

Table of Contents

Sample Case Report Form	3
Title Page.....	3
Volunteer Demographic Details Form	4
Volunteer Screening Form	7
P-I Check-In Medical Examination.....	13
P-I Check-In Vitals and Well-Being Questionnaire Record	14
P-I Alcohol Test.....	14
P-I Urine Drug Screening.....	15
P-I Serum (β -HCG) Pregnancy Test Evaluation Record.....	15
Inclusion Criteria and Exclusion Criteria.....	16
P-I Subject Check-In Record.....	19
P-I Pre-Dose Restrictions Compliance.....	20
P-I Post-Dose Restrictions Compliance.....	20
P-I Drug Administration Record	21
P-I Blood Sample Collection Record	22
P-I Vitals and Well-Being Questionnaire Record.....	24
P-I Meal Consumption Record	25
P-I Check-Out Medical Examination	26
P-I Subject Check-Out Record	27
P-II Check-In Medical Examination	28
P-II Check-In Vitals and Well-Being Questionnaire Record.....	29
P-II Alcohol Test.....	29
P-II Urine Drug Screening	30
P-II Serum (β -HCG) Pregnancy Test Evaluation Record.....	30
P-II Subject Check-In Record	31
P-II Pre-Dose Restrictions Compliance	32
P-II Post-Dose Restrictions Compliance	32
P-II Drug Administration Record	33
P-II Blood Sample Collection Record	34
P-II Vitals and Well-Being Questionnaire Record	36
P-II Meal Consumption Record	37
P-II Subject Check-Out Record	38
Subject Drop-Out Record.....	39
Subject Withdrawal Record.....	40
Post Study Medical Examination Record	41

Post Study Laboratory Evaluation Record	42
Adverse Event Recording Form.....	43
Adverse Event Follow Up Form.....	45
Concomitant Medication Form.....	47

DM=DEMOGRAPHICS**DS=DISPOSITION**

 ACTIMUS BIO		ACTIMUS BIOSCIENCES PRIVATE LIMITED					Page 1 of 29
		CASE REPORT FORM					
Study No.	PANT-126-22 STUDYID	Version No.	00	Volunteer ID		Subject No.	

APPENDIX-V**Dated: 03 Oct 2022****TITLE PAGE**

Study Title: An open label, randomized, balanced, single-dose, two-treatment, two-period, two-sequence, two-way crossover, oral bioequivalence study of Pantoprazole Sodium Delayed-Release Tablets 40 mg of Graviti Pharmaceuticals Pvt. Ltd. with Protonix® (pantoprazole sodium) delayed-release tablets 40 mg Distributed by Wyeth Pharmaceuticals LLC, A subsidiary of Pfizer Inc., Philadelphia, PA 19101 in healthy, adult, human subjects under fasting conditions.

Status of the subject in the Study	NOT SUBMITTED	<input type="checkbox"/> Withdrawn/Dropout	<input type="checkbox"/> NA
------------------------------------	----------------------	--	-----------------------------

Details of withdrawn/dropout	DTERM
------------------------------	--------------

NOT SUBMITTED ject had any AE/SAE during the study	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA
---	------------------------------	-----------------------------	-----------------------------

If 'Yes' status of AE/SAE:	<input type="checkbox"/> Resolved	<input type="checkbox"/> Under follow up
----------------------------	-----------------------------------	--

Whether the subject's Post study sample has been collected	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA
--	------------------------------	-----------------------------	-----------------------------

If 'No' whether the subject has been followed up	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA
--	------------------------------	-----------------------------	-----------------------------

Whether the subject had any AE/SAE during the Post study	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA
--	------------------------------	-----------------------------	-----------------------------

If 'Yes' whether the subject has been followed up	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA
---	------------------------------	-----------------------------	-----------------------------

Whether the subject has been declared as Lost to follow up	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA
--	------------------------------	-----------------------------	-----------------------------

Remarks (If any)

Total Number of Pages of the Case Report Form	
---	--

Documented by (Sign & Date)	
-----------------------------	--

INVESTIGATOR STATEMENT

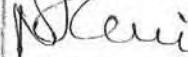
I have reviewed the subject study data and confirm that this CRF reflects the study data to the best of my knowledge.

