Day 2 to Day 14 by Treatment.pdf

Figure 14.2.1.4.3.2 Plot of Individual Rate of Change in TTP with Mean from Day 2 to Day 14 by Treatment.pdf

Figure 14.2.1.5.1.2 Plot of Mean Absolute Value for Log TTP with Standard Error over Time.pdf

Figure 14.2.1.5.2.2 Plot of Mean ChngBase for Log TTP with Standard Error over Time.pdf

Figure 14.2.1.6.1.2 Plot of Individual Rate of Change in Log TTP with Mean from Day 0 to Day 2 by Treatment.pdf

Figure 14.2.1.7.4 Plot of Individual Absolute Value for WBA by Treatment.pdf

Figure 14.2.1.6.3.2 Plot of Individual Rate of Change in Log TTP with Mean from Day 2 to Day 14 by Treatment.pdf

Figure 14.2.1.6.2.2 Plot of Individual Rate of Change in Log TTP with Mean from Day 0 to Day 14 by Treatment.pdf

CDS Carboprost1.pdf

Figure 14.2.1.7.3 Plot of Individual Absolute Value for WBA by Subject.pdf

CDS Carboprost3.pdf

Figure 14.2.1.7.2 Plot of Mean Absolute Value with Standard Error for WBA by Treatment.pdf

Figure 14.2.1.8.2 Plot of Mean ChngBase with Standard Error for WBA by Treatment.pdf

Figure 14.2.1.8.3 Plot of Individual ChngBase for WBA by Subject.pdf

Figure 14.2.1.8.4 Plot of Individual ChngBase for WBA by Treatment.pdf

Figure 14.4.2.2.1.1 Median Plasma PNU-100480 Conc - Time Plot (Linear Scale).pdf

Figure 14.2.1.9.2 Plot of Individual Base 24-hour AUC WBA and Cumulative WBA with Mean by Treatment.pdf

Figure 14.2.1.9.3 Plot of Mean Cumulative WBA over 24-hour Time Post Dose with Standard Error.pdf

Figure 14.4.2.2.1.2 Median Plasma PNU-101603 Conc - Time Plot (Linear Scale).pdf

Figure 14.4.2.2.2.1 Median Plasma PNU-100480 Conc - Time Plot (Semilog Scale).pdf

Figure 14.4.2.2.2.2 Median Plasma PNU-101603 Conc - Time Plot (Semilog Scale).pdf

Figure 14.4.2.2.3.1 Mean Plasma PNU-100480 Conc - Time Plot (Linear Scale).pdf

Figure 14.4.2.2.3.2 Mean Plasma PNU-101603 Conc - Time Plot (Linear Scale).pdf

Figure 14.4.2.2.4.1 Mean Plasma PNU-100480 Conc - Time Plot (Semilog Scale).pdf

Figure 14.4.2.2.4.2 Mean Plasma PNU-101603 Conc - Time Plot (Semilog Scale).pdf

Figure 14.4.3.2.1 Plot of Dose Normalized Plasma PNU-100480 AUCtau by Treatment.pdf

Figure 14.4.3.2.2 Plot of Dose Normalized Plasma PNU-100480 Cmax by Treatment.pdf

Figure 14.4.3.2.3 Plot of Dose Normalized Plasma PNU-101603 AUCtau by Treatment.pdf

Figure 14.4.3.2.4 Plot of Dose Normalized Plasma PNU-101603 Cmax by Treatment.pdf

Figure 16.2.5.4.2.3.2 Plasma PNU-101603 Conc - Time Plot by Treatment (Linear Scale).pdf

Figure 16.2.5.4.2.3.1 Plasma PNU-100480 Conc - Time Plot by Treatment (Linear Scale).pdf

[Figure 16.2.5.4.2.3.3 Plasma PNU-100480 Conc - Time Plot by Treatment \(Semilog Scale\).pdf](#)

[Figure 16.2.5.4.2.3.4 Plasma PNU-101603 Conc - Time Plot by Treatment \(Semilog Scale\).pdf](#)

[Figure 16.2.5.4.2.4.1 Plasma PNU-100480 Conc - Time Plot by Subject \(Linear Scale\).pdf](#)

[Figure 16.2.5.4.2.4.2 Plasma PNU-101603 Conc - Time Plot by Subject \(Linear Scale\).pdf](#)

[Figure 16.2.5.4.2.4.3 Plasma PNU-100480 Conc - Time Plot by Subject \(Semilog Scale\).pdf](#)

[Figure 16.2.5.4.2.4.4 Plasma PNU-101603 Conc - Time Plot by Subject \(Semilog Scale\).pdf](#)

[Table 14.1.1.1 Subject Evaluation Groups.pdf](#)

[Table 14.1.1.2 Discontinuations from Study.pdf](#)

[Table 14.1.2 Demographic Characteristics.pdf](#)

[Table 14.2.1.1.1.1 Dscrp Sum Absolute Value for Sputum Log CFU/ml over Time.pdf](#)

[Table 14.2.1.1.2.1 Dscrp Sum ChngBase for Sputum Log CFU/ml over Time.pdf](#)

[Table 14.2.1.2.1.1 Dscrp Sum Rate of Change in Sputum Log CFU/ml from Day 0 to Day 2.pdf](#)

[Table 14.2.1.2.2.1 Dscrp Sum Rate of Change in Sputum Log CFU/ml from Day 0 to Day 14.pdf](#)

[Table 14.2.1.2.3.1 Dscrp Sum Rate of Change in Sputum Log CFU/ml from Day 2 to Day 14.pdf](#)

[Table 14.2.1.3.1.1 Dscrp Sum Absolute Value for TTP over Time.pdf](#)

[Table 14.2.1.3.2.1 Dscrp Sum ChngBase for TTP over Time.pdf](#)

[Table 14.2.1.4.1.1 Dscrp Sum Rate of Change in TTP from Day 0 to Day 2.pdf](#)

[Table 14.2.1.4.2.1 Dscrp Sum Rate of Change in TTP from Day 0 to Day 14.pdf](#)

[Table 14.3.2.2 Serious AEs.pdf](#)

[Table 14.2.1.4.3.1 Dscrp Sum Rate of Change in TTP from Day 2 to Day 14.pdf](#)

[Table 14.2.1.5.1.1 Dscrp Sum Absolute Value for Log TTP over Time.pdf](#)

[Table 14.2.1.5.2.1 Dscrp Sum ChngBase for Log TTP over Time.pdf](#)

[Table 14.2.1.6.1.1 Dscrp Sum Rate of Change in Log TTP from Day 0 to Day 2.pdf](#)

[Table 14.2.1.6.2.1 Dscrp Sum Rate of Change in Log TTP from Day 0 to Day 14.pdf](#)

[Table 14.2.1.6.3.1 Dscrp Sum Rate of Change in Log TTP from Day 2 to Day 14.pdf](#)

Table 14.2.1.7.1 Dscrp Sum Absolute Values for WBA.pdf

Table 14.2.1.8.1 Dscrp Sum ChngBase for WBA.pdf

Table 14.2.1.9.1 Dscrp Sum Base 24-hour AUC WBA and Cumulative WBA.pdf

Table 14.2.2.1.1 Sum Stats ANCOVA Rate of Change in Sputum Log CFU/ml from Day 0 to Day 2 - FAS.pdf

Table 14.2.2.1.2 Sum Stats ANCOVA (2-Way Interactions) Rate of Change in Sputum Log CFU/ml from Day 0 to Day 2 - FAS.pdf

Table 14.2.2.2.1 Sum Stats ANCOVA Rate of Change in Sputum Log CFU/ml from Day 0 to Day 14 - FAS.pdf

Table 14.2.2.2.2 Sum Stats ANCOVA (2-Way Interactions) Rate of Change in Sputum Log CFU/ml from Day 0 to Day 14 - FAS.pdf

Table 14.2.2.3.1 Sum Stats ANCOVA Rate of Change in Sputum Log CFU/ml from Day 2 to Day 14 - FAS.pdf

Table 14.2.2.3.2 Sum Stats ANCOVA (2-Way Interactions) Rate of Change in Sputum Log CFU/ml from Day 2 to Day 14 - FAS.pdf

Table 14.2.2.6.1 Sum Stats ANCOVA Cumulative WBA - FAS.pdf

Table 14.2.2.1.3 Sum Stats ANCOVA (Slope from Linear Regression) Rate of Change in Sputum Log CFU/ml from Day 0 to Day 2 - FAS.pdf

Table 14.2.2.3 Sum Stats ANCOVA (Slope from Linear Regression) Rate of Change in Sputum Log CFU/ml from Day 0 to Day 14 - FAS.pdf

Table 14.2.2.4.1 Sum Stats ANCOVA Rate of Change in TTP from Day 0 to Day 2 - FAS.pdf

Table 14.2.2.4.2 Sum Stats ANCOVA Rate of Change in TTP from Day 0 to Day 14 - FAS.pdf

Table 14.2.2.5.2 Sum Stats ANCOVA Rate of Change in Log TTP from Day 0 to Day 14 - FAS.pdf

Table 14.2.2.5.1 Sum Stats ANCOVA Rate of Change in Log TTP from Day 0 to Day 2 - FAS.pdf

Table 14.2.2.4.3 Sum Stats ANCOVA Rate of Change in TTP from Day 2 to Day 14 - FAS.pdf

Table 14.2.2.3.3 Sum Stats ANCOVA (Slope from Linear Regression) Rate of Change in Sputum Log CFU/ml from Day 2 to Day 14 - FAS.pdf

Table 14.2.2.5.3 Sum Stats ANCOVA Rate of Change in Log TTP from Day 2 to Day 14 - FAS.pdf

Table 14.2.2.7.1 Sum Stats Repeated Measures (Exploratory Regression Analysis) Sputum Log CFU/ml - FAS.pdf

Table 14.2.2.7.2 Sum Stats Repeated Measures (Exploratory Classified Day Analysis) Sputum Log CFU/ml - FAS.pdf

Table 14.2.2.8.1 Sum Stats Repeated Measures (Exploratory Regression Analysis) TTP - FAS.pdf

Table 14.2.2.8.2 Sum Stats Repeated Measures (Exploratory Classified Day Analysis) TTP - FAS.pdf

Table 14.3.1.1.1 Discontinuations Due to AEs.pdf

Table 16.2.7 AEs.pdf

[Table 14.2.2.9.1 Sum Stats Repeated Measures \(Exploratory Regression Analysis\) Log TTP - FAS.pdf](#)

[Table 14.2.2.9.2 Sum Stats Repeated Measures \(Exploratory Classified Day Analysis\) Log TTP - FAS.pdf](#)

[Table 14.3.1.1.2 Temporary Discontinuations or Dose Reductions Due to AEs.pdf](#)

[Table 14.3.1.2.1 T-E AEs \(All Causalities\).pdf](#)

[Table 14.3.1.2.2 Incidence and Severity of T-E AEs \(All Causalities\).pdf](#)

[Table 14.3.1.3.1 T-E AEs \(Treatment Related\).pdf](#)

[Table 14.3.1.3.2 Incidence and Severity of T-E AEs \(Treatment Related\).pdf](#)

[Table 14.3.2.1 Individual Listing of Deaths.pdf](#)

[Table 14.3.4.1.1 Incidence of LTA's \(Normal Base\).pdf](#)

[Table 14.3.4.1.2 Incidence of LTA's \(Abnormal Base\).pdf](#)

[Table 14.3.4.1.3 Incidence of LTA's \(Without Regard to Base Abnormality\).pdf](#)

[Table 14.3.4.2.1 Mean Base and ChngBase for Vital Signs Data.pdf](#)

[Table 14.3.4.2.2.1 Categorical Sum Vital Signs Data - Absolute Values.pdf](#)

[Table 14.3.4.2.2.2 Categorical Sum Vital Signs Data - Increases from Base.pdf](#)

[Table 14.3.4.2.2.3 Categorical Sum Vital Signs Data - Decreases from Base.pdf](#)

[Table 14.3.4.3.1 Mean Base and ChngBase for ECG Data.pdf](#)

[Table 14.3.4.3.2.1 Categorical Sum ECG Data - Absolute Values.pdf](#)

[Table 14.3.4.3.2.2 Categorical Sum ECG Data - Increases from Base.pdf](#)

[Table 14.3.4.4.1 Physical Examination Findings at Base.pdf](#)

[Table 14.4.1 Administration Schedule.pdf](#)

[Table 14.4.2.1.1 Plasma PNU-100480 Conc \[ngmL\] vs Time Summary.pdf](#)

[Table 14.4.3.1.1 Dscrp Sum Plasma PNU-100480 PK Parameters.pdf](#)

[Table 14.4.2.1.2 Plasma PNU-101603 Conc \[ngmL\] vs Time Summary.pdf](#)

[Table 14.4.3.1.2 Dscrp Sum Plasma PNU-101603 PK Parameters.pdf](#)

[Table 14.4.3.1.3 Dscrp Sum Urine PNU-100480 PK Parameters.pdf](#)

Table 16.1.7.2 Randomization Treatment Assigned and Treatment Received.pdf

Table 16.1.9.2.1.1 Statistical Output ANCOVA Rate of Change in Sputum Log CFU/ml from Day 0 to Day 2 - FAS.pdf

Table 16.1.9.2.1.2 Statistical Output ANCOVA (2-Way Interactions) Rate of Change in Sputum Log CFU/ml from Day 0 to Day 2 - FAS.pdf

Table 16.1.9.2.1.3 Statistical Output ANCOVA (Slope from Linear Regression) Rate of Change in Sputum Log CFU/ml from Day 0 to Day 2 - FAS.pdf

Table 16.1.9.2.1.4 Statistical Output ANCOVA Rate of Change in Sputum Log CFU/ml from Day 0 to Day 2 - Sens Analy.pdf

Table 16.1.9.2.2.1 Statistical Output ANCOVA Rate of Change in Sputum Log CFU/ml from Day 0 to Day 14 - FAS.pdf

Table 16.1.9.2.2.4 Statistical Output ANCOVA Rate of Change in Sputum Log CFU/ml from Day 0 to Day 14 - Sens Analy.pdf

Table 16.1.9.2.3.1 Statistical Output ANCOVA Rate of Change in Sputum Log CFU/ml from Day 2 to Day 14 - FAS.pdf

Table 16.1.9.2.1.5 Statistical Output ANCOVA (Slope from Linear Regression) Rate of Change in Sputum Log CFU/ml from Day 0 to Day 2 - Sens Analy.pdf

Table 16.1.9.2.2.2 Statistical Output ANCOVA (2-Way Interactions) Rate of Change in Sputum Log CFU/ml from Day 0 to Day 14 - FAS.pdf

Table 16.1.9.2.5.1 Statistical Output ANCOVA Rate of Change in Log TTP from Day 0 to Day 2 - FAS.pdf

Table 16.1.9.2.5.2 Statistical Output ANCOVA Rate of Change in Log TTP from Day 0 to Day 14 - FAS.pdf

Table 16.1.9.2.5.3 Statistical Output ANCOVA Rate of Change in Log TTP from Day 2 to Day 14 - FAS.pdf

Table 16.1.9.2.6.1 Statistical Output ANCOVA Cumulative WBA - FAS.pdf

Table 16.2.4.1 Subject Evaluation Groups.pdf

Table 16.1.9.2.2.5 Statistical Output ANCOVA (Slope from Linear Regression) Rate of Change in Sputum Log CFU/ml from Day 0 to Day 14 - Sens Analy.pdf

Table 16.1.9.2.2.3 Statistical Output ANCOVA (Slope from Linear Regression) Rate of Change in Sputum Log CFU/ml from Day 0 to Day 14 - FAS.pdf

Table 16.1.9.2.7.1 Statistical Output Repeated Measures (Exploratory Regression Analysis) Sputum Log CFU/ml - FAS.pdf

Table 16.1.9.2.7.2 Statistical Output Repeated Measures (Exploratory Classified Day Analysis) Sputum Log CFU/ml - FAS.pdf

Table 16.1.9.2.8.1 Statistical Output Repeated Measures (Exploratory Regression Analysis) TTP - FAS.pdf

Table 16.1.9.2.8.2 Statistical Output Repeated Measures (Exploratory Classified Day Analysis) TTP - FAS.pdf

Table 16.1.9.2.3.2 Statistical Output ANCOVA (2-Way Interactions) Rate of Change in Sputum Log CFU/ml from Day 2 to Day 14 - FAS.pdf

Table 16.1.9.2.3.3 Statistical Output ANCOVA (Slope from Linear Regression) Rate of Change in Sputum Log CFU/ml from Day 2 to Day 14 - FAS.pdf

Table 16.1.9.2.3.4 Statistical Output ANCOVA Rate of Change in Sputum Log CFU/ml from Day 2 to Day 14 - Sens Analy.pdf

Table 16.1.9.2.4.1 Statistical Output ANCOVA Rate of Change in TTP from Day 0 to Day 2 - FAS.pdf

[Table 16.1.9.2.4.2 Statistical Output ANCOVA Rate of Change in TTP from Day 0 to Day 14 - FAS.pdf](#)

[Table 16.1.9.2.4.3 Statistical Output ANCOVA Rate of Change in TTP from Day 2 to Day 14 - FAS.pdf](#)

[Table 16.2.1 Subject Discontinuations.pdf](#)

[Table 16.1.9.2.3.5 Statistical Output ANCOVA \(Slope from Linear Regression\) Rate of Change in Sputum Log CFU/ml from Day 2 to Day 14 - Sens Analy.pdf](#)

[Table 16.1.9.2.9.1 Statistical Output Repeated Measures \(Exploratory Regression Analysis\) Log TTP - FAS.pdf](#)

[Table 16.1.9.2.9.2 Statistical Output Repeated Measures \(Exploratory Classified Day Analysis\) Log TTP - FAS.pdf](#)

[Table 16.2.4.2 Demographic Characteristics.pdf](#)

[Table 16.2.5.1 Administration Schedule.pdf](#)

[Table 16.2.4.3 Medical History.pdf](#)

[Table 16.2.5.2 Concomitant Drug Treatments.pdf](#)

[Table 16.2.5.3 Concomitant Non-drug Treatments.pdf](#)

[Table 16.2.5.4.1.1.1 Plasma PNU-100480 Conc vs Time Listing.pdf](#)

[Table 16.2.5.4.1.1.2 Plasma PNU-101603 Conc vs Time Listing.pdf](#)

[Table 16.2.5.4.1.2.1 Sample Deviations \(10\) and Comments for Plasma PNU-100480 Assay.pdf](#)

[Table 16.2.5.4.1.2.2 Sample Deviations \(10\) and Comments for Plasma PNU-101603 Assay.pdf](#)

[Table 16.2.5.4.3.1 Urine PNU-100480 ConcAmount Listing by Collection Interval.pdf](#)

[Table 16.2.5.4.3.2 Urine PNU-101603 ConcAmount Listing by Collection Interval.pdf](#)

[Table 16.2.5.5.1.1 Listing and Dscrp Sum Plasma PNU-100480 PK Parameters.pdf](#)

[Table 16.2.5.5.1.2 Listing and Dscrp Sum Plasma PNU-101603 PK Parameters.pdf](#)

[Table 16.2.6.1.2 Listing of Rate of Change in Sputum Log CFU/ml from Day 0 to Day 2.pdf](#)

[Table 16.2.6.1.1 Listing of Individual Sputum Log CFU/ml.pdf](#)

[Table 16.2.5.5.1.3 Listing and Dscrp Sum Urine PNU-100480 PK Parameters.pdf](#)

[Table 16.2.5.5.1.4 Listing and Dscrp Sum Urine PNU-101603 PK Parameters.pdf](#)

[Table 16.2.6.1.3 Listing of Rate of Change in Sputum Log CFU/ml from Day 0 to Day 14.pdf](#)

[Table 16.2.6.1.4 Listing of Rate of Change in Sputum Log CFU/ml from Day 2 to Day 14.pdf](#)

Table 16.2.6.2.1 Listing of Individual TTP.pdf

Table 16.2.6.2.2 Listing of Rate of Change in TTP from Day 0 to Day 2.pdf

Table 16.2.6.2.3 Listing of Rate of Change in TTP from Day 0 to Day 14.pdf

Table 16.2.6.2.4 Listing of Rate of Change in TTP from Day 2 to Day 14.pdf

Table 16.2.6.3.1 Listing of Individual Log TTP.pdf

Table 16.2.6.3.2 Listing of Rate of Change in Log TTP from Day 0 to Day 2.pdf

Table 16.2.6.3.4 Listing of Rate of Change in Log TTP from Day 2 to Day 14.pdf

Table 16.2.6.3.3 Listing of Rate of Change in Log TTP from Day 0 to Day 14.pdf

Table 16.2.6.4.2 Listing of Base 24-hour AUC WBA and Cumulative WBA.pdf

Table 16.2.6.4.1 Listing of Individual WBA.pdf

Table 16.2.6.6.1 Listing of Susceptibility Testing (Isoniazid and Rifampin).pdf

Table 16.2.6.5 Listing of Tuberculosis X-ray Assessment.pdf

Table 16.2.6.6.2 Listing of Susceptibility Testing (PNU-100480 and PNU-101603).pdf

Table 16.2.6.7 Listing of Microbiology Test - Pathogen Isolated.pdf

Table 16.2.8.1.1 Laboratory Data.pdf

Table 16.2.8.1.2 Laboratory Abnormalities, by Subject.pdf

Table 16.2.8.1.3 Laboratory Abnormalities, by Test.pdf

Table 16.2.8.2.1 Vital Signs Data.pdf

Table 16.2.8.2.2 Vital Signs Values Meeting Categorical Summarization Criteria.pdf

Table 16.2.8.3.1 ECG Data.pdf

Table 16.2.8.3.2 ECG Qualitative Results.pdf

Table 16.2.8.3.3 ECG Values Meeting Categorical Summarization Criteria.pdf

Table 16.2.8.4.1 Physical Examination Screen.pdf

Table 16.4 Patient Profile.pdf

Table 16.2.8.4.2 Physical Examination Changes from Screen.pdf

(CL) Orphan Drug AR 2013.doc1.pdf

16.1.5.1 - Sponsor.pdf

16.1.5.2 - CSR Investigator Declaration.doc

16.1.6 Study Drug Information.doc

16.1.5.2 - CSR Investigator Declaration.pdf

16.1.6 Study Drug Information.pdf

B1171003 Phase 2 ICH Study Rpt Synopsis.doc

B1171003 Phase 2 ICH Study Rpt Synopsis.pdf

B1171003 PH 2 ICH CSR.pdf

B1171003 Phase 2 ICH Study Rpt Body.docx

B1171003 Phase 2 ICH Study Rpt Body.pdf

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b1171003-analytical-reports.pdf

b1171003-compliance.pdf

b1171003-demographics.pdf

b1171003-discontinued-patients.pdf

b1171003-efficacy-response.pdf

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b1171003-invest-signature.pdf

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b1171003-lab-measurements.pdf

b1171003-protocol-deviations.pdf

b1171003-protocol.pdf

b1171003-randomization.pdf

b1171003-report-body.pdf

b1171003-sap.pdf

b1171003-sample-crf.pdf

b1171003-synopsis.pdf

b1171003-sponsor-signature.pdf

B1171003 ICD 23 March 2011.pdf

B1171003 ICD, 20 July 2010.doc

B1171003 ICD, 20 July 2010.pdf

B1171003QCCSRFINAL.pdf

B1171003QCCSRFINAL.xlsx

Sample-case-report-formB1171003FinalVersion126-MAY-2011.pdf

Sample-case-report-formB1171003FinalVersion217-JUN-2011.pdf

(1571) Annual Rpt 2012 serial 0022.pdf

(CL) Annual Rpt 2012.doc

(CL) Annual Rpt 2012.doc.pdf

(CL) IND Cover Letter - Pfizer Logo.doc

Cover Letter.pdf

(CL) IND Cover Letter - Pfizer Logo.doc.pdf

cover-letter.pdf

cover-letter2.pdf

FDA Type C Meeting Briefing Document.pdf

fda-1571-form.pdf

fda-form-1571.pdf

fda-form-15712.pdf

fda-form-3674.pdf

TB Orphan Drug Annual Rpt.docx

TB Orphan Drug Annual Rpt.docx.pdf

B1171003 Clinical Protocol Amend 2 Approval Form 21 March 2011.pdf

B1171003 FINAL Protocol 20 July 2010.doc

B1171003 Final Protocol Amend 1 Approval Form, 07 December 2010.pdf

B1171003 Final Protocol Amend 1 with Track Changes, 07 December 2010.pdf

B1171003 FINAL Protocol 20 July 2010.pdf

B1171003 Protocol Amend 1, 07 December 2010.doc

B1171003 Protocol Amend 1, 07 December 2010.pdf

B1171003 Protocol Amend 2 Track Change Version 21 March 2011.pdf

B1171003 Protocol Amend 2, 21 March 2011.doc

B1171003 Protocol Amend 2, 21 March 2011.pdf

B1171003 Protocol Approval Form, 20 July 2010.pdf

B1171003 Stats Plan Approval Form, 21 December 2010.pdf

B1171003 Stats Plan, 21 December 2010.pdf

B1171003 Stats Plan, v2.0, 05 April 2011.pdf

B1171003 Stats Plan Signature, v2.0, 05 April 2011.pdf

B1171003 Stats Plan, v2.0, 05 April 2011.doc

B1171003 Stats Plan, 21 December 2010.doc

B1171003 Revised analysis and reporting Sputum Log CFU Data.docx

B1171003 Revised analysis and reporting Sputum Log CFU Data.pdf

B1171003PPCSRFINAL.doc

B1171003PPCSRFINAL.pdf

14.3.3.2 Other Serious AE Narrative.pdf

14.3.3.2 Other Serious AE Narrative2.pdf

16.1.4.1 - List of Investigators and Corresponding Ethics Committees or Institutional Review Boards.doc

14.3.3.2 Other Serious AE Narrative{1}.pdf

16.1.4.1 - List of Investigators and Corresponding Ethics Committees or Institutional Review Boards1.doc

16.1.4.1 - List of Investigators and Corresponding Ethics Committees or Institutional Review Boards.pdf

16.1.4.1 - List of Investigators and Corresponding Ethics Committees or Institutional Review Boards1.pdf

16.1.4.1 - List of Investigators and Corresponding Ethics Committees or Institutional Review Boards{1}.doc

16.1.4.1 - List of Investigators and Corresponding Ethics Committees or Institutional Review Boards{1}.pdf

16.1.4.2 - No. Sites and Subjects by Country.doc

16.1.4.2 - No. Sites and Subjects by Country.pdf

16.1.4.2 - No. Sites and Subjects by Country1.doc

16.1.4.2 - No. Sites and Subjects by Country1.pdf

16.1.4.2 - No. Sites and Subjects by Country{1}.doc

16.1.4.3 Study Administrative Structure.doc

16.1.4.2 - No. Sites and Subjects by Country{1}.pdf

16.1.4.3 Study Administrative Structure.pdf

16.1.4.3 Study Administrative Structure1.doc

16.1.5.1 - Sponsor.pdf

16.1.4.3 Study Administrative Structure1.pdf

16.1.4.3 Study Administrative Structure{1}.doc

16.1.4.3 Study Administrative Structure{1}.pdf

16.1.5.1 - Sponsor2.pdf

16.1.5.2 - CSR Investigator Declaration.doc

16.1.5.2 - CSR Investigator Declaration.pdf

16.1.5.2 - CSR Investigator Declaration1.doc

16.1.6 Study Drug Information.doc

16.1.5.2 - CSR Investigator Declaration1.pdf

16.1.6 Study Drug Information.pdf

16.1.6 Study Drug Information{1}.doc

16.1.6 Study Drug Information{1}.pdf

b1171003-sap.pdf

16.1.7.1 - Description of Randomization.doc

16.1.7.1 - Description of Randomization.pdf

16.1.7.1 - Description of Randomization1.doc

16.1.7.1 - Description of Randomization1.pdf

16.1.7.1 - Description of Randomization{1}.doc

16.1.7.1 - Description of Randomization{1}.pdf

16.2.2 Protocol Deviations.doc

16.2.2 Protocol Deviations.pdf

16.2.2 Protocol Deviations1.doc

16.2.2 Protocol Deviations1.pdf

16.2.2 Protocol Deviations{1}.doc

16.2.2 Protocol Deviations{1}.pdf

b1171003-adverse-events.pdf

16.2.5.10.1 Analytical Rpt - B1171003 - PF-02341272 AND PF-04918975 IN HUMAN K2EDTA PLASMA.pdf

16.2.5.10.1 Analytical Rpt - B1171003 - PF-02341272 AND PF-04918975 IN HUMAN K2EDTA PLASMA2.pdf

16.2.5.10.2 Analytical Rpt - B1171003 - PF-02341272 AND PF-04918975 IN HUMAN URINE SAMPLES.pdf

16.2.5.10.2 Analytical Rpt - B1171003 - PF-02341272 AND PF-04918975 IN HUMAN URINE SAMPLES2.pdf

B1171003 Phase 2 ICH Study Rpt Synopsis.doc

B1171003 Phase 2 ICH Study Rpt Synopsis.pdf

B1171003 14.3.3.3.2 Non-serious AEs of Special Interest.pdf

B1171003 14.3.3.3.2 Non-serious AEs of Special Interest2.pdf

B1171003 14.3.3.3.2 Non-serious AEs of Special Interest{1}.pdf

B1171003 Final CSR QC Checklist.pdf

B1171003 Final Documentation of Knowledge Transfer Discussion.pdf

B1171003 Final Record of Study Rpt Review and Comment Incorporation.pdf

B1171003 ICD 23 March 2011.pdf

B1171003 ICD 23 March 20112.pdf

B1171003 Investigators CVs.pdf

B1171003 Investigators CVs2.pdf

B1171003 Investigators CVs{1}.pdf

B1171003 Phase 2 ICH Study Rpt Body.docx

B1171003 Phase 2 ICH Study Rpt Body.pdf

B1171003 Protocol Amend 2, 21 March 2011.doc

B1171003 Protocol Amend 2, 21 March 2011.pdf

B1171003 Protocol Amend 2, 21 March 20111.doc

B1171003 Protocol Amend 2, 21 March 20111.pdf

B1171003 Stats Plan, v2.0, 05 April 2011.doc

B1171003 Stats Plan, v2.0, 05 April 2011.pdf

B1171003 Stats Plan, v2.0, 05 April 20111.doc

B1171003 Stats Plan, v2.0, 05 April 20111.pdf

b1171003-analytical-reports.pdf

b1171003-compliance.pdf

b1171003-demographics.pdf

b1171003-discontinued-patients.pdf

b1171003-efficacy-response.pdf

b1171003-informed-consent.pdf

b1171003-invest-signature.pdf

b1171003-investigators.pdf

b1171003-lab-measurements.pdf

b1171003-patient-batches.pdf

b1171003-protocol-deviations.pdf

b1171003-protocol.pdf

b1171003-randomization.pdf

b1171003-report-body.pdf

b1171003-sample-crf.pdf

b1171003-sponsor-signature.pdf

b1171003-synopsis.pdf

Figure 14.2.1.1.1.2 Plot of Mean Absolute Value for Sputum Log CFU/ml with Standard Error over Time.pdf

Figure 14.2.1.1.1.2 Plot of Mean Absolute Value for Sputum Log CFU/ml with Standard Error over Time2.pdf

Table 16.2.7 AEs.pdf

Figure 14.2.1.1.2.2 Plot of Mean ChngBase for Sputum Log CFU/ml with Standard Error over Time.pdf

Figure 14.2.1.1.2.2 Plot of Mean ChngBase for Sputum Log CFU/ml with Standard Error over Time2.pdf

Figure 14.2.1.2.1.2 Plot of Individual Rate of Change in Sputum Log CFU/ml with Mean from Day 0 to Day 2 by Treatment.pdf

Figure 14.2.1.3.1.2 Plot of Mean Absolute Value for TTP with Standard Error over Time.pdf

Figure 14.2.1.3.1.2 Plot of Mean Absolute Value for TTP with Standard Error over Time2.pdf

Figure 14.2.1.3.2.2 Plot of Mean ChngBase for TTP with Standard Error over Time.pdf

Figure 14.2.1.3.2.2 Plot of Mean ChngBase for TTP with Standard Error over Time2.pdf

Table 14.3.2.2 Serious AEs.pdf

Figure 14.2.1.2.1.2 Plot of Individual Rate of Change in Sputum Log CFU/ml with Mean from Day 0 to Day 2 by Treatment2.pdf

Figure 14.2.1.2.2.2 Plot of Individual Rate of Change in Sputum Log CFU/ml with Mean from Day 0 to Day 14 by Treatment2.pdf

[Figure 14.2.1.4.1.2 Plot of Individual Rate of Change in TTP with Mean from Day 0 to Day 2 by Treatment.pdf](#)

[Figure 14.2.1.4.1.2 Plot of Individual Rate of Change in TTP with Mean from Day 0 to Day 2 by Treatment2.pdf](#)

[Figure 14.2.1.4.2.2 Plot of Individual Rate of Change in TTP with Mean from Day 0 to Day 14 by Treatment.pdf](#)

[Figure 14.2.1.4.2.2 Plot of Individual Rate of Change in TTP with Mean from Day 0 to Day 14 by Treatment2.pdf](#)

[Sample-case-report-formB1171003FinalVersion217-JUN-2011.pdf](#)

[Figure 14.2.1.2.2.2 Plot of Individual Rate of Change in Sputum Log CFU/ml with Mean from Day 0 to Day 14 by Treatment.pdf](#)

[Figure 14.2.1.2.3.2 Plot of Individual Rate of Change in Sputum Log CFU/ml with Mean from Day 2 to Day 14 by Treatment.pdf](#)

[Figure 14.2.1.4.3.2 Plot of Individual Rate of Change in TTP with Mean from Day 2 to Day 14 by Treatment2.pdf](#)

[Figure 14.2.1.4.3.2 Plot of Individual Rate of Change in TTP with Mean from Day 2 to Day 14 by Treatment.pdf](#)

[Figure 14.2.1.5.1.2 Plot of Mean Absolute Value for Log TTP with Standard Error over Time.pdf](#)

[Figure 14.2.1.5.1.2 Plot of Mean Absolute Value for Log TTP with Standard Error over Time2.pdf](#)

[Figure 14.2.1.7.3 Plot of Individual Absolute Value for WBA by Subject.pdf](#)

[Figure 14.2.1.2.3.2 Plot of Individual Rate of Change in Sputum Log CFU/ml with Mean from Day 2 to Day 14 by Treatment2.pdf](#)

[Figure 14.2.1.5.2.2 Plot of Mean ChngBase for Log TTP with Standard Error over Time.pdf](#)

[Figure 14.2.1.5.2.2 Plot of Mean ChngBase for Log TTP with Standard Error over Time2.pdf](#)

[Figure 14.2.1.6.1.2 Plot of Individual Rate of Change in Log TTP with Mean from Day 0 to Day 2 by Treatment.pdf](#)

[Figure 14.2.1.6.1.2 Plot of Individual Rate of Change in Log TTP with Mean from Day 0 to Day 2 by Treatment2.pdf](#)

[Figure 14.2.1.6.2.2 Plot of Individual Rate of Change in Log TTP with Mean from Day 0 to Day 14 by Treatment.pdf](#)

[Figure 14.2.1.7.2 Plot of Mean Absolute Value with Standard Error for WBA by Treatment.pdf](#)

[Figure 14.2.1.6.2.2 Plot of Individual Rate of Change in Log TTP with Mean from Day 0 to Day 14 by Treatment2.pdf](#)

[Figure 14.2.1.6.3.2 Plot of Individual Rate of Change in Log TTP with Mean from Day 2 to Day 14 by Treatment.pdf](#)

[Figure 14.2.1.6.3.2 Plot of Individual Rate of Change in Log TTP with Mean from Day 2 to Day 14 by Treatment2.pdf](#)

[Figure 14.2.1.7.2 Plot of Mean Absolute Value with Standard Error for WBA by Treatment2.pdf](#)

[Figure 14.2.1.7.3 Plot of Individual Absolute Value for WBA by Subject2.pdf](#)

[Figure 14.2.1.7.4 Plot of Individual Absolute Value for WBA by Treatment.pdf](#)

[Figure 14.2.1.7.4 Plot of Individual Absolute Value for WBA by Treatment2.pdf](#)

[Table 14.3.2.2 Serious AEs2.pdf](#)

[Figure 14.2.1.8.2 Plot of Mean ChngBase with Standard Error for WBA by Treatment.pdf](#)

[Figure 14.2.1.8.2 Plot of Mean ChngBase with Standard Error for WBA by Treatment2.pdf](#)

[Figure 14.2.1.8.3 Plot of Individual ChngBase for WBA by Subject.pdf](#)

[Figure 14.2.1.8.3 Plot of Individual ChngBase for WBA by Subject2.pdf](#)

[Figure 14.2.1.8.4 Plot of Individual ChngBase for WBA by Treatment.pdf](#)

[Figure 14.2.1.8.4 Plot of Individual ChngBase for WBA by Treatment2.pdf](#)

[Figure 14.2.1.9.2 Plot of Individual Base 24-hour AUC WBA and Cumulative WBA with Mean by Treatment.pdf](#)

[Figure 14.2.1.9.2 Plot of Individual Base 24-hour AUC WBA and Cumulative WBA with Mean by Treatment2.pdf](#)

[Figure 14.2.1.9.3 Plot of Mean Cumulative WBA over 24-hour Time Post Dose with Standard Error.pdf](#)

[Figure 14.2.1.9.3 Plot of Mean Cumulative WBA over 24-hour Time Post Dose with Standard Error2.pdf](#)

[Figure 14.4.2.2.1.1 Median Plasma PNU-100480 Conc - Time Plot \(Linear Scale\).pdf](#)

[Figure 14.4.2.2.1.1 Median Plasma PNU-100480 Conc - Time Plot \(Linear Scale\)2.pdf](#)

[Figure 14.4.2.2.1.2 Median Plasma PNU-101603 Conc - Time Plot \(Linear Scale\).pdf](#)

[Figure 14.4.2.2.1.2 Median Plasma PNU-101603 Conc - Time Plot \(Linear Scale\)2.pdf](#)

[Figure 14.4.2.2.2.1 Median Plasma PNU-100480 Conc - Time Plot \(Semilog Scale\).pdf](#)

[Figure 14.4.2.2.2.1 Median Plasma PNU-100480 Conc - Time Plot \(Semilog Scale\)2.pdf](#)

[Figure 14.4.2.2.2.2 Median Plasma PNU-101603 Conc - Time Plot \(Semilog Scale\).pdf](#)

[Figure 14.4.2.2.2.2 Median Plasma PNU-101603 Conc - Time Plot \(Semilog Scale\)2.pdf](#)

[Figure 14.4.2.2.3.1 Mean Plasma PNU-100480 Conc - Time Plot \(Linear Scale\).pdf](#)

[Figure 14.4.2.2.3.1 Mean Plasma PNU-100480 Conc - Time Plot \(Linear Scale\)2.pdf](#)

[Figure 14.4.2.2.3.2 Mean Plasma PNU-101603 Conc - Time Plot \(Linear Scale\).pdf](#)

[Figure 14.4.2.2.3.2 Mean Plasma PNU-101603 Conc - Time Plot \(Linear Scale\)2.pdf](#)

[Figure 14.4.2.2.4.1 Mean Plasma PNU-100480 Conc - Time Plot \(Semilog Scale\).pdf](#)

[Figure 14.4.2.2.4.1 Mean Plasma PNU-100480 Conc - Time Plot \(Semilog Scale\)2.pdf](#)

[Figure 14.4.2.2.4.2 Mean Plasma PNU-101603 Conc - Time Plot \(Semilog Scale\).pdf](#)

[Figure 14.4.2.2.4.2 Mean Plasma PNU-101603 Conc - Time Plot \(Semilog Scale\)2.pdf](#)

[Figure 14.4.3.2.1 Plot of Dose Normalized Plasma PNU-100480 AUCtau by Treatment.pdf](#)

[Figure 14.4.3.2.1 Plot of Dose Normalized Plasma PNU-100480 AUCtau by Treatment2.pdf](#)

[Figure 14.4.3.2.2 Plot of Dose Normalized Plasma PNU-100480 Cmax by Treatment.pdf](#)

[Figure 14.4.3.2.2 Plot of Dose Normalized Plasma PNU-100480 Cmax by Treatment2.pdf](#)

[Figure 14.4.3.2.3 Plot of Dose Normalized Plasma PNU-101603 AUCtau by Treatment.pdf](#)

[Figure 14.4.3.2.3 Plot of Dose Normalized Plasma PNU-101603 AUCtau by Treatment2.pdf](#)

[Figure 14.4.3.2.4 Plot of Dose Normalized Plasma PNU-101603 Cmax by Treatment.pdf](#)

[Figure 14.4.3.2.4 Plot of Dose Normalized Plasma PNU-101603 Cmax by Treatment2.pdf](#)

[Figure 16.2.5.4.2.3.1 Plasma PNU-100480 Conc - Time Plot by Treatment \(Linear Scale\).pdf](#)

[Figure 16.2.5.4.2.3.1 Plasma PNU-100480 Conc - Time Plot by Treatment \(Linear Scale\)2.pdf](#)

[Figure 16.2.5.4.2.3.2 Plasma PNU-101603 Conc - Time Plot by Treatment \(Linear Scale\).pdf](#)

[Figure 16.2.5.4.2.3.2 Plasma PNU-101603 Conc - Time Plot by Treatment \(Linear Scale\)2.pdf](#)

[Figure 16.2.5.4.2.3.3 Plasma PNU-100480 Conc - Time Plot by Treatment \(Semilog Scale\).pdf](#)

[Table 14.1.1.1 Subject Evaluation Groups.pdf](#)