Name	INVNAM	Dr. K. Srinivas
Designation	NOT SUBMITTED	Principal Investigator
Signature & Date	NOT SUBMITTED	

Confidential

APPROVED**VIRB**

08 APR 2023



Signature Page 3 of 47

VS=VITAL SIGNS SC=SUBJECT CHARACTERISTICS

ACTIMUS BIOSCIENCES PRIVATE LIMITED		Restricted Circulation	
Form Title:	Volunteer Demographic Details Form		
Relevant SOP No.	CR007-13	Page 1 of 3	
VOLUNTEER DEMOGRAPHIC DETAILS			
Volunteer ID Number	SUPPDM.QVAL when QNAM=VOLID	Date <input type="button" value="DMDTC"/> <input type="button" value="RFICDTC"/> <input type="button" value="VSDTC"/> <input type="button" value="SCDTC"/>	
Full Name of the Volunteer	NOT SUBMITTED		
Father's Name	NOT SUBMITTED		
Nationality	NOT SUBMITTED		
Date of Birth	BRTHDTC	Age (Years) (as on date) <input type="button" value="AGE"/> <input type="button" value="AGEU"/>	
Height (Metres)	VTEST when VTESTCD= <input type="button" value="VSORRES"/> <input type="button" value="VSORRESU"/>	Marital Status <input type="button" value="SCTEST when SCTESTCD=MARISTAT"/> <input type="button" value="SCORRES when SCTESTCD=MARISTAT"/>	
Weight (Kg)	HEIGHT <input type="button" value="WEIGHT"/>	Gender <input type="checkbox"/> Male <input type="button" value="SEX"/> Female <input type="checkbox"/> Others	
Body Mass Index (BMI) (kg/m ²)	BMI <input type="button" value="BMIS"/>		
NOT SUBMITTED Sign & Date			
Address	Present Address		
	Permanent Address		
State:		State:	
Nature of the occupation	<input type="checkbox"/> Employee <input type="checkbox"/> Self-Employed	Occupation	
Socio Economic Status			
Is the volunteer literate	SUPPSC.QVAL when QNAM=LITRAT <input type="checkbox"/> Yes <input type="checkbox"/> No	Education Qualification	NOT SUBMITTED
Languages Known: Tick (✓) Relevant:			
Telugu	SUPPSC.QVAL when QNAM=LANGTEL <input type="checkbox"/> Read <input type="checkbox"/> Write <input type="checkbox"/> Speak	<input type="checkbox"/> Understand	<input type="checkbox"/> NA
English	SUPPSC.QVAL when QNAM=LANGENG <input type="checkbox"/> Read <input type="checkbox"/> Write <input type="checkbox"/> Speak	<input type="checkbox"/> Understand	<input type="checkbox"/> NA
Hindi	SUPPSC.QVAL when QNAM=LANGHIN <input type="checkbox"/> Read <input type="checkbox"/> Write <input type="checkbox"/> Speak	<input type="checkbox"/> Understand	<input type="checkbox"/> NA
Others:	SUPPSC.QVAL when QNAM=LANGOTH <input type="checkbox"/> Read <input type="checkbox"/> Write <input type="checkbox"/> Speak	<input type="checkbox"/> Understand	<input type="checkbox"/> NA

SC=SUBJECT CHARACTERISTICS

ACTIMUS BIOSCIENCES PRIVATE LIMITED		Restricted Circulation
Form Title: Volunteer Demographic Details Form		
Relevant SOP No.	CR007-13	Page 2 of 3

HISTORY OF HABITS

Food/Diet	SUPPSC.QVAL when QNAM=DIET	Non-Vegetarian <input type="checkbox"/>
If Non-Vegetarian	<input type="checkbox"/> Egg <input type="checkbox"/> Chicken <input type="checkbox"/> Mutton <input type="checkbox"/> Beef <input type="checkbox"/> Bacon <input type="checkbox"/> Others	
If others, please specify: SUPPSC.QVAL when ONAM=NVGTYP		
SUPRESP Smoking <input type="checkbox"/> SUOCCUR when SUTRT=CIGARETTE <input type="checkbox"/> No Tobacco Chewing <input type="checkbox"/> SUOCCUR when SUTRT=TOBACCO <input type="checkbox"/> No Alcohol <input type="checkbox"/> SUOCCUR when SUTRT=ALCOHOL <input type="checkbox"/> No Drugs of Abuse <input type="checkbox"/> SUOCCUR when SUTRT=DRUGS OF ABUSE <input type="checkbox"/> No		

If the volunteer has the habit of cigarette or beedi smoking mention the details below

Present details	Total days/months/years of smoking	SUDUR when SUTRT=CIGARETTE	Frequency per day	SUDOSFRQ/SUDOSE when SUTRT=CIGARETTE
Past History	If the volunteer had a previous history of smoking, how many days/months/years ago did volunteer quit the same?			SUPPSU.QVAL when QNAM=QUITDUR

If the volunteer has the habit of chewing tobacco, gutka or pan masala, etc mention the details below

Present details	Total days/months/years of chewing	SUDUR when SUTRT=TOBACCO	packets per day	SUDOSFRQ/SUDOSE when SUTRT=TOBACCO
Past History	If the volunteer had a previous history of chewing, how many days/months/years ago did volunteer quit the same?			SUPPSU.QVAL when QNAM=QUITDUR

If the volunteer has the habit of consuming alcohol mention the details below

Present details	Total days/months/years of intake	SUDUR when SUTRT=ALCOHOL	Frequency and quantity	SUDOSFRQ/SUDOSE when SUTRT=ALCOHOL
Past History	If the volunteer had a previous history of consuming alcohol, how many days/months/years ago did volunteer quit the same?			SUPPSU.QVAL when QNAM=QUITDUR

If the volunteer has the habit of consuming drugs of abuse mention the details below

Present details	Total days/months/year of intake	SUDUR when SUTRT=DRUGS OF ABUSE	Frequency and quantity	SUDOSFRQ/SUDOSE when SUTRT=DRUGS OF ABUSE
Past History	If the volunteer had a previous history of drug abuse, how many days/months/years ago did volunteer quit the same?			SUPPSU.QVAL when QNAM=QUITDUR

DM=DEMOGRAPHICS

ACTIMUS BIOSCIENCES PRIVATE LIMITED		Restricted Circulation
Form Title: Volunteer Demographic Details Form		
Relevant SOP No.	CR007-13	Page 3 of 3

HISTORY OF BLOOD LOSS AND PREVIOUS STUDY DETAILS

Has the volunteer donated blood at any time other than ActimusBio? (If Yes, date of latest blood donation)	SUPPDM.QVAL when QNAM=BLODDNT	SUPPDM.QVAL when QNAM=BLODDAT
Has the volunteer participated in study before? (If Yes mention the details of latest study)	SUPPDM.QVAL when QNAM=VPRSBFE	SUPPDM.QVAL when QNAM=PRSTDAT
Has the volunteer encountered any adverse Event in study before? (If Yes mention the details of adverse event)	SUPPDM.QVAL when QNAM=PREAEVNT	SUPPDM.QVAL when QNAM=PREAEDT
Does the volunteers declared as Lost to Follow in the previous study participated? (If Yes mention the details)	SUPPDM.QVAL when QNAM=LFUPRE	SUPPDM.QVAL when QNAM=LFUPREDT
Have the volunteers found positive for Drug of Abuse & Alcohol tests in study before? (If Yes mention the details)	SUPPDM.QVAL when QNAM=DRGABPRE	SUPPDM.QVAL when QNAM=DRGPREDT

DATA DECLARATION

I, hereby declare all the above information provided by me is true as per my knowledge

Volunteer Sign & Date	NOT SUBMITTED
RC/designee Sign & Date	NOT SUBMITTED

Can the volunteer proceed further for screening?	SUPPDM.QVAL when QNAM=SCRSTAT
Comments (if any)	NOT SUBMITTED
Sign & Date of Investigator/Physician	NOT SUBMITTED

MH=MEDICAL HISTORY

CM=CONCOMITANT MEDICATIONS

MASTER COPY

ACTIMUS BIO

RP=REPRODUCTIVE SYSTEM FINDINGS

ACTIMUS BIOSCIENCES PRIVATE LIMITED		Restricted Circulation
Form Title:	Volunteer Screening Form	
Relevant SOP No.:	CR008-13	
Volunteer Registration No.:	NOT SUBMITTED	Date of Screening MHDTC RPDTC

MEDICAL HISTORY

PRESENT MEDICAL HISTORY MHCAT

Any Present Complaints	MHTERM	
------------------------	--------	--

MHCAT PAST MEDICAL HISTORY

Any Past Complaints	Yes	No	Remarks
	MHOCCUR		MHTERM SUPPMH.QVAL when QNAM=MHRMK
RECENT OPD VISIT / IPD STAY			

MEDICATION HISTORY (PRESCRIPTION / OTC)

Name/Type of Drug or Reason for taking Drug	Dosage & Quantity consumed			First & Last dose taken on	
CMTRT	CMDOSE	CMDOSU	CMDOSFRQ	CMSTDTC	CMENDTC