[Figure 16.2.5.4.2.3.4 Plasma PNU-101603 Conc - Time Plot by Treatment \(Semilog Scale\).pdf](#)

[Figure 16.2.5.4.2.3.3 Plasma PNU-100480 Conc - Time Plot by Treatment \(Semilog Scale\)2.pdf](#)

[Figure 16.2.5.4.2.3.4 Plasma PNU-101603 Conc - Time Plot by Treatment \(Semilog Scale\)2.pdf](#)

[Figure 16.2.5.4.2.4.1 Plasma PNU-100480 Conc - Time Plot by Subject \(Linear Scale\).pdf](#)

[Figure 16.2.5.4.2.4.1 Plasma PNU-100480 Conc - Time Plot by Subject \(Linear Scale\)2.pdf](#)

[Figure 16.2.5.4.2.4.2 Plasma PNU-101603 Conc - Time Plot by Subject \(Linear Scale\).pdf](#)

[Figure 16.2.5.4.2.4.2 Plasma PNU-101603 Conc - Time Plot by Subject \(Linear Scale\)2.pdf](#)

[Sample-case-report-formB1171003FinalVersion217-JUN-20112.pdf](#)

[Figure 16.2.5.4.2.4.3 Plasma PNU-100480 Conc - Time Plot by Subject \(Semilog Scale\).pdf](#)

[Figure 16.2.5.4.2.4.3 Plasma PNU-100480 Conc - Time Plot by Subject \(Semilog Scale\)2.pdf](#)

[Figure 16.2.5.4.2.4.4 Plasma PNU-101603 Conc - Time Plot by Subject \(Semilog Scale\).pdf](#)

[Figure 16.2.5.4.2.4.4 Plasma PNU-101603 Conc - Time Plot by Subject \(Semilog Scale\)2.pdf](#)

[Table 14.1.1.1 Subject Evaluation Groups2.pdf](#)

[Table 14.1.1.2 Discontinuations from Study2.pdf](#)

[Table 14.1.1.2 Discontinuations from Study.pdf](#)

[Table 14.1.2 Demographic Characteristics.pdf](#)

[Table 14.1.2 Demographic Characteristics2.pdf](#)

[Table 16.2.4.3 Medical History.pdf](#)

[Table 14.2.1.1.1.1 Dscrp Sum Absolute Value for Sputum Log CFU/ml over Time.pdf](#)

[Table 14.2.1.1.1.1 Dscrp Sum Absolute Value for Sputum Log CFU/ml over Time2.pdf](#)

[Table 14.2.1.1.2.1 Dscrp Sum ChngBase for Sputum Log CFU/ml over Time.pdf](#)

[Table 14.2.1.1.2.1 Dscrp Sum ChngBase for Sputum Log CFU/ml over Time2.pdf](#)

[Table 14.2.1.2.1.1 Dscrp Sum Rate of Change in Sputum Log CFU/ml from Day 0 to Day 2.pdf](#)

[Table 14.2.1.2.1.1 Dscrp Sum Rate of Change in Sputum Log CFU/ml from Day 0 to Day 22.pdf](#)

[Table 14.2.1.2.2.1 Dscrp Sum Rate of Change in Sputum Log CFU/ml from Day 0 to Day 14.pdf](#)

[Table 14.2.1.2.2.1 Dscrp Sum Rate of Change in Sputum Log CFU/ml from Day 0 to Day 142.pdf](#)

[Table 14.2.1.2.3.1 Dscrp Sum Rate of Change in Sputum Log CFU/ml from Day 2 to Day 142.pdf](#)

[Table 14.2.1.2.3.1 Dscrp Sum Rate of Change in Sputum Log CFU/ml from Day 2 to Day 14.pdf](#)

[Table 14.2.1.3.1.1 Dscrp Sum Absolute Value for TTP over Time.pdf](#)

[Table 14.2.1.3.1.1 Dscrp Sum Absolute Value for TTP over Time2.pdf](#)

[Table 14.2.1.3.2.1 Dscrp Sum ChngBase for TTP over Time.pdf](#)

[Table 14.2.1.3.2.1 Dscrp Sum ChngBase for TTP over Time2.pdf](#)

[Table 14.2.1.4.1.1 Dscrp Sum Rate of Change in TTP from Day 0 to Day 2.pdf](#)

[Table 14.2.1.4.1.1 Dscrp Sum Rate of Change in TTP from Day 0 to Day 22.pdf](#)

[Table 14.2.1.4.2.1 Dscrp Sum Rate of Change in TTP from Day 0 to Day 14.pdf](#)

[Table 14.2.1.4.2.1 Dscrp Sum Rate of Change in TTP from Day 0 to Day 142.pdf](#)

[Table 14.2.1.4.3.1 Dscrp Sum Rate of Change in TTP from Day 2 to Day 14.pdf](#)

[Table 14.2.1.4.3.1 Dscrp Sum Rate of Change in TTP from Day 2 to Day 142.pdf](#)

[Table 14.2.1.5.1.1 Dscrp Sum Absolute Value for Log TTP over Time.pdf](#)

[Table 14.2.1.5.1.1 Dscrp Sum Absolute Value for Log TTP over Time2.pdf](#)

[Table 14.2.1.5.2.1 Dscrp Sum ChngBase for Log TTP over Time2.pdf](#)

[Table 14.2.1.5.2.1 Dscrp Sum ChngBase for Log TTP over Time.pdf](#)

[Table 14.2.1.6.1.1 Dscrp Sum Rate of Change in Log TTP from Day 0 to Day 2.pdf](#)

[Table 14.2.1.6.1.1 Dscrp Sum Rate of Change in Log TTP from Day 0 to Day 22.pdf](#)

[Table 14.2.1.6.2.1 Dscrp Sum Rate of Change in Log TTP from Day 0 to Day 14.pdf](#)

[Table 14.2.1.6.2.1 Dscrp Sum Rate of Change in Log TTP from Day 0 to Day 142.pdf](#)

[Table 14.2.1.6.3.1 Dscrp Sum Rate of Change in Log TTP from Day 2 to Day 14.pdf](#)

[Table 14.2.1.6.3.1 Dscrp Sum Rate of Change in Log TTP from Day 2 to Day 142.pdf](#)

[Table 14.2.1.7.1 Dscrp Sum Absolute Values for WBA.pdf](#)

[Table 14.2.1.7.1 Dscrp Sum Absolute Values for WBA2.pdf](#)

[Table 14.2.1.8.1 Dscrp Sum ChngBase for WBA.pdf](#)

[Table 14.2.1.8.1 Dscrp Sum ChngBase for WBA2.pdf](#)

[Table 14.2.1.9.1 Dscrp Sum Base 24-hour AUC WBA and Cumulative WBA2.pdf](#)

[Table 14.2.1.9.1 Dscrp Sum Base 24-hour AUC WBA and Cumulative WBA.pdf](#)

[Table 14.2.2.1.1 Sum Stats ANCOVA Rate of Change in Sputum Log CFU/ml from Day 0 to Day 2 - FAS.pdf](#)

[Table 14.2.2.1.1 Sum Stats ANCOVA Rate of Change in Sputum Log CFU/ml from Day 0 to Day 2 - FAS2.pdf](#)

[Table 14.2.2.1.2 Sum Stats ANCOVA \(2-Way Interactions\) Rate of Change in Sputum Log CFU/ml from Day 0 to Day 2 - FAS.pdf](#)

[Table 14.2.2.1.2 Sum Stats ANCOVA \(2-Way Interactions\) Rate of Change in Sputum Log CFU/ml from Day 0 to Day 2 - FAS2.pdf](#)

Table 14.2.2.2.1 Sum Stats ANCOVA Rate of Change in Sputum Log CFU/ml from Day 0 to Day 14 - FAS.pdf

Table 14.2.2.2.1 Sum Stats ANCOVA Rate of Change in Sputum Log CFU/ml from Day 0 to Day 14 - FAS2.pdf

Table 14.2.2.1.3 Sum Stats ANCOVA (Slope from Linear Regression) Rate of Change in Sputum Log CFU/ml from Day 0 to Day 2 - FAS.pdf

Table 14.2.2.1.3 Sum Stats ANCOVA (Slope from Linear Regression) Rate of Change in Sputum Log CFU/ml from Day 0 to Day 2 - FAS2.pdf

Table 14.2.2.2.2 Sum Stats ANCOVA (2-Way Interactions) Rate of Change in Sputum Log CFU/ml from Day 0 to Day 14 - FAS.pdf

Table 14.2.2.3.1 Sum Stats ANCOVA Rate of Change in Sputum Log CFU/ml from Day 2 to Day 14 - FAS.pdf

Table 14.2.2.3.1 Sum Stats ANCOVA Rate of Change in Sputum Log CFU/ml from Day 2 to Day 14 - FAS2.pdf

Table 14.2.2.3.2 Sum Stats ANCOVA (2-Way Interactions) Rate of Change in Sputum Log CFU/ml from Day 2 to Day 14 - FAS.pdf

Table 16.2.4.3 Medical History2.pdf

Table 14.2.2.2.2 Sum Stats ANCOVA (2-Way Interactions) Rate of Change in Sputum Log CFU/ml from Day 0 to Day 14 - FAS2.pdf

Table 14.2.2.2.3 Sum Stats ANCOVA (Slope from Linear Regression) Rate of Change in Sputum Log CFU/ml from Day 0 to Day 14 - FAS.pdf

Table 14.2.2.4.3 Sum Stats ANCOVA Rate of Change in TTP from Day 2 to Day 14 - FAS2.pdf

Table 14.2.2.5.1 Sum Stats ANCOVA Rate of Change in Log TTP from Day 0 to Day 2 - FAS.pdf

Table 14.2.2.5.1 Sum Stats ANCOVA Rate of Change in Log TTP from Day 0 to Day 2 - FAS2.pdf

Table 14.2.2.5.2 Sum Stats ANCOVA Rate of Change in Log TTP from Day 0 to Day 14 - FAS.pdf

Table 14.2.2.5.2 Sum Stats ANCOVA Rate of Change in Log TTP from Day 0 to Day 14 - FAS2.pdf

Table 14.2.2.2.3 Sum Stats ANCOVA (Slope from Linear Regression) Rate of Change in Sputum Log CFU/ml from Day 0 to Day 14 - FAS2.pdf

Table 14.2.2.3.2 Sum Stats ANCOVA (2-Way Interactions) Rate of Change in Sputum Log CFU/ml from Day 2 to Day 14 - FAS2.pdf

Table 14.2.2.4.1 Sum Stats ANCOVA Rate of Change in TTP from Day 0 to Day 2 - FAS.pdf

Table 14.2.2.4.1 Sum Stats ANCOVA Rate of Change in TTP from Day 0 to Day 2 - FAS2.pdf

Table 14.2.2.4.2 Sum Stats ANCOVA Rate of Change in TTP from Day 0 to Day 14 - FAS2.pdf

Table 14.2.2.4.2 Sum Stats ANCOVA Rate of Change in TTP from Day 0 to Day 14 - FAS.pdf

Table 14.2.2.4.3 Sum Stats ANCOVA Rate of Change in TTP from Day 2 to Day 14 - FAS.pdf

Table 14.2.2.3.3 Sum Stats ANCOVA (Slope from Linear Regression) Rate of Change in Sputum Log CFU/ml from Day 2 to Day 14 - FAS.pdf

Table 14.2.2.3.3 Sum Stats ANCOVA (Slope from Linear Regression) Rate of Change in Sputum Log CFU/ml from Day 2 to Day 14 - FAS2.pdf

[Table 14.2.2.5.3 Sum Stats ANCOVA Rate of Change in Log TTP from Day 2 to Day 14 - FAS.pdf](#)

[Table 14.2.2.6.1 Sum Stats ANCOVA Cumulative WBA - FAS.pdf](#)

[Table 14.2.2.5.3 Sum Stats ANCOVA Rate of Change in Log TTP from Day 2 to Day 14 - FAS2.pdf](#)

[Table 14.2.2.6.1 Sum Stats ANCOVA Cumulative WBA - FAS2.pdf](#)

[Table 14.2.2.7.1 Sum Stats Repeated Measures \(Exploratory Regression Analysis\) Sputum Log CFU/ml - FAS.pdf](#)

[Table 16.2.7 AEs2.pdf](#)

[Table 14.2.2.7.1 Sum Stats Repeated Measures \(Exploratory Regression Analysis\) Sputum Log CFU/ml - FAS2.pdf](#)

[Table 14.2.2.7.2 Sum Stats Repeated Measures \(Exploratory Classified Day Analysis\) Sputum Log CFU/ml - FAS.pdf](#)

[Table 14.2.2.8.1 Sum Stats Repeated Measures \(Exploratory Regression Analysis\) TTP - FAS.pdf](#)

[Table 14.2.2.7.2 Sum Stats Repeated Measures \(Exploratory Classified Day Analysis\) Sputum Log CFU/ml - FAS2.pdf](#)

[Table 14.2.2.8.1 Sum Stats Repeated Measures \(Exploratory Regression Analysis\) TTP - FAS2.pdf](#)

[Table 14.2.2.8.2 Sum Stats Repeated Measures \(Exploratory Classified Day Analysis\) TTP - FAS.pdf](#)

[Table 14.2.2.8.2 Sum Stats Repeated Measures \(Exploratory Classified Day Analysis\) TTP - FAS2.pdf](#)

[Table 14.2.2.9.1 Sum Stats Repeated Measures \(Exploratory Regression Analysis\) Log TTP - FAS.pdf](#)

[Table 14.2.2.9.1 Sum Stats Repeated Measures \(Exploratory Regression Analysis\) Log TTP - FAS2.pdf](#)

[Table 14.2.2.9.2 Sum Stats Repeated Measures \(Exploratory Classified Day Analysis\) Log TTP - FAS.pdf](#)

[Table 14.2.2.9.2 Sum Stats Repeated Measures \(Exploratory Classified Day Analysis\) Log TTP - FAS2.pdf](#)

[Table 14.3.1.2.1 T-E AEs \(All Causalities\).pdf](#)

[Table 14.3.1.2.1 T-E AEs \(All Causalities\)2.pdf](#)

[Table 14.3.1.2.2 Incidence and Severity of T-E AEs \(All Causalities\).pdf](#)

[Table 14.3.1.2.2 Incidence and Severity of T-E AEs \(All Causalities\)2.pdf](#)

[Table 14.3.1.3.1 T-E AEs \(Treatment Related\).pdf](#)

[Table 14.3.1.3.1 T-E AEs \(Treatment Related\)2.pdf](#)

[Table 14.3.1.3.2 Incidence and Severity of T-E AEs \(Treatment Related\).pdf](#)

[Table 14.3.1.3.2 Incidence and Severity of T-E AEs \(Treatment Related\)2.pdf](#)

Table 14.3.4.1.1 Incidence of LTA'''s (Normal Base).pdf

Table 14.3.4.1.1 Incidence of LTA'''s (Normal Base)2.pdf

Table 14.3.4.1.2 Incidence of LTA'''s (Abnormal Base).pdf

Table 14.3.4.1.2 Incidence of LTA'''s (Abnormal Base)2.pdf

Table 14.3.4.1.3 Incidence of LTA'''s (Without Regard to Base Abnormality).pdf

Table 14.4.1 Administration Schedule.pdf

Table 14.3.4.2.1 Mean Base and ChngBase for Vital Signs Data.pdf

Table 14.3.4.1.3 Incidence of LTA'''s (Without Regard to Base Abnormality)2.pdf

Table 14.3.4.2.1 Mean Base and ChngBase for Vital Signs Data2.pdf

Table 14.3.4.2.2.1 Categorical Sum Vital Signs Data - Absolute Values.pdf

Table 14.3.4.2.2.1 Categorical Sum Vital Signs Data - Absolute Values2.pdf

Table 14.3.4.2.2.2 Categorical Sum Vital Signs Data - Increases from Base.pdf

Table 14.3.4.2.2.2 Categorical Sum Vital Signs Data - Increases from Base2.pdf

Table 14.3.4.2.2.3 Categorical Sum Vital Signs Data - Decreases from Base.pdf

Table 14.3.4.3.1 Mean Base and ChngBase for ECG Data2.pdf

Table 14.3.4.2.2.3 Categorical Sum Vital Signs Data - Decreases from Base2.pdf

Table 14.3.4.3.1 Mean Base and ChngBase for ECG Data.pdf

Table 14.3.4.3.2.1 Categorical Sum ECG Data - Absolute Values.pdf

Table 14.3.4.3.2.2 Categorical Sum ECG Data - Increases from Base.pdf

Table 14.3.4.3.2.1 Categorical Sum ECG Data - Absolute Values2.pdf

Table 14.3.4.3.2.2 Categorical Sum ECG Data - Increases from Base2.pdf

Table 14.3.4.4.1 Physical Examination Findings at Base.pdf

Table 14.3.4.4.1 Physical Examination Findings at Base2.pdf

Table 14.4.1 Administration Schedule2.pdf

Table 16.2.1 Subject Discontinuations.pdf

Table 14.4.2.1.1 Plasma PNU-100480 Conc [ngmL] vs Time Summary.pdf

Table 14.4.2.1.1 Plasma PNU-100480 Conc [ngmL] vs Time Summary2.pdf

Table 14.4.2.1.2 Plasma PNU-101603 Conc [ngmL] vs Time Summary.pdf

EU 1 1 Comprehensive Table of Contents.doc1.pdf

m1-0-cover1.pdf

Cover Letter1.pdf

m1-2-5-1-proof-of-payment1.pdf

PNU-100480 Annual Rpt1.pdf

EMA Annual Rpt Form1.pdf

m1-1-toc1.pdf

m1-2-form1.pdf

m1-3-1-04-3-contra-indications.doc1.pdf

m1-3-1-04-6-pregnancy-and-lactation.doc1.pdf

m1-3-1-04-8-undesirable-effects.doc1.pdf

m1-3-1-10-revision-date.doc1.pdf

m1-3-1-full-spc-clean1.pdf

m1-3-1-full-spc-highlighted1.pdf

m1-3-1-leaflet-clean1.pdf

m1-4-3-clinical1.pdf

m1-3-1-leaflet-highlighted1.pdf

m2-5-clinical-overview1.pdf

Table 14.4.2.1.2 Plasma PNU-101603 Conc [ngmL] vs Time Summary2.pdf

Table 14.4.3.1.1 Dscrp Sum Plasma PNU-100480 PK Parameters.pdf

Table 14.4.3.1.2 Dscrp Sum Plasma PNU-101603 PK Parameters.pdf

Table 14.4.3.1.1 Dscrp Sum Plasma PNU-100480 PK Parameters2.pdf

Table 14.4.3.1.2 Dscrp Sum Plasma PNU-101603 PK Parameters2.pdf

Table 14.4.3.1.3 Dscrp Sum Urine PNU-100480 PK Parameters.pdf

Table 14.4.3.1.3 Dscrp Sum Urine PNU-100480 PK Parameters2.pdf

Table 16.1.7.2 Randomization Treatment Assigned and Treatment Received.pdf

Table 16.1.7.2 Randomization Treatment Assigned and Treatment Received2.pdf

Table 16.1.9.2.1.1 Statistical Output ANCOVA Rate of Change in Sputum Log CFU/ml from Day 0 to Day 2 - FAS.pdf

Table 16.1.9.2.1.1 Statistical Output ANCOVA Rate of Change in Sputum Log CFU/ml from Day 0 to Day 2 - FAS2.pdf

Table 16.1.9.2.1.4 Statistical Output ANCOVA Rate of Change in Sputum Log CFU/ml from Day 0 to Day 2 - Sens Analy.pdf

Table 16.1.9.2.1.4 Statistical Output ANCOVA Rate of Change in Sputum Log CFU/ml from Day 0 to Day 2 - Sens Analy2.pdf

Table 16.1.9.2.1.2 Statistical Output ANCOVA (2-Way Interactions) Rate of Change in Sputum Log CFU/ml from Day 0 to Day 2 - FAS.pdf

Table 16.1.9.2.1.2 Statistical Output ANCOVA (2-Way Interactions) Rate of Change in Sputum Log CFU/ml from Day 0 to Day 2 - FAS2.pdf

Table 16.1.9.2.4.1 Statistical Output ANCOVA Rate of Change in TTP from Day 0 to Day 2 - FAS2.pdf

Table 16.1.9.2.4.1 Statistical Output ANCOVA Rate of Change in TTP from Day 0 to Day 2 - FAS.pdf

Table 16.1.9.2.4.2 Statistical Output ANCOVA Rate of Change in TTP from Day 0 to Day 14 - FAS.pdf

Table 16.1.9.2.4.2 Statistical Output ANCOVA Rate of Change in TTP from Day 0 to Day 14 - FAS2.pdf

Table 16.1.9.2.6.1 Statistical Output ANCOVA Cumulative WBA - FAS2.pdf

Table 16.1.9.2.1.3 Statistical Output ANCOVA (Slope from Linear Regression) Rate of Change in Sputum Log CFU/ml from Day 0 to Day 2 - FAS.pdf

Table 16.1.9.2.1.3 Statistical Output ANCOVA (Slope from Linear Regression) Rate of Change in Sputum Log CFU/ml from Day 0 to Day 2 - FAS2.pdf

Table 16.1.9.2.5.2 Statistical Output ANCOVA Rate of Change in Log TTP from Day 0 to Day 14 - FAS.pdf

Table 16.1.9.2.5.2 Statistical Output ANCOVA Rate of Change in Log TTP from Day 0 to Day 14 - FAS2.pdf

Table 16.1.9.2.5.3 Statistical Output ANCOVA Rate of Change in Log TTP from Day 2 to Day 14 - FAS.pdf

Table 16.1.9.2.5.3 Statistical Output ANCOVA Rate of Change in Log TTP from Day 2 to Day 14 - FAS2.pdf

Table 16.2.1 Subject Discontinuations2.pdf

Table 16.1.9.2.1.5 Statistical Output ANCOVA (Slope from Linear Regression) Rate of Change in Sputum Log CFU/ml from Day 0 to Day 2 - Sens Analy.pdf

Table 16.1.9.2.1.5 Statistical Output ANCOVA (Slope from Linear Regression) Rate of Change in Sputum Log CFU/ml from Day 0 to Day 2 - Sens Analy2.pdf

Table 16.1.9.2.2.1 Statistical Output ANCOVA Rate of Change in Sputum Log CFU/ml from Day 0 to Day 14 - FAS.pdf
Table 16.1.9.2.2.1 Statistical Output ANCOVA Rate of Change in Sputum Log CFU/ml from Day 0 to Day 14 - FAS2.pdf
Table 16.1.9.2.2.4 Statistical Output ANCOVA Rate of Change in Sputum Log CFU/ml from Day 0 to Day 14 - Sens Analy.pdf
Table 16.1.9.2.2.4 Statistical Output ANCOVA Rate of Change in Sputum Log CFU/ml from Day 0 to Day 14 - Sens Analy2.pdf
Table 16.1.9.2.2.2 Statistical Output ANCOVA (2-Way Interactions) Rate of Change in Sputum Log CFU/ml from Day 0 to Day 14 - FAS.pdf
Table 16.1.9.2.2.2 Statistical Output ANCOVA (2-Way Interactions) Rate of Change in Sputum Log CFU/ml from Day 0 to Day 14 - FAS2.pdf
Table 16.1.9.2.6.1 Statistical Output ANCOVA Cumulative WBA - FAS.pdf
Table 16.1.9.2.7.1 Statistical Output Repeated Measures (Exploratory Regression Analysis) Sputum Log CFU/ml - FAS.pdf
Table 16.1.9.2.7.1 Statistical Output Repeated Measures (Exploratory Regression Analysis) Sputum Log CFU/ml - FAS2.pdf
Table 16.1.9.2.7.2 Statistical Output Repeated Measures (Exploratory Classified Day Analysis) Sputum Log CFU/ml - FAS.pdf
Table 16.2.4.1 Subject Evaluation Groups.pdf
Table 16.1.9.2.2.3 Statistical Output ANCOVA (Slope from Linear Regression) Rate of Change in Sputum Log CFU/ml from Day 0 to Day 14 - FAS2.pdf
Table 16.1.9.2.2.3 Statistical Output ANCOVA (Slope from Linear Regression) Rate of Change in Sputum Log CFU/ml from Day 0 to Day 14 - FAS.pdf
Table 16.1.9.2.8.1 Statistical Output Repeated Measures (Exploratory Regression Analysis) TTP - FAS2.pdf
Table 16.1.9.2.8.1 Statistical Output Repeated Measures (Exploratory Regression Analysis) TTP - FAS.pdf
Table 16.1.9.2.8.2 Statistical Output Repeated Measures (Exploratory Classified Day Analysis) TTP - FAS2.pdf
Table 16.1.9.2.8.2 Statistical Output Repeated Measures (Exploratory Classified Day Analysis) TTP - FAS.pdf
Table 16.1.9.2.2.5 Statistical Output ANCOVA (Slope from Linear Regression) Rate of Change in Sputum Log CFU/ml from Day 0 to Day 14 - Sens Analy.pdf
Table 16.1.9.2.2.5 Statistical Output ANCOVA (Slope from Linear Regression) Rate of Change in Sputum Log CFU/ml from Day 0 to Day 14 - Sens Analy2.pdf
Table 16.1.9.2.3.1 Statistical Output ANCOVA Rate of Change in Sputum Log CFU/ml from Day 2 to Day 14 - FAS.pdf
Table 16.1.9.2.3.1 Statistical Output ANCOVA Rate of Change in Sputum Log CFU/ml from Day 2 to Day 14 - FAS2.pdf
Table 16.1.9.2.3.4 Statistical Output ANCOVA Rate of Change in Sputum Log CFU/ml from Day 2 to Day 14 - Sens Analy.pdf
Table 16.1.9.2.3.4 Statistical Output ANCOVA Rate of Change in Sputum Log CFU/ml from Day 2 to Day 14 - Sens Analy2.pdf
Table 16.1.9.2.3.2 Statistical Output ANCOVA (2-Way Interactions) Rate of Change in Sputum Log CFU/ml from Day 2 to Day 14 - FAS.pdf
Table 16.1.9.2.3.2 Statistical Output ANCOVA (2-Way Interactions) Rate of Change in Sputum Log CFU/ml from Day 2 to Day 14 - FAS2.pdf

Table 16.1.9.2.9.1 Statistical Output Repeated Measures (Exploratory Regression Analysis) Log TTP - FAS.pdf

Table 16.1.9.2.9.1 Statistical Output Repeated Measures (Exploratory Regression Analysis) Log TTP - FAS2.pdf

Table 16.1.9.2.9.2 Statistical Output Repeated Measures (Exploratory Classified Day Analysis) Log TTP - FAS.pdf

Table 16.1.9.2.9.2 Statistical Output Repeated Measures (Exploratory Classified Day Analysis) Log TTP - FAS2.pdf

Table 16.2.8.3.1 ECG Data.pdf

Table 16.1.9.2.3.3 Statistical Output ANCOVA (Slope from Linear Regression) Rate of Change in Sputum Log CFU/ml from Day 2 to Day 14 - FAS.pdf

Table 16.1.9.2.3.3 Statistical Output ANCOVA (Slope from Linear Regression) Rate of Change in Sputum Log CFU/ml from Day 2 to Day 14 - FAS2.pdf

Table 16.2.4.2 Demographic Characteristics.pdf

Table 16.2.4.2 Demographic Characteristics2.pdf

Table 16.2.4.1 Subject Evaluation Groups2.pdf

Table 16.2.5.1 Administration Schedule.pdf

Table 16.2.5.2 Concomitant Drug Treatments.pdf

Table 16.2.5.1 Administration Schedule2.pdf

Table 16.2.5.2 Concomitant Drug Treatments2.pdf

Table 16.1.9.2.3.5 Statistical Output ANCOVA (Slope from Linear Regression) Rate of Change in Sputum Log CFU/ml from Day 2 to Day 14 - Sens Analy.pdf

Table 16.1.9.2.3.5 Statistical Output ANCOVA (Slope from Linear Regression) Rate of Change in Sputum Log CFU/ml from Day 2 to Day 14 - Sens Analy2.pdf

Table 16.1.9.2.4.3 Statistical Output ANCOVA Rate of Change in TTP from Day 2 to Day 14 - FAS.pdf

Table 16.1.9.2.5.1 Statistical Output ANCOVA Rate of Change in Log TTP from Day 0 to Day 2 - FAS.pdf

Table 16.1.9.2.5.1 Statistical Output ANCOVA Rate of Change in Log TTP from Day 0 to Day 2 - FAS2.pdf

Table 16.1.9.2.4.3 Statistical Output ANCOVA Rate of Change in TTP from Day 2 to Day 14 - FAS2.pdf

Table 16.2.8.1.1 Laboratory Data.pdf

Table 16.1.9.2.7.2 Statistical Output Repeated Measures (Exploratory Classified Day Analysis) Sputum Log CFU/ml - FAS2.pdf

Table 16.2.5.4.1.1.1 Plasma PNU-100480 Conc vs Time Listing.pdf

Table 16.2.5.4.1.1.1 Plasma PNU-100480 Conc vs Time Listing2.pdf

Table 16.2.5.4.1.1.2 Plasma PNU-101603 Conc vs Time Listing.pdf

Table 16.2.5.4.1.2.1 Sample Deviations (10) and Comments for Plasma PNU-100480 Assay.pdf

Table 16.2.5.4.1.2.1 Sample Deviations (10) and Comments for Plasma PNU-100480 Assay2.pdf

Table 16.2.5.4.1.1.2 Plasma PNU-101603 Conc vs Time Listing2.pdf

Table 16.2.5.4.1.2.2 Sample Deviations (10) and Comments for Plasma PNU-101603 Assay.pdf

Table 16.2.5.4.3.1 Urine PNU-100480 ConcAmount Listing by Collection Interval.pdf

Table 16.2.5.4.1.2.2 Sample Deviations (10) and Comments for Plasma PNU-101603 Assay2.pdf

Table 16.2.5.4.3.1 Urine PNU-100480 ConcAmount Listing by Collection Interval2.pdf

Table 16.2.5.4.3.2 Urine PNU-101603 ConcAmount Listing by Collection Interval2.pdf

Table 16.2.5.4.3.2 Urine PNU-101603 ConcAmount Listing by Collection Interval.pdf

Table 16.2.5.5.1.1 Listing and Dscrp Sum Plasma PNU-100480 PK Parameters.pdf

Table 16.2.5.5.1.1 Listing and Dscrp Sum Plasma PNU-100480 PK Parameters2.pdf

Table 16.2.5.5.1.2 Listing and Dscrp Sum Plasma PNU-101603 PK Parameters.pdf

Table 16.2.5.5.1.2 Listing and Dscrp Sum Plasma PNU-101603 PK Parameters2.pdf

Table 16.2.5.5.1.3 Listing and Dscrp Sum Urine PNU-100480 PK Parameters.pdf

Table 16.2.5.5.1.3 Listing and Dscrp Sum Urine PNU-100480 PK Parameters2.pdf

Table 16.2.5.5.1.4 Listing and Dscrp Sum Urine PNU-101603 PK Parameters.pdf

Table 16.2.6.1.1 Listing of Individual Sputum Log CFU/ml.pdf

Table 16.2.5.5.1.4 Listing and Dscrp Sum Urine PNU-101603 PK Parameters2.pdf

Table 16.2.6.1.1 Listing of Individual Sputum Log CFU/ml2.pdf

Table 16.2.6.1.2 Listing of Rate of Change in Sputum Log CFU/ml from Day 0 to Day 2.pdf

Table 16.2.6.2.1 Listing of Individual TTP2.pdf

Table 16.2.6.1.2 Listing of Rate of Change in Sputum Log CFU/ml from Day 0 to Day 22.pdf

Table 16.2.6.1.3 Listing of Rate of Change in Sputum Log CFU/ml from Day 0 to Day 142.pdf

Table 16.2.6.1.3 Listing of Rate of Change in Sputum Log CFU/ml from Day 0 to Day 14.pdf

Table 16.2.6.1.4 Listing of Rate of Change in Sputum Log CFU/ml from Day 2 to Day 14.pdf

[Table 16.2.6.1.4 Listing of Rate of Change in Sputum Log CFU/ml from Day 2 to Day 142.pdf](#)

[Table 16.2.6.2.1 Listing of Individual TTP.pdf](#)

[Table 16.2.6.2.2 Listing of Rate of Change in TTP from Day 0 to Day 2.pdf](#)

[Table 16.2.6.2.3 Listing of Rate of Change in TTP from Day 0 to Day 14.pdf](#)

[Table 16.2.6.2.2 Listing of Rate of Change in TTP from Day 0 to Day 22.pdf](#)

[Table 16.2.6.2.3 Listing of Rate of Change in TTP from Day 0 to Day 142.pdf](#)

[Table 16.2.6.2.4 Listing of Rate of Change in TTP from Day 2 to Day 142.pdf](#)

[Table 16.2.6.2.4 Listing of Rate of Change in TTP from Day 2 to Day 14.pdf](#)

[Table 16.2.6.3.1 Listing of Individual Log TTP.pdf](#)

[Table 16.2.6.3.1 Listing of Individual Log TTP2.pdf](#)

[Table 16.2.6.3.2 Listing of Rate of Change in Log TTP from Day 0 to Day 2.pdf](#)

[Table 16.2.6.3.2 Listing of Rate of Change in Log TTP from Day 0 to Day 22.pdf](#)

[Table 16.2.6.3.3 Listing of Rate of Change in Log TTP from Day 0 to Day 14.pdf](#)

[Table 16.2.6.3.3 Listing of Rate of Change in Log TTP from Day 0 to Day 142.pdf](#)

[Table 16.2.6.3.4 Listing of Rate of Change in Log TTP from Day 2 to Day 14.pdf](#)

[Table 16.2.6.4.1 Listing of Individual WBA.pdf](#)

[Table 16.2.6.3.4 Listing of Rate of Change in Log TTP from Day 2 to Day 142.pdf](#)

[Table 16.2.6.4.1 Listing of Individual WBA2.pdf](#)

[Table 16.2.6.4.2 Listing of Base 24-hour AUC WBA and Cumulative WBA2.pdf](#)

[Table 16.2.6.4.2 Listing of Base 24-hour AUC WBA and Cumulative WBA.pdf](#)

[Table 16.2.6.5 Listing of Tuberculosis X-ray Assessment.pdf](#)

[Table 16.2.6.5 Listing of Tuberculosis X-ray Assessment2.pdf](#)

[Table 16.2.6.6.1 Listing of Susceptibility Testing \(Isoniazid and Rifampin\).pdf](#)

[Table 16.2.6.6.2 Listing of Susceptibility Testing \(PNU-100480 and PNU-101603\).pdf](#)

[Table 16.2.6.6.1 Listing of Susceptibility Testing \(Isoniazid and Rifampin\)2.pdf](#)

Table 16.2.6.6.2 Listing of Susceptibility Testing (PNU-100480 and PNU-101603)2.pdf

Table 16.2.6.7 Listing of Microbiology Test - Pathogen Isolated2.pdf

Table 16.2.6.7 Listing of Microbiology Test - Pathogen Isolated.pdf

Table 16.2.8.1.1 Laboratory Data2.pdf

Table 16.2.8.1.2 Laboratory Abnormalities, by Subject.pdf

Table 16.2.8.1.2 Laboratory Abnormalities, by Subject2.pdf

Table 16.2.8.1.3 Laboratory Abnormalities, by Test.pdf

Table 16.2.8.1.3 Laboratory Abnormalities, by Test2.pdf

Table 16.2.8.2.1 Vital Signs Data.pdf

Table 16.2.8.2.1 Vital Signs Data2.pdf

Table 16.2.8.2.2 Vital Signs Values Meeting Categorical Summarization Criteria.pdf

Table 16.2.8.2.2 Vital Signs Values Meeting Categorical Summarization Criteria2.pdf

Table 16.2.8.3.1 ECG Data2.pdf

Table 16.2.8.3.2 ECG Qualitative Results.pdf

Table 16.2.8.3.2 ECG Qualitative Results2.pdf

Table 16.2.8.3.3 ECG Values Meeting Categorical Summarization Criteria.pdf

Table 16.2.8.3.3 ECG Values Meeting Categorical Summarization Criteria2.pdf

Table 16.2.8.4.1 Physical Examination Screen.pdf

Table 16.2.8.4.1 Physical Examination Screen2.pdf

Table 16.2.8.4.2 Physical Examination Changes from Screen.pdf

Table 16.2.8.4.2 Physical Examination Changes from Screen2.pdf

Annotated PM1.pdf

Annotated PM3.pdf

Clarifax of Jul-11-20131.pdf

Cover Letter of Jul-25-20131.pdf

cover-letter-aug-28-20131.pdf

cover-letter-may-23-20131.pdf

hc-request-may-22-20131.pdf

hc-sc-3011-en1.pdf

LCM Table1.pdf

LCM Table3.pdf

LCM Table5.pdf

Non-Annotated PM1.pdf

pm-certification1.pdf

pristine-pm-request-aug-27-20131.pdf

pristine-pm1.pdf

Response to Clarifax of Jul-11-20131.pdf

Response to Clarifax of Jul-11-20133.pdf

B1171003 Distribution Instructions.pdf

CPR for CSP07435.doc

CPR for CSP07435.pdf

CPR for CSP09649.doc

CPR for CSP09649.pdf

CSP07846.doc

CSP08785.doc

CSP07846.doc.pdf

CSP08785.pdf

Stability packaging requets for PNU-0100480 100 mg MST. CSP6526.doc

Stability packaging requets for PNU-0100480 100 mg MST. CSP6526.pdf

BR 31085.1.pdf

BR 31085.12.pdf

BR 32321.1.pdf

BR 32321.2.pdf

BR 32321.22.pdf

Post-Executed BR for Prt. B1171003; CSP09649; FCS Job 33679.1.pdf

Pre-Executed BR for CSP07846, 29727.1 - Stability only.pdf

Pre-Executed BR for CSP09649, Prt.B1171003, FCS Job 33679.1.pdf

Pre-Executed BR for Prt. B1171003; CSP07435; FCS Job 32321.1.pdf

prelim 28257.1.pdf

Checklist for CSP07435.doc

Checklist for CSP07435.pdf

Checklist for CSP09649.doc

Checklist for CSP09649.pdf

Packaging Checklist for CSP08785.doc

Packaging Checklist for CSP08785.pdf

INX100042583 (SOH0760409).pdf

INX100042583 (SOH0760409).xls

Study B1171003 - PMAR003181.pdf

BR Approved Label, B1171003.pdf

CLR for CSP07435.pdf

CLR for CSP09649, B1171003.pdf

Links Rpt for CSP07435.pdf

Master Specification Cover Sheet for CSP07435.pdf

PF04685698HERG.doc

PF04685698HERG1.pdf

2013 07 19 MAA QQR Q11.pdf

PF-02341272-00-0004.doc

PF-02341272-00-0004.pdf

2.3 QOS DP Comparability Protocol Kalamazoo APS Pressurization NDA 179891.pdf

16.1.6 Study Drug Information1.pdf

16.1.5.1 - Sponsor1.pdf

B1171003 Phase 2 ICH Study Rpt Synopsis1.pdf

B1171003 CSR Sum Changes1.pdf

B1171003 Phase 2 ICH Study Rpt Body1.pdf

b1171003-adverse-events1.pdf

b1171003-analytical-reports1.pdf

b1171003-compliance1.pdf

b1171003-demographics1.pdf

b1171003-discontinued-patients1.pdf

b1171003-efficacy-response1.pdf

b1171003-informed-consent1.pdf

b1171003-investigators1.pdf

b1171003-sap1.pdf

b1171003-invest-signature1.pdf

b1171003-lab-measurements1.pdf

b1171003-patient-batches1.pdf

b1171003-protocol-deviations1.pdf

b1171003-protocol1.pdf

b1171003-randomization1.pdf

b1171003-report-body1.pdf

b1171003-sample-crf1.pdf

b1171003-sponsor-signature1.pdf

b1171003-summary-of-changes1.pdf

b1171003-synopsis1.pdf

3.2.P.5.1 Specification(s)1.pdf

3.2.P.5.2 Analytical Procedure - TM-01-1574A1.pdf

3.2.P.5.2 Analytical Procedures1.pdf

3.2.P.5.3 Validation of Analytical Procedures - TM-01-1574A1.pdf

3.2.P.5.4 Batch Analyses1.pdf

3.2.P.5.6 Justification of Specifications1.pdf

P.3.1 Batch Formula1.pdf

P.1 Description and Composition of the Drug Product1.pdf

C of C for Labelling for CSP09649, (B1171003).doc

C of C for Labelling for CSP09649, (B1171003).pdf

Certificate of Quality11031610361400013-16-2011.pdf

CofC for CSP07435 B1171003 10-087867, 10-087868.doc

CofC for CSP07435 B1171003 10-087867, 10-087868.pdf

Table 14.2.1.10.1 Shift Table of Day 0 (Pre-Treatment) and Day 15 (Post-Treatment) for MIC1.pdf

Table 14.2.1.10.2 Sum Median and Difference from Day 15 (Post-Treatment) vs Day 0 (Pre-Treatment) for MIC1.pdf

Table 16.2.6.6.1 Listing of Susceptibility Testing (Isoniazid and Rifampin)1.pdf

Table 16.2.6.6.2 Listing of MIC (PNU-100480 and PNU-101603)1.pdf

Table 16.1.9.2.10.1 Statistic Output Cumulative Logistic Rpted Meas Dff from Day 15 (Post-Treat) vs Day 0 (Pre-Treat) for MIC1.pdf

Table 16.1.9.2.10.2 Statistical Output Sign Test Difference from Day 15 (Post-Treatment) vs Day 0 (Pre-Treatment) for MIC1.pdf