SIGNIFICANT FAMILY HISTORY MHCAT

MHTERM MENSTRUAL AND OBSTETRIC HISTORY <input type="checkbox"/> APPLICABLE or <input type="checkbox"/> NOT APPLICABLE					
LMP					
Obstetric History	RPTEST when RPTESTCD= RPORRES/RPORRESU when RPTESTCD= LMPSTDTC MENFDUR MENREG SUPPRP.QVAL when QNAM=MENRERMK				
	PREGNN	SUPPRP.QVAL when QNAM=OBSRMK			
Method of Contraception	BRTHLVN MENSUR <input type="checkbox"/> Pills BCMETHOD <input type="checkbox"/> Surgery	<input type="checkbox"/> Post menopausal <input type="checkbox"/> Husband underwent vasectomy		<input type="checkbox"/> Abstinence <input type="checkbox"/> NA	
Duration of Contraception if not post menopausal		SUPPRP.QVAL when QNAM=CONTRMKS			

Format No.: CR008/F/001-09

Effective Date: 29 Apr 2023





VS=VITAL SIGNS

ACTIMUS BIOSCIENCES PRIVATE LIMITED			Restricted Circulation	
Form Title:	Volunteer Screening Form			
Relevant SOP No.:	CR008-13 Page 2 of 6			
Volunteer Registration No.:	NOT SUBMITTED	Date of Screening	PEDTC VSDTC	
PHYSICAL EXAMINATION				
PECAT GENERAL EXAMINATION				
	Trait	Normal	Abnormal	Describe Abnormalities (if any)
PETEST when PETESTCD=		PEORRES		PEORRES= Description of abnormality,when examination result is abnormal.
BUILD	Built	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
NOURISH	Nourishment	<input type="checkbox"/>	<input type="checkbox"/>	
POSTR	Posture	<input type="checkbox"/>	<input type="checkbox"/>	
	Trait	Present	Absent	Describe Abnormalities (if any)
PALOR	Pallor	<input type="checkbox"/>	<input type="checkbox"/>	
ICTER	Icterus	<input type="checkbox"/>	<input type="checkbox"/>	
CYANO	Cyanosis	<input type="checkbox"/>	<input type="checkbox"/>	
CLUBB	Clubbing	<input type="checkbox"/>	<input type="checkbox"/>	
EDEMA	Edema	<input type="checkbox"/>	<input type="checkbox"/>	
LYMPAH	Lymphadenopathy	<input type="checkbox"/>	<input type="checkbox"/>	
VENIPTR	Signs of Venipuncture	<input type="checkbox"/>	<input type="checkbox"/>	
VITAL SIGNS				
VTEST when VTESTCD=				
Oral Temperature ($^{\circ}$ F)/ Body Temperature ($^{\circ}$ F)	VSORRES/VSORRESU when VTESTCD=	Pulse rate (per min)	PULSE	
	TEMP			
Blood Pressure (mm of Hg)	SYSBP DIABP	Respiratory Rate (per min)	RESP	
Oxygen Saturation- SPO ₂ (%)	OXYSAT	Others (if any)		

PE=PHYSICAL EXAMINATION

ACTIMUS BIOSCIENCES PRIVATE LIMITED		Restricted Circulation	
Form Title:	Volunteer Screening Form		
Relevant SOP No.:	CR008-13		
Volunteer Registration No.:	NOT SUBMITTED	Date of Screening	PEDTC

SYSTEMIC EXAMINATION

	System	Normal	Abnormal	Not Applicable	Describe Abnormalities (if any)
HEDNEK	Head and Neck	<input type="checkbox"/>	PEORRES	<input type="checkbox"/>	<input type="checkbox"/> PEORRES=Description of abnormality,when examination result is abnormal.
EENT	Eye, Ear, Nose & Throat	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
CARDIO	Cardio - Vascular	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
RESP	Respiratory	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
GASTRO	Gastro - Intestinal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
MUSCULO	Musculo – Skeletal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
NEURO	Neurological	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
GENURI	Genito - Urinary	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
DERMA	Dermatologic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
PSYCHI	Psychiatric	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
PEOTH	Others:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

In case of females only NOT SUBMITTED Not Applicable

BREST	<input type="checkbox"/>	PEORRES	<input type="checkbox"/>	<input type="checkbox"/> NOTE: Populated if any other Examination is Performed
--------------	--------------------------	----------------	--------------------------	---

Remarks	SUPPPE.QVAL when QNAM=PERMK			
----------------	-----------------------------	--	--	--