B1171003 Phase 2 ICH Study Rpt Synopsis1.pdf

B1171003 CSR Sum Changes1.pdf

B1171003 (CSR revisions) Record of Study Rpt Review and Comment Incorporation1.pdf

B1171003 Final CSR (Revisions) QC checklist1.pdf

B1171003 Phase 2 ICH Study Rpt Body1.pdf

b1171003-invest-signature1.pdf

b1171003-efficacy-response1.pdf

b1171003-report-body1.pdf

b1171003-sap1.pdf

b1171003-summary-of-changes1.pdf

b1171003-sponsor-signature1.pdf

b1171003-synopsis1.pdf

Figure 14.2.1.1.2.2 Plot of Mean ChngBase for Sputum Log CFUml with Standard Error over Time1.pdf

Figure 14.2.1.1.1.2 Plot of Mean Absolute Value for Sputum Log CFUml with Standard Error over Time1.pdf

Figure 14.2.1.3.1.2 Plot of Mean Absolute Value for TTP with Standard Error over Time1.pdf

Figure 14.2.1.4.2.2 Plot of Individual Rate of Change in TTP with Mean from Day 0 to Day 14 by Treatment1.pdf

Figure 14.2.1.4.1.2 Plot of Individual Rate of Change in TTP with Mean from Day 0 to Day 2 by Treatment1.pdf

Figure 14.2.1.3.2.2 Plot of Mean ChngBase for TTP with Standard Error over Time1.pdf

Figure 14.2.1.4.3.2 Plot of Individual Rate of Change in TTP with Mean from Day 2 to Day 14 by Treatment1.pdf

Figure 14.2.1.2.1.2 Plot of Individual Rate of Change in Sputum Log CFUml with Mean from Day 0 to Day 2 by Treatment1.pdf

Figure 14.2.1.2.2.2 Plot of Individual Rate of Change in Sputum Log CFUml with Mean from Day 0 to Day 14 by Treatment1.pdf

Figure 14.2.1.5.1.2 Plot of Mean Absolute Value for Log TTP with Standard Error over Time1.pdf

Figure 14.2.1.6.1.2 Plot of Individual Rate of Change in Log TTP with Mean from Day 0 to Day 2 by Treatment1.pdf

Figure 14.2.1.5.2.2 Plot of Mean ChngBase for Log TTP with Standard Error over Time1.pdf

Figure 14.2.1.6.2.2 Plot of Individual Rate of Change in Log TTP with Mean from Day 0 to Day 14 by Treatment1.pdf

Figure 14.2.1.7.3 Plot of Individual Absolute Value for WBA by Subject1.pdf

Figure 14.2.1.2.3.2 Plot of Individual Rate of Change in Sputum Log CFUml with Mean from Day 2 to Day 14 by Treatment1.pdf

[Figure 14.2.1.6.3.2 Plot of Individual Rate of Change in Log TTP with Mean from Day 2 to Day 14 by Treatment1.pdf](#)

[Figure 14.2.1.7.2 Plot of Mean Absolute Value with Standard Error for WBA by Treatment1.pdf](#)

[Figure 14.2.1.7.4 Plot of Individual Absolute Value for WBA by Treatment1.pdf](#)

[Figure 14.2.1.8.2 Plot of Mean ChngBase with Standard Error for WBA by Treatment1.pdf](#)

[Figure 14.2.1.8.4 Plot of Individual ChngBase for WBA by Treatment1.pdf](#)

[Figure 14.2.1.9.2 Plot of Individual Base 24-hour AUC WBA and Cumulative WBA with Mean by Treatment1.pdf](#)

[Figure 14.2.1.8.3 Plot of Individual ChngBase for WBA by Subject1.pdf](#)

[Figure 14.2.1.9.3 Plot of Mean Cumulative WBA over 24-hour Time Post Dose with Standard Error1.pdf](#)

[Table 14.2.1.1.1.1 Dscrp Sum Absolute Value for Sputum Log CFUml over Time1.pdf](#)

[Table 14.2.1.1.2.1 Dscrp Sum ChngBase for Sputum Log CFUml over Time1.pdf](#)

[Table 14.2.1.10.1 Shift Table of Day 0 \(Pre-Treatment\) and Day 15 \(Post-Treatment\) for MIC1.pdf](#)

[Table 14.2.1.10.2 Sum Median and Difference from Day 15 \(Post-Treatment\) vs Day 0 \(Pre-Treatment\) for MIC1.pdf](#)

[Table 14.2.1.2.1.1 Dscrp Sum Rate of Change in Sputum Log CFUml from Day 0 to Day 21.pdf](#)

[Table 14.2.1.3.1.1 Dscrp Sum Absolute Value for TTP over Time1.pdf](#)

[Table 14.2.1.2.2.1 Dscrp Sum Rate of Change in Sputum Log CFUml from Day 0 to Day 141.pdf](#)

[Table 14.2.1.2.3.1 Dscrp Sum Rate of Change in Sputum Log CFUml from Day 2 to Day 141.pdf](#)

[Table 14.2.1.4.1.1 Dscrp Sum Rate of Change in TTP from Day 0 to Day 21.pdf](#)

[Table 14.2.1.3.2.1 Dscrp Sum ChngBase for TTP over Time1.pdf](#)

[Table 14.2.1.4.2.1 Dscrp Sum Rate of Change in TTP from Day 0 to Day 141.pdf](#)

[Table 14.2.1.4.3.1 Dscrp Sum Rate of Change in TTP from Day 2 to Day 141.pdf](#)

[Table 14.2.1.5.1.1 Dscrp Sum Absolute Value for Log TTP over Time1.pdf](#)

[Table 14.2.1.5.2.1 Dscrp Sum ChngBase for Log TTP over Time1.pdf](#)

[Table 14.2.1.8.1 Dscrp Sum ChngBase for WBA1.pdf](#)

[Table 14.2.1.6.1.1 Dscrp Sum Rate of Change in Log TTP from Day 0 to Day 21.pdf](#)

[Table 14.2.1.6.2.1 Dscrp Sum Rate of Change in Log TTP from Day 0 to Day 141.pdf](#)

Table 14.2.1.6.3.1 Dscrp Sum Rate of Change in Log TTP from Day 2 to Day 141.pdf

Table 14.2.1.7.1 Dscrp Sum Absolute Values for WBA1.pdf

Table 14.2.1.9.1 Dscrp Sum Base 24-hour AUC WBA and Cumulative WBA1.pdf

Table 14.2.2.1.1 Sum Stats ANCOVA Rate of Change in Sputum Log CFU/ml from Day 0 to Day 2 - FAS1.pdf

Table 14.2.2.2.1 Sum Stats ANCOVA Rate of Change in Sputum Log CFU/ml from Day 0 to Day 14 - FAS1.pdf

Table 14.2.2.1.3 Sum Stats ANCOVA (Slope from Linear Regress) Rate of Chg in Sputum Log CFU/ml from Day 0 to Day 2 - FAS1.pdf

Table 14.2.2.1.2 Sum Stats ANCOVA (2-Way Interactions) Rate of Change in Sputum Log CFU/ml from Day 0 to Day 2 - FAS1.pdf

Table 14.2.2.2 Sum Stats ANCOVA (2-Way Interactions) Rate of Change in Sputum Log CFU/ml from Day 0 to Day 14 - FAS1.pdf

Table 14.2.2.3.1 Sum Stats ANCOVA Rate of Change in Sputum Log CFU/ml from Day 2 to Day 14 - FAS1.pdf

Table 14.2.2.2.3 Sum Stats ANCOVA (Slope from Linear Regress) Rate of Chg in Sputum Log CFU/ml from Day 0 to Day 14 - FAS1.pdf

Table 14.2.2.3.3 Sum Stats ANCOVA (Slope from Linear Regress Rate of Chg in Sputum Log CFU/ml from Day 2 to Day 14 - FAS1.pdf

Table 14.2.2.4.1 Sum Stats ANCOVA Rate of Change in TTP from Day 0 to Day 2 - FAS1.pdf

Table 14.2.2.6.1 Sum Stats ANCOVA Cumulative WBA - FAS1.pdf

Table 14.2.2.3.2 Sum Stats ANCOVA (2-Way Interactions) Rate of Change in Sputum Log CFU/ml from Day 2 to Day 14 - FAS1.pdf

Table 14.2.2.4.2 Sum Stats ANCOVA Rate of Change in TTP from Day 0 to Day 14 - FAS1.pdf

Table 14.2.2.4.3 Sum Stats ANCOVA Rate of Change in TTP from Day 2 to Day 14 - FAS1.pdf

Table 14.2.2.5.1 Sum Stats ANCOVA Rate of Change in Log TTP from Day 0 to Day 2 - FAS1.pdf

Table 14.2.2.5.3 Sum Stats ANCOVA Rate of Change in Log TTP from Day 2 to Day 14 - FAS1.pdf

Table 14.2.2.5.2 Sum Stats ANCOVA Rate of Change in Log TTP from Day 0 to Day 14 - FAS1.pdf

Table 14.2.2.7.1 Sum Stats Repeated Measures (Exploratory Regression Analysis) Sputum Log CFU/ml - FAS1.pdf

Table 14.2.2.8.1 Sum Stats Repeated Measures (Exploratory Regression Analysis) TTP - FAS1.pdf

Table 14.2.2.7.2 Sum Stats Repeated Measures (Exploratory Classified Day Analysis) Sputum Log CFU/ml - FAS1.pdf

Table 14.2.2.8.2 Sum Stats Repeated Measures (Exploratory Classified Day Analysis) TTP - FAS1.pdf

Table 14.2.2.9.1 Sum Stats Repeated Measures (Exploratory Regression Analysis) Log TTP - FAS1.pdf

Table 14.2.2.9.2 Sum Stats Repeated Measures (Exploratory Classified Day Analysis) Log TTP - FAS1.pdf

Table 16.1.9.2.1.1 Statistical Output ANCOVA Rate of Change in Sputum Log CFU/ml from Day 0 to Day 2 - FAS1.pdf
Table 16.1.9.2.1.4 Statistical Output ANCOVA Rate of Change in Sputum Log CFU/ml from Day 0 to Day 2 Sensitivity Analy1.pdf
Table 16.1.9.2.1.2 Statistical Output ANCOVA (2-Way Interactions) Rate of Change in Sputum Log CFU/ml from Day 0 to Day 2 - FAS1.pdf
Table 16.1.9.2.1.3 Statistical Output ANCOVA (Slope from Linear Regression) Rate of Change in Sputum Log CFU/ml from Day 0 to Day 2 - FAS1.pdf
Table 16.1.9.2.4.1 Statistical Output ANCOVA Rate of Change in TTP from Day 0 to Day 2 - FAS1.pdf
Table 16.1.9.2.4.2 Statistical Output ANCOVA Rate of Change in TTP from Day 0 to Day 14 - FAS1.pdf
Table 16.1.9.2.4.3 Statistical Output ANCOVA Rate of Change in TTP from Day 2 to Day 14 - FAS1.pdf
Table 16.1.9.2.5.1 Statistical Output ANCOVA Rate of Change in Log TTP from Day 0 to Day 2 - FAS1.pdf
Table 16.2.6.1.1 Listing of Individual Sputum Log CFU/ml1.pdf
Table 16.1.9.2.1.5 Statistical Output ANCOVA (Slope from Linear Regression) Rate of Change in Sputum Log CFU/ml from Day 0 to Day 2 Sensitivity Analy1.pdf
Table 16.1.9.2.10.1 Statistical Output Cumulative Logistic Repeated Measures Difference from Day 15 (Post-Treatment) vs Day 0 (Pre-Treatment) for MIC1.pdf
Table 16.1.9.2.2.1 Statistical Output ANCOVA Rate of Change in Sputum Log CFU/ml from Day 0 to Day 14 - FAS1.pdf
Table 16.1.9.2.2.4 Statistical Output ANCOVA Rate of Change in Sputum Log CFU/ml from Day 0 to Day 14 Sensitivity Analy1.pdf
Table 16.1.9.2.3.1 Statistical Output ANCOVA Rate of Change in Sputum Log CFU/ml from Day 2 to Day 14 - FAS1.pdf
Table 16.1.9.2.3.4 Statistical Output ANCOVA Rate of Change in Sputum Log CFU/ml from Day 2 to Day 14 Sensitivity Analy1.pdf
Table 16.1.9.2.10.2 Statistical Output Sign Test Difference from Day 15 (Post-Treatment) vs Day 0 (Pre-Treatment) for MIC1.pdf
Table 16.1.9.2.2.2 Statistical Output ANCOVA (2-Way Interactions) Rate of Change in Sputum Log CFU/ml from Day 0 to Day 14 - FAS1.pdf
Table 16.1.9.2.5.2 Statistical Output ANCOVA Rate of Change in Log TTP from Day 0 to Day 14 - FAS1.pdf
Table 16.1.9.2.5.3 Statistical Output ANCOVA Rate of Change in Log TTP from Day 2 to Day 14 - FAS1.pdf
Table 16.1.9.2.6.1 Statistical Output ANCOVA Cumulative WBA - FAS1.pdf
Table 16.1.9.2.7.1 Statistical Output Repeated Measures (Exploratory Regression Analysis) Sputum Log CFU/ml - FAS1.pdf
Table 16.2.6.2.1 Listing of Individual TTP1.pdf
Table 16.1.9.2.2.3 Statistical Output ANCOVA (Slope from Linear Regression) Rate of Change in Sputum Log CFU/ml from Day 0 to Day 14 - FAS1.pdf
Table 16.1.9.2.2.5 Statistical Output ANCOVA (Slope from Linear Regression) Rate of Change in Sputum Log CFU/ml from Day 0 to Day 14 Sensitivity Analy1.pdf
Table 16.2.6.1.2 Listing of Rate of Change in Sputum Log CFU/ml from Day 0 to Day 21.pdf

Table 16.2.6.1.3 Listing of Rate of Change in Sputum Log CFU/ml from Day 0 to Day 141.pdf

Table 16.2.6.1.4 Listing of Rate of Change in Sputum Log CFU/ml from Day 2 to Day 141.pdf

Table 16.2.6.2.2 Listing of Rate of Change in TTP from Day 0 to Day 21.pdf

Table 16.2.6.2.3 Listing of Rate of Change in TTP from Day 0 to Day 141.pdf

Table 16.1.9.2.3.2 Statistical Output ANCOVA (2-Way Interactions) Rate of Change in Sputum Log CFU/ml from Day 2 to Day 14 - FAS1.pdf

Table 16.1.9.2.3.3 Statistical Output ANCOVA (Slope from Linear Regression) Rate of Change in Sputum Log CFU/ml from Day 2 to Day 14 - FAS1.pdf

Table 16.2.6.2.4 Listing of Rate of Change in TTP from Day 2 to Day 141.pdf

Table 16.2.6.3.1 Listing of Individual Log TTP1.pdf

Table 16.2.6.3.2 Listing of Rate of Change in Log TTP from Day 0 to Day 21.pdf

Table 16.2.6.3.3 Listing of Rate of Change in Log TTP from Day 0 to Day 141.pdf

Table 16.2.6.3.4 Listing of Rate of Change in Log TTP from Day 2 to Day 141.pdf

Table 16.2.6.4.1 Listing of Individual WBA1.pdf

Table 16.1.9.2.3.5 Statistical Output ANCOVA (Slope from Linear Regression) Rate of Change in Sputum Log CFU/ml from Day 2 to Day 14 Sensitivity Analysis1.pdf

Table 16.1.9.2.7.2 Statistical Output Repeated Measures (Exploratory Classified Day Analysis) Sputum Log CFU/ml - FAS1.pdf

Table 16.1.9.2.8.1 Statistical Output Repeated Measures (Exploratory Regression Analysis) TTP - FAS1.pdf

Table 16.1.9.2.8.2 Statistical Output Repeated Measures (Exploratory Classified Day Analysis) TTP - FAS1.pdf

Table 16.1.9.2.9.1 Statistical Output Repeated Measures (Exploratory Regression Analysis) Log TTP - FAS1.pdf

Table 16.1.9.2.9.2 Statistical Output Repeated Measures (Exploratory Classified Day Analysis) Log TTP - FAS1.pdf

Table 16.2.6.6.1 Listing of Susceptibility Testing (Isoniazid and Rifampin)1.pdf

Table 16.2.6.4.2 Listing of Base 24-hour AUC WBA and Cumulative WBA1.pdf

Table 16.2.6.5 Listing of Tuberculosis X-ray Assessment1.pdf

Table 16.2.6.6.2 Listing of MIC (PNU-100480 and PNU-101603)1.pdf

Table 16.2.6.7 Listing of Microbiology Test - Pathogen Isolated1.pdf

PF-02341272NA15.doc

PF-02341272NA151.pdf

10GR247 Protocol V01.pdf

10GR247 Protocol V02.pdf

10GR247 Protocol V03.pdf

08GR370 Abstract.doc

08GR370 Abstract.pdf

08GR370 Abstract1.doc

08GR370 Abstract{1}.doc

08GR370 Abstract1.pdf

08GR370 Abstract{1}.pdf

08GR370 Analytical Contributing Scientist Rpt.doc

08GR370 Analytical Contributing Scientist Rpt{1}.doc

08GR370 Analytical Contributing Scientist Rpt.pdf

08GR370 Analytical Contributing Scientist Rpt{1}.pdf

08GR370 Appendix A Individual Results Lead Sheet.doc

08GR370 Appendix A Individual Results Lead Sheet.pdf

08GR370 Appendix A Lead Sheet.doc

08GR370 Appendix A Individual Results Lead Sheet1.doc

08GR370 Appendix A Individual Results Lead Sheet1.pdf

08GR370 Appendix A Individual Results Lead Sheet2.doc

08GR370 Appendix A Individual Results Lead Sheet2.pdf

08GR370 Appendix A Individual Results Lead Sheet3.doc

08GR370 Appendix A Individual Results Lead Sheet3.pdf

08GR370 Appendix A Individual Results Lead Sheet4.doc

08GR370 Appendix A Individual Results Lead Sheet5.doc

08GR370 Appendix A Individual Results Lead Sheet4.pdf

08GR370 Appendix A Individual Results Lead Sheet{1}.doc

08GR370 Appendix A Individual Results Lead Sheet5.pdf

08GR370 Appendix A Individual Results Lead Sheet{1}.pdf

08GR370 Appendix A Individual Results Lead Sheet{2}1.doc

08GR370 Appendix A Individual Results Lead Sheet{2}1.pdf

08GR370 Appendix A Individual Results Lead Sheet{4}2.doc

08GR370 Appendix A Individual Results Lead Sheet{4}2.pdf

08GR370 Appendix A Individual Results.doc

08GR370 Appendix A Individual Results.pdf

08GR370 Appendix A Individual Results.xls

08GR370 Appendix A Individual Results1.xls

08GR370 Appendix A Individual Results1.doc

08GR370 Appendix A Individual Results11.pdf

08GR370 Appendix A Individual Results2.pdf

08GR370 Appendix A Individual Results3.pdf

08GR370 Appendix A Individual Results5.pdf

08GR370 Appendix A Individual Results6.pdf

08GR370 Appendix A Individual Results8.pdf

08GR370 Appendix A Individual Results9.pdf

08GR370 Appendix A Individual Results{1}.pdf

08GR370 Appendix A Individual Results{2}.doc

08GR370 Appendix A Individual Results{2}2.pdf

08GR370 Appendix A Individual Results{3}3.pdf

08GR370 Appendix A Individual Results{4}.xls

08GR370 Appendix A Individual Results{4}5.pdf

08GR370 Appendix A Lead Sheet.pdf

08GR370 Appendix A Lead Sheet1.doc

08GR370 Appendix A Lead Sheet1.pdf

08GR370 Appendix A Lead Sheet2.doc

08GR370 Appendix A Lead Sheet2.pdf

08GR370 Appendix A Lead Sheet{1}.doc

08GR370 Appendix A Lead Sheet{1}.pdf

08GR370 Appendix A Methods and Results.pdf

08GR370 Appendix A Methods and Results{2}.pdf

08GR370 Appendix B Lead Sheet.doc

08GR370 Appendix B Lead Sheet.pdf

08GR370 Appendix B Lead Sheet1.doc

08GR370 Appendix B Lead Sheet1.pdf

08GR370 Appendix B Lead Sheet{1}.doc

08GR370 Appendix B Lead Sheet{1}.pdf

08GR370 GLP Compliance Statement.doc

08GR370 GLP Compliance Statement.pdf

08GR370 GLP Compliance Statement1.doc

08GR370 GLP Compliance Statement1.pdf

08GR370 GLP Compliance Statement{1}.doc

08GR370 GLP Compliance Statement{1}.pdf

08GR370 Other Personnel Responsibilities.doc

08GR370 Other Personnel Responsibilities.pdf

08GR370 Other Personnel Responsibilities1.doc

08GR370 Study Rpt Text.doc

10CA010_protocol.doc

08GR370 Other Personnel Responsibilities1.pdf

10CA010_protocol.doc.pdf

08GR370 Other Personnel Responsibilities{1}.doc

10CA010 Amend 10.doc

08GR370 RQA Audit Certificate.pdf

10CA010 Amend 10.pdf

08GR370 RQA Audit Certificate2.pdf

10CA010 Amend 9.doc

08GR370 Study Director Signature Page.doc

10CA010 Amend 9.pdf

08GR370 RQA Audit Certificate{1}.pdf

10CA010 Protocol Amend 1 .docx.pdf

08GR370 Study Director Signature Page.pdf

10CA010 Protocol Amend 1.docx

08GR370 Study Director Signature Page1.doc

10CA010 Protocol Amend 11.docx

08GR370 Study Director Signature Page1.pdf

10CA010 Protocol Amend 11.pdf

08GR370 Study Director Signature Page{1}.doc

10CA010 Protocol Amend 2.docx

08GR370 Study Director Signature Page{1}.pdf

10CA010 Protocol Amend 2.docx.pdf

08GR370 Study Rpt Text.pdf

10CA010 Protocol Amend 3.doc

08GR370 Study Rpt Text1.doc

10CA010 Protocol Amend 3.doc.pdf

08GR370 Study Rpt Text1.pdf

Protocol 10CA010 Amend 6.doc

08GR370 Study Rpt Text{2}.doc

Protocol 10CA010 Amend 6.doc.pdf

08GR370 Title Page.doc

Study Protocol 10CA010 Amend 4.doc

08GR370 Study Rpt Text{2}.pdf

Study Protocol 10CA010 Amend 4.doc.pdf

08GR370 Title Page.pdf

Study Protocol 10CA010 Amend 5 signed by SD.doc

08GR370 Title Page1.pdf

Study Protocol 10CA010 Amend 5 signed by SD.doc.pdf

08GR370 Title Page1.doc

Study Protocol 10CA010 Amend 7.doc

08GR370 Title Page{1}.doc

Study Protocol 10CA010 Amend 7.doc.pdf

Study Protocol 10CA010 Amend 8.doc

08GR37008GR364 Analytical Contributing Scientist Rpt.pdf

Study Protocol 10CA010 Amend 8.doc.pdf

08GR370 Title Page{1}.pdf

08GR37008GR364 Analytical Contributing Scientist Rpt2.pdf

08GR370{1}08GR364 Analytical Contributing Scientist Rpt.pdf

10CA009 Pathology Principal Investigator Rpt.doc

10CA009 Appendix 1 Microscopic Findings Pathology Principal Investigator Rpt.pdf

10CA009 Pathology Principal Investigator Rpt.pdf

10CA009 Table 1 Macroscopic Findings (Main Test) Pathology Principal Investigator Rpt.pdf

10CA009 Table 1 Macroscopic Findings (Recovery) Pathology Principal Investigator Rpt.pdf

10CA009 Table 2 Microscopic Findings Pathology Principal Investigator Rpt.pdf

08GR365 Abstract.doc

08GR365 Abstract.pdf

08GR365 Analytical Contributing Scientist Rpt.pdf

08GR365 Appendix A Lead Sheet.doc

08GR365 Appendix A Lead Sheet.pdf

08GR365 Appendix A Lead Sheet1.doc

08GR365 Appendix A Lead Sheet1.pdf

08GR365 Appendix A Methods and Results.pdf

08GR365 Appendix B Lead Sheet.doc

08GR365 Appendix B Lead Sheet.pdf

08GR365 Appendix B Rat Historical Control Summary.doc

08GR365 Appendix B Rat Historical Control Summary.pdf

08GR365 Table 1.doc

08GR365 Appendix C Individual Animal Values (Male and Female).doc

08GR365 Appendix C Individual Animal Values (Male and Female).pdf

08GR365 Appendix C Lead Sheet.doc

08GR365 Appendix C Lead Sheet.pdf

08GR365 Appendix D Lead Sheet.doc

08GR365 Appendix D Lead Sheet.pdf

08GR365 Appendix E Lead Sheet.doc

08GR365 BA QA Statement.pdf

08GR365 Appendix E Lead Sheet.pdf

08GR365 GLP Compliance Statement.doc

08GR365 GLP Compliance Statement.pdf

08GR365 RQA Audit Certificate.pdf

08GR365 Study Director Compliance Signature Page.doc

08GR365 Study Personnel.doc

08GR365 Study Director Compliance Signature Page.pdf

08GR365 Study Personnel.pdf

08GR365 Study Rpt Text.doc

08GR365 Study Rpt Text.pdf

08GR365 Table 1 Lead Sheet.doc

08GR365 Table 1 Lead Sheet.pdf

08GR365 Table 1.pdf

08GR365 Table 2 Lead Sheet.doc

08GR365 Table 2 Lead Sheet.pdf

08GR365 Table 2.doc

08GR365 Title Page.doc

08GR365 Table 2.pdf

08GR365 Title Page.pdf

10CA010 Bone Marrow Evaluation Rpt Final Rpt.pdf

08GR365 Amend 1.doc

08GR365 Amend 1.pdf

08GR365 Amend 11.pdf

08GR365 Deviation 2.pdf

08GR365 Deviation 3.pdf

08GR365 Protocol.pdf

08GR365.doc

08GR365.pdf

Deviation 2.pdf

Deviation 3.pdf

08GR364 Abstract.doc

08GR364 Abstract.pdf

08GR364 Abstract1.doc

08GR364 Abstract1.pdf

08GR364 Abstract{1}.doc

08GR364 Abstract{1}.pdf

08GR364 Appendix B Lead Sheet.doc

08GR364 Appendix B Lead Sheet1.doc

08GR364 Appendix B Lead Sheet.pdf

08GR364 Appendix B Lead Sheet1.pdf

08GR364 Appendix B Lead Sheet2.doc

08GR364 Appendix B Lead Sheet2.pdf

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08GR364 Appendix B Lead Sheet6.pdf

08GR364 Appendix B Lead Sheet7.doc

08GR364 Appendix B Lead Sheet7.pdf

08GR364 Appendix B Lead Sheet{1}.doc

08GR364 Appendix B Lead Sheet{1}.pdf

08GR364 Appendix B Lead Sheet{2}1.doc

08GR364 Appendix B Lead Sheet{2}1.pdf

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08GR364 Appendix B Lead Sheet{3}2.pdf

08GR364 Appendix B Lead Sheet{4}3.doc

08GR364 Appendix B.doc

08GR364 Appendix B Lead Sheet{4}3.pdf

08GR364 Appendix B.pdf

08GR364 Appendix B1.doc

08GR364 Appendix B1.pdf

08GR364 Appendix B2.doc

08GR364 Appendix B2.pdf

08GR364 Appendix B3.doc

08GR364 Appendix B4.pdf

08GR364 Appendix B3.pdf

08GR364 Appendix B4.doc

08GR364 Appendix B5.doc

08GR364 Appendix B5.pdf

08GR364 Appendix B{1}.doc

08GR364 Appendix B{1}.pdf

08GR364 Appendix B{2}1.doc

08GR364 Appendix B{2}1.pdf

08GR364 Appendix B{3}2.doc

08GR364 Appendix B{3}2.pdf

08GR364 Appendix D Lead Sheet.doc

08GR364 Appendix D Lead Sheet.pdf

08GR364 Appendix D Lead Sheet1.doc

08GR364 Appendix D Lead Sheet1.pdf

08GR364 GLP Compliance Statement.doc

08GR364 GLP Compliance Statement.pdf

08GR364 GLP Compliance Statement1.doc

08GR364 Individual Results.doc

08GR364 GLP Compliance Statement1.pdf

08GR364 GLP Compliance Statement{1}.doc

08GR364 GLP Compliance Statement{1}.pdf

08GR364 Individual Results Lead Sheet.doc

08GR364 Individual Results Lead Sheet.pdf

08GR364 Individual Results Lead Sheet1.doc

08GR364 Individual Results Lead Sheet1.pdf

08GR364 Individual Results Lead Sheet2.doc

08GR364 Individual Results Lead Sheet2.pdf

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08GR364 Individual Results Lead Sheet4.doc

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08GR364 Individual Results Lead Sheet5.pdf

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08GR364 Individual Results Lead Sheet6.pdf

08GR364 Individual Results Lead Sheet7.doc

08GR364 Individual Results Lead Sheet7.pdf

08GR364 Individual Results Lead Sheet{1}.doc

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08GR364 Individual Results Lead Sheet{2}1.doc

08GR364 Individual Results Lead Sheet{2}1.pdf

08GR364 Individual Results Lead Sheet{3}2.doc

08GR364 Individual Results Lead Sheet{3}2.pdf

08GR364 Individual Results Lead Sheet{4}3.doc

08GR364 Individual Results Lead Sheet{4}3.pdf

08GR364 Individual Results.pdf

08GR364 Individual Results1.doc

08GR364 Individual Results1.pdf

08GR364 Individual Results2.doc

08GR364 Individual Results2.pdf

08GR364 Individual Results3.doc

08GR364 Individual Results3.pdf

08GR364 Individual Results4.doc

08GR364 Individual Results4.pdf

08GR364 Individual Results5.doc

08GR364 Individual Results5.pdf

08GR364 Individual Results{1}1.doc

08GR364 Individual Results{1}1.pdf

08GR364 Individual Results{2}2.doc

08GR364 Individual Results{2}2.pdf

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08GR364 Other Personnel Responsibilities1.doc

08GR364 Other Personnel Responsibilities1.pdf

08GR364 Other Personnel Responsibilities{1}.doc

08GR364 Other Personnel Responsibilities{1}.pdf

08GR364 RQA Audit Certificate.pdf

08GR364 RQA Audit Certificate2.pdf

08GR364 RQA Audit Certificate{1}.pdf

08GR364 Study Director Signature Page.doc

08GR364 Study Director Signature Page.pdf

08GR364 Study Director Signature Page1.doc

08GR364 Study Director Signature Page1.pdf

08GR364 Study Director Signature Page{1}.doc

08GR364 Study Director Signature Page{1}.pdf

08GR364 Study Rpt Text.doc

08GR364 Study Rpt Text.pdf

08GR364 Study Rpt Text1.doc

08GR364 Study Rpt Text1.pdf

08GR364 Study Rpt Text{1}.doc

08GR364 Study Rpt Text{1}.pdf

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08GR364 Summary Tables Lead Sheet.pdf

08GR364 Summary Tables Lead Sheet1.doc

08GR364 Summary Tables Lead Sheet{1}.doc

08GR364 Summary Tables Lead Sheet1.pdf

08GR364 Summary Tables Lead Sheet{1}.pdf

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08GR364 Table 1 Lead Sheet.pdf

08GR364 Table 1 Lead Sheet1.doc

08GR364 Table 1 Lead Sheet1.pdf

08GR364 Table 1 Lead Sheet{1}.doc

08GR364 Table 1.doc

08GR364 Table 1 Lead Sheet{1}.pdf

08GR364 Table 1.pdf

08GR364 Table 11.doc

08GR364 Table 11.pdf

08GR364 Table 1{1}.doc

08GR364 Table 1{1}.pdf

08GR364 Table 2 Lead Sheet.doc

08GR364 Table 2 Lead Sheet.pdf

08GR364 Table 2 Lead Sheet1.doc

08GR364 Table 2 Lead Sheet1.pdf

08GR364 Table 2 Lead Sheet{1}.doc

08GR364 Table 2 Lead Sheet{1}.pdf

08GR364 Table 2.doc

08GR364 Table 2.pdf

08GR364 Table 21.doc

08GR364 Table 21.pdf

08GR364 Table 2{1}.doc

08GR364 Table 2{1}.pdf

08GR364 Table 3 Lead Sheet.doc

08GR364 Table 3 Lead Sheet.pdf

08GR364 Table 3 Lead Sheet1.doc

08GR364 Table 3 Lead Sheet1.pdf

08GR364 Table 3 Lead Sheet{1}.doc

08GR364 Table 3 Lead Sheet{1}.pdf

08GR364 Table 3.doc

08GR364 Table 3.pdf

08GR364 Table 31.doc

08GR364 Table 31.pdf

08GR364 Table 3{1}.doc

08GR364 Table 3{1}.pdf

08GR364 Title Page.doc

08GR364 Title Page.pdf

08GR364 Title Page1.doc

08GR364 Title Page1.pdf

08GR37008GR364 Analytical Contributing Scientist Rpt.pdf

08GR37008GR364 Analytical Contributing Scientist Rpt2.pdf

08GR360 Abstract.doc

08GR360 Abstract.pdf

08GR360 Analytical Contributing Scientist Rpt.doc

08GR360 Analytical Contributing Scientist Rpt.pdf

08GR360 Appendix A Individual Results Lead Sheet.pdf

08GR360 Appendix A Individual Results Lead Sheet.doc

08GR360 Appendix A Individual Results.doc

08GR360 Appendix A Individual Results.pdf

08GR360 Appendix A Lead Sheet.doc

08GR360 Appendix A Lead Sheet.pdf

08GR360 Appendix A Lead Sheet1.doc

08GR360 Appendix A Lead Sheet1.pdf

08GR360 Appendix A Methods and Results.pdf

08GR360 Appendix B Lead Sheet.doc

08GR360 Appendix B Lead Sheet.pdf

08GR360 Appendix C Data Evaluation Summary.pdf

08GR360 Appendix C Individual Results.pdf

08GR360 Appendix C Individual Results.doc

08GR360 Appendix C Lead Sheet.doc

08GR360 Appendix C Lead Sheet.pdf

08GR360 Appendix D Lead Sheet.doc

08GR360 Appendix D Lead Sheet.pdf

08GR360 CSR.pdf

08GR360 Figure 1 Lead Sheet.doc

08GR360 Figure 1 Lead Sheet.pdf

08GR360 Figure 1.doc

08GR360 Figure 1.pdf

08GR360 Final Rpt Amend 1 Title Page.doc

08GR360 Final Rpt Amend 1 Title Page.pdf

08GR360 Final Rpt Amend 1 TK report.pdf

08GR360 Final Rpt Amend 1.doc

08GR360 Final Rpt Amend 1.pdf

08GR360 Final Rpt Amend 11.pdf

08GR360 Other Personnel Responsibilities.doc

08GR360 Other Personnel Responsibilities.pdf

08GR360 RQA Audit Certificate.pdf

08GR360 Study Director Signature Page.doc

08GR360 Study Director Signature Page.pdf

08GR360 Study Rpt Text.doc

08GR360 Study Rpt Text.pdf

08GR360 Table 1 Lead Sheet.doc

08GR360 Table 1 Lead Sheet.pdf

08GR360 Table 1.doc

08GR360 Table 1.pdf

08GR360 Title Page.doc

08GR360 Title Page.pdf

08GR364 Amend 1.doc

08GR364 Amend 1.pdf

08GR364 Amend 1.pdf

08GR364 Protocol.pdf

08GR364.doc

08GR364.pdf

08GR360 Amend 1.pdf

08GR360 Protocol.pdf

08GR360.doc

08GR360.pdf

10CA009 Bone Marrow Evaluation Rpt.pdf

10CA009 Final Pathology Rpt.pdf

10CA009 Protocol Amend 1.doc.pdf

10CA009 Protocol Amend 1.doc

10CA009 Protocol Amend 3.doc

10CA009 Protocol Amend 3.doc.pdf

10CA009 Protocol Amend 4.doc

10CA009 Protocol Amend 4.doc.pdf

10CA009 Protocol Amend 5.doc

10CA009 Protocol Amend 5.doc.pdf

10CA009 Protocol Amend 6.doc

10CA009 Protocol Amend 6.doc.pdf

10CA009 Protocol Amend 2.doc.docx

10CA009 Protocol Amend 2.doc.pdf

10CA009 protocol.doc

10CA009 protocol.doc.pdf

08GR370 Amend 1.doc

08GR370 Amend 1.pdf

08GR370 Amend 1.pdf

08GR370 Protocol.pdf

08GR370.doc

08GR370.pdf

08GR351 Abstract.doc

08GR351 Abstract.pdf

08GR351 Abstract1.doc

08GR351 Abstract1.pdf

08GR351 Abstract{1}.pdf

08GR351 Abstract{1}.doc

08GR351 Amend 12.pdf

08GR351 Amend 1.pdf

08GR351 Amend 22.pdf

08GR351 Amend 2.pdf

08GR351 Appendix A Lead Sheet.doc

08GR351 Appendix A Lead Sheet1.doc

08GR351 Appendix A Lead Sheet.pdf

08GR351 Appendix A Lead Sheet1.pdf

08GR351 Appendix A Lead Sheet{1}.doc

08GR351 Appendix A Lead Sheet{1}.pdf

08GR351 Appendix B Historical Control Values2.pdf

08GR351 Appendix B Historical Control Values.pdf

08GR351 Appendix B Lead Sheet.doc

08GR351 Appendix B Historical Control Values{1}.pdf

08GR351 Appendix B Lead Sheet.pdf

08GR351 Appendix B Lead Sheet1.doc

08GR351 Appendix B Lead Sheet1.pdf

08GR351 Appendix B Lead Sheet{1}.doc

08GR351 Appendix B Lead Sheet{1}.pdf

08GR351 Appendix C Individual Values.pdf

08GR351 Appendix C Individual Values2.pdf

08GR351 Appendix C Individual Values{1}.pdf

08GR351 Appendix C Lead Sheet.doc

08GR351 Appendix C Lead Sheet.pdf

08GR351 Appendix C Lead Sheet1.doc

08GR351 Appendix C Lead Sheet1.pdf

08GR351 Appendix C Lead Sheet{1}.doc

08GR351 Appendix C Lead Sheet{1}.pdf

08GR351 Appendix D Lead Sheet.doc

08GR351 Appendix D Lead Sheet.pdf

08GR351 Appendix D Lead Sheet1.doc

08GR351 Appendix D Lead Sheet1.pdf

08GR351 Appendix D Lead Sheet{1}.doc

08GR351 Appendix D Lead Sheet{1}.pdf

08GR351 Appendix D Quality Control Results.pdf

08GR351 Appendix D Quality Control Results2.pdf

08GR351 Appendix D Quality Control Results{1}.pdf

08GR351 Appendix E Lead Sheet.doc

08GR351 Appendix E Lead Sheet.pdf

08GR351 Appendix E Lead Sheet1.doc

08GR351 Appendix E Lead Sheet1.pdf

08GR351 Appendix E Lead Sheet{1}.doc

08GR351 Appendix E Lead Sheet{1}.pdf

08GR351 Appendix E.doc

08GR351 Appendix E.pdf

08GR351 Appendix E1.doc

08GR351 Appendix E1.pdf

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08GR351 Contributing Personnel Test Substance Charcter1.doc

08GR351 Contributing Personnel Test Substance Charcter1.pdf

08GR351 Contributing Personnel {1} Test Substance Charcter.pdf

08GR351 Contributing Personnel {1} Test Substance Charcter.doc

08GR351 Protocol.pdf

08GR351 Protocol2.pdf

08GR351 RQA Audit Certificate.pdf

08GR351 RQA Audit Certificate2.pdf

08GR351 RQA Audit Certificate{1}.pdf

08GR351 Signatures and Study Personnel.doc

08GR351 Signatures and Study Personnel.pdf

08GR351 Signatures and Study Personnel1.pdf

08GR351 Signatures and Study Personnel1.doc

08GR351 Signatures and Study Personnel{1}.doc

08GR351 Study Director Compliance Signature Page.pdf

08GR351 Signatures and Study Personnel{1}.pdf

08GR351 Study Director Compliance Signature Page2.pdf

08GR351 Study Director Compliance Signature Page{1}.pdf

08GR351 Study Rpt Text.pdf

08GR351 Study Rpt Text.doc

08GR351 Study Rpt Text1.doc

08GR351 Study Rpt Text1.pdf

08GR351 Study Rpt Text{1}.doc

08GR351 Study Rpt Text{1}.pdf

08GR351 Table 1 Lead Sheet.doc

08GR351 Table 1 Lead Sheet.pdf

08GR351 Table 1 Lead Sheet1.doc

08GR351 Table 1 Lead Sheet1.pdf

08GR351 Table 1.pdf

08GR351 Table 12.pdf

08GR351 Table 2 Lead Sheet.doc

08GR351 Table 1{1}.pdf

08GR351 Table 2 Lead Sheet.pdf

08GR351 Table 2 Lead Sheet1.doc

08GR351 Table 2 Lead Sheet1.pdf

08GR351 Table 2 Lead Sheet{1}.doc

08GR351 Table 2 Lead Sheet{1}.pdf

08GR351 Table 2.pdf

08GR351 Table 22.pdf

08GR351 Table 2{1}.pdf

08GR351 Title Page.doc

08GR351 Title Page.pdf

08GR351 Title Page1.doc

08GR351 Title Page1.pdf

08GR349 Abstract.doc

08GR349 Abstract.pdf

08GR349 Appendix A Lead Sheet.doc

08GR349 Appendix A Lead Sheet.pdf

08GR349 Appendix B Historical Controls.doc

08GR349 Appendix B Historical Controls.pdf

08GR349 Appendix B Lead Sheet.doc

08GR349 Appendix B Lead Sheet.pdf

08GR349 Appendix C 24D.pdf

08GR349 Appendix C 3D.pdf

08GR349 Appendix C ACT.pdf

08GR349 Appendix C Lead Sheet.doc

08GR349 Appendix C Lead Sheet.pdf

08GR349 Appendix C title1.pdf

08GR349 Appendix C title1.xls

08GR349 Appendix C title2.pdf

08GR349 Appendix C title2.xls

08GR349 Appendix C title3.pdf

08GR349 Appendix C title3.xls

08GR349 Contributing PersonnelTest Substance Charcter.doc

08GR349 Contributing PersonnelTest Substance Charcter.pdf

08GR349 RQA Audit Certificate.pdf

08GR349 Signatures and Study Personnel.doc

08GR349 Signatures and Study Personnel.pdf

08GR349 Study Director Compliance Signature Page.doc

08GR349 Study Director Compliance Signature Page.pdf

08GR349 Study Rpt Text.doc

08GR349 Study Rpt Text.pdf

08GR349 Table 1 Lead Sheet.doc

08GR349 Table 1 Lead Sheet.pdf

08GR349 Table 1.pdf

08GR349 Table 1.xls

08GR349 Table 2 Lead Sheet.doc

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08GR349 Table 2A.pdf

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08GR349 Table 3 Lead Sheet.doc

08GR349 Table 3 Lead Sheet.pdf

08GR349 Table 3A.xls

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08GR349 Table 4 Lead Sheet.doc

08GR349 Table 3B.pdf

08GR349 Table 4 Lead Sheet.pdf

08GR349 Table 4A.pdf

08GR349 Table 4A.xls

08GR349 Title Page.pdf

08GR349 Title Page.doc

08GR343 Abstract.doc

08GR343 Abstract.pdf

08GR343 Analytical Rpt.pdf

08GR343 Appendix A Lead Sheet.doc

08GR343 Appendix A Lead Sheet.pdf

08GR343 Appendix B Lead Sheet.pdf

08GR343 Appendix B Lead Sheet.doc

08GR343 Appendix C Lead Sheet.pdf

08GR343 Appendix C.pdf

08GR343 Appendix C Lead Sheet.doc

08GR343 Appendix D Lead Sheet.doc

08GR343 Appendix D Lead Sheet.pdf

08GR343 Approval Signature Page.doc

08GR343 Study Rpt Text.doc

08GR343 Approval Signature Page.pdf

08GR343 CRO Audit Certificate.pdf

08GR343 GLP Compliance Statement.doc

08GR343 GLP Compliance Statement.pdf

08GR343 Individual Results Lead Sheet.doc

08GR343 Individual Results Lead Sheet.pdf

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08GR343 Individual Results.pdf

08GR343 Individual Results10.pdf

08GR343 Individual Results12.pdf

08GR343 Individual Results14.pdf

08GR343 Individual Results16.pdf

08GR343 Individual Results18.pdf

08GR343 Individual Results2.pdf

08GR343 Individual Results20.pdf

08GR343 Individual Results22.pdf

08GR343 Individual Results24.pdf

08GR343 Individual Results4.pdf

08GR343 Individual Results6.pdf

08GR343 Other Contributing Scientists.doc

08GR343 Individual Results8.pdf

08GR343 Other Contributing Scientists.pdf

08GR343 RQA Audit Certificate.pdf

08GR343 Study Rpt Text.pdf

08GR343 Table 1 Lead Sheet.doc

08GR343 Table 1.pdf

08GR343 Table 1 Lead Sheet.pdf

08GR343 Table 10 Lead Sheet.doc

08GR343 Table 10 Lead Sheet.pdf

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08GR312 Approval Signature Page.pdf

08GR312 Approval Signature Page2.pdf

08GR312 Approval Signature Page{1}.pdf

08GR312 GLP Compliance Statement.doc

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08GR312 GLP Compliance Statement{1}.doc

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08GR312 Individual Results Lead Sheet.doc

08GR312 Individual Results Lead Sheet.pdf

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08GR312 Individual Results12.pdf

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08GR312 Individual Results16.pdf

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08GR312 Individual Results6.pdf

08GR312 Individual Results8.pdf

08GR312 Individual Results{2}2.pdf

08GR312 Individual Results{1}.pdf

08GR312 Individual Results{3}4.pdf

08GR312 Individual Results{4}6.pdf

08GR312 Individual Results{5}8.pdf

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08GR312 Table 2 Lead Sheet.doc

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08GR338 Abstract.doc

08GR338 Abstract.pdf

08GR338 Analytical Rpt.pdf

08GR338 Appendix A Lead Sheet.doc

08GR338 Appendix B Lead Sheet.doc

08GR338 Appendix A Lead Sheet.pdf

08GR338 Appendix B Lead Sheet.pdf

08GR338 Appendix C Lead Sheet.doc

08GR338 Appendix C.doc

08GR338 Appendix C Lead Sheet.pdf

08GR338 Appendix C.pdf

08GR338 Appendix D Analytical.doc

08GR338 Appendix D Analytical.pdf

08GR338 Approval Signature Page.doc

08GR338 Approval Signature Page.pdf

08GR338 GLP Compliance Statement.doc

08GR338 GLP Compliance Statement.pdf

08GR338 Individual Results - Urinalysis.pdf

08GR338 Individual Results Lead Sheet.doc

08GR338 Individual Results Lead Sheet.pdf

08GR338 Individual Results Lead Sheet1.pdf

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08GR338 Individual Results Lead Sheet9.doc

08GR338 Individual Results Lead Sheet9.pdf

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08GR338 Individual Results LS Urinalysis.pdf

08GR338 Individual Results.pdf

08GR338 Individual Results10.pdf

08GR338 Individual Results12.pdf

08GR338 Individual Results16.pdf

08GR338 Individual Results14.pdf

08GR338 Individual Results18.pdf

08GR338 Individual Results2.pdf

08GR338 Individual Results20.pdf

08GR338 Individual Results4.pdf

08GR338 Individual Results6.pdf

08GR338 Individual Results8.pdf

08GR338 Other Contributing Scientists.doc

08GR338 Other Contributing Scientists.pdf

08GR338 Pathology Rpt.pdf

08GR338 RQA Audit Certificate.pdf

08GR338 Study Rpt Text.doc

08GR338 Study Rpt Text.pdf

08GR338 Table 1 Lead Sheet.pdf

08GR338 Table 1 Lead Sheet.doc

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08GR338 Table 10 Lead Sheet.doc

08GR338 Table 10 Lead Sheet.pdf

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08GR338 Table 8 Lead Sheet.doc

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08GR338 Table 8.pdf

08GR338 Table 9 Lead Sheet.doc

08GR338 Table 9 Lead Sheet.pdf

08GR338 Table 9.pdf

08GR338 Title Page.doc

08GR338 Title Page.pdf

BAS QA Statement.pdf

08GR310 Abstract.doc

08GR310 Abstract.pdf

08GR310 Abstract1.doc

08GR310 Abstract1.pdf

08GR310 Abstract{1}.doc

08GR310 Abstract{1}.pdf

08GR310 Appendix A Lead Sheet.doc

08GR310 Appendix A Lead Sheet.pdf

08GR310 Appendix A Lead Sheet1.doc

08GR310 Appendix A Lead Sheet1.pdf

08GR310 Appendix A Lead Sheet{1}.doc

08GR310 Appendix A Lead Sheet{1}.pdf

08GR310 Appendix B Lead Sheet.doc

08GR310 Appendix B Lead Sheet.pdf

08GR310 Appendix B Lead Sheet1.doc

08GR310 Appendix B Lead Sheet1.pdf

08GR310 Appendix B Lead Sheet{1}.doc

08GR310 Appendix B Lead Sheet{1}.pdf

08GR310 Approval Signature Page.pdf

08GR310 Approval Signature Page2.pdf

08GR310 Approval Signature Page{1}.pdf

08GR310 Figure 1 Lead Sheet.doc

08GR310 Figure 1 Lead Sheet.pdf

08GR310 Figure 1 Lead Sheet1.doc

08GR310 Figure 1 Lead Sheet{1}.doc

08GR310 Figure 1 Lead Sheet1.pdf

08GR310 Figure 1.doc

08GR310 Figure 1.pdf

08GR310 Figure 11.doc

08GR310 Figure 11.pdf

08GR310 Figure 1{1}.doc

08GR310 Figure 1{1}.pdf

08GR310 Figure 2 Lead Sheet.doc

08GR310 Figure 2 Lead Sheet.pdf

08GR310 Figure 2 Lead Sheet1.doc

08GR310 Figure 2 Lead Sheet1.pdf

08GR310 Figure 2 Lead Sheet{1}.doc

08GR310 Figure 2 Lead Sheet{1}.pdf

08GR310 Figure 2.doc

08GR310 Figure 2.pdf

08GR310 Figure 21.doc

08GR310 Figure 21.pdf

08GR310 Figure 2{1}.doc

08GR310 Figure 3 Lead Sheet.doc

08GR310 Figure 2{1}.pdf

08GR310 Figure 3 Lead Sheet.pdf

08GR310 Figure 3 Lead Sheet1.doc

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08GR310 Figure 3 Lead Sheet{1}.doc

08GR310 Figure 3 Lead Sheet{1}.pdf

08GR310 Figure 3.doc

08GR310 Figure 3.pdf

08GR310 Figure 31.doc

08GR310 Figure 31.pdf

08GR310 Figure 3{1}.doc

08GR310 GLP Compliance Statement.doc

08GR310 Figure 3{1}.pdf

08GR310 Study Rpt Text.doc

08GR310 GLP Compliance Statement1.doc

08GR310 GLP Compliance Statement.pdf

08GR310 GLP Compliance Statement1.pdf

08GR310 GLP Compliance Statement{1}.doc

08GR310 GLP Compliance Statement{1}.pdf

08GR310 Other Contributing Scientists.pdf

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08GR310 Table 1 Lead Sheet.doc

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08GR310 Table 2.pdf

08GR310 Table 21.doc

08GR310 Table 21.pdf

08GR310 Table 2{1}.doc

08GR310 Table 2{1}.pdf

08GR310 Table 3 Lead Sheet.doc

08GR310 Table 3 Lead Sheet.pdf

08GR310 Table 3 Lead Sheet1.pdf

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08GR310 Table 31.doc

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08GR310 Table 3{1}.doc

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08GR310 Table 4 Lead Sheet.doc

08GR310 Table 4 Lead Sheet.pdf

08GR310 Table 4 Lead Sheet1.doc

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08GR310 Table 4 Lead Sheet{1}.pdf

08GR310 Table 4.pdf

08GR310 Table 41.doc

08GR310 Table 4{1}.doc

08GR310 Table 41.pdf

08GR310 Table 4{1}.pdf

08GR310 Table 5 Lead Sheet.pdf

08GR310 Table 5 Lead Sheet.doc

08GR310 Table 5 Lead Sheet1.pdf

08GR310 Table 5 Lead Sheet1.doc

08GR310 Table 5 Lead Sheet{1}.doc

08GR310 Table 5 Lead Sheet{1}.pdf

08GR310 Table 5.doc

08GR310 Table 51.doc

08GR310 Table 5.pdf

08GR310 Table 51.pdf

08GR310 Table 5{1}.doc

08GR310 Table 5{1}.pdf

08GR310 Title Page.doc

08GR310 Title Page.pdf

08GR310 Title Page1.doc

08GR310 Title Page{1}.doc

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08GR310 Title Page{1}.pdf

08GR188 Abstract.doc

08GR188 Abstract.pdf

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08GR188 Appendix A Lead Sheet.doc

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08GR188 Approval Signature Page.pdf

08GR188 Approval Signature Page1.pdf

08GR188 Approval Signature Page{1}.pdf

08GR188 GLP Compliance Statement.doc

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08GR188 GLP Compliance Statement{1}.doc

08GR188 GLP Compliance Statement{1}.pdf

08GR188 Individual Results Lead Sheet.doc

08GR188 Individual Results Lead Sheet.pdf

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08GR188 Individual Results.pdf

08GR188 Individual Results10.pdf

08GR188 Individual Results12.pdf

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08GR188 Individual Results2.pdf

08GR188 Individual Results4.pdf

08GR188 Individual Results6.pdf

08GR188 Individual Results8.pdf

08GR188 Individual Results{1}.pdf

08GR188 Individual Results{2}2.pdf

08GR188 Individual Results{3}4.pdf

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08GR188 Individual Results{5}8.pdf

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08GR188 Study Rpt Text.pdf

08GR188 Study Rpt Text1.doc

08GR188 Study Rpt Text1.pdf

08GR188 Study Rpt Text{1}.doc

08GR188 Study Rpt Text{1}.pdf

08GR188 Table 1 Lead Sheet.doc

08GR188 Table 1 Lead Sheet.pdf

08GR188 Table 1 Lead Sheet1.doc

08GR188 Table 1.pdf

08GR188 Table 1 Lead Sheet1.pdf

08GR188 Table 12.pdf

08GR188 Table 2 Lead Sheet.doc

08GR188 Table 2 Lead Sheet.pdf

08GR188 Table 2 Lead Sheet1.doc

08GR1882.pdf

08GR188 Table 2 Lead Sheet1.pdf

08GR188 Table 2 Lead Sheet{2}.doc

08GR188 Table 2 Lead Sheet{2}.pdf

08GR188 Table 2.pdf

08GR188 Table 2{1}.pdf

08GR188 Table 22.pdf

08GR188 Table 3 Lead Sheet.doc

08GR188 Table 3 Lead Sheet.pdf

08GR188 Table 3 Lead Sheet1.doc

08GR188 Table 3 Lead Sheet1.pdf

08GR188 Table 3 Lead Sheet{2}.doc

08GR188 Table 3 Lead Sheet{2}.pdf

08GR188 Table 3.pdf

08GR188 Table 32.pdf

08GR188 Table 3{1}.pdf

08GR188 Table 4 Lead Sheet.doc

08GR188 Table 4 Lead Sheet.pdf

08GR188 Table 4 Lead Sheet1.doc

08GR188 Table 4 Lead Sheet{2}.doc

08GR188 Table 4 Lead Sheet1.pdf

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08GR188 Table 4.pdf

08GR188 Table 42.pdf

08GR188 Table 4{1}.pdf

08GR188 Table 5 Lead Sheet.doc

08GR188 Table 5 Lead Sheet.pdf

08GR188 Table 5 Lead Sheet1.doc

08GR188 Table 5 Lead Sheet1.pdf

08GR188.pdf

08GR188 Table 5 Lead Sheet{2}.doc

08GR188 Table 5 Lead Sheet{2}.pdf

08GR188 Table 5.pdf

08GR188 Table 52.pdf

08GR188 Table 5{1}.pdf

08GR188 Title Page.doc

08GR188 Title Page.pdf

08GR188 Title Page1.doc

08GR188 Title Page1.pdf

08GR188 Title Page{1}.doc

08GR188 Title Page{1}.pdf

08GR104 Abstract.doc

08GR104 Abstract.pdf

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08GR104 Abstract1.pdf

08GR104 Abstract{1}.doc

08GR104 Appendix A Lead Sheet.doc

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08GR104 Approval Signature Page.pdf

08GR104 Approval Signature Page2.pdf

08GR104 Approval Signature Page{1}.pdf

08GR104 GLP Compliance Statement.doc

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08GR104 Individual Results Lead Sheet.doc

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08GR104 Amend 1.doc.pdf

08GR104 Individual Results Lead Sheet4.pdf

08GR104 Amend 1.pdf

08GR104 Individual Results Lead Sheet5.doc

08GR104 Amend 2.doc

08GR104 Individual Results Lead Sheet5.pdf

08GR104 Amend 2.doc.pdf

08GR104 Amend 2.pdf

08GR104 Individual Results Lead Sheet6.doc

08GR104 Amend 3.doc

08GR104 Amend 3.doc.pdf

08GR104 Individual Results Lead Sheet6.pdf

08GR104 Amend 3.pdf

08GR104 Amend 4.doc

08GR104 Individual Results Lead Sheet7.doc

08GR104 Amend 4.doc.pdf

08GR104 Amend 4.pdf

08GR104 Individual Results Lead Sheet7.pdf

08GR104 Amend 5.doc

08GR104 Amend 5.pdf

08GR104 Individual Results Lead Sheet8.doc

08GR104 Amend 51.pdf

08GR104 Deviation 6.doc

08GR104 Individual Results Lead Sheet8.pdf

08GR104 Deviation 6.doc.pdf

08GR104 Individual Results Lead Sheet9.doc

08GR104 Deviation 6.pdf

08GR104 Protocol.pdf

08GR104 Individual Results Lead Sheet9.pdf

08GR104.doc

08GR104.pdf

08GR104 Individual Results Lead Sheet{1}.doc

08GR104 Individual Results Lead Sheet{1}.pdf

08GR104 Individual Results Lead Sheet{2}1.doc

08GR104 Individual Results Lead Sheet{2}1.pdf

08GR104 Individual Results Lead Sheet{3}2.doc

08GR104 Individual Results10.pdf

08GR104 Individual Results Lead Sheet{3}2.pdf

08GR104 Individual Results Lead Sheet{4}3.doc

08GR104 Individual Results Lead Sheet{4}3.pdf

08GR104 Individual Results Lead Sheet{5}4.doc

08GR104 Individual Results Lead Sheet{5}4.pdf

08GR104 Individual Results Lead Sheet{6}5.doc

08GR104 Individual Results Lead Sheet{6}5.pdf

08GR104 Individual Results Lead Sheet{7}6.doc

08GR104 Individual Results Lead Sheet{7}6.pdf

08GR104 Individual Results Lead Sheet{8}7.doc

08GR104 Individual Results Lead Sheet{8}7.pdf

08GR104.pdf

08GR104 Individual Results12.pdf

08GR104 Individual Results14.pdf

08GR104 Individual Results16.pdf

08GR104 Individual Results18.pdf

08GR104 Individual Results2.pdf

08GR104 Individual Results20.pdf

08GR104 Individual Results22.pdf

08GR104 Individual Results24.pdf

08GR104 Individual Results26.pdf

08GR104 Individual Results28.pdf

08GR104 Individual Results30.pdf

08GR104 Individual Results4.pdf

08GR104 Individual Results6.pdf

08GR104 Individual Results8.pdf

08GR104 Individual Results{1}.pdf

08GR104 Individual Results{2}2.pdf

08GR104 Individual Results{4}6.pdf

08GR104 Individual Results{3}4.pdf

08GR104 Individual Results{5}8.pdf

08GR104 Individual Results{6}10.pdf

08GR104 Individual Results{7}12.pdf

08GR104 Individual Results{8}14.pdf

08GR104 Other Contributing Scientists.doc

08GR104 Other Contributing Scientists.pdf

08GR104 Other Contributing Scientists1.doc

08GR104 Other Contributing Scientists1.pdf

08GR104 Study Rpt Text.pdf

08GR104 Other Contributing Scientists{1}.doc

08GR104 Other Contributing Scientists{1}.pdf

08GR104 Study Rpt Text.doc

08GR104 Study Rpt Text1.doc

08GR104 Study Rpt Text1.pdf

08GR104 Study Rpt Text{1}.doc

08GR104 Study Rpt Text{1}.pdf

08GR104 Table 1 Lead Sheet.doc

08GR104 Table 1 Lead Sheet.pdf

08GR104 Table 1 Lead Sheet1.doc

08GR104 Table 1 Lead Sheet1.pdf

08GR104 Table 1 Lead Sheet{1}.doc

08GR104 Table 1 Lead Sheet{1}.pdf

08GR104 Table 1.pdf

08GR104 Table 12.pdf

08GR104 Table 1{1}.pdf

08GR104 Table 2 Lead Sheet.doc

08GR104 Table 2 Lead Sheet.pdf

08GR104 Table 2 Lead Sheet1.doc

08GR104 Table 2 Lead Sheet1.pdf

08GR104 Table 2 Lead Sheet{1}.doc

08GR104 Table 2 Lead Sheet{1}.pdf

08GR104 Table 22.pdf

08GR104 Table 2.pdf

08GR104 Table 2{1}.pdf

08GR104 Title Page.doc

08GR104 Title Page.pdf

08GR104 Title Page1.doc

08GR104 Title Page1.pdf

08GR1042.pdf

08GR188 Amend 1.doc

08GR188 Amend 1.doc.pdf

08GR188 Amend 1.pdf

08GR188 Amend 2.doc

08GR188 Amend 2.doc.pdf

08GR188 Amend 2.pdf

08GR188 Amend 3.doc

08GR188 Amend 3.doc.pdf

08GR188 Amend 3.pdf

08GR188 Deviation 4.doc

08GR188 Deviation 4.doc.pdf

08GR188 Deviation 4.pdf

08GR188.doc

08GR1881.pdf

08GR188.pdf

08GR310 - Protocol.pdf

08GR310.doc

08GR310.pdf

08GR312 Amend 1.pdf

08GR312 Protocol.pdf

08GR312 Amend 2.pdf

08GR312.doc

08GR312.pdf

Amend 1.doc

Amend 1.pdf

Amend 2.doc

Amend 2.pdf

08GR338 Protocol Amends 1,2,3, 5.pdf

08GR338 Protocol.pdf

Deviation 1.doc

Deviation 2.doc

Deviation 1.pdf

Deviation 4.pdf

Deviation 2.pdf

Deviation3.doc

Deviation3.pdf

08GR343 Deviation 1.doc.pdf

08GR343 Deviation 1.doc

08GR343 Protocol Amends.pdf

08GR343 Protocol.pdf

08GR349 Amend 1.doc

08GR349 Amend 1.pdf

08GR349 Amend 1.pdf

08GR349 Protocol.pdf

08GR349.doc

08GR349.pdf

08GR351 Amend 1.doc

08GR351 Amend 1.pdf

08GR351 Amend 11.pdf

08GR351 Amend 2.doc

08GR351 Amend 2.pdf

08GR351 Amend 21.pdf

08GR351 Protocol.pdf

08GR351.doc

08GR351.pdf

07GR383 Deviation 5.doc

07GR383 Deviation 5.doc.pdf

07GR383 Deviation 5.doc1.pdf

07GR383 Deviation 51.doc

07GR384 Amend 1.pdf

07GR384 Amend 5.pdf

07GR384 Deviation 2.doc

07GR384 Deviation 2.doc.pdf

07GR384 Deviation 2.pdf

07GR384 Deviation 3.doc

07GR384 Deviation 3.pdf

07GR384 Deviation 31.pdf

07GR384 Deviation 4.doc

07GR384 Deviation 4.pdf

07GR384 Deviation 41.pdf

07GR384 Protocol.pdf

07GR384.doc

07GR384.pdf

PNU-10048030NOV09163108.pdf

PNU-10048030Nov09162538.pdf

PNU-100480 TB MIC90s.doc

PNU-100480 TB MIC90s.pdf

RR PNU-10048005Dec08121656.pdf

RR PNU-10048005Dec08121656.doc

PNU-10048005JAN09135656.doc

PNU-10048005JAN09135656.pdf

75701035.pdf

07GR383 Abstract.doc

07GR383 Abstract.pdf

07GR383 Abstract{1}.doc

07GR383 Abstract{1}.pdf

07GR383 Appendix A Lead Sheet.doc

07GR383 Appendix A Lead Sheet.pdf

07GR383 Appendix A Lead Sheet{1}.doc

07GR383 Appendix A Lead Sheet{1}.pdf

07GR383 Appendix B Lead Sheet.doc

07GR383 Appendix B Lead Sheet.pdf

07GR383 Appendix B Lead Sheet{1}.doc

07GR383 Appendix B Lead Sheet{1}.pdf

07GR383 Appendix C Lead Sheet.doc

07GR383 Study Rpt Text.doc

07GR383 Appendix C Lead Sheet.pdf

07GR383 Approval Signature Page.doc

07GR383 Approval Signature Page.pdf

07GR383 Approval Signature Page{1}.doc

07GR383 Approval Signature Page{1}.pdf

07GR383 GLP Compliance Statement.doc

07GR383 GLP Compliance Statement.pdf

07GR383 GLP Compliance Statement{1}.doc

07GR383 GLP Compliance Statement{1}.pdf

07GR383 Individual Results Lead Sheet.doc

07GR383 Individual Results Lead Sheet1.doc

07GR383 Individual Results Lead Sheet.pdf

07GR383 Study Rpt Text.pdf

07GR383 Individual Results Lead Sheet1.pdf

07GR383 Individual Results Lead Sheet{1}.doc

07GR383 Individual Results Lead Sheet{1}.pdf

07GR383 Individual Results Lead Sheet{2}1.doc

07GR383 Individual Results Lead Sheet{2}1.pdf

07GR383 Individual Results.pdf

07GR383 Individual Results2.pdf

07GR383 Individual Results{1}.pdf

07GR383 Individual Results{2}2.pdf

07GR383 Other Contributing Scientists.doc

07GR383 Other Contributing Scientists.pdf

07GR383 Other Contributing Scientists{1}.doc

07GR383 Other Contributing Scientists{1}.pdf

07GR383 Study Rpt Text{1}.doc

07GR383 Study Rpt Text{1}.pdf

07GR383 Table 1 Lead Sheet.doc

07GR383 Table 1 Lead Sheet.pdf

07GR383 Table 1 Lead Sheet{1}.doc

07GR383 Table 1 Lead Sheet{1}.pdf

07GR383 Table 1.pdf

07GR383 Table 1{1}.pdf

07GR383 Title Page.doc

07GR383 Title Page.pdf

07GR383 Deviation 1.doc

07GR383 Deviation 1.doc.pdf

07GR383 Deviation 1.doc1.pdf

07GR383 Deviation 1.pdf

07GR383 Deviation 11.doc

07GR383 Protocol.pdf

07GR383.doc

07GR383.pdf

Module 1.13.3 Sum SI.pdf

Module 1.13.8 Individual Study Information.pdf

PNU-100,480 (PF-02341272) IND AR 2011 Table 1.13.3-1 PFE.pdf

PNU-100,480 Table 1.13.8-1draft.pdf

PNU-100,480 Table 1.13.8-3draft.pdf

1.13.8-1-CS-INDAR-2010-PNU-100480.pdf

PNU-100480 Module 1.13.3 Sum SI.pdf

PNU-100480 Module 1.13.8 Individual Study Information.pdf

07GR384 Abstract.doc

07GR384 Abstract.pdf

07GR384 Abstract{1}.doc

07GR384 Abstract{1}.pdf

07GR384 Appendix A Lead Sheet.doc

07GR384 Appendix A Lead Sheet.pdf

07GR384 Appendix A Lead Sheet{1}.doc

07GR384 Appendix A Lead Sheet{1}.pdf

07GR384 Appendix B Lead Sheet.doc

07GR384 Appendix B Lead Sheet.pdf

07GR384 Appendix B Lead Sheet{1}.doc

07GR384 Appendix B Lead Sheet{1}.pdf

07GR384 Appendix C Lead Sheet.doc

07GR384 Appendix C.pdf

07GR384 Appendix C Lead Sheet.pdf

07GR384 Appendix C Lead Sheet{1}.doc

07GR384 Appendix C Lead Sheet{1}.pdf

07GR384 Appendix C{1}.pdf

07GR384 Approval Signature Page.doc

07GR384 Approval Signature Page.pdf

07GR384 Approval Signature Page{1}.doc

07GR384 GLP Compliance Statement.doc

07GR384 Approval Signature Page{1}.pdf

07GR384 GLP Compliance Statement.pdf

07GR384 GLP Compliance Statement{1}.doc

07GR384 GLP Compliance Statement{1}.pdf

07GR384 Individual Results Lead Sheet.doc

07GR384 Individual Results Lead Sheet.pdf

07GR384 Individual Results Lead Sheet1.doc

07GR384 Individual Results Lead Sheet1.pdf

07GR384 Individual Results Lead Sheet2.doc

07GR384 Individual Results Lead Sheet2.pdf

07GR384 Individual Results Lead Sheet3.doc

07GR384 Individual Results Lead Sheet4.doc

07GR384 Individual Results Lead Sheet3.pdf

07GR384 Individual Results Lead Sheet4.pdf

07GR384 Individual Results Lead Sheet5.doc

07GR384 Individual Results Lead Sheet5.pdf

07GR384 Individual Results Lead Sheet6.doc

07GR384 Individual Results Lead Sheet6.pdf

07GR384 Individual Results Lead Sheet7.doc

07GR384 Individual Results Lead Sheet7.pdf

07GR384 Individual Results Lead Sheet8.doc

07GR384 Individual Results Lead Sheet8.pdf

07GR384 Individual Results Lead Sheet{1}.doc

07GR384 Individual Results Lead Sheet{2}1.doc

07GR384 Individual Results Lead Sheet{2}1.pdf

07GR384 Individual Results Lead Sheet{3}2.doc

07GR384 Individual Results Lead Sheet{3}2.pdf

07GR384 Individual Results Lead Sheet{4}3.doc

07GR384 Individual Results.pdf

07GR384 Individual Results Lead Sheet{4}3.pdf

07GR384 Individual Results Lead Sheet{5}4.doc

07GR384 Individual Results Lead Sheet{5}4.pdf

07GR384 Individual Results Lead Sheet{6}5.doc

07GR384 Individual Results Lead Sheet{6}5.pdf

07GR384 Individual Results Lead Sheet{7}6.doc

07GR384 Individual Results Lead Sheet{7}6.pdf

07GR384 Individual Results Lead Sheet{8}7.doc

07GR384 Individual Results Lead Sheet{9}8.doc

07GR384 Individual Results Lead Sheet{8}7.pdf

07GR384 Individual Results Lead Sheet{9}8.pdf

07GR384.pdf

07GR384 Individual Results10.pdf

07GR384 Individual Results12.pdf

07GR384 Individual Results14.pdf

07GR384 Individual Results16.pdf

07GR384 Individual Results2.pdf

07GR384 Individual Results4.pdf

07GR384 Individual Results6.pdf

07GR384 Individual Results8.pdf

07GR384 Individual Results{1}.pdf

07GR384 Individual Results{2}2.pdf

07GR384 Individual Results{3}4.pdf

07GR384 Individual Results{4}6.pdf

07GR384 Individual Results{5}8.pdf

07GR384 Study Rpt Text.doc

07GR384 Individual Results{6}10.pdf

07GR384 Individual Results{7}12.pdf

07GR384 Individual Results{8}14.pdf

07GR384 Individual Results{9}16.pdf

07GR384 Other Contributing Scientists.doc

07GR384 Other Contributing Scientists.pdf

07GR384 Other Contributing Scientists{1}.doc

07GR384 Other Contributing Scientists{1}.pdf

07GR384 Study Rpt Text.pdf

07GR384 Study Rpt Text{1}.doc

07GR384 Study Rpt Text{1}.pdf

07GR384 Table 1 Lead Sheet.doc

07GR384 Table 1 Lead Sheet.pdf

07GR384 Table 1 Lead Sheet{1}.doc

07GR384 Table 1 Lead Sheet{1}.pdf

07GR384 Table 1.pdf

07GR384 Table 1{1}.pdf

07GR384 Table 2 Lead Sheet.doc

07GR384 Table 2 Lead Sheet.pdf

07GR384 Table 2 Lead Sheet{1}.doc

07GR384 Table 2 Lead Sheet{1}.pdf

07GR384 Table 2.pdf

07GR384 Table 2{1}.pdf

07GR384 Title Page.doc

07GR384 Title Page.pdf

75701038.pdf

75701048.pdf

RR 7246-94-077.pdf

2 Summary.doc

3 Introduction.doc

4 Physical Chemical and Pharmaceutical Properties and Formulation.doc

5.1 NoCln PharmaC.doc

5.2 PK and Product Metabolism in Animals.doc

6.1 PK and Product Metabolism in Humans.doc

6 Effects in Humans Introduction.doc

5.3 Tox.docx

6.2 Safety and Efficacy.doc

6.3 Marketing Experience.doc

7 Sum Data and Guidance for the Investigator (DCSI format).doc

IB Abbreviations wo macro.doc

IB Cover Page and TOC.doc

PF-02341272 PNU-0100480 IB 2012.pdf

Sum Changes in a Revised compound IB - Date.pdf

2 Summary.pdf

3 Introduction.pdf

4 Physical Chemical and Pharmaceutical Properties and Formulation.pdf

5.1 NoCln PharmaC.pdf

5.2 PK and Product Metabolism in Animals.pdf

5.3 Tox.pdf

6 Effects in Humans Introduction.pdf

6.1 PK and Product Metabolism in Humans.pdf

6.2 Safety and Efficacy.pdf

6.3 Marketing Experience.pdf

7 Sum Data and Guidance for the Investigator (DCSI format).pdf

IB Abbreviations wo macro.pdf

IB Cover Page and TOC.pdf

B117Finaldeliverables2013.xls

2 Summary.doc

2 Summary.pdf

3 Introduction.doc

3 Introduction.pdf

4 Physical Chemical and Pharmaceutical Properties and Formulation.pdf

4 Physical Chemical and Pharmaceutical Properties and Formulation.doc

5.1 NoCln PharmaC.doc

5.2 PK and Product Metabolism in Animals.doc

5.1 NoCln PharmaC.pdf

5.2 PK and Product Metabolism in Animals.pdf

5.3 Tox.doc

5.3 Tox.pdf

51650 B1171003 DPD BR Feb 11.msg

6 Effects in Humans Introduction.doc

6 Effects in Humans Introduction.pdf

6.1 PK and Product Metabolism in Humans.doc

6.1 PK and Product Metabolism in Humans.pdf

6.2 Safety and Efficacy.doc

6.2 Safety and Efficacy.pdf

7 (Revised) Sum Data and Guidance for the Investigator.doc

7 (Revised) Sum Data and Guidance for the Investigator.pdf

B1171003 FINAL Protocol 20 July 2010.doc

B1171003 FINAL Protocol 20 July 2010.pdf

B1171003 ICD, 20 July 2010.doc

B1171003 ICD, 20 July 2010.pdf

BR Study Drug Information.doc

IB Cover Page and TOC.doc

BR Study Drug Information.pdf

CTA-C-Availability of Study Med After Study Completion-01.doc

CTA-C-Availability of Study Med After Study Completion-01.pdf

CTA-C-Inclusion Exclusion Criteria Rationale-01.doc

CTA-C-Inclusion Exclusion Criteria Rationale-01.pdf

CTA-C-PbO Rationale (if applicable)-01.doc

CTA-C-PbO Rationale (if applicable)-01.pdf

CTA-C-Rationale for not conducting the trial in Sponsor-01.pdf

CTA-C-Rationale for not conducting the trial in Sponsor-01.doc

CTA-C-Subject Selection Criteria Stat Consideration-EU.doc

CTA-G-(Core) Table of Contents Int-01.doc

CTA-C-Subject Selection Criteria Stat Consideration-EU.pdf

CTA-G-(Core) Cover Letter to Int PCO(s)-01.doc

CTA-G-(Core) Cover Letter to Int PCO(s)-01.pdf

CTA-G-(Core) Table of Contents Int-01.pdf

CTA-R-(Core) Countries Participating in this CT and Decis-01.doc

CTA-R-(Core) Countries Participating in this CT and Decis-01.pdf

CTA-R-Worldwide Registration Status and Date-01.doc

CTA-R-Worldwide Registration Status and Date-01.pdf

IB Abbreviations wo macro.doc

IB Abbreviations wo macro.pdf

IB Cover Page and TOC.pdf

OLD PNU-0100480 IB 2009.pdf

Sum Changes in a Revised compound IB - Date.doc

Sum Changes in a Revised compound IB - Date.pdf

Lettr.pdf

Orphan Product Annual Rpt.doc

Orphan Product Annual Rpt.pdf

PNU-100480 Letter.pdf

Preclinical studies.doc

Preclinical studies.pdf

rINN L68.pdf

EU - 1.0 Cover Letter - ODD Letter of Intent.pdf

51650 B1171003 CTRU QC Sign Off CTA.msg

51650 B1171003 WRS-EM Sign Off CTA.msg

CTA-C-Availability of Study Med After Study Completion-01.doc

51650 Final Sign Off Form-B1171003.msg

CTA-C-Availability of Study Med After Study Completion-01.pdf

CTA-C-Availability of Study Med After Study Completion-01{1}.doc

CTA-C-Availability of Study Med After Study Completion-01{1}.pdf

CTA-C-Inclusion Exclusion Criteria Rationale-01.doc

CTA-C-Inclusion Exclusion Criteria Rationale-01.pdf

CTA-C-Inclusion Exclusion Criteria Rationale-01{1}.doc

CTA-C-Inclusion Exclusion Criteria Rationale-01{1}.pdf

CTA-C-PbO Rationale (if applicable)-01.doc

CTA-C-PbO Rationale (if applicable)-01.pdf

CTA-C-PbO Rationale (if applicable)-01{1}.pdf

CTA-C-PbO Rationale (if applicable)-01{1}.doc

CTA-C-Rationale for not conducting the trial in Sponsor-01.doc

CTA-C-Rationale for not conducting the trial in Sponsor-01.pdf

CTA-C-Rationale for not conducting the trial in Sponsor-01{1}.doc

CTA-C-Rationale for not conducting the trial in Sponsor-01{1}.pdf

CTA-C-Subject Selection Criteria Stat Consideration-EU.doc

CTA-C-Subject Selection Criteria Stat Consideration-EU.pdf

CTA-C-Subject Selection Criteria Stat Consideration-EU{1}.doc

CTA-C-Subject Selection Criteria Stat Consideration-EU{1}.pdf

CTA-G-(Core) Cover Letter to Int PCO(s)-01.doc

CTA-G-(Core) Cover Letter to Int PCO(s)-01.pdf

CTA-G-(Core) Table of Contents Int-01.doc

CTA-G-(Core) Table of Contents Int-01.pdf

CTA-R-(Core) Countries Participating in this CT and Decis-01.doc

CTA-R-(Core) Countries Participating in this CT and Decis-01.pdf

CTA-R-Worldwide Registration Status and Date-01.doc

CTA-R-Worldwide Registration Status and Date-01.pdf

CTA-R-Worldwide Registration Status and Date-01{1}.doc

CTA-R-Worldwide Registration Status and Date-01{1}.pdf

16.1.6 Study Drug Information.doc

Study B1171003 - PMAR00318.doc

B1171003 Phase 2 ICH Study Rpt Synopsis.doc

B1171003 CSR Sum Changes.doc

B1171003 Phase 2 ICH Study Rpt Body.docx

51650 B1171003 CTA Package Emails.zip

51650-B1171003-INI-INT-Jul10-VOL-00001.pdf

2013 07 19 MAA QQR Q1.doc

2.3 QOS DP Comparability Protocol Kalamazoo APS Pressurization NDA 17989.doc

3.2.P.5.1 Specification(s).doc

3.2.P.5.2 Analytical Procedures.doc

3.2.P.5.4 Batch Analyses.doc

3.2.P.5.6 Justification of Specifications.doc

P.3.1 Batch Formula.doc

(CL) Orphan Drug AR 2013.doc

P.1 Description and Composition of the Drug Product.doc

B1171003 Phase 2 ICH Study Rpt Synopsis.doc

B1171003 CSR Sum Changes.doc

B1171003 Phase 2 ICH Study Rpt Body.docx

CDS Carboprost.doc

CDS Carboprost1.doc

EU - 1.0 Cover Letter - ODD Letter of IntentUpdate.doc

EU - 1.0 Cover Letter - ODD Letter of IntentUpdate.pdf

20110113REG07-WRS-EU02 - QCPNU-100480 EMA Pre-Subm Mtg package for ODD - 13 Jan 2011.doc

20110113REG07-WRS-EU02 - QCPNU-100480 EMA Pre-Subm Mtg package for ODD - 13 Jan 2011.pdf

20110120REG07 Confirmation of Quality Control FormPNU-100480.pdf

EMA FDAApplication Form - ODD - PNU-100480.doc

EMA FDAApplication Form - ODD - PNU-100480.pdf

EU - 1.0 Cover Letter - Package for Pre-Submission Meeting.pdf

Final MinutesPre-Submission Meeting 21 Jan 2011 - 31 Jan 2011.doc

Final MinutesPre-Submission Meeting 21 Jan 2011 - 31 Jan 2011.pdf

PNU-100480 - EMA Orphan Medicinal Products Presentation - 21 Jan 2011.pdf

PNU-100489 - Translations.doc

PNU-100480 - EMA Orphan Medicinal Products Presentation - 21 Jan 2011.pptx

PNU-100489 - Translations.pdf

s A-F EU Orphan Medicinal Product DesignationPNU-100480Tuberculosis.doc

s A-F EU Orphan Medicinal Product DesignationPNU-100480Tuberculosis.pdf

Unsigned Letter of Authorisation - PNU-100480 ODD.doc

Unsigned Letter of Authorisation - PNU-100480 ODD.pdf

US ODD - Cover Letter to FDA - 12 Nov 2010.pdf

5.1 NoCln PharmaC.doc

2.5 Clinical Overview.doc

20110317REG07-WRS-EU02 - QCPNU-100480 EMA App for ODD - 17 Mar 2011.doc

20110317REG07-WRS-EU02 - QCPNU-100480 EMA App for ODD - 17 Mar 2011.pdf

20110318REG07 Confirmation of Quality Control FormPNU-100480 App.pdf

20110318REG07 Confirmation of Quality Control FormPNU-100480 AppA Silvia.pdf

20110405EMA Timetable - Received 8 Apr 2011.pdf

20110610PNU-100480Outcome of COMP - Positive OpinionEMAOD02911 - 10 Jun 2011.pdf

2011071201Eudralink - PNU-100480 - OpinionSumm Rpt - 12 July 2011.pdf

2011071202PNU-100480EU Orphan DesignationLetterTranslationsA9R2C.pdf

2011071203PNU-100480EU Orphan DesignationOpinionA9R2D.pdf

2011071204PNU-100480EU Orphan DesignationSummary RptA9R29.pdf

20110728Eudralink - PNU-100480 - Draft PSO - 28 July 2011.htm

20110728PNU-100480 Draft Public Summary Opinion - 28 July 2011.doc

20110728PNU-100480 Draft Public Summary Opinion - 28 July 2011.pdf

20110804Eudralink - PNU-100480 - Draft PSO - 4 August 2011.htm

EMA FDAApplication Form - ODD - PNU-100480.pdf

EMA FDAApplication Form - ODD - PNU-100480.doc

EU - 1.0 Cover Letter - EU Orphan Medicinal Product Designation Application.doc

EU - 1.0 Cover Letter - EU Orphan Medicinal Product Designation Application.pdf

PNU-100489 - Translations.doc

EU 1.1 Comprehensive Table of Contents.doc

Letter of Authorisation - PNU-100480 EU OD.pdf

EU 1.1 Comprehensive Table of Contents.pdf

PNU-100489 - Translations.pdf

Proof of Establishment.pdf

Proof of EstablishmentCertificate of incorporation of Pfizer Ltd.pdf

s A-F EU Orphan Medicinal Product DesignationPNU-100480Tuberculosis.doc

s A-F EU Orphan Medicinal Product DesignationPNU-100480Tuberculosis.pdf

US FDA CorrspdPNU-1004804 Feb 2011 - US ODD.pdf

2 Summary.doc

3 Introduction.doc

4 Physical Chemical and Pharmaceutical Properties and Formulation.doc

5.1 NoCln PharmaC.doc

5.2 PK and Product Metabolism in Animals.doc

5.3 Tox.docx

6 Effects in Humans Introduction.doc

6.1 PK and Product Metabolism in Humans.doc

6.2 Safety and Efficacy.doc

6.3 Marketing Experience.doc

7 Sum Data and Guidance for the Investigator (DCSI format).doc

IB Abbreviations wo macro.doc

IB Cover Page and TOC.doc

Sum Changes in a Revised compound IB - Date.pdf

2 Summary.pdf

3 Introduction.pdf

4 Physical Chemical and Pharmaceutical Properties and Formulation.pdf

5.1 NoCln PharmaC.pdf

5.2 PK and Product Metabolism in Animals.pdf

5.3 Tox.pdf

6 Effects in Humans Introduction.pdf

6.1 PK and Product Metabolism in Humans.pdf

6.2 Safety and Efficacy.pdf

6.3 Marketing Experience.pdf

7 Sum Data and Guidance for the Investigator (DCSI format).pdf

IB Abbreviations wo macro.pdf

IB Cover Page and TOC.pdf

1.13.2 Sum Clinical PharmaC.doc

1.13.3 - Summary Page.doc

1.13.3 - TOC.doc

1.13.8 - Summary Page.doc

1.13.8 - TOC.doc

1.13.9 General Investigational Plan.doc

1.14.4.1 IB (paper submission only).doc

B117Finaldeliverables2013.xls

Table 1.13.1-1 Sum Non-Clinical Studies - Tox.doc

IND Annual Rpt carboprost tromethamine PNU-0100480 22 Jan 2012 - 21 Jan 2013.doc

EU 1 1 Comprehensive Table of Contents.doc

Cover Letter.doc

EMA Annual Rpt Form.doc

PNU-100480 Annual Rpt.doc

1.13.2 Sum Clinical PharmaC.doc

1.13.3 - Summary Page.doc

1.13.3 - TOC.doc

1.13.8 - Summary Page.doc

1.13.9 General Investigational Plan.doc

1.13.8 - TOC.doc

1.14.4.1 IB (paper submission only).doc

Table 1.13.1-1 Sum Non-Clinical Studies - Tox.doc

B1171002 Phase 1 ICH CSR.pdf

B1171002 PhRMA Web Synopsis Approval Form.pdf

B1171002 PhRMA Web Synopsis.docx

B1171002 PhRMA Web Synopsis.pdf

b1171002-adverse-events.pdf

b1171002-analytical-reports.pdf

b1171002-compliance.pdf

b1171002-demographics.pdf

b1171002-discontinued-patients.pdf

b1171002-efficacy-response.pdf

b1171002-iec-irb-list.pdf

b1171002-invest-signature.pdf

b1171002-investigators.pdf

b1171002-lab-measurements.pdf

b1171002-patient-batches.pdf

b1171002-protocol-deviations.pdf

b1171002-protocol.pdf

b1171002-publications.pdf

b1171002-randomization.pdf

b1171002-report-body.pdf

b1171002-sponsor-signature.pdf

b1171002-sap.pdf

b1171002-synopsis.pdf

LCM Table.doc

Annotated PM.doc

LCM Table1.doc

LCM Table2.doc

Non-Annotated PM.doc

pristine-pm.doc

Response to Clarifax of Jul-11-2013.doc

m1-3-1-04-3-contraindications.doc

m1-3-1-04-6-pregnancy-and-lactation.doc

m1-3-1-04-8-undesirable-effects.doc

m1-3-1-10-revision-date.doc

Anger 2010.pdf

Attassi, 2001.pdf

Barnes 1988.pdf

Boehme 2010.pdf

Caminero 2004.pdf

Cattamanchi 2009.pdf

Condos R, Hadgiangelis N, Leibert E, et al..pdf

Fortun 2005.pdf

Grassi 1996.pdf

Helb 2010.pdf

Hopewell 2006.pdf

Kaplan 2009.pdf

Koh 2009.pdf

Ling 2008.pdf

Lee 2005.pdf

MacGregor 1975.pdf

McKee 2006.pdf

Migliori 2009.pdf

Migliori GB 2008.pdf

Mitchison 1986.pdf

Morgan 1983.pdf

Nagiec 2005.pdf

Nam 2009.pdf

Ntziora 2007.pdf

Park 2006.pdf

Poppius 1957.pdf

Poulsen 1951.pdf

Udwadia 2010.pdf

Stead 1968.pdf

von der Lippe 2006.pdf

Wallis bRS, Palaci 2001.pdf

Wallis RS, Jakubiec W, Kumar V 2011.pdf

Wallis RS, Jakubiec WM, Kumar V 2010.pdf

Yew 2008.pdf

Wallis RS, Vinhas 2003.pdf

Williams KN, Brickner 2009.pdf

Williams KN, Stover 2009.pdf

PMF PBO PNU-0100480 tab.pdf

B1171002-Center-1001-rando.pdf

16.1.11 - Publications Based on the Study.doc

16.1.11 - Publications Based on the Study.pdf

16.1.4 - Invesgitator CVs.pdf

16.1.4 - List of Investigators and Corresponding Ethics Committees or Institutional Review Boards.doc

16.1.5.1 - Sponsor.pdf

16.1.4 - List of Investigators and Corresponding Ethics Committees or Institutional Review Boards.pdf

16.1.5.2 - CSR Investigator Declaration.doc

16.1.5.2 - CSR Investigator Declaration.pdf

16.1.6 Study Drug Information.doc

16.1.6 Study Drug Information.pdf

16.1.7.1 - Description of Randomization.doc

16.1.7.1 - Description of Randomization.pdf

16.2.2 Protocol Deviations.doc

16.2.2 Protocol Deviations{1}.doc

16.2.2 Protocol Deviations.pdf

16.2.2 Protocol Deviations{1}.pdf

16.2.5.10.1 B1171002 Analytical Rpt Plasma Linezolid.pdf

16.2.5.10.2 B1171002 Analytical Rpt - Plasma.pdf

16.2.5.10.3 B1171002 Analytical Rpt - Urine.pdf

B1171002 CTD Abstract.doc

B1171002 CTD Abstract.pdf

B1171002 Errata.doc

B1171002 Errata.pdf

B1171002 Phase 1 ICH Study Rpt Body.doc

B1171002 Phase 1 ICH Study Rpt Body.pdf

B1171002 Phase 1 ICH Study Rpt Synopsis.doc

B1171002 Phase 1 ICH Study Rpt Synopsis.pdf

B1171002 PhRMA Web Synopsis Approval Form.pdf

B1171002 PhRMA Web Synopsis.docx

B1171002 PhRMA Web Synopsis.pdf

b1171002-adverse-events.pdf

b1171002-analytical-reports.pdf

b1171002-compliance.pdf

b1171002-demographics.pdf

b1171002-discontinued-patients.pdf

b1171002-efficacy-response.pdf

b1171002-iec-irb-list.pdf

b1171002-invest-signature.pdf

b1171002-investigators.pdf

b1171002-lab-measurements.pdf

b1171002-patient-batches.pdf

b1171002-protocol-deviations.pdf

b1171002-protocol.pdf

b1171002-publications.pdf

b1171002-randomization.pdf

b1171002-report-body.pdf

b1171002-sap.pdf

b1171002-sponsor-signature.pdf

b1171002-synopsis.pdf

Figure 14.2.1.1 Individual and Mean profiles of the Whole Blood Bactericidal Activity (WBA).pdf

Table 14.2.2 Dscrp Sum WBA AUC.pdf

Figure 14.4.2.2.1.1 Median PNU-100480 Plasma Conc - Time Plot (Linear Scale) (Cohort 1 to Cohort 4).pdf

Figure 14.4.2.2.1.2 Median PNU-100480 Plasma Conc - Time Plot (Semi-log Scale) (Cohort 1 to Cohort 4).pdf

[Figure 14.4.2.2.10.1 Mean PNU-101244 Plasma Conc - Time Plot \(Linear Scale\) \(Cohort 5\).pdf](#)

[Figure 14.4.2.2.10.2 Mean PNU-101244 Plasma Conc - Time Plot \(Semi-log\) \(Cohort 5\).pdf](#)

[Figure 14.4.2.2.11 Median Plasma PNU-100480 Trough Conc Plot \(Cohort 1 to Cohort 5\).pdf](#)

[Figure 14.4.2.2.12 Median Plasma PNU-101603 Trough Conc Plot \(Cohort 1 to Cohort 5\).pdf](#)

[Figure 14.4.2.2.13 Median Plasma PNU-101244 Trough Conc Plot \(Cohort 1 to Cohort 5\).pdf](#)

[Table 14.1.1.1 Subject Evaluation Groups.pdf](#)

[Figure 14.4.2.2.2.1 Median PNU-101603 Plasma Conc - Time Plot \(Linear Scale\) \(Cohort 1 to Cohort 4\).pdf](#)

[Figure 14.4.2.2.2.2 Median PNU-101603 Plasma Conc - Time Plot \(Semi-log Scale\) \(Cohort 1 to Cohort 4\).pdf](#)

[Figure 14.4.2.2.3.1 Median PNU-101244 Plasma Conc - Time Plot \(Linear Scale\) \(Cohort 1 to Cohort 4\).pdf](#)

[Figure 14.4.2.2.3.2 Median PNU-101244 Plasma Conc - Time Plot \(Semi-log Scale\) \(Cohort 1 to Cohort 4\).pdf](#)

[Figure 14.4.2.2.4.2 Median PNU-100480 Plasma Conc - Time Plot \(Semi-log\) \(Cohort 5\).pdf](#)

[Figure 14.4.2.2.4.1 Median PNU-100480 Plasma Conc - Time Plot \(Linear Scale\) \(Cohort 5\).pdf](#)

[Figure 14.4.2.2.5.1 Median PNU-101603 Plasma Conc - Time Plot \(Linear Scale\) \(Cohort 5\).pdf](#)

[Figure 14.4.2.2.5.2 Median PNU-101603 Plasma Conc - Time Plot \(Semi-log\) \(Cohort 5\).pdf](#)

[Figure 14.4.2.2.6.1 Median PNU-101244 Plasma Conc - Time Plot \(Linear Scale\) \(Cohort 5\).pdf](#)

[Figure 14.4.2.2.6.2 Median PNU-101244 Plasma Conc - Time Plot \(Semi-log\) \(Cohort 5\).pdf](#)

[Figure 14.4.2.2.7.1 Median Linezolid Plasma Conc - Time Plot \(Linear Scale\) \(LZD Cohort\).pdf](#)

[Figure 14.4.2.2.7.2 Median Linezolid Plasma Conc - Time Plot \(Semi-log\) \(LZD Cohort\).pdf](#)

[Figure 14.4.2.2.8.1 Mean PNU-100480 Plasma Conc - Time Plot \(Linear Scale\) \(Cohort 5\).pdf](#)

[Figure 14.4.2.2.8.2 Mean PNU-100480 Plasma Conc - Time Plot \(Semi-log\) \(Cohort 5\).pdf](#)

[Figure 16.2.6.2.1 AUCwba Individual Subject Plot by Treatment.pdf](#)

[Figure 14.4.2.2.9.1 Mean PNU-101603 Plasma Conc - Time Plot \(Linear Scale\) \(Cohort 5\).pdf](#)

[Figure 14.4.2.2.9.2 Mean PNU-101603 Plasma Conc - Time Plot \(Semi-log\) \(Cohort 5\).pdf](#)

[Figure 16.2.5.4.2.1.2 PNU-100480 Plasma Conc \(Cohort 5\) -Time Plot by Subject \(Semi-log\).pdf](#)

[Figure 16.2.5.4.2.1.1 PNU-100480 Plasma Conc \(Cohort 5\) -Time Plot by Subject \(Linear Scale\).pdf](#)

[Figure 16.2.5.4.2.10.1 PNU-101244 Plasma Conc-Time Plot by Treatment \(Linear Scale\) \(Cohort 5\).pdf](#)

[Figure 16.2.5.4.2.10.2 PNU-101244 Plasma Conc-Time Plot by Treatment \(Semi-log\) \(Cohort 5\).pdf](#)

[Figure 16.2.5.4.2.11.1 Linezolid Plasma Conc -Time Plot by Treatment \(Linear Scale\).pdf](#)

[Table 14.1.1.2 Discontinuations from Study.pdf](#)

[Figure 16.2.5.4.2.11.2 Linezolid Plasma Conc -Time Plot by Treatment \(Semi-log\).pdf](#)

[Figure 16.2.5.4.2.14 PNU-100480 Trough Conc - Day Plot by Treatment \(Cohort 1 to Cohort 5\).pdf](#)

[Figure 16.2.5.4.2.15 PNU-101603 Trough Conc - Day Plot by Treatment \(Cohort 1 to Cohort 5\).pdf](#)

[Figure 16.2.5.4.2.16 PNU-101244 Trough Conc - Day Plot by Treatment \(Cohort 1 to Cohort 5\).pdf](#)

[Figure 16.2.5.4.2.2.1 PNU-101603 Plasma Conc \(Cohort 5\) -Time Plot by Subject \(Linear Scale\).pdf](#)

[Figure 16.2.5.4.2.2.2 PNU-101603 Plasma Conc \(Cohort 5\) -Time Plot by Subject \(Semi-log\).pdf](#)

[Figure 16.2.5.4.2.3.1 PNU-101244 Plasma Conc \(Cohort 5\) -Time Plot by Subject \(Linear Scale\).pdf](#)

[Table 14.1.2 Demographic Characteristics.pdf](#)

[Figure 16.2.5.4.2.3.2 PNU-101244 Plasma Conc \(Cohort 5\) -Time Plot by Subject \(Semi-log\).pdf](#)

[Figure 16.2.5.4.2.4.1 Linezolid Plasma Conc -Time Plot by Subject \(Linear Scale\).pdf](#)

[Figure 16.2.5.4.2.5.1 PNU-100480 Plasma Conc-Time Plot by Treatment \(Linear Scale\) \(Cohort 1 to Cohort 4\).pdf](#)

[Figure 16.2.5.4.2.4.2 Linezolid Plasma Conc -Time Plot by Subject\(Semi-log\).pdf](#)

[Figure 16.2.5.4.2.5.2 PNU-100480 Plasma Conc-Time Plot by Treatment \(Semi-log Scale\) \(Cohort 1 to Cohort 4\).pdf](#)

[Figure 16.2.5.4.2.6.1 PNU-101603 Plasma Conc-Time Plot by Treatment \(Linear Scale\) \(Cohort 1 to Cohort 4\).pdf](#)

[Figure 16.2.5.4.2.6.2 PNU-101603 Plasma Conc-Time Plot by Treatment \(Semi-log Scale\) \(Cohort 1 to Cohort 4\).pdf](#)

[Figure 16.2.5.4.2.7 Plasma PNU-100480 Trough Conc Plot\(Cohort 1- Cohort 5\) - Day Plot by Subject.pdf](#)

[Figure 16.2.5.4.2.7.1 PNU-101244 Plasma Conc-Time Plot by Treatment \(Linear Scale\) \(Cohort 1 to Cohort 4\).pdf](#)

[Figure 16.2.5.4.2.7.2 PNU-101244 Plasma Conc-Time Plot by Treatment \(Semi-log Scale\) \(Cohort 1 to Cohort 4\).pdf](#)

[Figure 16.2.5.4.2.8 Plasma PNU-101603 Trough Conc Plot\(Cohort 1- Cohort 5\) - Day Plot by Subject.pdf](#)

[Figure 16.2.5.4.2.8.1 PNU-100480 Plasma Conc-Time Plot by Treatment \(Linear Scale\) \(Cohort 5\).pdf](#)

[Figure 16.2.5.4.2.9.1 PNU-101603 Plasma Conc-Time Plot by Treatment \(Linear Scale\) \(Cohort 5\).pdf](#)

[Figure 16.2.5.4.2.8.2 PNU-100480 Plasma Conc-Time Plot by Treatment \(Semi-log\) \(Cohort 5\).pdf](#)

[Figure 16.2.5.4.2.9 Plasma PNU-101244 Trough Conc Plot\(Cohort 1- Cohort 5\) - Day Plot by Subject.pdf](#)

[Figure 16.2.5.4.2.9.2 PNU-101603 Plasma Conc-Time Plot by Treatment \(Semi-log\) \(Cohort 5\).pdf](#)

[Figure 16.2.5.6.4.1 Box and Whisker Plot for Individual Plasma PNU-100480 AUCtau vs Dosing Day for Cohort 5.pdf](#)

[Figure 16.2.5.6.4.2 Box and Whisker Plot for Individual Plasma PNU-100480 Cmax vs Dosing Day for Cohort 5.pdf](#)

[Figure 16.2.5.6.5.1 Box and Whisker Plot for Individual Plasma PNU-101603 AUCtau vs Dosing Day for Cohort 5.pdf](#)

[Figure 16.2.5.6.5.2 Box and Whisker Plot for Individual Plasma PNU-101603 Cmax vs Dosing Day for Cohort 5.pdf](#)

[Figure 16.2.6.3.1 WBAmx Individual Subject Plot by Treatment.pdf](#)

[Figure 16.2.5.6.1.1 Plot of Dose Normalized Plasma PNU-100480 AUCtau vs Treatment By Day 1 and Day 14 \(Cohort 1 -Cohort 5\).pdf](#)

[Figure 16.2.5.6.1.2 Plot of Dose Normalized Plasma PNU-100480 Cmax vs Treatment By Day 1 and Day 14 \(Cohort 1 -Cohort 5\).pdf](#)

[Figure 16.2.5.6.6.1 Box and Whisker Plot for Individual Plasma PNU-101244 AUCtau vs Dosing Day for Cohort 5.pdf](#)

[Figure 16.2.5.6.6.2 Box and Whisker Plot for Individual Plasma PNU-101244 Cmax vs Dosing Day for Cohort 5.pdf](#)

[Figure 16.2.6.1.1 Whole Blood Bactericidal Activity \(WBA\) Individual Subject Plot by Treatment.pdf](#)

[Figure 16.2.6.4.1 Scatter Plot of WBA vs. Total Fold MIC.pdf](#)

[Narratives of Deaths, Other Serious and Certain Other Significant Adverse.pdf](#)

[Figure 16.2.5.6.1.3 Plot of Plasma PNU-100480 Observed Accumulation Ratio Rac for AUCtau vs Treatment in Day 14 \(Cohort 1 -Cohort 5\).pdf](#)

[Figure 16.2.5.6.1.4 Plot of Plasma PNU-100480 Observed Accumulation Ratio Rac for Cmax vs Treatment in Day 14 \(Cohort 1 -Cohort 5\).pdf](#)

[Table 14.2.1 Whole Blood Bactericidal Activity \(WBA\) Mean Values.pdf](#)

[Table 14.2.3.2 Sum Stats of WBA AUC.pdf](#)

[Table 14.4.1 Administration Schedule.pdf](#)

[Table 14.4.2.1.1 PNU-100480 Plasma Conc vs Time Summary \(Cohort 1 to Cohort 4\).pdf](#)

[Table 14.4.2.1.2 PNU-101603 Plasma Conc vs Time Summary \(Cohort 1 to Cohort 4\).pdf](#)

[Table 14.4.2.1.3 PNU-101244 Plasma Conc vs Time Summary \(Cohort 1 to Cohort 4\).pdf](#)

[Figure 16.2.5.6.2.1 Plot of Dose Normalized Plasma PNU-101603 AUCtau vs Treatment By Day 1 and Day 14 \(Cohort 1 -Cohort 5\).pdf](#)

[Figure 16.2.5.6.2.2 Plot of Dose Normalized Plasma PNU-101603 Cmax vs Treatment By Day 1 and Day 14 \(Cohort 1 -Cohort 5\).pdf](#)

[Table 14.4.2.1.4 PNU-100480 Plasma Conc vs Time Summary \(Cohort 5\).pdf](#)

[Table 14.4.2.1.5 PNU-101603 Plasma Conc vs Time Summary \(Cohort 5\).pdf](#)

[Table 14.4.2.1.6 PNU-101244 Plasma Conc vs Time Summary \(Cohort 5\).pdf](#)

[Table 14.4.2.1.7 Linezolid Plasma Conc vs Time Summary \(LZD Cohort\).pdf](#)

[Table 14.4.3.1.1 Dscrp Sum PNU-100480 Plasma PK Parameters \(Cohort 1 to Cohort 4\).pdf](#)

[Table 14.4.3.1.4 Dscrp Sum PNU-100480 Plasma PK Parameters \(Cohort 5\).pdf](#)

[Figure 16.2.5.6.2.3 Plot of Plasma PNU-101603 Observed Accumulation Ratio Rac for AUCtau vs Treatment in Day 14 \(Cohort 1 -Cohort 5\).pdf](#)

[Figure 16.2.5.6.2.4 Plot of Plasma PNU-101603 Observed Accumulation Ratio Rac for Cmax vs Treatment in Day 14 \(Cohort 1 -Cohort 5\).pdf](#)

[Table 14.4.3.1.2 Dscrp Sum PNU-101603 Plasma PK Parameters \(Cohort 1 to Cohort 4\).pdf](#)

[Table 14.4.3.1.3 Dscrp Sum PNU-101244 Plasma PK Parameters \(Cohort 1 to Cohort 4\).pdf](#)

[Table 14.4.3.1.5 Dscrp Sum PNU-101603 Plasma PK Parameters \(Cohort 5\).pdf](#)

[Table 14.4.3.1.6 Dscrp Sum PNU-101244 Plasma PK Parameters \(Cohort 5\).pdf](#)

[Table 14.4.3.1.7 Dscrp Sum Linezolid Plasma PK Parameters.pdf](#)

[Table 16.2.6.3 Listing of WBAmox.pdf](#)

[Figure 16.2.5.6.3.1 Plot of Dose Normalized Plasma PNU-101244 AUCtau vs Treatment By Day 1 and Day 14 \(Cohort 1 -Cohort 5\).pdf](#)

[Figure 16.2.5.6.3.2 Plot of Dose Normalized Plasma PNU-101244 Cmax vs Treatment By Day 1 and Day 14 \(Cohort 1 -Cohort 5\).pdf](#)

[Table 14.4.3.3.1 Sum Stats of PNU-100480 Cohort 1 Pharmacokinetic Parameters \(Day 14 vs. Day 1\).pdf](#)

[Table 14.4.3.3.10 Sum Stats of PNU-101603 Cohort 5 Pharmacokinetic Parameters \(Day 14 vs. Day 1\).pdf](#)

[Table 14.4.3.3.11 Sum Stats of PNU-101244 Cohort 1 Pharmacokinetic Parameters \(Day 14 vs. Day 1\).pdf](#)

[Table 14.4.3.3.12 Sum Stats of PNU-101244 Cohort 2 Pharmacokinetic Parameters \(Day 14 vs. Day 1\).pdf](#)

[Table 16.2.4.2 Demographic Characteristics.pdf](#)

[Figure 16.2.5.6.3.3 Plot of Plasma PNU-101244 Observed Accumulation Ratio Rac for AUCtau vs Treatment in Day 14 \(Cohort 1 -Cohort 5\).pdf](#)

[Figure 16.2.5.6.3.4 Plot of Plasma PNU-101244 Observed Accumulation Ratio Rac for Cmax vs Treatment in Day 14 \(Cohort 1 -Cohort 5\).pdf](#)

[Table 14.4.3.3.13 Sum Stats of PNU-101244 Cohort 3 Pharmacokinetic Parameters \(Day 14 vs. Day 1\).pdf](#)

[Table 14.4.3.3.14 Sum Stats of PNU-101244 Cohort 4 Pharmacokinetic Parameters \(Day 14 vs. Day 1\).pdf](#)

[Table 14.4.3.3.15 Sum Stats of PNU-101244 Cohort 5 Pharmacokinetic Parameters \(Day 14 vs. Day 1\).pdf](#)

[Table 14.4.3.3.16 Sum Stats of PNU-100480 Pharmacokinetic Parameters \(Day 28 vs. Day 14\)-Cohort 5.pdf](#)

[Table 16.2.1 Subject Discontinuations.pdf](#)

[Figure 16.2.8.2.4.1 Individual Changes from Base in Supine Systolic Blood Pressure \(mmHg\) - Day 1 and Day 14 \(Cohort 1-5\).pdf](#)

[Figure 16.2.8.2.4.2 Individual Changes from Base in Supine Diastolic Blood Pressure \(mmHg\) - Day 1 and Day 14 \(Cohort 1-5\).pdf](#)

[Figure 16.2.8.2.4.3 Individual Changes from Base in Supine Pulse Rate \(BPM\) - Day 1 and Day 14 \(Cohort 1-5\).pdf](#)

[Figure 16.2.8.3.5.1 Individual Changes from Base in QT \(msec\) - Day 1, Day 14 and Day 28 \(Cohort 1-5\).pdf](#)

[Figure 16.2.8.3.5.2 Individual Changes from Base in QTcF \(msec\) - Day 1, Day 14 and Day 28 \(Cohort 1-5\).pdf](#)

[Figure 16.2.8.3.5.3 Individual Changes from Base in Heart Rate \(BPM\) - Day 1, Day 14 and Day 28 \(Cohort 1-5\).pdf](#)

[Table 14.2.3.1 Dscrp Sum WBAmx.pdf](#)

[Table 14.4.3.3.2 Sum Stats of PNU-100480 Cohort 2 Pharmacokinetic Parameters \(Day 14 vs. Day 1\).pdf](#)

[Table 14.4.3.3.3 Sum Stats of PNU-100480 Cohort 3 Pharmacokinetic Parameters \(Day 14 vs. Day 1\).pdf](#)

[Table 14.4.3.3.4 Sum Stats of PNU-100480 Cohort 4 Pharmacokinetic Parameters \(Day 14 vs. Day 1\).pdf](#)

[Table 14.4.3.3.5 Sum Stats of PNU-100480 Cohort 5 Pharmacokinetic Parameters \(Day 14 vs. Day 1\).pdf](#)

[Table 14.4.3.3.6 Sum Stats of PNU-101603 Cohort 1 Pharmacokinetic Parameters \(Day 14 vs. Day 1\).pdf](#)

[Table 14.4.3.3.7 Sum Stats of PNU-101603 Cohort 2 Pharmacokinetic Parameters \(Day 14 vs. Day 1\).pdf](#)

[Table 14.4.3.3.8 Sum Stats of PNU-101603 Cohort 3 Pharmacokinetic Parameters \(Day 14 vs. Day 1\).pdf](#)

[Table 14.4.3.3.9 Sum Stats of PNU-101603 Cohort 4 Pharmacokinetic Parameters \(Day 14 vs. Day 1\).pdf](#)

[Table 16.2.4.1 Subject Evaluation Groups.pdf](#)

[Table 16.2.5.1 Administration Schedule.pdf](#)

[Table 16.2.5.2 Concomitant Drug Treatments.pdf](#)

[Table 16.2.5.3 Concomitant Nondrug Treatments.pdf](#)

[Table 16.2.5.4.1.1.1 PNU-100480 Plasma Conc vs Time Listing \(Cohort 1 to Cohort 4\).pdf](#)

[Table 16.2.5.4.1.1.2 PNU-101603 Plasma Conc vs Time Listing \(Cohort 1 to Cohort 4\).pdf](#)

[Table 16.2.5.4.1.1.3 PNU-101244 Plasma Conc vs Time Listing \(Cohort 1 to Cohort 4\).pdf](#)

Table 16.2.5.4.1.1.4 PNU-100480 Plasma Conc vs Time Listing (Cohort 5).pdf

Table 16.2.5.4.1.1.5 PNU-101603 Plasma Conc vs Time Listing (Cohort 5).pdf

Table 16.2.5.4.1.1.6 PNU-101244 Plasma Conc vs Time Listing (Cohort 5).pdf

Table 16.2.5.4.1.1.7 Linezolid Plasma Conc vs Time Listing (LZD Cohort).pdf

Table 16.2.5.4.1.1.9 Urine PNU-101244 ConcAmount Listing by Collection Interval.pdf

Table 16.2.5.4.1.1.8 Urine PNU-101603 ConcAmount Listing by Collection Interval.pdf

Table 16.2.5.4.1.2.1 Sample Deviations (10) and Comments for PNU-100480 Plasma Assay (Cohort 1 to Cohort 4).pdf

Table 16.2.5.4.1.2.2 Sample Deviations (10) and Comments for PNU-101603 Plasma Assay (Cohort 1 to Cohort 4).pdf

Table 16.2.5.5.1.7 Listing and Dscrp Sum Linezolid Plasma PK Parameters.pdf

Table 16.2.5.4.1.2.3 Sample Deviations (10) and Comments for PNU-101244 Plasma Assay (Cohort 1 to Cohort 4).pdf

Table 16.2.5.4.1.2.4 Sample Deviations (10) and Comments for PNU-100480 Plasma Assay (Cohort 5).pdf

Table 16.2.5.4.1.2.5 Sample Deviations (10) and Comments for PNU-101603 Plasma Assay (Cohort 5).pdf

Table 16.2.5.4.1.2.7 Sample Deviations (10) and Comments for Linezolid Plasma Assay (LZD Cohort).pdf

Table 16.2.5.4.1.2.6 Sample Deviations (10) and Comments for PNU-101244 Plasma Assay (Cohort 5).pdf

Table 16.2.5.5.1.1 Listing and Dscrp Sum PNU-100480 Plasma PK Parameters (Cohort 1 to Cohort 4).pdf

Table 16.2.5.5.1.2 Listing and Dscrp Sum PNU-101603 Plasma PK Parameters (Cohort 1 to Cohort 4).pdf

Table 16.2.5.5.1.3 Listing and Dscrp Sum PNU-101244 Plasma PK Parameters (Cohort 1 to Cohort 4).pdf

Table 16.2.5.5.1.4 Listing and Dscrp Sum PNU-100480 Plasma PK Parameters (Cohort 5).pdf

Table 16.2.5.5.1.5 Listing and Dscrp Sum PNU-101603 Plasma PK Parameters (Cohort 5).pdf

Table 16.2.5.5.1.6 Listing and Dscrp Sum PNU-101244 Plasma PK Parameters (Cohort 5).pdf

Table 16.2.6.1 Whole Blood Bactericidal Activity (WBA) Data.pdf

Table 16.2.6.2 Listing of WBA AUC.pdf

Table 16.2.6.4 Listing of WBA and Total Fold MIC.pdf

Table 16.2.7 AEs.pdf

Table 16.2.8.1.1 Laboratory Data.pdf

Table 16.2.8.1.2 LTA's, by Subject.pdf

Table 16.2.8.1.3 LTA's, by Test.pdf

Table 16.2.8.2.1 Vitals Signs Data.pdf

Table 16.2.8.2.2 Values Meeting Categorical Sum Post Base Vital Signs Criteria.pdf

Table 16.2.8.3.1 ECG Data.pdf

Table 16.2.8.2.3 Vital Signs ChngBase.pdf

Table 16.2.8.3.2 ECG Qualitative Results.pdf

Table 16.2.8.3.3 Values Meeting Categorical Sum Post Base ECG Criteria.pdf

Table 16.2.8.3.4 ECG ChngBase.pdf

WBA MGIT protocol and spreadsheet instructions.pdf

Table 16.2.8.3.5 ECG Subjects with Any Single Postdose QTcF interval Value Greater than or Equal to 500msec.pdf

Figure 14.2.1.1 Individual and Mean profiles of the Whole Blood Bactericidal Activity (WBA).pdf

Figure 14.3.4.2.1.2.1 Mean Changes from Base in Supine Systolic Blood Pressure (mmHg) - Day 1 and Day 14 (Cohort 1-5).pdf

Figure 14.3.4.2.1.2.3 Mean Changes from Base in Supine Pulse Rate (mmHg) - Day 1 and Day 14 (Cohort 1-5).pdf

Figure 14.3.4.3.1.2.1 Mean Changes from Base in QT (msec) - Day 1,Day 14 and Day 28(Cohort 1-5).pdf

Figure 14.3.4.3.1.2.2 Mean Changes from Base in QTcF (msec) - Day 1,Day 14 and Day 28(Cohort 1-5).pdf

Figure 14.3.4.3.1.2.3 Mean Changes from Base in Heart Rate (BPM) - Day 1,Day 14 and Day 28(Cohort 1-5).pdf

Figure 14.3.4.3.1.3.1 Scatter Plot of ChngBase in QTcF vs. PNU-100480 Conc.pdf

Figure 14.3.4.2.1.2.2 Mean Changes from Base in Supine Diastolic Blood Pressure (mmHg) - Day 1 and Day 14 (Cohort 1-5).pdf

Figure 14.3.4.3.1.3.2 Scatter Plot of ChngBase in QTcF vs. PNU-101603 Conc.pdf

Figure 14.3.4.3.1.3.3 Scatter Plot of ChngBase in QTcF vs. PNU-101244 Conc.pdf

Figure 14.4.2.2.1.1 Median PNU-100480 Plasma Conc - Time Plot (Linear Scale) (Cohort 1 to Cohort 4).pdf

Figure 14.4.2.2.10.1 Mean PNU-101244 Plasma Conc - Time Plot (Linear Scale) (Cohort 5).pdf

Figure 14.4.2.2.1.2 Median PNU-100480 Plasma Conc - Time Plot (Semi-log Scale) (Cohort 1 to Cohort 4).pdf

Figure 14.4.2.2.10.2 Mean PNU-101244 Plasma Conc - Time Plot (Semi-log) (Cohort 5).pdf

[Figure 14.4.2.2.11 Median Plasma PNU-100480 Trough Conc Plot \(Cohort 1 to Cohort 5\).pdf](#)

[Figure 14.4.2.2.12 Median Plasma PNU-101603 Trough Conc Plot \(Cohort 1 to Cohort 5\).pdf](#)

[Figure 14.4.2.2.13 Median Plasma PNU-101244 Trough Conc Plot \(Cohort 1 to Cohort 5\).pdf](#)

[Figure 14.4.2.2.2.1 Median PNU-101603 Plasma Conc - Time Plot \(Linear Scale\) \(Cohort 1 to Cohort 4\).pdf](#)

[Figure 14.4.2.2.2.2 Median PNU-101603 Plasma Conc - Time Plot \(Semi-log Scale\) \(Cohort 1 to Cohort 4\).pdf](#)

[Figure 14.4.2.2.3.1 Median PNU-101244 Plasma Conc - Time Plot \(Linear Scale\) \(Cohort 1 to Cohort 4\).pdf](#)

[Figure 14.4.2.2.3.2 Median PNU-101244 Plasma Conc - Time Plot \(Semi-log Scale\) \(Cohort 1 to Cohort 4\).pdf](#)

[Figure 14.4.2.2.4.1 Median PNU-100480 Plasma Conc - Time Plot \(Linear Scale\) \(Cohort 5\).pdf](#)

[Figure 14.4.2.2.4.2 Median PNU-100480 Plasma Conc - Time Plot \(Semi-log\) \(Cohort 5\).pdf](#)

[Figure 14.4.2.2.5.1 Median PNU-101603 Plasma Conc - Time Plot \(Linear Scale\) \(Cohort 5\).pdf](#)

[Figure 14.4.2.2.5.2 Median PNU-101603 Plasma Conc - Time Plot \(Semi-log\) \(Cohort 5\).pdf](#)

[Figure 14.4.2.2.6.1 Median PNU-101244 Plasma Conc - Time Plot \(Linear Scale\) \(Cohort 5\).pdf](#)

[Figure 14.4.2.2.6.2 Median PNU-101244 Plasma Conc - Time Plot \(Semi-log\) \(Cohort 5\).pdf](#)

[Figure 14.4.2.2.7.1 Median Linezolid Plasma Conc - Time Plot \(Linear Scale\) \(LZD Cohort\).pdf](#)

[Figure 16.2.6.2.1 AUCwba Individual Subject Plot by Treatment.pdf](#)

[Figure 14.4.2.2.7.2 Median Linezolid Plasma Conc - Time Plot \(Semi-log\) \(LZD Cohort\).pdf](#)

[Figure 14.4.2.2.8.1 Mean PNU-100480 Plasma Conc - Time Plot \(Linear Scale\) \(Cohort 5\).pdf](#)

[Figure 14.4.2.2.8.2 Mean PNU-100480 Plasma Conc - Time Plot \(Semi-log\) \(Cohort 5\).pdf](#)

[Figure 14.4.2.2.9.1 Mean PNU-101603 Plasma Conc - Time Plot \(Linear Scale\) \(Cohort 5\).pdf](#)

[Figure 14.4.2.2.9.2 Mean PNU-101603 Plasma Conc - Time Plot \(Semi-log\) \(Cohort 5\).pdf](#)

[Figure 16.2.5.4.2.1.1 PNU-100480 Plasma Conc \(Cohort 5\) -Time Plot by Subject \(Linear Scale\).pdf](#)

[Figure 16.2.5.4.2.1.2 PNU-100480 Plasma Conc \(Cohort 5\) -Time Plot by Subject \(Semi-log\).pdf](#)

[Figure 16.2.6.3.1 WBAmx Individual Subject Plot by Treatment.pdf](#)

[Figure 16.2.5.4.2.10.1 PNU-101244 Plasma Conc-Time Plot by Treatment \(Linear Scale\) \(Cohort 5\).pdf](#)

[Figure 16.2.5.4.2.10.2 PNU-101244 Plasma Conc-Time Plot by Treatment \(Semi-log\) \(Cohort 5\).pdf](#)

[Figure 16.2.5.4.2.11.1 Linezolid Plasma Conc -Time Plot by Treatment \(Linear Scale\).pdf](#)

[Figure 16.2.5.4.2.11.2 Linezolid Plasma Conc -Time Plot by Treatment \(Semi-log\).pdf](#)

[Figure 16.2.5.4.2.15 PNU-101603 Trough Conc - Day Plot by Treatment \(Cohort 1 to Cohort 5\).pdf](#)

[Figure 16.2.5.4.2.14 PNU-100480 Trough Conc - Day Plot by Treatment \(Cohort 1 to Cohort 5\).pdf](#)

[Figure 16.2.5.4.2.16 PNU-101244 Trough Conc - Day Plot by Treatment \(Cohort 1 to Cohort 5\).pdf](#)

[Table 14.1.1.1 Subject Evaluation Groups.pdf](#)

[Figure 16.2.5.4.2.2.1 PNU-101603 Plasma Conc \(Cohort 5\) -Time Plot by Subject \(Linear Scale\).pdf](#)

[Figure 16.2.5.4.2.2.2 PNU-101603 Plasma Conc \(Cohort 5\) -Time Plot by Subject \(Semi-log\).pdf](#)

[Figure 16.2.5.4.2.3.1 PNU-101244 Plasma Conc \(Cohort 5\) -Time Plot by Subject \(Linear Scale\).pdf](#)

[Figure 16.2.5.4.2.3.2 PNU-101244 Plasma Conc \(Cohort 5\) -Time Plot by Subject \(Semi-log\).pdf](#)

[Figure 16.2.5.4.2.4.1 Linezolid Plasma Conc -Time Plot by Subject \(Linear Scale\).pdf](#)

[Figure 16.2.5.4.2.4.2 Linezolid Plasma Conc -Time Plot by Subject\(Semi-log\).pdf](#)

[Figure 16.2.5.4.2.5.1 PNU-100480 Plasma Conc-Time Plot by Treatment \(Linear Scale\) \(Cohort 1 to Cohort 4\).pdf](#)

[Table 14.1.2 Demographic Characteristics.pdf](#)

[Figure 16.2.5.4.2.5.2 PNU-100480 Plasma Conc-Time Plot by Treatment \(Semi-log Scale\) \(Cohort 1 to Cohort 4\).pdf](#)

[Figure 16.2.5.4.2.6.1 PNU-101603 Plasma Conc-Time Plot by Treatment \(Linear Scale\) \(Cohort 1 to Cohort 4\).pdf](#)

[Figure 16.2.5.4.2.7.1 PNU-101244 Plasma Conc-Time Plot by Treatment \(Linear Scale\) \(Cohort 1 to Cohort 4\).pdf](#)

[Figure 16.2.5.4.2.6.2 PNU-101603 Plasma Conc-Time Plot by Treatment \(Semi-log Scale\) \(Cohort 1 to Cohort 4\).pdf](#)

[Figure 16.2.5.4.2.7 Plasma PNU-100480 Trough Conc Plot\(Cohort 1- Cohort 5\) - Day Plot by Subject.pdf](#)

[Figure 16.2.5.4.2.7.2 PNU-101244 Plasma Conc-Time Plot by Treatment \(Semi-log Scale\) \(Cohort 1 to Cohort 4\).pdf](#)

[Figure 16.2.6.4.1 Scatter Plot of WBA vs. Total Fold MIC.pdf](#)

[Figure 16.2.5.4.2.8 Plasma PNU-101603 Trough Conc Plot\(Cohort 1- Cohort 5\) - Day Plot by Subject.pdf](#)

[Figure 16.2.5.4.2.8.1 PNU-100480 Plasma Conc-Time Plot by Treatment \(Linear Scale\) \(Cohort 5\).pdf](#)

[Figure 16.2.5.4.2.8.2 PNU-100480 Plasma Conc-Time Plot by Treatment \(Semi-log\) \(Cohort 5\).pdf](#)

[Figure 16.2.5.4.2.9 Plasma PNU-101244 Trough Conc Plot\(Cohort 1- Cohort 5\) - Day Plot by Subject.pdf](#)

[Figure 16.2.5.4.2.9.1 PNU-101603 Plasma Conc-Time Plot by Treatment \(Linear Scale\) \(Cohort 5\).pdf](#)

[Figure 16.2.5.4.2.9.2 PNU-101603 Plasma Conc-Time Plot by Treatment \(Semi-log\) \(Cohort 5\).pdf](#)

[Figure 16.2.5.6.4.1 Box and Whisker Plot for Individual Plasma PNU-100480 AUCtau vs Dosing Day for Cohort 5.pdf](#)

[Figure 16.2.5.6.1.1 Plot of Dose Normalized Plasma PNU-100480 AUCtau vs Treatment By Day 1 and Day 14 \(Cohort 1 -Cohort 5\).pdf](#)

[Figure 16.2.5.6.1.2 Plot of Dose Normalized Plasma PNU-100480 Cmax vs Treatment By Day 1 and Day 14 \(Cohort 1 -Cohort 5\).pdf](#)

[Figure 16.2.5.6.4.2 Box and Whisker Plot for Individual Plasma PNU-100480 Cmax vs Dosing Day for Cohort 5.pdf](#)

[Figure 16.2.5.6.5.2 Box and Whisker Plot for Individual Plasma PNU-101603 Cmax vs Dosing Day for Cohort 5.pdf](#)

[Figure 16.2.5.6.5.1 Box and Whisker Plot for Individual Plasma PNU-101603 AUCtau vs Dosing Day for Cohort 5.pdf](#)

[Figure 16.2.5.6.6.1 Box and Whisker Plot for Individual Plasma PNU-101244 AUCtau vs Dosing Day for Cohort 5.pdf](#)

[Table 14.2.2 Dscrp Sum WBA AUC.pdf](#)

[Figure 16.2.5.6.1.4 Plot of Plasma PNU-100480 Observed Accumulation Ratio Rac for Cmax vs Treatment in Day 14 \(Cohort 1 -Cohort 5\).pdf](#)

[Figure 16.2.5.6.1.3 Plot of Plasma PNU-100480 Observed Accumulation Ratio Rac for AUCtau vs Treatment in Day 14 \(Cohort 1 -Cohort 5\).pdf](#)

[Figure 16.2.5.6.6.2 Box and Whisker Plot for Individual Plasma PNU-101244 Cmax vs Dosing Day for Cohort 5.pdf](#)

[Figure 16.2.6.1.1 Whole Blood Bactericidal Activity \(WBA\) Individual Subject Plot by Treatment.pdf](#)

[Figure 16.2.8.2.4.3 Individual Changes from Base in Supine Pulse Rate \(BPM\) - Day 1 and Day 14 \(Cohort 1-5\).pdf](#)

[Figure 16.2.8.3.5.1 Individual Changes from Base in QT \(msec\) - Day 1,Day 14 and Day 28\(Cohort 1-5\).pdf](#)

[Table 14.2.3.1 Dscrp Sum WBAmay.pdf](#)

[Figure 16.2.5.6.2.1 Plot of Dose Normalized Plasma PNU-101603 AUCtau vs Treatment By Day 1 and Day 14 \(Cohort 1 -Cohort 5\).pdf](#)

[Figure 16.2.5.6.2.2 Plot of Dose Normalized Plasma PNU-101603 Cmax vs Treatment By Day 1 and Day 14 \(Cohort 1 -Cohort 5\).pdf](#)

[Table 14.3.1.2.1 T-E AEs \(All Causalities\).pdf](#)

[Table 14.3.1.2.2 Incidence and Severity of T-E AEs \(All Causalities\).pdf](#)

[Table 14.3.1.3.1 T-E AEs \(Treatment Related\).pdf](#)

[Table 14.3.1.3.2 Incidence and Severity of T-E AEs \(Treatment Related\).pdf](#)

[Table 14.3.2.2 Serious AEs.pdf](#)

[Table 14.3.4.1.1 Incidence of LTA's \(Without Regard to Base Abnormality\).pdf](#)

[Table 14.3.4.3.1.1 ECG Absolute Value Summary.pdf](#)

[Figure 16.2.5.6.2.3 Plot of Plasma PNU-101603 Observed Accumulation Ratio Rac for AUCtau vs Treatment in Day 14 \(Cohort 1 -Cohort 5\).pdf](#)

[Figure 16.2.5.6.2.4 Plot of Plasma PNU-101603 Observed Accumulation Ratio Rac for Cmax vs Treatment in Day 14 \(Cohort 1 -Cohort 5\).pdf](#)

[Table 14.3.4.1.2 Incidence of LTA'''s \(Normal Base\).pdf](#)

[Table 14.3.4.1.3 Incidence of LTA'''s \(Abnormal Base\).pdf](#)

[Table 14.3.4.2.1.1 Vital Signs Absolute Values Summary.pdf](#)

[Table 14.3.4.2.1.2 Mean Base and ChngBase for Vital Signs Data.pdf](#)

[Table 14.3.4.2.2.1 Categorical Sum Post-Base Vital Signs Data - Absolute Values.pdf](#)

[Table 14.3.4.2.2.2 Categorical Sum Post-Base Vital Signs Data - Increases from Base.pdf](#)

[Figure 16.2.5.6.3.1 Plot of Dose Normalized Plasma PNU-101244 AUCtau vs Treatment By Day 1 and Day 14 \(Cohort 1 -Cohort 5\).pdf](#)

[Figure 16.2.5.6.3.2 Plot of Dose Normalized Plasma PNU-101244 Cmax vs Treatment By Day 1 and Day 14 \(Cohort 1 -Cohort 5\).pdf](#)

[Table 14.3.4.2.2.3 Categorical Sum Post-Base Vital Signs Data - Decreases from Base.pdf](#)

[Table 14.3.4.3.2.1 Categorical Sum Post-Base ECG Data - Absolute Values.pdf](#)

[Table 14.3.4.3.1.2 Mean Base and ChngBase for ECG Data.pdf](#)

[Table 14.3.4.3.2.2 Categorical Sum Post-Base ECG Data - Increases from Base.pdf](#)

[Table 14.3.4.3.3.1 Max Absolute Value\(postdose\) Summary.pdf](#)

[Table 14.3.4.3.3.2 ECG Max Increases from Base.pdf](#)

[Figure 16.2.5.6.3.3 Plot of Plasma PNU-101244 Observed Accumulation Ratio Rac for AUCtau vs Treatment in Day 14 \(Cohort 1 -Cohort 5\).pdf](#)

[Figure 16.2.5.6.3.4 Plot of Plasma PNU-101244 Observed Accumulation Ratio Rac for Cmax vs Treatment in Day 14 \(Cohort 1 -Cohort 5\).pdf](#)

[Table 14.4.1 Administration Schedule.pdf](#)

[Table 14.4.2.1.1 PNU-100480 Plasma Conc vs Time Summary \(Cohort 1 to Cohort 4\).pdf](#)

[Table 14.4.2.1.2 PNU-101603 Plasma Conc vs Time Summary \(Cohort 1 to Cohort 4\).pdf](#)

[Table 14.4.2.1.3 PNU-101244 Plasma Conc vs Time Summary \(Cohort 1 to Cohort 4\).pdf](#)

[Table 14.4.2.1.4 PNU-100480 Plasma Conc vs Time Summary \(Cohort 5\).pdf](#)

[Table 14.4.3.1.7 Dscrp Sum Linezolid Plasma PK Parameters.pdf](#)

Figure 16.2.8.2.4.1 Individual Changes from Base in Supine Systolic Blood Pressure (mmHg) - Day 1 and Day 14 (Cohort 1-5).pdf
Figure 16.2.8.2.4.2 Individual Changes from Base in Supine Diastolic Blood Pressure (mmHg) - Day 1 and Day 14 (Cohort 1-5).pdf
Figure 16.2.8.3.5.2 Individual Changes from Base in QTcF (msec) - Day 1,Day 14 and Day 28(Cohort 1-5).pdf
Figure 16.2.8.3.5.3 Individual Changes from Base in Heart Rate (BPM) - Day 1,Day 14 and Day 28(Cohort 1-5).pdf
Table 14.1.1.2 Discontinuations from Study.pdf
Table 14.2.1 Whole Blood Bactericidal Activity (WBA) Mean Values.pdf
Table 14.2.3.2 Sum Stats of WBA AUC.pdf
Table 14.3.1.1.1 Discontinuations Due to AEs.pdf
Table 14.4.2.1.5 PNU-101603 Plasma Conc vs Time Summary (Cohort 5).pdf
Table 14.4.2.1.6 PNU-101244 Plasma Conc vs Time Summary (Cohort 5).pdf
Table 14.4.2.1.7 Linezolid Plasma Conc vs Time Summary (LZD Cohort).pdf
Table 14.4.3.1.1 Dscrp Sum PNU-100480 Plasma PK Parameters (Cohort 1 to Cohort 4).pdf
Table 14.4.3.1.2 Dscrp Sum PNU-101603 Plasma PK Parameters (Cohort 1 to Cohort 4).pdf
Table 14.4.3.1.3 Dscrp Sum PNU-101244 Plasma PK Parameters (Cohort 1 to Cohort 4).pdf
Table 14.4.3.1.4 Dscrp Sum PNU-100480 Plasma PK Parameters (Cohort 5).pdf
Table 14.4.3.1.5 Dscrp Sum PNU-101603 Plasma PK Parameters (Cohort 5).pdf
Table 14.4.3.1.6 Dscrp Sum PNU-101244 Plasma PK Parameters (Cohort 5).pdf
Table 14.4.3.3.1 Sum Stats of PNU-100480 Cohort 1 Pharmacokinetic Parameters (Day 14 vs. Day 1).pdf
Table 14.4.3.3.10 Sum Stats of PNU-101603 Cohort 5 Pharmacokinetic Parameters (Day 14 vs. Day 1).pdf
Table 14.4.3.3.11 Sum Stats of PNU-101244 Cohort 1 Pharmacokinetic Parameters (Day 14 vs. Day 1).pdf
Table 14.4.3.3.12 Sum Stats of PNU-101244 Cohort 2 Pharmacokinetic Parameters (Day 14 vs. Day 1).pdf
Table 14.4.3.3.13 Sum Stats of PNU-101244 Cohort 3 Pharmacokinetic Parameters (Day 14 vs. Day 1).pdf
Table 14.4.3.3.14 Sum Stats of PNU-101244 Cohort 4 Pharmacokinetic Parameters (Day 14 vs. Day 1).pdf
Table 14.4.3.3.15 Sum Stats of PNU-101244 Cohort 5 Pharmacokinetic Parameters (Day 14 vs. Day 1).pdf
Table 14.4.3.3.16 Sum Stats of PNU-100480 Pharmacokinetic Parameters (Day 28 vs. Day 14)-Cohort 5.pdf

[Table 14.4.3.3.2 Sum Stats of PNU-100480 Cohort 2 Pharmacokinetic Parameters \(Day 14 vs. Day 1\).pdf](#)

[Table 14.4.3.3.3 Sum Stats of PNU-100480 Cohort 3 Pharmacokinetic Parameters \(Day 14 vs. Day 1\).pdf](#)

[Table 14.4.3.3.4 Sum Stats of PNU-100480 Cohort 4 Pharmacokinetic Parameters \(Day 14 vs. Day 1\).pdf](#)

[Table 14.4.3.3.5 Sum Stats of PNU-100480 Cohort 5 Pharmacokinetic Parameters \(Day 14 vs. Day 1\).pdf](#)

[Table 14.4.3.3.6 Sum Stats of PNU-101603 Cohort 1 Pharmacokinetic Parameters \(Day 14 vs. Day 1\).pdf](#)

[Table 14.4.3.3.7 Sum Stats of PNU-101603 Cohort 2 Pharmacokinetic Parameters \(Day 14 vs. Day 1\).pdf](#)

[Table 14.4.3.3.8 Sum Stats of PNU-101603 Cohort 3 Pharmacokinetic Parameters \(Day 14 vs. Day 1\).pdf](#)

[Table 14.4.3.3.9 Sum Stats of PNU-101603 Cohort 4 Pharmacokinetic Parameters \(Day 14 vs. Day 1\).pdf](#)

[Table 16.1.7.2 Randomization Treatment Assigned and Treatment Received.pdf](#)

[Table 16.1.9.2.1.1 Stats of PNU-100480 Cohort 1 Pharmacokinetic Parameters\(Day 14 vs. Day 1\).pdf](#)

[Table 16.1.9.2.1.10 Stats of PNU-101603 Cohort 5 Pharmacokinetic Parameters\(Day 14 vs. Day 1\).pdf](#)

[Table 16.1.9.2.1.11 Stats of PNU-101244 Cohort 1 Pharmacokinetic Parameters\(Day 14 vs. Day 1\).pdf](#)

[Table 16.1.9.2.1.12 Stats of PNU-101244 Cohort 2 Pharmacokinetic Parameters\(Day 14 vs. Day 1\).pdf](#)

[Table 16.1.9.2.1.13 Stats of PNU-101244 Cohort 3 Pharmacokinetic Parameters\(Day 14 vs. Day 1\).pdf](#)

[Table 16.1.9.2.1.15 Stats of PNU-101244 Cohort 5 Pharmacokinetic Parameters\(Day 14 vs. Day 1\).pdf](#)

[Table 16.1.9.2.1.14 Stats of PNU-101244 Cohort 4 Pharmacokinetic Parameters\(Day 14 vs. Day 1\).pdf](#)

[Table 16.1.9.2.1.16 Output Listing for Stats of PNU-100480 Pharmacokinetic Parameters \(Day 28 vs. Day 14\)- Cohort 5.pdf](#)

[Table 16.1.9.2.1.2 Stats of PNU-100480 Cohort 2 Pharmacokinetic Parameters\(Day 14 vs. Day 1\).pdf](#)

[Table 16.1.9.2.1.21 Mixed Effects ANOVA - Statistical Sum AUCWBA.pdf](#)

[Table 16.2.7 AEs.pdf](#)

[Table 16.1.9.2.1.3 Stats of PNU-100480 Cohort 3 Pharmacokinetic Parameters\(Day 14 vs. Day 1\).pdf](#)

[Table 16.1.9.2.1.4 Stats of PNU-100480 Cohort 4 Pharmacokinetic Parameters\(Day 14 vs. Day 1\).pdf](#)

[Table 16.1.9.2.1.5 Stats of PNU-100480 Cohort 5 Pharmacokinetic Parameters\(Day 14 vs. Day 1\).pdf](#)

[Table 16.1.9.2.1.6 Stats of PNU-101603 Cohort 1 Pharmacokinetic Parameters\(Day 14 vs. Day 1\).pdf](#)

[Table 16.1.9.2.1.7 Stats of PNU-101603 Cohort 2 Pharmacokinetic Parameters\(Day 14 vs. Day 1\).pdf](#)

Table 16.1.9.2.1.8 Stats of PNU-101603 Cohort 3 Pharmacokinetic Parameters(Day 14 vs. Day 1).pdf

Table 16.1.9.2.1.9 Stats of PNU-101603 Cohort 4 Pharmacokinetic Parameters(Day 14 vs. Day 1).pdf

Table 16.2.1 Subject Discontinuations.pdf

Table 16.2.4.1 Subject Evaluation Groups.pdf

Table 16.2.4.2 Demographic Characteristics.pdf

Table 16.2.5.1 Administration Schedule.pdf

Table 16.2.5.2 Concomitant Drug Treatments.pdf

Table 16.2.5.3 Concomitant Nondrug Treatments.pdf

Table 16.2.5.4.1.1.2 PNU-101603 Plasma Conc vs Time Listing (Cohort 1 to Cohort 4).pdf

Table 16.2.5.4.1.1.1 PNU-100480 Plasma Conc vs Time Listing (Cohort 1 to Cohort 4).pdf

Table 16.2.5.4.1.1.3 PNU-101244 Plasma Conc vs Time Listing (Cohort 1 to Cohort 4).pdf

Table 16.2.5.4.1.1.4 PNU-100480 Plasma Conc vs Time Listing (Cohort 5).pdf

Table 16.2.5.4.1.1.5 PNU-101603 Plasma Conc vs Time Listing (Cohort 5).pdf

Table 16.2.5.4.1.1.6 PNU-101244 Plasma Conc vs Time Listing (Cohort 5).pdf

Table 16.2.5.4.1.1.7 Linezolid Plasma Conc vs Time Listing (LZD Cohort).pdf

Table 16.2.5.4.1.1.8 Urine PNU-101603 ConcAmount Listing by Collection Interval.pdf

Table 16.2.5.4.1.2.1 Sample Deviations (10) and Comments for PNU-100480 Plasma Assay (Cohort 1 to Cohort 4).pdf

Table 16.2.5.4.1.1.9 Urine PNU-101244 ConcAmount Listing by Collection Interval.pdf

Table 16.2.5.4.1.2.2 Sample Deviations (10) and Comments for PNU-101603 Plasma Assay (Cohort 1 to Cohort 4).pdf

Table 16.2.5.5.1.7 Listing and Dscrp Sum Linezolid Plasma PK Parameters.pdf

Table 16.2.5.4.1.2.3 Sample Deviations (10) and Comments for PNU-101244 Plasma Assay (Cohort 1 to Cohort 4).pdf

Table 16.2.5.4.1.2.4 Sample Deviations (10) and Comments for PNU-100480 Plasma Assay (Cohort 5).pdf

Table 16.2.5.4.1.2.5 Sample Deviations (10) and Comments for PNU-101603 Plasma Assay (Cohort 5).pdf

Table 16.2.5.4.1.2.6 Sample Deviations (10) and Comments for PNU-101244 Plasma Assay (Cohort 5).pdf

Table 16.2.5.4.1.2.7 Sample Deviations (10) and Comments for Linezolid Plasma Assay (LZD Cohort).pdf

Table 16.2.5.5.1.1 Listing and Dscrp Sum PNU-100480 Plasma PK Parameters (Cohort 1 to Cohort 4).pdf

Table 16.2.5.5.1.2 Listing and Dscrp Sum PNU-101603 Plasma PK Parameters (Cohort 1 to Cohort 4).pdf

Table 16.2.5.5.1.4 Listing and Dscrp Sum PNU-100480 Plasma PK Parameters (Cohort 5).pdf

Table 16.2.5.5.1.3 Listing and Dscrp Sum PNU-101244 Plasma PK Parameters (Cohort 1 to Cohort 4).pdf

Table 16.2.5.5.1.6 Listing and Dscrp Sum PNU-101244 Plasma PK Parameters (Cohort 5).pdf

Table 16.2.5.5.1.5 Listing and Dscrp Sum PNU-101603 Plasma PK Parameters (Cohort 5).pdf

Table 16.2.6.1 Whole Blood Bactericidal Activity (WBA) Data.pdf

Table 16.2.6.2 Listing of WBA AUC.pdf

Table 16.2.6.3 Listing of WBAmax.pdf

Table 16.2.6.4 Listing of WBA and Total Fold MIC.pdf

Table 16.2.8.1.1 Laboratory Data.pdf

Table 16.2.8.1.2 LTA'''s, by Subject.pdf

Table 16.2.8.1.3 LTA'''s, by Test.pdf

Table 16.2.8.2.1 Vitals Signs Data.pdf

Table 16.2.8.2.2 Values Meeting Categorical Sum Post Base Vital Signs Criteria.pdf

Table 16.2.8.2.3 Vital Signs ChngBase.pdf

Table 16.2.8.3.1 ECG Data.pdf

Table 16.2.8.3.2 ECG Qualitative Results.pdf

Table 16.2.8.3.3 Values Meeting Categorical Sum Post Base ECG Criteria.pdf

Table 16.2.8.3.4 ECG ChngBase.pdf

Table 16.2.8.3.5 ECG Subjects with Any Single Postdose QTcF interval Value Greater than or Equal to 500msec.pdf

PbO PNU-0100480 100mg Tablet.doc.pdf

PbO PNU-0100480 100mg Tablet.doc

A10.2.2 Stats of PNU-100480 Pharmacokinetic Parameters Dose Response (Fasted only).pdf

A10.2.1 Stats of PNU-100480 600mg Pharmacokinetic Parameters (Fed vs. Fasted).pdf

A10.3.1 Mixed Effects ANOVA - Statistical Sum AUC24WBA.pdf

A10.3.2.1 Regression Model - Statistical Sum AUC24WBA vs AUC24total (300 mg).pdf

A10.3.2.2 Regression Model - Statistical Sum AUC24WBA vs AUC24total (600 mg fasted).pdf

A10.3.2.3 Regression Model - Statistical Sum AUC24WBA vs AUC24total (1000 mg).pdf

A10.3.2.4 Regression Model - Statistical Sum AUC24WBA vs AUC24total (1500 mg).pdf

A7.2 Randomization Treatment Assigned and Treatment Received.pdf

B6 AEs.pdf

B1.1 Subject Evaluation Groups.pdf

B1.2 Subject Discontinuations.pdf

B2 Demographic Characteristics.pdf

B3.1 Administration Schedule.pdf

B3.2 Concomitant Drug Treatments.pdf

B3.3 Concomitant Nondrug Treatments.pdf

B4.1.1 Whole Blood Bactericidal Activity (WBA) Data.pdf

B4.1.3 Listing of Individual Value of WBA AUC24.pdf

B4.1.2 Whole Blood Bactericidal Activity (WBA) ChngBase.pdf

B5.1.1.1 Plasma Concs of PNU-100480.pdf

B5.1.1.2 Plasma Concs of PNU-101603.pdf

B5.1.1.3 Plasma Concs of PNU-101244.pdf

B5.1.2.1 Plasma Sample Time Deviations and Sample Comments of PNU-100480.pdf

B5.1.2.2 Plasma Sample Time Deviations and Sample Comments of PNU-101603.pdf

B5.1.2.3 Plasma Sample Time Deviations and Sample Comments of PNU-101244.pdf

B5.2.1 Listing and Dscrp Sum Serum PNU-100480 PK Parameters.pdf

B5.2.3 Listing and Dscrp Sum Serum PNU-101244 PK Parameters.pdf

B5.2.2 Listing and Dscrp Sum Serum PNU-101603 PK Parameters.pdf

B5.3.1.1 PNU-100480 Plasma Concs vs Time by Treatment.pdf

B5.3.1.2 PNU-100480 Plasma Concs vs Time by Treatment (Semi-log).pdf

B5.3.2.1 PNU-101603 Plasma Concs vs Time by Treatment.pdf

B5.3.2.2 PNU-101603 Plasma Concs vs Time by Treatment (Semi-log).pdf

B5.3.3.1 PNU-101244 Plasma Concs vs Time by Treatment.pdf

B5.3.3.2 PNU-101244 Plasma Concs vs Time by Treatment (Semi-log).pdf

B7.2 LTA'''s, by Subject.pdf

B7.1 Laboratory Data.pdf

B7.3 LTA'''s, by Test.pdf

B8.1 Vital Signs Data.pdf

B8.2 Vital Signs ChngBase.pdf

B8.3 Values Meeting Categorical Sum Post Base Vital Signs Criteria.pdf

B8.4 Vital Signs Difference from PbO.pdf

B9.1 ECG Data.pdf

B9.2 ECG ChngBase.pdf

B9.3 ECG Qualitative Results.pdf

B9.4 Values Meeting Categorical Sum Post Base ECG Criteria.pdf

B9.5 ECG Difference from PbO.pdf

Figure 14.1.1.1 Median Plasma Conc of PNU-100480 vs Time (Linear).pdf

Figure 14.1.1.2 Median Plasma Conc of PNU-100480 vs Time (Semi-Log).pdf

Figure 14.1.2.1 Median Plasma Conc of PNU-101603 vs Time (Linear).pdf

Figure 14.1.3.1 Median Plasma Conc of PNU-101244 vs Time (Linear).pdf

Figure 14.1.2.2 Median Plasma Conc of PNU-101603 vs Time (Semi-Log).pdf

Figure 14.1.3.2 Median Plasma Conc of PNU-101244 vs Time (Semi-Log).pdf

Figure 14.5.1.1 ECG Mean ChngBase in HR (BPM).pdf

[Figure 14.2.1.1 Individual and Mean Plasma PNU-100480 Dose Normalized AUCinf vs Dose \(Fasted only\).pdf](#)

[Figure 14.2.1.2 Individual and Mean Plasma PNU-100480 Dose Normalized AUClast vs Dose \(Fasted only\).pdf](#)

[Figure 14.2.1.3 Individual and Mean Plasma PNU-100480 Dose Normalized AUC24 vs Dose \(Fasted only\).pdf](#)

[Figure 14.2.1.4 Individual and Mean Plasma PNU-100480 Dose Normalized Cmax vs Dose \(Fasted only\).pdf](#)

[Figure 14.2.2.1 Individual and Mean Plasma PNU-101603 Dose Normalized AUCinf vs Dose \(Fasted only\).pdf](#)

[Figure 14.2.2.2 Individual and Mean Plasma PNU-101603 Dose Normalized AUClast vs Dose \(Fasted only\).pdf](#)

[Figure 14.2.2.3 Individual and Mean Plasma PNU-101603 Dose Normalized AUC24 vs Dose \(Fasted only\).pdf](#)

[Figure 14.2.2.4 Individual and Mean Plasma PNU-101603 Dose Normalized Cmax vs Dose \(Fasted only\).pdf](#)

[Figure 14.2.3.1 Individual and Mean Plasma PNU-101244 Dose Normalized AUCinf vs Dose \(Fasted only\).pdf](#)

[Figure 14.2.3.2 Individual and Mean Plasma PNU-101244 Dose Normalized AUClast vs Dose \(Fasted only\).pdf](#)

[Figure 14.2.3.3 Individual and Mean Plasma PNU-101244 Dose Normalized AUC24 vs Dose \(Fasted only\).pdf](#)

[Figure 14.2.3.4 Individual and Mean Plasma PNU-101244 Dose Normalized Cmax vs Dose \(Fasted only\).pdf](#)

[Figure 14.2.4.1 Individual and Mean Plasma PNU-100480 Dose Normalized AUCinf \(600 mg Fed vs. Fasted\).pdf](#)

[Figure 14.2.4.2 Individual and Mean Plasma PNU-100480 Dose Normalized AUClast \(600 mg Fed vs. Fasted\).pdf](#)

[Figure 14.2.4.3 Individual and Mean Plasma PNU-100480 Dose Normalized AUC24 \(600 mg Fed vs. Fasted\).pdf](#)

[Figure 14.2.4.4 Individual and Mean Plasma PNU-100480 Dose Normalized Cmax \(600 mg Fed vs. Fasted\).pdf](#)

[Figure 14.2.5.1 Individual and Mean Plasma PNU-101603 Dose Normalized AUCinf \(600 mg Fed vs. Fasted\).pdf](#)

[Figure 14.2.5.2 Individual and Mean Plasma PNU-101603 Dose Normalized AUClast \(600 mg Fed vs. Fasted\).pdf](#)

[Figure 14.2.5.3 Individual and Mean Plasma PNU-101603 Dose Normalized AUC24 \(600 mg Fed vs. Fasted\).pdf](#)

[Figure 14.2.5.4 Individual and Mean Plasma PNU-101603 Dose Normalized Cmax \(600 mg Fed vs. Fasted\).pdf](#)

[Figure 14.4.1.1 Vital Signs Mean ChngBase in Supine Systolic Blood Pressure \(mmHg\).pdf](#)

[Figure 14.2.6.1 Individual and Mean Plasma PNU-101244 Dose Normalized AUCinf \(600 mg Fed vs. Fasted\).pdf](#)

[Figure 14.2.6.2 Individual and Mean Plasma PNU-101244 Dose Normalized AUClast \(600 mg Fed vs. Fasted\).pdf](#)

[Figure 14.2.6.3 Individual and Mean Plasma PNU-101244 Dose Normalized AUC24 \(600 mg Fed vs. Fasted\).pdf](#)

[Figure 14.2.6.4 Individual and Mean Plasma PNU-101244 Dose Normalized Cmax \(600 mg Fed vs. Fasted\).pdf](#)

Figure 14.3.1 Scatter Plot of WBA AUC24 vs Total AUC24 (PNU-100480 plus Metabolites) (Linear).pdf

Figure 14.4.1.2 Vital Signs Mean ChngBase in Supine Diastolic Blood Pressure (mmHg).pdf

Figure 14.4.1.3 Vital Signs Mean ChngBase in Supine Pulse Rate (BPM).pdf

Figure 14.4.2.1 Vital Signs Individual Profiles of Changes from Base in Supine Systolic Blood Pressure (mmHg).pdf

Figure 14.4.2.2 Vital Signs Individual Profiles of Changes from Base in Supine Diastolic Blood Pressure (mmHg).pdf

Figure 14.4.2.3 Vital Signs Individual Profiles of Changes from Base in Supine Pulse Rate (BPM).pdf

Figure 14.4.3.1 Vital Signs Differences from PbO Results in Supine Systolic Blood Pressure (mmHg).pdf

Figure 14.4.3.2 Vital Signs Differences from PbO Results in Supine Diastolic Blood Pressure (mmHg).pdf

Figure 14.4.3.3 Vital Signs Differences from PbO Results in Supine Pulse Rate (BPM).pdf

Figure 14.5.1.2 ECG Mean ChngBase in QT (msec).pdf

Figure 14.5.1.3 ECG Mean ChngBase in QTcF (msec).pdf

Figure 14.5.2.1 ECG Individual Profiles of Changes from Base in HR (BPM).pdf

Figure 14.5.2.2 ECG Individual Profiles of Changes from Base in QT (msec).pdf

Figure 14.5.2.3 ECG Individual Profiles of Changes from Base in QTcF (msec).pdf

Figure 14.5.3.1 ECG Differences from PbO Results in QT (msec).pdf

Figure 14.5.3.2 ECG Differences from PbO Results in HR (BPM).pdf

Figure 14.5.3.3 ECG Differences from PbO Results in QTcF (msec).pdf

Figure 14.5.4.1.1 ECG ChngBase in QTcF (msec) vs PNU-100480 Conc (NGML) (Cohort 1).pdf

Table 13.1.1 Subject Evaluation Groups.pdf

Figure 14.5.4.1.2 ECG ChngBase in QTcF (msec) vs PNU-100480 Conc (NGML) (Cohort 1) (Semi-Log).pdf

Figure 14.5.4.1.4 ECG ChngBase in QTcF (msec) vs PNU-100480 Conc (NGML) (Cohort 2) (Semi-Log).pdf

Figure 14.5.4.1.3 ECG ChngBase in QTcF (msec) vs PNU-100480 Conc (NGML) (Cohort 2).pdf

Figure 14.5.4.2.1 ECG ChngBase in QTcF (msec) vs PNU-101603 Conc (NGML) (Cohort 1).pdf

Figure 14.5.4.2.2 ECG ChngBase in QTcF (msec) vs PNU-101603 Conc (NGML) (Cohort 1) (Semi-Log).pdf

Figure 14.5.4.2.3 ECG ChngBase in QTcF (msec) vs PNU-101603 Conc (NGML) (Cohort 2).pdf

[Figure 14.5.4.2.4 ECG ChngBase in QTcF \(msec\) vs PNU-101603 Conc \(NGML\) \(Cohort 2\) \(Semi-Log\).pdf](#)

[Table 13.4.3 Dscrp Sum WBA AUC24.pdf](#)

[Figure 14.5.4.3.1 ECG ChngBase in QTcF \(msec\) vs PNU-101244 Conc \(NGML\) \(Cohort 1\).pdf](#)

[Figure 14.5.4.3.2 ECG ChngBase in QTcF \(msec\) vs PNU-101244 Conc \(NGML\) \(Cohort 1\) \(Semi-Log\).pdf](#)

[Figure 14.5.4.3.3 ECG ChngBase in QTcF \(msec\) vs PNU-101244 Conc \(NGML\) \(Cohort 2\).pdf](#)

[Figure 14.5.4.3.4 ECG ChngBase in QTcF \(msec\) vs PNU-101244 Conc \(NGML\) \(Cohort 2\) \(Semi-Log\).pdf](#)

[Table 13.1.2 Discontinuations from Study.pdf](#)

[Table 13.2.2 Demographic Characteristics \(All Subjects\).pdf](#)

[Table 13.2.1 Demographic Characteristics \(by Cohort\).pdf](#)

[Table 13.3 Administration Schedule.pdf](#)

[Table 13.4.1 Whole Blood Bactericial Activity \(WBA\) Mean Values.pdf](#)

[Table 13.4.2 Whole Blood Bactericial Activity \(WBA\) Mean Base and Mean ChngBase.pdf](#)

[Table 13.4.4 Sum Stats of WBA AUC24.pdf](#)

[Table 13.4.5.1 Regression Model Statistical Sum WBA AUC24 vs Total AUC24 \(300 mg\).pdf](#)

[Table 13.4.5.2 Regression Model Statistical Sum WBA AUC24 vs Total AUC24 \(600 mg fasted\).pdf](#)

[Table 13.4.5.3 Regression Model Statistical Sum WBA AUC24 vs Total AUC24 \(1000 mg\).pdf](#)

[Table 13.4.5.4 Regression Model Statistical Sum WBA AUC24 vs Total AUC24 \(1500 mg\).pdf](#)

[Table 13.5.1.1 Sum PNU-100480 Plasma Concs.pdf](#)

[Table 13.5.1.2 Sum PNU-101603 Plasma Concs.pdf](#)

[Table 13.5.1.3 Sum PNU-101244 Plasma Concs.pdf](#)

[Table 13.5.2.1 Sum PNU-100480 Plasma Pharmacokinetic Parameters.pdf](#)

[Table 13.5.2.2 Sum PNU-101603 Plasma Pharmacokinetic Parameters.pdf](#)

[Table 13.5.2.3 Sum PNU-101244 Plasma Pharmacokinetic Parameters.pdf](#)

[Table 13.5.3.1 Sum Stats of PNU-100480 600mg Pharmacokinetic Parameters \(Fed vs. Fasted\).pdf](#)

[Table 13.6.1.2 Temporary Discontinuations or Dose Reductions Due to AEs.pdf](#)

Table 13.5.3.2 Sum Stats of PNU-100480 Pharmacokinetic Parameters Dose Response (Fasted only).pdf

Table 13.6.1.1 Discontinuations Due to AEs.pdf

Table 13.6.2.1 T-E AEs (All Causalities).pdf

Table 13.6.2.2 Incidence and Severity of T-E AEs (All Causalities).pdf

Table 13.6.3.1 T-E AEs (Treatment Related).pdf

Table 13.6.4.1 ResDisclos for Treatment Emergent Non Serious AEs.pdf

Table 13.6.3.2 Incidence and Severity of T-E AEs (Treatment Related).pdf

Table 13.6.4.2 ResDisclos for Treatment Emergent Serious AEs.pdf

Table 13.7.1 Incidence of LTA's (Normal Base).pdf

Table 13.7.2 Incidence of LTA's (Abnormal Base).pdf

Table 13.8.1 Vital Signs Absolute Values.pdf

Table 13.8.2 Vital Signs ChngBase.pdf

Table 13.8.3 Vital Signs Categorical Sum Post Base Max Absolute Values.pdf

Table 13.8.4 Vital Signs Categorical Sum Increase from Base Values.pdf

Table 13.8.5 Vital Signs Categorical Sum Decrease from Base Values.pdf

Table 13.8.6 Vital Signs Difference from PbO.pdf

Table 13.9.1 ECG Absolute Values.pdf

Table 13.9.2 ECG ChngBase.pdf

Table 13.9.3.1 ECG Categorical Sum Post Base Max Absolute Values.pdf

Table 13.9.3.2 ECG Categorical Sum Max Increase from Base Values.pdf

Table 13.9.4 ECG Max Increase from Base for QTcF (0-4h).pdf

Table 13.9.5 ECG Difference from PbO.pdf

MAT-037-F02 for API CSP 6541.doc

MAT-037-F02 for CSP07474.doc

MAT-037-F02 for API CSP 6541.doc.pdf

MAT-037-F02 for CSP07474.pdf

MAT-037-F02 for CSP4857.doc

MAT-037-F02 for CSP4857.pdf

MAT-037-F02 for CSP6342.doc

MAT-037-F02 for CSP6342.pdf

MAT-037-F02 for CSP6541 3.doc

MAT-037-F02 for CSP6541 3.pdf

MAT-037-F02 for CSP6541 4.doc

MAT-037-F02 for CSP6541 4.pdf

MAT-037-F02 for CSP6541.doc

MAT-037-F02 for CSP6542.doc

MAT-037-F02 for CSP6541.pdf

MAT-037-F02 for CSP6542.pdf

DP EBR PbO Common Blend D0602883.04 CM-1501009 CSM Groton 16Dec2009.pdf

DP EBR PbO for PNU-0100480 100mg tablet D0904911.00 CM-1511009 11009 09-080619.pdf

B1.2 Subject Discontinuations.pdf

B1.1 Subject Evaluation Groups.pdf

B1171001 - Published CSR.pdf

B1171001 A6 - Study Drug Information.doc

B1171001 A6 - Study Drug Information.pdf

B1171001 CTD Abstract.doc

B1171001 CTD Abstract.pdf

B1171001 Study Rpt Body.doc

B1171001 Study Rpt Body.pdf

B1171001 Study Rpt Cover Page.doc

B1171001 Study Rpt Cover Page.pdf

B1171001 Study Rpt Synopsis.doc

B1171001 Study Rpt Synopsis.pdf

B6 AEs.pdf

B12 Protocol Deviation.doc

B12 Protocol Deviation.pdf

B12 Protocol Deviation{1}.doc

B12 Protocol Deviation{1}.pdf

B2 Demographic Characteristics.pdf

B3.1 Administration Schedule.pdf

B3.2 Concomitant Drug Treatments.pdf

B3.3 Concomitant Nondrug Treatments.pdf

B4.1.1 Whole Blood Bactericidal Activity (WBA) Data.pdf

B4.1.2 Whole Blood Bactericidal Activity (WBA) ChngBase.pdf

B4.1.3 Listing of Individual Value of WBA AUC24.pdf

B5.1.1.1 Plasma Concs of PNU-100480.pdf

B7.1 Laboratory Data.pdf

B5.1.1.2 Plasma Concs of PNU-101603.pdf

B5.1.1.3 Plasma Concs of PNU-101244.pdf

B5.1.2.1 Plasma Sample Time Deviations and Sample Comments of PNU-100480.pdf

B5.1.2.2 Plasma Sample Time Deviations and Sample Comments of PNU-101603.pdf

B5.1.2.3 Plasma Sample Time Deviations and Sample Comments of PNU-101244.pdf

B5.2.1 Listing and Dscrp Sum Serum PNU-100480 PK Parameters.pdf

B5.2.2 Listing and Dscrp Sum Serum PNU-101603 PK Parameters.pdf

B5.2.3 Listing and Dscrp Sum Serum PNU-101244 PK Parameters.pdf

B5.3.1.1 PNU-100480 Plasma Concs vs Time by Treatment.pdf

B5.3.2.1 PNU-101603 Plasma Concs vs Time by Treatment.pdf

B5.3.1.2 PNU-100480 Plasma Concs vs Time by Treatment (Semi-log).pdf

B5.3.2.2 PNU-101603 Plasma Concs vs Time by Treatment (Semi-log).pdf

B5.3.3.1 PNU-101244 Plasma Concs vs Time by Treatment.pdf

B5.3.3.2 PNU-101244 Plasma Concs vs Time by Treatment (Semi-log).pdf

B7.2 LTA'''s, by Subject.pdf

B7.3 LTA'''s, by Test.pdf

B8.1 Vital Signs Data.pdf

B8.2 Vital Signs ChngBase.pdf

B8.4 Vital Signs Difference from PbO.pdf

B8.3 Values Meeting Categorical Sum Post Base Vital Signs Criteria.pdf

B9.1 ECG Data.pdf

B9.2 ECG ChngBase.pdf

B9.3 ECG Qualitative Results.pdf

B9.4 Values Meeting Categorical Sum Post Base ECG Criteria.pdf

B9.5 ECG Difference from PbO.pdf

Figure 14.1.1.1 Median Plasma Conc of PNU-100480 vs Time (Linear).pdf

Figure 14.1.1.2 Median Plasma Conc of PNU-100480 vs Time (Semi-Log).pdf

Figure 14.1.2.1 Median Plasma Conc of PNU-101603 vs Time (Linear).pdf

Figure 14.1.2.2 Median Plasma Conc of PNU-101603 vs Time (Semi-Log).pdf

Figure 14.1.3.1 Median Plasma Conc of PNU-101244 vs Time (Linear).pdf

Figure 14.2.1.1 Individual and Mean Plasma PNU-100480 Dose Normalized AUCinf vs Dose (Fasted only).pdf

Figure 14.1.3.2 Median Plasma Conc of PNU-101244 vs Time (Semi-Log).pdf

Figure 14.2.1.2 Individual and Mean Plasma PNU-100480 Dose Normalized AUClast vs Dose (Fasted only).pdf

[Figure 14.2.1.3 Individual and Mean Plasma PNU-100480 Dose Normalized AUC₂₄ vs Dose \(Fasted only\).pdf](#)

[Figure 14.2.1.4 Individual and Mean Plasma PNU-100480 Dose Normalized C_{max} vs Dose \(Fasted only\).pdf](#)

[Figure 14.2.2.1 Individual and Mean Plasma PNU-101603 Dose Normalized AUC_{inf} vs Dose \(Fasted only\).pdf](#)

[Figure 14.2.2.2 Individual and Mean Plasma PNU-101603 Dose Normalized AUC_{last} vs Dose \(Fasted only\).pdf](#)

[Figure 14.2.2.3 Individual and Mean Plasma PNU-101603 Dose Normalized AUC₂₄ vs Dose \(Fasted only\).pdf](#)

[Figure 14.2.2.4 Individual and Mean Plasma PNU-101603 Dose Normalized C_{max} vs Dose \(Fasted only\).pdf](#)

[Figure 14.2.3.1 Individual and Mean Plasma PNU-101244 Dose Normalized AUC_{inf} vs Dose \(Fasted only\).pdf](#)

[Figure 14.2.3.2 Individual and Mean Plasma PNU-101244 Dose Normalized AUC_{last} vs Dose \(Fasted only\).pdf](#)

[Figure 14.2.3.3 Individual and Mean Plasma PNU-101244 Dose Normalized AUC₂₄ vs Dose \(Fasted only\).pdf](#)

[Figure 14.2.3.4 Individual and Mean Plasma PNU-101244 Dose Normalized C_{max} vs Dose \(Fasted only\).pdf](#)

[Figure 14.2.4.1 Individual and Mean Plasma PNU-100480 Dose Normalized AUC_{inf} \(600 mg Fed vs. Fasted\).pdf](#)

[Figure 14.2.4.2 Individual and Mean Plasma PNU-100480 Dose Normalized AUC_{last} \(600 mg Fed vs. Fasted\).pdf](#)

[Figure 14.2.4.3 Individual and Mean Plasma PNU-100480 Dose Normalized AUC₂₄ \(600 mg Fed vs. Fasted\).pdf](#)

[Figure 14.2.4.4 Individual and Mean Plasma PNU-100480 Dose Normalized C_{max} \(600 mg Fed vs. Fasted\).pdf](#)

[Figure 14.2.5.1 Individual and Mean Plasma PNU-101603 Dose Normalized AUC_{inf} \(600 mg Fed vs. Fasted\).pdf](#)

[Figure 14.2.5.2 Individual and Mean Plasma PNU-101603 Dose Normalized AUC_{last} \(600 mg Fed vs. Fasted\).pdf](#)

[Figure 14.2.5.3 Individual and Mean Plasma PNU-101603 Dose Normalized AUC₂₄ \(600 mg Fed vs. Fasted\).pdf](#)

[Figure 14.2.5.4 Individual and Mean Plasma PNU-101603 Dose Normalized C_{max} \(600 mg Fed vs. Fasted\).pdf](#)

[Figure 14.4.1.1 Vital Signs Mean ChngBase in Supine Systolic Blood Pressure \(mmHg\).pdf](#)

[Figure 14.2.6.1 Individual and Mean Plasma PNU-101244 Dose Normalized AUC_{inf} \(600 mg Fed vs. Fasted\).pdf](#)

[Figure 14.2.6.2 Individual and Mean Plasma PNU-101244 Dose Normalized AUC_{last} \(600 mg Fed vs. Fasted\).pdf](#)

[Figure 14.2.6.3 Individual and Mean Plasma PNU-101244 Dose Normalized AUC₂₄ \(600 mg Fed vs. Fasted\).pdf](#)

[Figure 14.2.6.4 Individual and Mean Plasma PNU-101244 Dose Normalized C_{max} \(600 mg Fed vs. Fasted\).pdf](#)

[Figure 14.3.1 Scatter Plot of WBA AUC₂₄ vs Total AUC₂₄ \(PNU-100480 plus Metabolites\) \(Linear\).pdf](#)

[Figure 14.4.1.2 Vital Signs Mean ChngBase in Supine Diastolic Blood Pressure \(mmHg\).pdf](#)

Figure 14.4.1.3 Vital Signs Mean ChngBase in Supine Pulse Rate (BPM).pdf

Figure 14.4.2.1 Vital Signs Individual Profiles of Changes from Base in Supine Systolic Blood Pressure (mmHg).pdf

Figure 14.4.2.2 Vital Signs Individual Profiles of Changes from Base in Supine Diastolic Blood Pressure (mmHg).pdf

Figure 14.4.2.3 Vital Signs Individual Profiles of Changes from Base in Supine Pulse Rate (BPM).pdf

Figure 14.4.3.1 Vital Signs Differences from PbO Results in Supine Systolic Blood Pressure (mmHg).pdf

Figure 14.4.3.2 Vital Signs Differences from PbO Results in Supine Diastolic Blood Pressure (mmHg).pdf

Figure 14.4.3.3 Vital Signs Differences from PbO Results in Supine Pulse Rate (BPM).pdf

Figure 14.5.1.1 ECG Mean ChngBase in HR (BPM).pdf

Figure 14.5.1.2 ECG Mean ChngBase in QT (msec).pdf

Figure 14.5.1.3 ECG Mean ChngBase in QTcF (msec).pdf

Figure 14.5.2.1 ECG Individual Profiles of Changes from Base in HR (BPM).pdf

Figure 14.5.2.2 ECG Individual Profiles of Changes from Base in QT (msec).pdf

Figure 14.5.2.3 ECG Individual Profiles of Changes from Base in QTcF (msec).pdf

Figure 14.5.3.1 ECG Differences from PbO Results in QT (msec).pdf

Figure 14.5.3.2 ECG Differences from PbO Results in HR (BPM).pdf

Figure 14.5.4.1.1 ECG ChngBase in QTcF (msec) vs PNU-100480 Conc (NGML) (Cohort 1).pdf

Figure 14.5.3.3 ECG Differences from PbO Results in QTcF (msec).pdf

Figure 14.5.4.1.2 ECG ChngBase in QTcF (msec) vs PNU-100480 Conc (NGML) (Cohort 1) (Semi-Log).pdf

Figure 14.5.4.1.3 ECG ChngBase in QTcF (msec) vs PNU-100480 Conc (NGML) (Cohort 2).pdf

Figure 14.5.4.1.4 ECG ChngBase in QTcF (msec) vs PNU-100480 Conc (NGML) (Cohort 2) (Semi-Log).pdf

Figure 14.5.4.2.1 ECG ChngBase in QTcF (msec) vs PNU-101603 Conc (NGML) (Cohort 1).pdf

Figure 14.5.4.2.2 ECG ChngBase in QTcF (msec) vs PNU-101603 Conc (NGML) (Cohort 1) (Semi-Log).pdf

Figure 14.5.4.2.3 ECG ChngBase in QTcF (msec) vs PNU-101603 Conc (NGML) (Cohort 2).pdf

Figure 14.5.4.2.4 ECG ChngBase in QTcF (msec) vs PNU-101603 Conc (NGML) (Cohort 2) (Semi-Log).pdf

Table 13.4.3 Dscrp Sum WBA AUC24.pdf

[Figure 14.5.4.3.2 ECG ChngBase in QTcF \(msec\) vs PNU-101244 Conc \(NGML\) \(Cohort 1\) \(Semi-Log\).pdf](#)

[Figure 14.5.4.3.1 ECG ChngBase in QTcF \(msec\) vs PNU-101244 Conc \(NGML\) \(Cohort 1\).pdf](#)

[Figure 14.5.4.3.3 ECG ChngBase in QTcF \(msec\) vs PNU-101244 Conc \(NGML\) \(Cohort 2\).pdf](#)

[Table 13.1.1 Subject Evaluation Groups.pdf](#)

[Figure 14.5.4.3.4 ECG ChngBase in QTcF \(msec\) vs PNU-101244 Conc \(NGML\) \(Cohort 2\) \(Semi-Log\).pdf](#)

[Table 13.1.2 Discontinuations from Study.pdf](#)

[Table 13.2.1 Demographic Characteristics \(by Cohort\).pdf](#)

[Table 13.2.2 Demographic Characteristics \(All Subjects\).pdf](#)

[Table 13.3 Administration Schedule.pdf](#)

[Table 13.4.1 Whole Blood Bacterial Activity \(WBA\) Mean Values.pdf](#)

[Table 13.4.2 Whole Blood Bacterial Activity \(WBA\) Mean Base and Mean ChngBase.pdf](#)

[Table 13.4.4 Sum Stats of WBA AUC24.pdf](#)

[Table 13.4.5.1 Regression Model Statistical Sum WBA AUC24 vs Total AUC24 \(300 mg\).pdf](#)

[Table 13.4.5.2 Regression Model Statistical Sum WBA AUC24 vs Total AUC24 \(600 mg fasted\).pdf](#)

[Table 13.4.5.4 Regression Model Statistical Sum WBA AUC24 vs Total AUC24 \(1500 mg\).pdf](#)

[Table 13.4.5.3 Regression Model Statistical Sum WBA AUC24 vs Total AUC24 \(1000 mg\).pdf](#)

[Table 13.5.1.1 Sum PNU-100480 Plasma Concs.pdf](#)

[Table 13.5.1.2 Sum PNU-101603 Plasma Concs.pdf](#)

[Table 13.5.1.3 Sum PNU-101244 Plasma Concs.pdf](#)

[Table 13.5.2.1 Sum PNU-100480 Plasma Pharmacokinetic Parameters.pdf](#)

[Table 13.5.2.2 Sum PNU-101603 Plasma Pharmacokinetic Parameters.pdf](#)

[Table 13.5.2.3 Sum PNU-101244 Plasma Pharmacokinetic Parameters.pdf](#)

[Table 13.5.3.1 Sum Stats of PNU-100480 600mg Pharmacokinetic Parameters \(Fed vs. Fasted\).pdf](#)

[Table 13.5.3.2 Sum Stats of PNU-100480 Pharmacokinetic Parameters Dose Response \(Fasted only\).pdf](#)

[Table 13.6.2.1 T-E AEs \(All Causalities\).pdf](#)

Table 13.6.2.2 Incidence and Severity of T-E AEs (All Causalities).pdf

Table 13.7.1 Incidence of LTA's (Normal Base).pdf

Table 13.6.3.2 Incidence and Severity of T-E AEs (Treatment Related).pdf

Table 13.6.3.1 T-E AEs (Treatment Related).pdf

Table 13.7.2 Incidence of LTA's (Abnormal Base).pdf

Table 13.8.1 Vital Signs Absolute Values.pdf

Table 13.8.2 Vital Signs ChngBase.pdf

Table 13.8.3 Vital Signs Categorical Sum Post Base Max Absolute Values.pdf

Table 13.8.4 Vital Signs Categorical Sum Increase from Base Values.pdf

Table 13.8.5 Vital Signs Categorical Sum Decrease from Base Values.pdf

Table 13.8.6 Vital Signs Difference from PbO.pdf

Table 13.9.1 ECG Absolute Values.pdf

Table 13.9.2 ECG ChngBase.pdf

Table 13.9.3.2 ECG Categorical Sum Max Increase from Base Values.pdf

Table 13.9.3.1 ECG Categorical Sum Post Base Max Absolute Values.pdf

Table 13.9.4 ECG Max Increase from Base for QTcF (0-4h).pdf

Table 13.9.5 ECG Difference from PbO.pdf

B1171001 Protocol 12 March 2009.doc

b1171001-1001-fda-1572-form-16-mar-2009.pdf

B1171001 Protocol 12 March 2009.pdf

B1171001 Protocol Amend 1 06 May 2009.doc

B1171001 Protocol Amend 1 06 May 2009.pdf

B1171001 ICD, 07 May 2009.pdf

B1171001 SAP eSignature Page, 22 Apr 2009.pdf

B1171001 ICD, 02 July 2009.pdf

B1171001 Stats Plan Amend 1 eSignature, 03 June 2009.pdf

B1171001 Stats Plan eSignature, 03 June 2009.pdf

B1171001 Stats Plan eSignature, 22 Apr 2009.pdf

B1171001 Stats Plan eSignature, 22 Apr 20092.pdf

B1171001 Stats Plan v2, 03 June 2009.doc

B1171001 Stats Plan v2, 03 June 2009.pdf

B1171001 Stats Plan, 22 Apr 2009.doc

B1171001 Stats Plan, 22 Apr 2009.pdf

B1171001 ICD, 31 March 2009.pdf

B1171001 Protocol Amend 1 Approval Form 06 May 2009.pdf

02 A -F Appendix 1 - FDA Letter confirming US Orphan Drug Designation.pdf

01 A-F of the application (scientific part).pdf

03 A-F Appendix 2 -IB.pdf

04 A -F Appendix 3 - Clinical Protocol for Study B1171003.pdf

05Proof of Establishment.pdf

06Proof of EstablishmentCertificate of incorporation of Pfizer Ltd.pdf

07Letter of Authorisation - PNU-100480 EU OD.pdf

08Translations.doc

08Translations.doc.pdf

08Translations.pdf

GPS-LAB-006-F01 V6.0.doc

GPS-LAB-006-F01 V6.0.pdf

DP BDC for PbO for PNU-0100480 100mg Tablet; CM-1511009; 09-080619; D0904911.doc

DP BDC for PbO for PNU-0100480 100mg Tablet; CM-1511009; 09-080619; D0904911.pdf

D0904911-00-G1.doc

D0904911-00-G1.pdf

EU 1.1 Comprehensive Table of Contents.pdf

EMA FDAApplication Form - ODD - PNU-100480.doc.pdf

EMA FDAApplication Form - ODD - PNU-100480.pdf

EMA FDAApplication Form - ODD - PNU-100480.doc

EU - 1.0 Cover Letter - EU Orphan Medicinal Product Designation Application.pdf

A10 - Documentation of Statistical Methods TOC.doc

A10 - Documentation of Statistical Methods TOC.pdf

A10 - Documentation of Statistical Methods TOC1.doc

A10 - Documentation of Statistical Methods TOC1.pdf

A10 - Documentation of Statistical Methods TOC{1}.doc

A10.2.1 Stats of PNU-100480 600mg Pharmacokinetic Parameters (Fed vs. Fasted).pdf

A10 - Documentation of Statistical Methods TOC{1}.pdf

A10.2.1 Stats of PNU-100480 600mg Pharmacokinetic Parameters (Fed vs. Fasted)2.pdf

A10.2.2 Stats of PNU-100480 Pharmacokinetic Parameters Dose Response (Fasted only).pdf

B1171001 A13 - Errata.doc

A10.2.2 Stats of PNU-100480 Pharmacokinetic Parameters Dose Response (Fasted only)2.pdf

A10.3.1 Mixed Effects ANOVA - Statistical Sum AUC24WBA.pdf

A10.3.1 Mixed Effects ANOVA - Statistical Sum AUC24WBA2.pdf

A10.3.2.1 Regression Model - Statistical Sum AUC24WBA vs AUC24total (300 mg).pdf

A10.3.2.1 Regression Model - Statistical Sum AUC24WBA vs AUC24total (300 mg)2.pdf

A10.3.2.2 Regression Model - Statistical Sum AUC24WBA vs AUC24total (600 mg fasted).pdf

A10.3.2.2 Regression Model - Statistical Sum AUC24WBA vs AUC24total (600 mg fasted)2.pdf

A10.3.2.3 Regression Model - Statistical Sum AUC24WBA vs AUC24total (1000 mg).pdf

B1171001 A13 - Errata.pdf

A10.3.2.4 Regression Model - Statistical Sum AUC24WBA vs AUC24total (1500 mg).pdf

A10.3.2.3 Regression Model - Statistical Sum AUC24WBA vs AUC24total (1000 mg)2.pdf

A10.3.2.4 Regression Model - Statistical Sum AUC24WBA vs AUC24total (1500 mg)2.pdf

A4 - List of Investigators and Corresponding Ethics Committees or Institutional Review Boards.doc

A4 - List of Investigators and Corresponding Ethics Committees or Institutional Review Boards.pdf

A4 - List of Investigators and Corresponding Ethics Committees or Institutional Review Boards1.doc

A4 - List of Investigators and Corresponding Ethics Committees or Institutional Review Boards1.pdf

A7.1 - Description of Randomization.doc

A4 - List of Investigators and Corresponding Ethics Committees or Institutional Review Boards{1}.doc

A4 - List of Investigators and Corresponding Ethics Committees or Institutional Review Boards{1}.pdf

A7.1 - Description of Randomization.pdf

A7.1 - Description of Randomization1.doc

A7.1 - Description of Randomization{1}.pdf

A7.1 - Description of Randomization{1}.doc

A7.1 - Description of Randomization1.pdf

A7.2 Randomization Treatment Assigned and Treatment Received.pdf

A7.2 Randomization Treatment Assigned and Treatment Received2.pdf

A8 - Analytical Rpts Cover Page.doc

A8 - Analytical Rpts Cover Page.pdf

A8 - Analytical Rpts Cover Page1.doc

A8 - Analytical Rpts Cover Page1.pdf

A8 - Analytical Rpts Cover Page{1}.doc

A8 - Analytical Rpts Cover Page{1}.pdf

A8.1 Analytical Rpt plasma.pdf

A8.1 Analytical Rpt plasma2.pdf

Appendix A4 Supplemental Rpt.doc

Appendix A4 Supplemental Rpt.pdf

Appendix A4 Supplemental Rpt1.doc

Appendix A4 Supplemental Rpt1.pdf

Appendix A4 Supplemental Rpt{1}.doc

Appendix A4 Supplemental Rpt{1}.pdf

B1.1 Subject Evaluation Groups.pdf

B1.2 Subject Discontinuations.pdf

B1171001 A5.1 - Sponsor.pdf

B1171001 A5.1 - Sponsor2.pdf

B1171001 A5.1 - Sponsor{1}.pdf

B1171001 A5.2 - CSR Investigator Declaration.doc

B1171001 A5.2 - CSR Investigator Declaration.pdf

B1171001 A5.2 - CSR Investigator Declaration1.doc

B1171001 A5.2 - CSR Investigator Declaration1.pdf

B1171001 A5.2 - CSR Investigator Declaration{1}.doc

B1171001 A5.2 - CSR Investigator Declaration{1}.pdf

B1171001 A6 - Study Drug Information.doc

B1171001 A6 - Study Drug Information.pdf

B1171001 A6 - Study Drug Information{1}.doc

B1171001 A6 - Study Drug Information{1}.pdf

B1171001 CTD Abstract.doc

B1171001 CTD Abstract.pdf

B1171001 ICD, 02 July 2009.pdf

B1171001 ICD, 02 July 20092.pdf

B1171001 Investigator declaration.pdf

B1171001 Investigators CVs.pdf

B1171001 Investigators CVs{1}.pdf

B1171001 Investigators CVs2.pdf

B1171001 PhRMA Web Synopsis Approval Form.pdf

B1171001 PhRMA Web Synopsis.doc

B1171001 PhRMA Web Synopsis.pdf

B1171001 Protocol Amend 1 06 May 2009.doc

B1171001 Protocol Amend 1 06 May 2009.pdf

B1171001 Protocol Amend 1 06 May 20091.doc

B1171001 Protocol Amend 1 06 May 20091.pdf

B1171001 Stats Plan v2, 03 June 2009.doc

B1171001 Stats Plan v2, 03 June 2009.pdf

B1171001 Stats Plan v2, 03 June 20091.doc

B1171001 Stats Plan v2, 03 June 20091.pdf

B1171001 Study Rpt Body.doc

B1171001 Study Rpt Body.pdf

B1171001 Study Rpt Cover Page.doc

B1171001 Study Rpt Cover Page.pdf

B1171001 Study Rpt Synopsis.doc

B1171001 Study Rpt Synopsis.pdf

B12 Protocol Deviation.doc

B12 Protocol Deviation.pdf

B3.1 Administration Schedule.pdf

B2 Demographic Characteristics.pdf

B3.2 Concomitant Drug Treatments.pdf

B3.3 Concomitant Nondrug Treatments.pdf

B4.1.1 Whole Blood Bactericidal Activity (WBA) Data.pdf

B4.1.2 Whole Blood Bactericidal Activity (WBA) ChngBase.pdf

B4.1.3 Listing of Individual Value of WBA AUC₂₄.pdf

B5.1.1.1 Plasma Concs of PNU-100480.pdf

B6 AEs.pdf

B5.1.1.2 Plasma Concs of PNU-101603.pdf

B5.1.1.3 Plasma Concs of PNU-101244.pdf

B5.1.2.1 Plasma Sample Time Deviations and Sample Comments of PNU-100480.pdf

B5.1.2.2 Plasma Sample Time Deviations and Sample Comments of PNU-101603.pdf

B5.2.1 Listing and Dscrp Sum Serum PNU-100480 PK Parameters.pdf

B5.1.2.3 Plasma Sample Time Deviations and Sample Comments of PNU-101244.pdf

B5.2.2 Listing and Dscrp Sum Serum PNU-101603 PK Parameters.pdf

B5.2.3 Listing and Dscrp Sum Serum PNU-101244 PK Parameters.pdf

B5.3.1.1 PNU-100480 Plasma Concs vs Time by Treatment.pdf

B5.3.2.1 PNU-101603 Plasma Concs vs Time by Treatment.pdf

B5.3.1.2 PNU-100480 Plasma Concs vs Time by Treatment (Semi-log).pdf

B5.3.2.2 PNU-101603 Plasma Concs vs Time by Treatment (Semi-log).pdf

B5.3.3.1 PNU-101244 Plasma Concs vs Time by Treatment.pdf

B5.3.3.2 PNU-101244 Plasma Concs vs Time by Treatment (Semi-log).pdf

B7.1 Laboratory Data.pdf

B7.3 LTA^{'''}s, by Test.pdf

B7.2 LTA^{'''}s, by Subject.pdf

B8.1 Vital Signs Data.pdf

B8.2 Vital Signs ChngBase.pdf

B8.3 Values Meeting Categorical Sum Post Base Vital Signs Criteria.pdf

B8.4 Vital Signs Difference from PbO.pdf

B9.1 ECG Data.pdf

B9.2 ECG ChngBase.pdf

B9.3 ECG Qualitative Results.pdf

B9.4 Values Meeting Categorical Sum Post Base ECG Criteria.pdf

B9.5 ECG Difference from PbO.pdf

Figure 14.1.1.1 Median Plasma Conc of PNU-100480 vs Time (Linear).pdf

Figure 14.1.2.2 Median Plasma Conc of PNU-101603 vs Time (Semi-Log).pdf

Figure 14.1.2.1 Median Plasma Conc of PNU-101603 vs Time (Linear).pdf

Figure 14.1.1.2 Median Plasma Conc of PNU-100480 vs Time (Semi-Log).pdf

Figure 14.1.3.1 Median Plasma Conc of PNU-101244 vs Time (Linear).pdf

Figure 14.1.3.2 Median Plasma Conc of PNU-101244 vs Time (Semi-Log).pdf

Figure 14.2.1.1 Individual and Mean Plasma PNU-100480 Dose Normalized AUCinf vs Dose (Fasted only).pdf

Figure 14.2.1.2 Individual and Mean Plasma PNU-100480 Dose Normalized AUClast vs Dose (Fasted only).pdf

Figure 14.2.1.3 Individual and Mean Plasma PNU-100480 Dose Normalized AUC24 vs Dose (Fasted only).pdf

Figure 14.2.1.4 Individual and Mean Plasma PNU-100480 Dose Normalized Cmax vs Dose (Fasted only).pdf

Figure 14.2.2.1 Individual and Mean Plasma PNU-101603 Dose Normalized AUCinf vs Dose (Fasted only).pdf

Figure 14.2.2.2 Individual and Mean Plasma PNU-101603 Dose Normalized AUClast vs Dose (Fasted only).pdf

Figure 14.2.2.3 Individual and Mean Plasma PNU-101603 Dose Normalized AUC24 vs Dose (Fasted only).pdf

Figure 14.2.2.4 Individual and Mean Plasma PNU-101603 Dose Normalized Cmax vs Dose (Fasted only).pdf

Figure 14.2.3.1 Individual and Mean Plasma PNU-101244 Dose Normalized AUCinf vs Dose (Fasted only).pdf

Figure 14.2.3.2 Individual and Mean Plasma PNU-101244 Dose Normalized AUClast vs Dose (Fasted only).pdf

Figure 14.2.3.3 Individual and Mean Plasma PNU-101244 Dose Normalized AUC24 vs Dose (Fasted only).pdf

[Figure 14.2.3.4 Individual and Mean Plasma PNU-101244 Dose Normalized Cmax vs Dose \(Fasted only\).pdf](#)

[Figure 14.2.4.1 Individual and Mean Plasma PNU-100480 Dose Normalized AUCinf \(600 mg Fed vs. Fasted\).pdf](#)

[Figure 14.2.4.2 Individual and Mean Plasma PNU-100480 Dose Normalized AUClast \(600 mg Fed vs. Fasted\).pdf](#)

[Figure 14.2.4.3 Individual and Mean Plasma PNU-100480 Dose Normalized AUC24 \(600 mg Fed vs. Fasted\).pdf](#)

[Figure 14.2.5.1 Individual and Mean Plasma PNU-101603 Dose Normalized AUCinf \(600 mg Fed vs. Fasted\).pdf](#)

[Figure 14.2.4.4 Individual and Mean Plasma PNU-100480 Dose Normalized Cmax \(600 mg Fed vs. Fasted\).pdf](#)

[Figure 14.2.5.2 Individual and Mean Plasma PNU-101603 Dose Normalized AUClast \(600 mg Fed vs. Fasted\).pdf](#)

[Figure 14.2.5.4 Individual and Mean Plasma PNU-101603 Dose Normalized Cmax \(600 mg Fed vs. Fasted\).pdf](#)

[Figure 14.2.6.1 Individual and Mean Plasma PNU-101244 Dose Normalized AUCinf \(600 mg Fed vs. Fasted\).pdf](#)

[Figure 14.4.1.1 Vital Signs Mean ChngBase in Supine Systolic Blood Pressure \(mmHg\).pdf](#)

[Figure 14.2.5.3 Individual and Mean Plasma PNU-101603 Dose Normalized AUC24 \(600 mg Fed vs. Fasted\).pdf](#)

[Figure 14.2.6.2 Individual and Mean Plasma PNU-101244 Dose Normalized AUClast \(600 mg Fed vs. Fasted\).pdf](#)

[Figure 14.2.6.3 Individual and Mean Plasma PNU-101244 Dose Normalized AUC24 \(600 mg Fed vs. Fasted\).pdf](#)

[Figure 14.2.6.4 Individual and Mean Plasma PNU-101244 Dose Normalized Cmax \(600 mg Fed vs. Fasted\).pdf](#)

[Figure 14.3.1 Scatter Plot of WBA AUC24 vs Total AUC24 \(PNU-100480 plus Metabolites\) \(Linear\).pdf](#)

[Figure 14.4.1.2 Vital Signs Mean ChngBase in Supine Diastolic Blood Pressure \(mmHg\).pdf](#)

[Figure 14.4.2.1 Vital Signs Individual Profiles of Changes from Base in Supine Systolic Blood Pressure \(mmHg\).pdf](#)

[Figure 14.4.1.3 Vital Signs Mean ChngBase in Supine Pulse Rate \(BPM\).pdf](#)

[Figure 14.4.2.2 Vital Signs Individual Profiles of Changes from Base in Supine Diastolic Blood Pressure \(mmHg\).pdf](#)

[Figure 14.4.3.1 Vital Signs Differences from PbO Results in Supine Systolic Blood Pressure \(mmHg\).pdf](#)

[Figure 14.4.3.2 Vital Signs Differences from PbO Results in Supine Diastolic Blood Pressure \(mmHg\).pdf](#)

[Figure 14.4.2.3 Vital Signs Individual Profiles of Changes from Base in Supine Pulse Rate \(BPM\).pdf](#)

[Figure 14.4.3.3 Vital Signs Differences from PbO Results in Supine Pulse Rate \(BPM\).pdf](#)

[Figure 14.5.1.1 ECG Mean ChngBase in HR \(BPM\).pdf](#)

[Figure 14.5.1.2 ECG Mean ChngBase in QT \(msec\).pdf](#)

[Figure 14.5.2.1 ECG Individual Profiles of Changes from Base in HR \(BPM\).pdf](#)

[Figure 14.5.1.3 ECG Mean ChngBase in QTcF \(msec\).pdf](#)

[Figure 14.5.2.2 ECG Individual Profiles of Changes from Base in QT \(msec\).pdf](#)

[Figure 14.5.2.3 ECG Individual Profiles of Changes from Base in QTcF \(msec\).pdf](#)

[Figure 14.5.3.1 ECG Differences from PbO Results in QT \(msec\).pdf](#)

[Figure 14.5.3.2 ECG Differences from PbO Results in HR \(BPM\).pdf](#)

[Figure 14.5.3.3 ECG Differences from PbO Results in QTcF \(msec\).pdf](#)

[Figure 14.5.4.1.1 ECG ChngBase in QTcF \(msec\) vs PNU-100480 Conc \(NGML\) \(Cohort 1\).pdf](#)

[study-b1171001-additional-data-listings.pdf](#)

[Figure 14.5.4.1.2 ECG ChngBase in QTcF \(msec\) vs PNU-100480 Conc \(NGML\) \(Cohort 1\) \(Semi-Log\).pdf](#)

[Figure 14.5.4.1.3 ECG ChngBase in QTcF \(msec\) vs PNU-100480 Conc \(NGML\) \(Cohort 2\).pdf](#)

[Figure 14.5.4.1.4 ECG ChngBase in QTcF \(msec\) vs PNU-100480 Conc \(NGML\) \(Cohort 2\) \(Semi-Log\).pdf](#)

[Figure 14.5.4.2.1 ECG ChngBase in QTcF \(msec\) vs PNU-101603 Conc \(NGML\) \(Cohort 1\).pdf](#)

[Figure 14.5.4.2.2 ECG ChngBase in QTcF \(msec\) vs PNU-101603 Conc \(NGML\) \(Cohort 1\) \(Semi-Log\).pdf](#)

[Figure 14.5.4.2.3 ECG ChngBase in QTcF \(msec\) vs PNU-101603 Conc \(NGML\) \(Cohort 2\).pdf](#)

[Figure 14.5.4.2.4 ECG ChngBase in QTcF \(msec\) vs PNU-101603 Conc \(NGML\) \(Cohort 2\) \(Semi-Log\).pdf](#)

[study-b1171001.pdf](#)

[Figure 14.5.4.3.2 ECG ChngBase in QTcF \(msec\) vs PNU-101244 Conc \(NGML\) \(Cohort 1\) \(Semi-Log\).pdf](#)

[Figure 14.5.4.3.1 ECG ChngBase in QTcF \(msec\) vs PNU-101244 Conc \(NGML\) \(Cohort 1\).pdf](#)

[Figure 14.5.4.3.3 ECG ChngBase in QTcF \(msec\) vs PNU-101244 Conc \(NGML\) \(Cohort 2\).pdf](#)

[Figure 14.5.4.3.4 ECG ChngBase in QTcF \(msec\) vs PNU-101244 Conc \(NGML\) \(Cohort 2\) \(Semi-Log\).pdf](#)

[Table 13.1.1 Subject Evaluation Groups.pdf](#)

[Table 13.1.2 Discontinuations from Study.pdf](#)

[Table 13.2.1 Demographic Characteristics \(by Cohort\).pdf](#)

[Table 13.2.2 Demographic Characteristics \(All Subjects\).pdf](#)

Table 13.3 Administration Schedule.pdf

Table 13.4.1 Whole Blood Bactericidal Activity (WBA) Mean Values.pdf

Table 13.4.2 Whole Blood Bactericidal Activity (WBA) Mean Base and Mean ChngBase.pdf

Table 13.4.3 Dscrp Sum WBA AUC24.pdf

Table 13.4.4 Sum Stats of WBA AUC24.pdf

Table 13.4.5.1 Regression Model Statistical Sum WBA AUC24 vs Total AUC24 (300 mg).pdf

Table 13.4.5.2 Regression Model Statistical Sum WBA AUC24 vs Total AUC24 (600 mg fasted).pdf

Table 13.4.5.3 Regression Model Statistical Sum WBA AUC24 vs Total AUC24 (1000 mg).pdf

Table 13.4.5.4 Regression Model Statistical Sum WBA AUC24 vs Total AUC24 (1500 mg).pdf

Table 13.5.1.1 Sum PNU-100480 Plasma Concs.pdf

Table 13.5.1.2 Sum PNU-101603 Plasma Concs.pdf

Table 13.5.1.3 Sum PNU-101244 Plasma Concs.pdf

Table 13.5.2.1 Sum PNU-100480 Plasma Pharmacokinetic Parameters.pdf

Table 13.5.2.2 Sum PNU-101603 Plasma Pharmacokinetic Parameters.pdf

Table 13.5.2.3 Sum PNU-101244 Plasma Pharmacokinetic Parameters.pdf

Table 13.5.3.1 Sum Stats of PNU-100480 600mg Pharmacokinetic Parameters (Fed vs. Fasted).pdf

Table 13.5.3.2 Sum Stats of PNU-100480 Pharmacokinetic Parameters Dose Response (Fasted only).pdf

Table 13.6.2.1 T-E AEs (All Causalities).pdf

Table 13.6.2.2 Incidence and Severity of T-E AEs (All Causalities).pdf

Table 13.6.3.1 T-E AEs (Treatment Related).pdf

Table 13.6.3.2 Incidence and Severity of T-E AEs (Treatment Related).pdf

Table 13.7.1 Incidence of LTA's (Normal Base).pdf

Table 13.7.2 Incidence of LTA's (Abnormal Base).pdf

Table 13.8.2 Vital Signs ChngBase.pdf

Table 13.8.1 Vital Signs Absolute Values.pdf

[Table 13.8.3 Vital Signs Categorical Sum Post Base Max Absolute Values.pdf](#)

[Table 13.8.5 Vital Signs Categorical Sum Decrease from Base Values.pdf](#)

[Table 13.8.4 Vital Signs Categorical Sum Increase from Base Values.pdf](#)

[Table 13.8.6 Vital Signs Difference from PbO.pdf](#)

[Table 13.9.1 ECG Absolute Values.pdf](#)

[Table 13.9.2 ECG ChngBase.pdf](#)

[Table 13.9.3.1 ECG Categorical Sum Post Base Max Absolute Values.pdf](#)

[Table 13.9.3.2 ECG Categorical Sum Max Increase from Base Values.pdf](#)

[Table 13.9.4 ECG Max Increase from Base for QTcF \(0-4h\).pdf](#)

[Table 13.9.5 ECG Difference from PbO.pdf](#)

[B1171002 ICD, 01 April 2010.pdf](#)

[B1171002 ICD, 21 Dec 2009.pdf](#)

[B1171002 ICD, 2 March 2010.pdf](#)

[B1171002 ICD, 29 Sept 2009.pdf](#)

[B1171002 Final Stats Plan, 26 Oct 2009.doc](#)

[b1171002-1001-fda-1572-form-21-sep-2009.pdf](#)

[B1171002 Final Stats Plan, 26 Oct 2009.pdf](#)

[B1171002 Protocol 15 September 2009.doc](#)

[B1171002 Protocol Amend 1, 16 December 2009.doc](#)

[B1171002 Protocol 15 September 2009.pdf](#)

[B1171002 Protocol Amend 1, 16 December 2009.pdf](#)

[B1171002 Protocol Amend 2 Approval Form, 23 March 2010.pdf](#)

[B1171002 Protocol Amend 2, 23 March 2010.pdf](#)

[B1171002 Protocol Amend 2, 23 March 2010.doc](#)

[B1171002 Stats Plan Amend 2 Final 30 April 2010.doc](#)

B1171002 Stats Plan Amend 2 Final 30 April 2010.pdf

B1171002 Stats Plan ESignature, 26 Oct 2009.pdf

B1171002 Stats Plan Amend 2 Signature Form 30 April 2010.pdf

B1171002 Stats Plan, Amend 1, e-Signature, v2, 26 January 2010.pdf

B1171002 Stats Plan, Amend 1, v2, 26 January 2010.doc

B1171002 Stats Plan, Amend 1, v2, 26 January 2010.pdf

11-001172 (517414) CSM06630-1.pdf

BR Approved Label, B1171003.pdf

Checklist for CSP09649.doc

Checklist for CSP09649.pdf

CLR for CSP09649, B1171003.pdf

CPR for CSP09649.doc

CPR for CSP09649.pdf

CSA for B1171003 -- CSP07435.pdf

CSA for B1171003 -- CSP07435.xml

PD for CSP09649.pdf

PD for CSP09649.ppt

Post-Executed BR for Prt. B1171003; CSP09649; FCS Job 33679.1.pdf

Pre-Executed BR for CSP09649, Prt.B1171003, FCS Job 33679.1.pdf

PSF for CSP09649.doc

PSF for CSP09649.pdf

08GR349.pdf

08GR351.pdf

08GR365.pdf

NonClinical Tox Studies for PF 02341272.pdf

\$100000254.doc

TM000004394.doc

TM000004394.pdf

TM100000254.pdf

TM100000254.doc

TM100001204.doc

TM100001204.pdf

TM100000624.doc

TM100000624.pdf

TM100000688.doc

TM100000688.pdf

TM100000950.doc

TM100000950.pdf

TM100000957.doc

TM100000957.pdf

07GR383.pdf

07GR384.pdf

08GR104.pdf

08GR338.pdf

10CA009 Final Rpt.pdf

10GR247 Final Rpt.pdf

1.13.2 Sum Clinical PharmaC.doc

1.13.2 Sum Clinical PharmaC.pdf

1.13.2 Sum Clinical PharmaC1.doc

1.13.2 Sum Clinical PharmaC1.pdf

1.13.2 Sum Clinical PharmaC2.doc

1.13.2 Sum Clinical PharmaC2.pdf

PF-02341272NA15.pdf

1.13.3 - Sum SI.pdf

PF-04918975HERG.pdf

1.13.3 - Summary Page.doc

PF04685698HERG.pdf

1.13.3 - Summary Page.pdf

PF02341272hERG.pdf

1.13.3 - Summary Page1.pdf

1.13.3 - Summary Page1.doc

1.13.3 - TOC.doc

1.13.3 - TOC.pdf

1.13.3 - TOC1.pdf

1.13.3 - TOC1.doc

1.13.5 Status of Manufacturing Changes.doc

1.13.5 Status of Manufacturing Changes.pdf

1.13.5 Status of Manufacturing Changes1.doc

1.13.5 Status of Manufacturing Changes1.pdf

1.13.5 Status of Manufacturing Changes2.pdf

1.13.5 Status of Manufacturing Changes2.doc

1.13.8 - Individual Study Information.pdf

1.13.8 - Summary Page.doc

1.13.8 - Summary Page.pdf

1.13.8 - Summary Page1.doc

1.13.8 - Summary Page1.pdf

1.13.8 - TOC.doc

1.13.8 - TOC.pdf

1.13.8 - TOC1.doc

1.13.8 - TOC1.pdf

1.13.9 General Investigational Plan.doc

1.13.9 General Investigational Plan.pdf

1.13.9 General Investigational Plan1.doc

1.13.9 General Investigational Plan1.pdf

1.13.9 General Investigational Plan2.doc

1.13.9 General Investigational Plan2.pdf

Table 1.13.1 Sum Non Clinical Studies - Tox.doc

Table 1.13.1 Sum Non Clinical Studies - Tox.pdf

Table 1.13.1 Sum Non-Clinical Studies - PharmaC.doc

Table 1.13.1 Sum Non-Clinical Studies - PharmaC.pdf

Table 1.13.1-1 Sum Non-Clinical Studies - Tox.doc

Table 1.13.1-1 Sum Non-Clinical Studies - Tox.pdf

Table 1.13.3-3 Listing of Clin Safety Rpts.doc

Table 1.13.3-3 Listing of Clin Safety Rpts.pdf

08GR310.pdf

08GR364.pdf

08GR370.pdf

S.5 Reference.doc

S.5 Reference.pdf

SPC100001913.doc

SPC100001913.pdf

S.1.1 Nomenclature.doc

S.1.1 Nomenclature.pdf

S.1.2 Structure.doc

S.1.2 Structure.pdf

S.1.3 General Properties.pdf

S.1.3 General Properties.doc

S.2.1 Manufacturer(s).doc

S.2.1 Manufacturer(s).pdf

S.2.1 Manufacturer(s)1.doc

S.2.1 Manufacturer(s)1.pdf

S.2.2 Description of Manufacturing Process and Process Controls.doc

S.2.2 Description of Manufacturing Process and Process Controls.pdf

S.2.2 Description of Manufacturing Process and Process Controls1.doc

S.2.2 Description of Manufacturing Process and Process Controls1.pdf

S.2.3 Control of Materials.doc

S.2.3 Control of Materials.pdf

S.2.6. Manufacturing Process Dev.doc

S.2.6. Manufacturing Process Dev.pdf

S.2.6. Manufacturing Process Dev1.doc

S.2.6. Manufacturing Process Dev2.doc

S.2.6. Manufacturing Process Dev1.pdf

S.2.6. Manufacturing Process Dev2.pdf

S.3.1 Elucidation of Structure and Other Characteristics.doc

S.3.2 Impurities.doc

S.3.1 Elucidation of Structure and Other Characteristics.pdf

S.3.2 Impurities.pdf

S.3.2 Impurities1.doc

S.3.2 Impurities1.pdf

S.4.1 Specification.pdf

S.4.1 Specification.doc

S.4.1 Specification1.doc

S.4.1 Specification1.pdf

S.4.2 Analytical Procedures.doc

S.4.2 Analytical Procedures.pdf

S.4.3 Validation of Analytical Procedures.doc

S.4.3 Validation of Analytical Procedures1.doc

S.4.3 Validation of Analytical Procedures.pdf

S.4.3 Validation of Analytical Procedures1.pdf

S.4.4 Batch Analyses.doc

S.4.4 Batch Analyses.pdf

S.4.4 Batch Analyses1.doc

S.4.4 Batch Analyses1.pdf

S.4.4 Batch Analyses2.doc

S.4.4 Batch Analyses2.pdf

S.4.4 Batch Analyses3.doc

S.4.4 Batch Analyses3.pdf

S.4.5 Justification of Specification.doc

S.4.5 Justification of Specification.pdf

S.4.5 Justification of Specification1.doc

S.4.5 Justification of Specification1.pdf

S.5 Reference.doc

S.5 Reference.pdf

S.6 CCSsystem.doc

S.7.1 Stability Summary and Conclusions.doc

S.6 CCSsystem.pdf

S.7.1 Stability Summary and Conclusions.pdf

S.7.1 Stability Summary and Conclusions1.doc

S.7.1 Stability Summary and Conclusions1.pdf

S.7.1 Stability Summary and Conclusions2.doc

S.7.1 Stability Summary and Conclusions2.pdf

S.7.1 Stability Summary and Conclusions3.pdf

S.7.1 Stability Summary and Conclusions3.doc

S.7.3 Stability Data.doc

S.7.3 Stability Data.pdf

S.7.3 Stability Data1.doc

S.7.3 Stability Data1.pdf

S.7.3 Stability Data2.doc

S.7.3 Stability Data2.pdf

S.7.3 Stability Data3.doc

S.7.3 Stability Data3.pdf

08GR312 Rpt Amend 1.pdf

08GR312.pdf

1.12.14 Environmental Assessment Claim for a Categorical Exclusion.doc

1.12.14 Environmental Assessment Claim for a Categorical Exclusion.pdf

1.14.4.2 Labeling.doc

1.14.4.2 Labeling.pdf

3.2.R GMP Statement - aa Belgian Eudra GMP 277 H English.pdf

CoA CM-0310210 (10-083600) 200mg tablet.pdf

CoA CM-1180809 100mg tablet.pdf

2009 04 24 eIND QQR - SQ0002.doc

2009 04 24 eIND QQR - SQ0002.pdf

08GR360 Final Rpt Amend.pdf

08GR360.pdf

CoA CM-1180809 100mg tablet.pdf

CoA CM-0310210 (10-083600) 200mg tablet.pdf

CoA CM-0310210 (10-083600) 200mg tablet.pdf

CoA CM-1180809 100mg tablet.pdf

Drug Product (PbO for PNU-100480).doc

Drug Product (PbO for PNU-100480).pdf

Drug Product (PbO for PNU-100480)1.doc

Drug Product (PbO for PNU-100480)2.doc

Drug Product (PbO for PNU-100480)1.pdf

Drug Product (PbO for PNU-100480)2.pdf

P.7 CCSystem.doc

P.8.1 Stability Summary and Conclusion.doc

P.7 CCSystem.pdf

P.8.1 Stability Summary and Conclusion.pdf

P.8.1 Stability Summary and Conclusion1.doc

P.8.1 Stability Summary and Conclusion1.pdf

P.8.1 Stability Summary and Conclusion2.doc

P.8.1 Stability Summary and Conclusion2.pdf

P.8.1 Stability Summary and Conclusion3.doc

P.8.1 Stability Summary and Conclusion3.pdf

P.8.1 Stability Summary and Conclusion4.doc

P.8.1 Stability Summary and Conclusion4.pdf

P.8.1 Stability Summary and Conclusion5.doc

P.8.3 Stability Data.doc

P.8.1 Stability Summary and Conclusion5.pdf

P.8.3 Stability Data.pdf

P.8.3 Stability Data1.doc

P.8.3 Stability Data1.pdf

P.8.3 Stability Data2.doc

P.8.3 Stability Data2.pdf

P.8.3 Stability Data3.doc

P.8.3 Stability Data3.pdf

P.8.3 Stability Data4.doc

P.8.3 Stability Data5.doc

P.8.3 Stability Data4.pdf

P.8.3 Stability Data5.pdf

P.8.3 Stability Data6.doc

P.8.3 Stability Data6.pdf

P.6 Reference.doc

P.6 Reference.pdf

P.5.1 Specification(s).doc

P.5.1 Specification(s).pdf

P.5.1 Specification(s)1.doc

P.5.1 Specification(s)1.pdf

P.5.1 Specification(s)2.doc

P.5.1 Specification(s)2.pdf

P.5.2 Analytical Procedures.doc

P.5.2 Analytical Procedures.pdf

P.5.2 Analytical Procedures1.doc

P.5.2 Analytical Procedures1.pdf

P.5.2 Analytical Procedures2.doc

P.5.2 Analytical Procedures2.pdf

P.5.2 Analytical Procedures3.doc

P.5.2 Analytical Procedures3.pdf

P.5.2 Analytical Procedures4.doc

P.5.2 Analytical Procedures4.pdf

P.5.2 Analytical Procedures5.doc

P.5.2 Analytical Procedures5.pdf

P.5.3 Validation of Analytical Procedures.pdf

P.5.3 Validation of Analytical Procedures.doc

P.5.4 Batch Analyses.doc

P.5.4 Batch Analyses.pdf

P.5.5 Characterisation of Impurities.doc

P.5.5 Characterisation of Impurities.pdf

P.5.5 Characterisation of Impurities1.doc

P.5.5 Characterisation of Impurities1.pdf

P.5.6 Justification of Specifications.doc

P.5.6 Justification of Specifications1.doc

P.5.6 Justification of Specifications.pdf

P.5.6 Justification of Specifications1.pdf

3.2.P.4.2 Analytical Procedures Compendial.doc

3.2.P.4.2 Analytical Procedures Compendial.pdf

P.4 Control of Excipients (Compendial).doc

P.4 Control of Excipients (Compendial).pdf

QP-P.4.2 Analytical Procedures-ACTD.doc

QP-P.4.2 Analytical Procedures-ACTD.pdf

QP-P.4.4 Justification of Specifications-ACTD.doc

QP-P.4.4 Justification of Specifications-ACTD.pdf

P.3.1 Manufacturer(s).doc

P.3.1 Manufacturer(s).pdf

P.3.2 Batch Formula.doc

P.3.2 Batch Formula.pdf

P.3.3 Description of Manufacturing Process and Process Controls.doc

P.3.3 Description of Manufacturing Process and Process Controls.pdf

P.3.4 Controls of Critical Steps and Intmds.doc

P.3.4 Controls of Critical Steps and Intmds.pdf

P.1 Description and Composition of the Drug Product.doc

P.1 Description and Composition of the Drug Product.pdf

P.2 Pharmaceutical Dev.doc

P.2 Pharmaceutical Dev.pdf

2.3 Introduction.doc

2.3 Introduction.pdf

2.3 Introduction1.doc

2.3 Introduction1.pdf

BR Study Drug Information (Stability Notification).doc

BR Study Drug Information (Stability Notification).pdf

BR Study Drug Information.doc

BR Study Drug Information.pdf

Introduction.doc

Introduction.pdf

Introduction1.doc

Introduction1.pdf

A.2 Adventitious Agents Safety Evaluation.doc

A.2 Adventitious Agents Safety Evaluation.pdf

Avicel FMC BioPolymer BSETSE statement.pdf

Lactose Foremost Farms BSETSE statement.pdf

Magnesium stearate Mallinckrodt Baker BSETSE.pdf

Sodium starch glycolate (Explotab) JRS Pharma BSETSE statement.pdf

P.1 Description and Composition of the Drug Product.doc

P.1 Description and Composition of the Drug Product.pdf

P.4 Control of Excipients (Compendial and Non-compendial).doc

P.4 Control of Excipients (Compendial and Non-compendial).pdf

P.8.1 Stability Summary and Conclusion.doc

P.8.1 Stability Summary and Conclusion.pdf

P.8.1 Stability Summary and Conclusion1.doc

P.8.1 Stability Summary and Conclusion1.pdf

P.8.3 Stability Data.doc

P.8.3 Stability Data.pdf

P.8.3 Stability Data1.doc

P.8.3 Stability Data1.pdf

BR-PN-100480-CTSUR-22JUL2011-21JAN2012.pdf

BR-PNU-100480(PF-02341272)-CTSUR-22-JAN-2011-21-JUL-2011.pdf

BR-PN-100480-CTSUR-22JUL2011-21JAN2012{1}.pdf

BR-PNU-100480(PF-02341272)-CTSUR-22JUL2010-21JAN2011.pdf

BR-REBLINDED-PN-100480-CTSUR-22JUL2011-21JAN2012.pdf

BR-REBLINDED-PNU-100480-CTSUR-22JAN2012-21JUL2012.pdf

BR-REBLINDED-PN-100480-CTSUR-22JUL2011-21JAN2012{1}.pdf

BR-REBLINDED-PNU-100480-CTSUR-22JAN2012-21JUL2012{1}.pdf

CTSUR Template Child.doc

CTSUR Template Child.pdf

CTSUR Template Child{1}.doc

CTSUR Template Child{1}.pdf

LL-PN-100480- 22-JUL-2011 THROUGH 21-JAN-2012.pdf

LL REBLINDED-PN-100480- 22-JUL-2011 THROUGH 21-JAN-2012.pdf

LL REBLINDED-PN-100480- 22-JUL-2011 THROUGH 21-JAN-2012{1}.pdf

LL-PN-100480- 22-JUL-2011 THROUGH 21-JAN-2012{1}.pdf

LL-PNU-100480(PF-02341272)-CTSUR-22JAN2011-21JUL2011.pdf

LL-PNU-100480(PF-02341272)-CTSUR-22JUL2010-21JAN2011.pdf

LL-PNU-100480-CTSUR-22-JAN-2012 THROUGH 21-JUL-2012.pdf

LL-PNU-100480-CTSUR-22-JAN-2012 THROUGH 21-JUL-2012{1}.pdf

LL-REBLINDED-PNU-100480-CTSUR-22-JAN-2012 THROUGH 21-JUL-2012.pdf

LL-REBLINDED-PNU-100480-CTSUR-22-JAN-2012 THROUGH 21-JUL-2012{1}.pdf

PNU-100480 January 2011 SUSAR LL.doc

PNU-100480 January 2011 SUSAR LL.pdf

PNU-100480 January 2012 SUSAR LL.pdf

PNU-100480 January 2012 SUSAR LL.doc

PNU-100480 January 2012 SUSAR LL2.pdf

PNU-100480 January 2012 SUSAR LL{1}.pdf

PNU-100480 January 2012 SUSAR LL{2}.doc

PNU-100480 July 2011 SUSAR LL.pdf

PNU-100480 July 2012 SUSAR LL.pdf

Review and Approval-SRL Email-PN-100480-CTSUR-22-JUL-2011 through 21-JAN-2012.msg

08GR188.pdf

1.13.2 Sum Clinical PharmaC.doc

08GR343.pdf

D0904839-02.doc

D0904839-02.pdf

D0904840 PNU-0100480 100mg Tablet.pdf

D0904841 PNU-0100480 200mg Oval Tablet.pdf

Nomination of Extemporaneous Prep (NEP) for PNU-0100480 (PF-02341272).doc

Nomination of Extemporaneous Prep (NEP) for PNU-0100480 (PF-02341272).pdf

Extemporaneous dispensing record (EDR) for oral suspension 35-1500 mg..doc

Extemporaneous dispensing record (EDR) for oral suspension 35-1500 mg..doc.pdf

Extemporaneous dispensing record (EDR) for PNU-100480 B1171001 oral suspension 35-1500 mg..doc

Extemporaneous dispensing record (EDR) for PNU-100480 B1171001 oral suspension 35-1500 mg..pdf

1.13.2 Sum Clinical PharmaC.pdf

1.13.2 Sum Clinical PharmaC1.doc

1.13.2 Sum Clinical PharmaC2.pdf

1.13.2 Sum Clinical PharmaC2.doc

1.13.2 Sum Clinical PharmaC1.pdf

1.13.3 - Sum SI.pdf

1.13.3 - Summary Page.doc

1.13.3 - Summary Page.pdf

1.13.3 - Summary Page1.doc

1.13.3 - Summary Page1.pdf

1.13.3 - TOC.doc

1.13.3 - TOC.pdf

1.13.3 - TOC1.doc

1.13.3 - TOC1.pdf

1.13.5 Status of Manufacturing Changes.pdf

1.13.5 Status of Manufacturing Changes.doc

1.13.5 Status of Manufacturing Changes1.doc

1.13.5 Status of Manufacturing Changes1.pdf

1.13.5 Status of Manufacturing Changes2.doc

1.13.5 Status of Manufacturing Changes2.pdf

1.13.8 - Individual Study Information.pdf

1.13.8 - Summary Page.doc

1.13.8 - Summary Page.pdf

1.13.8 - Summary Page1.doc

1.13.8 - Summary Page1.pdf

1.13.8 - TOC.doc

1.13.8 - TOC1.doc

1.13.8 - TOC.pdf

1.13.8 - TOC1.pdf

1.13.8-1-CS-INDAR-2010-PNU-100480.pdf

1.13.9 General Investigational Plan.doc

1.13.9 General Investigational Plan.pdf

1.13.9 General Investigational Plan1.doc

1.13.9 General Investigational Plan1.pdf

1.13.9 General Investigational Plan2.doc

1.13.9 General Investigational Plan2.pdf

IND Annual Rpt carboprost tromethamine PNU-0100480 IND 104,806 22 Jan 2010 - 21 Jan 2011.doc

IND Annual Rpt carboprost tromethamine PNU-0100480 IND 104,806 22 Jan 2010 - 21 Jan 2011.pdf

Module 1.13.3 Sum SI.pdf

IND Annual Rpt carboprost tromethamine PNU-0100480 IND 104,806 22 Jan 2011 - 21 Jan 2012.pdf

IND Annual Rpt carboprost tromethamine PNU-0100480 IND 104,806 22 Jan 2011 - 21 Jan 2012.doc

Module 1.13.8 Individual Study Information.pdf

PNU-100,480 (PF-02341272) IND AR 2011 Table 1.13.3-1 PFE.pdf

PNU-100,480 Table 1.13.8-1draft.pdf

PNU-100,480 Table 1.13.8-3draft.pdf

PNU-100480 Module 1.13.3 Sum SI.pdf

PNU-100480 Module 1.13.8 Individual Study Information.pdf

Table 1.13.1 Sum Non Clinical Studies - Tox.doc

Table 1.13.1 Sum Non Clinical Studies - Tox.pdf

Table 1.13.1 Sum Non-Clinical Studies - PharmaC.doc

Table 1.13.1 Sum Non-Clinical Studies - PharmaC.pdf

Table 1.13.1-1 Sum Non-Clinical Studies - Tox.doc

Table 1.13.1-1 Sum Non-Clinical Studies - Tox.pdf

Table 1.13.3-3 Listing of Clin Safety Rpts.doc

Table 1.13.3-3 Listing of Clin Safety Rpts.pdf

PF-02341272 MSCA Rpt.doc

PF-02341272 MSCA Rpt.doc.pdf

PMF for PNU-0100480 200mg tablet Apr 10 Mfg.pdf

PMFPNU-0100480 200mg tab (Sep 2010).pdf

PMFPNU-0100480 MST 100mg200mg Tab (Sep 09).pdf

PNU-100480 (PF-02341272) API related impurity memo for RRT 1.04, 200 mg tablet.doc

PNU-100480 (PF-02341272) API related impurity memo for RRT 1.04, 200 mg tablet.pdf

PNU-100480Drug Product Design Risk AssessmentMullarneyMP.pdf

PNU100480 drug product development plan.pdf

PNU100480EC Protocol.pdf

1.12.14 Environmental Assessment Claim for a Categorical Exclusion.doc

1.12.14 Environmental Assessment Claim for a Categorical Exclusion.pdf

1.13.5 Status of Manufacturing Changes.doc

1.13.5 Status of Manufacturing Changes.pdf

1.14.4.2 Labeling.doc

1.14.4.2 Labeling.pdf

2.3 Introduction.doc

2.3 Introduction.pdf

2.3 Introduction1.doc

2.3 Introduction1.pdf

Drug Product (PbO for PNU-100480).doc

Drug Product (PbO for PNU-100480).pdf

Introduction.doc

Drug Product (PbO for PNU-100480)1.doc

Drug Product (PbO for PNU-100480)1.pdf

Drug Product (PbO for PNU-100480)2.doc

Drug Product (PbO for PNU-100480)2.pdf

Introduction.pdf

Introduction1.doc

Introduction1.pdf

P.1 Description and Composition of the Drug Product.doc

P.1 Description and Composition of the Drug Product.pdf

P.1 Description and Composition of the Drug Product1.doc

P.1 Description and Composition of the Drug Product1.pdf

P.2 Pharmaceutical Dev.doc

P.2 Pharmaceutical Dev.pdf

P.3.1 Manufacturer(s).pdf

P.3.1 Manufacturer(s).doc

P.3.2 Batch Formula.pdf

P.3.2 Batch Formula.doc

P.3.3 Description of Manufacturing Process and Process Controls.doc

P.3.3 Description of Manufacturing Process and Process Controls.pdf

P.3.4 Controls of Critical Steps and Intmds.doc

P.3.4 Controls of Critical Steps and Intmds.pdf

P.4 Control of Excipients (Compendial and Non-compendial).doc

P.4 Control of Excipients (Compendial and Non-compendial).pdf

P.4 Control of Excipients (Compendial).doc

P.5.1 Specification(s).doc

P.4 Control of Excipients (Compendial).pdf

P.5.1 Specification(s).pdf

P.5.1 Specification(s)1.pdf

P.5.1 Specification(s)1.doc

P.5.2 Analytical Procedures.doc

P.5.2 Analytical Procedures.pdf

P.5.2 Analytical Procedures1.doc

P.5.2 Analytical Procedures1.pdf

P.5.3 Validation of Analytical Procedures.doc

P.5.3 Validation of Analytical Procedures.pdf

P.5.4 Batch Analyses.doc

P.5.4 Batch Analyses.pdf

P.5.5 Characterisation of Impurities.doc

P.6 Reference.doc

P.5.5 Characterisation of Impurities.pdf

P.5.5 Characterisation of Impurities1.doc

P.5.5 Characterisation of Impurities1.pdf

P.5.6 Justification of Specifications.doc

P.5.6 Justification of Specifications.pdf

P.5.6 Justification of Specifications1.doc

P.5.6 Justification of Specifications1.pdf

P.6 Reference.pdf

P.7 CCSsystem.doc

P.7 CCSsystem.pdf

P.8.1 Stability Summary and Conclusion.doc

P.8.1 Stability Summary and Conclusion1.doc

P.8.1 Stability Summary and Conclusion.pdf

P.8.1 Stability Summary and Conclusion1.pdf

P.8.1 Stability Summary and Conclusion2.doc

P.8.1 Stability Summary and Conclusion2.pdf

P.8.1 Stability Summary and Conclusion3.doc

P.8.1 Stability Summary and Conclusion3.pdf

P.8.1 Stability Summary and Conclusion4.doc

P.8.1 Stability Summary and Conclusion4.pdf

P.8.3 Stability Data.doc

P.8.3 Stability Data.pdf

P.8.3 Stability Data1.doc

P.8.3 Stability Data2.doc

P.8.3 Stability Data1.pdf

P.8.3 Stability Data2.pdf

P.8.3 Stability Data3.doc

P.8.3 Stability Data3.pdf

P.8.3 Stability Data4.doc

S.1.1 Nomenclature.doc

P.8.3 Stability Data4.pdf

S.1.1 Nomenclature.pdf

S.1.2 Structure.doc

S.1.2 Structure.pdf

S.1.3 General Properties.doc

S.1.3 General Properties.pdf

S.2.1 Manufacturer(s).doc

S.2.1 Manufacturer(s).pdf

S.2.1 Manufacturer(s)1.doc

S.2.1 Manufacturer(s)1.pdf

S.2.3 Control of Materials.doc

S.2.2 Description of Manufacturing Process and Process Controls.doc

S.2.2 Description of Manufacturing Process and Process Controls.pdf

S.2.2 Description of Manufacturing Process and Process Controls1.doc

S.2.2 Description of Manufacturing Process and Process Controls1.pdf

S.2.3 Control of Materials.pdf

S.2.6. Manufacturing Process Dev.pdf

S.2.6. Manufacturing Process Dev.doc

S.2.6. Manufacturing Process Dev1.doc

S.2.6. Manufacturing Process Dev1.pdf

S.2.6. Manufacturing Process Dev2.doc

S.2.6. Manufacturing Process Dev2.pdf

S.3.1 Elucidation of Structure and Other Characteristics.doc

S.3.1 Elucidation of Structure and Other Characteristics.pdf

S.3.2 Impurities.doc

S.3.2 Impurities.pdf

S.3.2 Impurities1.doc

S.3.2 Impurities1.pdf

S.4.1 Specification.pdf

S.4.1 Specification.doc

S.4.1 Specification1.doc

S.4.1 Specification1.pdf

S.4.2 Analytical Procedures.doc

S.4.2 Analytical Procedures.pdf

S.4.3 Validation of Analytical Procedures.doc

S.4.4 Batch Analyses.doc

S.4.3 Validation of Analytical Procedures.pdf

S.4.3 Validation of Analytical Procedures1.doc

S.4.3 Validation of Analytical Procedures1.pdf

S.4.4 Batch Analyses.pdf

S.4.4 Batch Analyses1.pdf

S.4.4 Batch Analyses1.doc

S.4.4 Batch Analyses2.pdf

S.4.4 Batch Analyses2.doc

S.4.4 Batch Analyses3.doc

S.4.4 Batch Analyses3.pdf

S.4.5 Justification of Specification.doc

S.4.5 Justification of Specification.pdf

S.4.5 Justification of Specification1.doc

S.4.5 Justification of Specification1.pdf

S.5 Reference.doc

S.5 Reference.pdf

S.5 Reference1.doc

S.6 CCSsystem.doc

S.5 Reference1.pdf

S.6 CCSystem.pdf

S.7.1 Stability Summary and Conclusions.doc

S.7.1 Stability Summary and Conclusions.pdf

S.7.1 Stability Summary and Conclusions1.doc

S.7.1 Stability Summary and Conclusions1.pdf

S.7.1 Stability Summary and Conclusions2.doc

S.7.1 Stability Summary and Conclusions2.pdf

S.7.3 Stability Data.doc

S.7.3 Stability Data.pdf

S.7.3 Stability Data1.doc

S.7.3 Stability Data2.doc

S.7.3 Stability Data1.pdf

S.7.3 Stability Data2.pdf

Waterman KC, Carella AJ, Gumkowski MJ, et al..pdf

A.2 Adventitious Agents Safety Evaluation.doc

Avicel FMC BioPolymer BSETSE statement.pdf

A.2 Adventitious Agents Safety Evaluation.pdf

BR Study Drug Information.doc

BR Study Drug Information.pdf

CoA CM-1180809 100mg tablet.pdf

CoA CM-0310210 (10-083600) 200mg tablet.pdf

GMP Pfizer Groton dd 20 Aug 09.pdf

Lactose Foremost Farms BSETSE statement.pdf

MA Fisher UK IMP 19Jan2009.pdf

Magnesium stearate Mallinckrodt Baker BSETSE.pdf

Sandwich licence MA version 014(Apr2010).pdf

MHRA GMP Fisher Allentown 2007.pdf

Sodium starch glycolate (Explotab) JRS Pharma BSETSE statement.pdf

BR Study Drug Information.pdf

A.2 Adventitious Agents Safety Evaluation.pdf

A.2 Adventitious Agents Safety Evaluation.doc

Avicel FMC BioPolymer BSETSE statement.pdf

CoA CM-1180809 100mg tablet.pdf

CoA CM-0310210 (10-083600) 200mg tablet.pdf

GEN-016 2011 02 PNU-100480 stability Notification approval form.doc

GEN-016 2011 02 PNU-100480 stability Notification approval form.pdf

GMP Pfizer Groton dd 20 Aug 09.pdf

Magnesium stearate Mallinckrodt Baker BSETSE.pdf

Lactose Foremost Farms BSETSE statement.pdf

MA Fisher UK IMP 19Jan2009.pdf

Sandwich licence MA version 014(Apr2010).pdf

MHRA GMP Fisher Allentown 2007.pdf

Sodium starch glycolate (Explotab) JRS Pharma BSETSE statement.pdf

INX000074768.doc

INX000074768.pdf

10CA010 Final Rpt.pdf

Study 10CA010 Rpt Amend 1 - 13-Month Oral Gavage TxStd of PF-02341272 in S-D Rats with 1-Month Recovery.pdf

1.12.14 Environmental Assessment Claim for a Categorical Exclusion.doc

1.12.14 Environmental Assessment Claim for a Categorical Exclusion.pdf

1.14.4.2 Labeling.doc

1.14.4.2 Labeling.pdf

2.3 Introduction.doc

2.3 Introduction.pdf

2.3 Introduction1.doc

2.3 Introduction1.pdf

Drug Product (PbO for PNU-100480).doc

Drug Product (PbO for PNU-100480)1.doc

Drug Product (PbO for PNU-100480).pdf

Drug Product (PbO for PNU-100480)1.pdf

GEN-016 2009 (11) IB CMC approval form.doc

GEN-016 2009 03 B1171001 eIND approval form.doc

GEN-016 2009 (11) IB CMC approval form.doc.pdf

GEN-016 2009 03 B1171001 eIND approval form.pdf

GEN-016 2009 04 QQR eIND approval form.doc

GEN-016 2009 04 QQR eIND approval form.pdf

GEN-016 2010 01 AR approval form.pdf

GEN-016 2010 01 AR approval form.doc

GEN-016 2010 06 eIND Am approval form.doc

GEN-016 2011 02 eIND Am approval form.doc

GEN-016 2010 06 eIND Am approval form.pdf

GEN-016 2011 02 eIND Am approval form.pdf

GEN-016 2011 02 PNU-100480 eIND AR approval form.doc

GEN-016 2011 02 PNU-100480 eIND AR approval form.pdf

GEN016 PNU-100480 eIND Am B1171002 DP s 2009.doc

Introduction.doc

GEN016 PNU-100480 eIND Am B1171002 DP s 2009.doc.pdf

Introduction.pdf

P.1 Description and Composition of the Drug Product1.doc

P.1 Description and Composition of the Drug Product.doc

P.1 Description and Composition of the Drug Product.pdf

P.1 Description and Composition of the Drug Product1.pdf

P.2 Pharmaceutical Dev.doc

P.2 Pharmaceutical Dev.pdf

P.3.1 Manufacturer(s).doc

P.3.1 Manufacturer(s).pdf

P.3.2 Batch Formula.doc

P.3.2 Batch Formula.pdf

P.3.3 Description of Manufacturing Process and Process Controls.doc

P.3.3 Description of Manufacturing Process and Process Controls.pdf

P.3.4 Controls of Critical Steps and Intmds.doc

P.3.4 Controls of Critical Steps and Intmds.pdf

P.4 Control of Excipients (Compendial and Non-compendial).doc

P.4 Control of Excipients (Compendial and Non-compendial).pdf

P.4 Control of Excipients (Compendial).doc

P.4 Control of Excipients (Compendial).pdf

P.6 Reference.doc

P.5.1 Specification(s).doc

P.5.1 Specification(s)1.doc

P.5.1 Specification(s).pdf

P.5.1 Specification(s)1.pdf

P.5.2 Analytical Procedures.doc

P.5.2 Analytical Procedures.pdf

P.5.2 Analytical Procedures1.doc

P.5.2 Analytical Procedures1.pdf

P.5.3 Validation of Analytical Procedures.doc

P.5.3 Validation of Analytical Procedures.pdf

P.5.4 Batch Analyses.doc

P.5.4 Batch Analyses.pdf

P.5.5 Characterisation of Impurities.doc

P.7 CCSsystem.doc

P.5.5 Characterisation of Impurities1.doc

P.5.5 Characterisation of Impurities.pdf

P.5.5 Characterisation of Impurities1.pdf

CM-0290210 granulation.pdf

CM-0290210 granulation{1}.pdf

P.5.6 Justification of Specifications.doc

CM-0310210.pdf

CM-0310210{1}.pdf

P.5.6 Justification of Specifications.pdf

CM-1240810.pdf

P.5.6 Justification of Specifications1.doc

P.5.6 Justification of Specifications1.pdf

P.6 Reference.pdf

P.7 CCSsystem.pdf

CM-1250810.pdf

P.8.1 Stability Summary and Conclusion.doc

DP EBR PNU-0100480 200mg Tablet D0904841 CM-1190809 09-078305 12Nov09.pdf

DP EBR PNU-0100480 100mg Tablet D0904840 CM-1180809 09-078304 09Nov09.pdf

Drug Product PNU-0100480 200mg tablet CM0310210, 10-083600, D0904841.doc

PNU-0100480 25 Common Granulation CM-1170809 D090483913Oct09.pdf

Drug Product PNU-0100480 200mg tablet CM0310210, 10-083600, D0904841.pdf

P.8.1 Stability Summary and Conclusion1.doc

P.8.1 Stability Summary and Conclusion.pdf

P.8.3 Stability Data.pdf

P.8.1 Stability Summary and Conclusion1.pdf

P.8.1 Stability Summary and Conclusion2.doc

P.8.1 Stability Summary and Conclusion2.pdf

P.8.1 Stability Summary and Conclusion3.doc

P.8.1 Stability Summary and Conclusion3.pdf

P.8.1 Stability Summary and Conclusion4.doc

P.8.1 Stability Summary and Conclusion4.pdf

P.8.3 Stability Data.doc

P.8.3 Stability Data1.doc

P.8.3 Stability Data2.doc

P.8.3 Stability Data1.pdf

P.8.3 Stability Data2.pdf

P.8.3 Stability Data3.doc

P.8.3 Stability Data3.pdf

P.8.3 Stability Data4.doc

P.8.3 Stability Data4.pdf

PNU-100480 GPS-GEN-016-F01.doc

S.1.1 Nomenclature.doc

PNU-100480 GPS-GEN-016-F01.doc.pdf

S.1.1 Nomenclature.pdf

S.1.2 Structure.doc

S.1.2 Structure.pdf

S.1.3 General Properties.doc

S.1.3 General Properties.pdf

S.2.1 Manufacturer(s).doc

S.2.1 Manufacturer(s).pdf

S.2.1 Manufacturer(s)1.doc

S.2.1 Manufacturer(s)1.pdf

S.2.2 Description of Manufacturing Process and Process Controls.doc

S.2.2 Description of Manufacturing Process and Process Controls1.doc

S.2.2 Description of Manufacturing Process and Process Controls.pdf

S.2.2 Description of Manufacturing Process and Process Controls1.pdf

S.2.3 Control of Materials.doc

S.2.3 Control of Materials.pdf

S.2.6. Manufacturing Process Dev.doc

S.2.6. Manufacturing Process Dev.pdf

S.2.6. Manufacturing Process Dev1.doc

S.2.6. Manufacturing Process Dev1.pdf

S.2.6. Manufacturing Process Dev2.doc

S.2.6. Manufacturing Process Dev2.pdf

S.3.1 Elucidation of Structure and Other Characteristics.doc

S.3.2 Impurities.doc

S.3.1 Elucidation of Structure and Other Characteristics.pdf

S.3.2 Impurities.pdf

S.3.2 Impurities1.doc

S.4.1 Specification.doc

S.3.2 Impurities1.pdf

S.4.1 Specification.pdf

S.4.1 Specification1.doc

S.4.1 Specification1.pdf

S.4.2 Analytical Procedures.doc

S.4.2 Analytical Procedures.pdf

S.4.3 Validation of Analytical Procedures.doc

S.4.3 Validation of Analytical Procedures.pdf

S.4.3 Validation of Analytical Procedures1.doc

S.4.3 Validation of Analytical Procedures1.pdf

S.4.4 Batch Analyses.doc

S.4.4 Batch Analyses.pdf

S.4.4 Batch Analyses1.doc

S.4.4 Batch Analyses1.pdf

S.4.4 Batch Analyses2.doc

S.4.4 Batch Analyses2.pdf

S.4.4 Batch Analyses3.doc

S.4.4 Batch Analyses3.pdf

S.4.5 Justification of Specification.doc

S.4.5 Justification of Specification.pdf

S.5 Reference.doc

S.4.5 Justification of Specification1.doc

S.4.5 Justification of Specification1.pdf

S.5 Reference.pdf

S.5 Reference1.doc

S.5 Reference1.pdf

S.6 CCSystem.doc

S.6 CCSystem.pdf

S.7.1 Stability Summary and Conclusions.doc

S.7.1 Stability Summary and Conclusions.pdf

S.7.1 Stability Summary and Conclusions1.doc

S.7.1 Stability Summary and Conclusions1.pdf

S.7.1 Stability Summary and Conclusions2.pdf

S.7.1 Stability Summary and Conclusions2.doc

S.7.3 Stability Data.doc

S.7.3 Stability Data.pdf

S.7.3 Stability Data1.doc

S.7.3 Stability Data1.pdf

S.7.3 Stability Data2.doc

S.7.3 Stability Data2.pdf

Risk assessment for out of target particle size Distrb for PNU-100480 batch 6-4140.doc

Risk assessment for out of target particle size Distrb for PNU-100480 batch 6-4140.pdf

GR02779.pdf

GPS-LAB-006-F01 V6.0.pdf

INX000070594.doc

INX000070594.pdf

GPS-LAB-006-F01 V6.0.doc

Micron Tech 081272, (GR01567).pdf

PNU-0100480 Lot 1001P7201 BR Review Checklist (ingoing lot for GR03496).doc.pdf

PNU-0100480 Lot 1001P7201 BR Review Checklist (ingoing lot for GR03496).doc

PNU-0100480 Lot 1002P7202 BR Review Checklist (ingoing lot for GR03497).doc

PNU-0100480 Lot 1002P7202 BR Review Checklist (ingoing lot for GR03497).doc.pdf

PNU-0100480 Lot 1002P7203 BR Review Checklist (ingoing lot for GR03498).doc

PNU-0100480 Lot 1002P7203 BR Review Checklist (ingoing lot for GR03498).doc.pdf

PNU-100480 Lot 1010P7204 BR Review Checklist (ingoing lot for GR04431).pdf

PNU-100480 Lot 102068 (Micron Tech) BR (ingoing lot for PFX000096, seed material).pdf

PNU-100480 Lot 102068 (Micron Tech) BR Checklist (ingoing lot for PFX000096, seed material).pdf

SAFC 0807P7201, (GR01567 umicronized).pdf

SAFC BR for PNU-100480 Lot 1001P7201 (ingoing lot to GR03496).pdf

SAFC BR for PNU-100480 Lot 1002P7203 (ingoing lot to GR03498).pdf

SAFC BR for PNU-100480 Lot 1010P7204 (ingoing lot to GR04431).pdf

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GPS-LAB-036-F02.doc

D0904839-02-G1.doc

GPS-LAB-036-F02.doc.pdf

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D0904840-00-G1.doc.pdf

D0904841-00-G2.doc

D0904841-00-G2.doc.pdf

SPC100001409.doc

SPC100001409.pdf

INX000071988.pdf

CSR-038(P72-005OKORpt).pdf

PNU-0100480 Campaign Summary Rpt from SAFC R2 Campaign (Pfizer lots GR03496, GR03497, GR03498).pdf

DP BDC PNU-0100480 100 mg tablet CM-1180809; 09-078304;D0904840 DPBDC .doc.pdf

DP BDC PNU-0100480 100 mg tablet CM-1180809; 09-078304;D0904840 DPBDC.doc

DP BDC PNU-0100480 200mg tablet; CM-1190809; 09-078305; D0904841.doc

DP BDC PNU-0100480 200mg tablet; CM-1190809; 09-078305; D0904841.pdf

Drug Product PNU-0100480 200mg tablet CM0310210, 10-083600, D0904841.doc

Drug Product PNU-0100480 200mg tablet CM0310210, 10-083600, D0904841.pdf

A1.doc

A1.pdf

API SM for PF-02341272 R1 Campaign.doc

API SM for PF-02341272 R1 Campaign.pdf

PF2341272GR01567DEC2009.doc

PF2341272GR01567DEC2009.doc.pdf

PNU-100480 (PF-02341272) GPS-LAB-021-F01 30 month API review period.doc

PNU-100480 (PF-02341272) GPS-LAB-021-F01 30 month API review period.pdf

Certificate of Compliance for PNU-0100480 Lot 1001P7201 (GR03496).pdf

Certificate of Compliance for PNU-0100480 Lot 1002P7202 (for GR03497).pdf

Certificate of Compliance for PNU-0100480 Lot 1002P7203 (GR03498).pdf

CoC (Clinical) 000005898 GR01567.doc

INX000070537.pdf

CoC (Clinical) 000005898 GR01567.pdf

INX000070684.pdf

INX000070346.pdf

INX000070350.pdf

PNU-1000480 (PF-02341272) Regulatory Tox CoA for GR04431.pdf

PNU-1000480 (PF-02341272) Regulatory Tox CoA for GR04431.doc

GPS-LAB-036-F01 6 week waiver for PNU-0100480 (PF-02341272).doc

GPS-LAB-036-F01 6 week waiver for PNU-0100480 (PF-02341272).pdf

BSETSE Certificate for PNU-0100480 lot 1001P7201 (GR03496).pdf

BSETSE Certificate for PNU-0100480 Lot 1002P7202 (for GR03497).pdf

INX000070688.pdf

BSETSE Certificate for PNU-0100480 Lot 1002P7203 (GR03498).pdf

PF02341272GM2009-226BclowsBRS.doc

PF02341272GM2009-226BclowsBRS.doc.pdf

PF02341272GM2009-370BtaylorgrBRS.doc

PF02341272GM2009-370BtaylorgrBRS.doc.pdf

DP PNU-0100480 200mg tablet; CM-1250810; 10-086598; D0904841.doc

DP PNU-0100480 200mg tablet; CM-1250810; 10-086598; D0904841.pdf

medwatch-2010026268-fu1.pdf

medwatch-2010026268.pdf

PF02341272GM2009-394BDDL.doc

PF02341272GM2009-394BDDL.doc.pdf

PF02341272GM2010-098BDDL.doc

PF02341272GM2010-082RA.doc

PF02341272GM2010-082RA.doc.pdf

PF02341272GM2010-098BDDL.doc.pdf

PF02341272GM2010-522BDDL.doc

PF02341272GM2010-522BDDL.doc.pdf

AMTE TM000004394 SAFC.pdf

AMTE TM100001024 SAFC.pdf

SEG2008-0466.doc

SEG2008-0466.doc.pdf

Analytical Campaign Plan for PNU-100480 (PF-02341272).doc

Analytical Campaign Plan for PNU-100480 (PF-02341272).pdf

Analytical Campaign Plan for PNU-100480 micronization.doc

Analytical Campaign Plan for PNU-100480 micronization.pdf

Analytical Campaign Plan for R2 batches of PNU-100480 (PF-02341272).doc

Analytical Campaign Plan for R3 campaign of PNU-0100480 (PF-02341272).doc

Analytical Campaign Plan for R2 batches of PNU-100480 (PF-02341272).pdf

Analytical Campaign Plan for R3 campaign of PNU-0100480 (PF-02341272).pdf

PNU-100480 (PF-02341272, lot GR03496) API micronized reduced testing memo.doc

PNU-100480 (PF-02341272, lot GR03496) API micronized reduced testing memo.pdf

Reduced ACP memo for recrystallization of API.doc

Reduced ACP memo for recrystallization of API.pdf

Reduced ACP memo for sieving of R2 API batch two, P72-003 (lot 1002P7202 or 6-3929 or GR03497).doc

Reduced ACP memo for sieving of R2 API batch two, P72-003 (lot 1002P7202 or 6-3929 or GR03497).pdf

Reduced ACP memo for sieving of R2 API batches one (P72-002 lot 1001P7201 or 6-3824 or GR03496 and three (P72-004 lot 1002P7203 or 6-4140 or GR03498).doc

Reduced ACP memo for sieving of R2 API batches one (P72-002 lot 1001P7201 or 6-3824 or GR03496 and three (P72-004 lot 1002P7203 or 6-4140 or GR03498).pdf

16.2.5.10.1 Analytical Rpt - B1171003 - PF-02341272 AND PF-04918975 IN HUMAN K2EDTA PLASMA.pdf

16.2.5.10.2 Analytical Rpt - B1171003 - PF-02341272 AND PF-04918975 IN HUMAN URINE SAMPLES.pdf

16.2.5.10.1 B1171002 Analytical Rpt Plasma Linezolid.pdf

16.2.5.10.3 B1171002 Analytical Rpt - Urine.pdf

16.2.5.10.2 B1171002 Analytical Rpt - Plasma.pdf

B1179006 -PF-02341272and PF-04918975 Plasma LTS Addendum 01.pdf

B1179006 Validation Rpt - K2EDTA Plasma.pdf

B1179002 Validation Rpt - Urine.pdf

B1179007 Validation Rpt - Urine - Addendum 01 - LTS.pdf

B1179007 Validation Rpt - Urine.pdf

B1179001 Validaiton Rpt Plasma.pdf

B1179005 Validation Rpt - K3EDTA Plasma.pdf

B1179003 Validation Rpt Addendum 1 - Linezolid in Human K2EDTA Plasma1.pdf

B1179003 Validation Rpt K2EDTA Plasma1.pdf

A8.1 Analytical Rpt plasma.pdf

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