	Signature	Date
Screening Performed by	NOT SUBMITTED	NOT SUBMITTED

ACTIMUS BIOSCIENCES PRIVATE LIMITED		Restricted Circulation		
Form Title:	Volunteer Screening Form			
Relevant SOP No.:	CR008-13			
Volunteer Registration No.:	NOT SUBMITTED	Date of Screening: LBDTC		
ECG, X-RAY, PAP SMEAR & MAMMOGRAM TEST DETAILS				
Particulars	Performed By	Date		
ECG	NOT SUBMITTED			
Particulars	Performed At	Performed Date		
X-Ray	NOT SUBMITTED			
Pap Smear Test	NOT SUBMITTED			
Mammogram	NOT SUBMITTED			
BLOOD AND URINE SAMPLE COLLECTION DETAILS				
Sample	Amount collected (ml)	Blood Sample collection and Urine sample Receipt time	Remarks	Sign & Date
LBSPEC				
Blood	SUPPLB.QVAL when QNAM=BLDSMP1	NOT SUBMITTED		NOT SUBMITTED
Urine	SUPPLB.QVAL when QNAM=URSMPCL	NOT SUBMITTED		NOT SUBMITTED
Others:				
Others:				

LB=LABORATORY RESULTS
PE=PHYSICAL EXAMINATION
ACTIMUS BIO EG=ECG TEST RESULTS
MB=MICROBIOLOGY SPECIMEN

MASTER COPY

ACTIMUS BIOSCIENCES PRIVATE LIMITED				Restricted Circulation		
Form Title:	Volunteer Screening Form					
Relevant SOP No.:	CR008-13			Page 5 of 6		
Volunteer Registration No.:	NOT SUBMITTED	Date of Screening:	<input type="checkbox"/> LBDTC <input type="checkbox"/> MBDTC <input type="checkbox"/> PEDTC <input type="checkbox"/> EGDTTC			
SCREENING EVALUATION						
Assessment	Status		If Abnormal		Remarks	
	Normal	Abnormal	CS	CNS		
Medical History	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Physical Examination	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
EGTEST when EGTESTCD=INTP	EGORRES when EGTESTCD=INTP		<input type="checkbox"/>		SUPPEG.QVAL when QNAM=EGCLSIG	
ECG			<input type="checkbox"/>		SUPPEG.QVAL when QNAM=DIAGINFR	
PEMETHOD X	PETEST when PETESTCD=CHESTPA	PEORRES when PETESTCD=CHESTPA		<input type="checkbox"/>		SUPPEG.QVAL when QNAM=EGRMK
LBCAT	PETESTCD=CHESTPA					
LBCAT	Clinical Chemistry	<input type="checkbox"/>	LBNRIND <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	SUPPLB.QVAL when QNAM=LBCLSIG
LBCAT	Hematology	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
MBCAT	Serology	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
LBCAT	Urine analysis	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
LBTEST when LBTESTCD=	In case of females only	LBORRES when LBTESTCD=	Applicable <input type="checkbox"/>		<input type="checkbox"/>	
HCG	Serum Pregnancy Test	HCG <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	SUPPLB.QVAL when QNAM=LBCLSIG
PAPSM	Pap Smear Test	PAPSM <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Mammogram	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Other Tests (if any):						
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
PETEST when PETESTCD=CHESTPA	<input type="checkbox"/>		PEORRES when PETESTCD=CHESTPA		<input type="checkbox"/>	
	PEDTC <input type="checkbox"/>					
Chest X-ray-taken on Date:		Normal <input type="checkbox"/>		Abnormal <input type="checkbox"/>		
Note:Lab reports & ECG are valid for 28 days, X-ray is valid for 6 months excluding the day of test performed and check-in day or as per protocol.						
All the general screening investigations are within acceptable Limits: Yes <input type="checkbox"/> No <input type="checkbox"/>						
Remarks	NOT SUBMITTED					
Evaluated By	NOT SUBMITTED					

For Annotations see CRF page no 10

ACTIMUS BIOSCIENCES PRIVATE LIMITED		Restricted Circulation
Form Title:	Volunteer Screening Form	
Relevant SOP No.:	CR008-13	Page 6 of 6

Volunteer Registration No.:		Date of Screening:	
<input type="checkbox"/> Applicable <input type="checkbox"/> Not Applicable	Sample Collection for Repeat Investigations		

Sample	Amount collected (ml)	Time of Sample Collection	Remarks	Signature and Date
Blood				
Urine				
Others:				
Others:				

Evaluation of Repeat Parameters	Status		If Abnormal		Remarks
	Normal	Abnormal	CS	CNS	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Comments(s) about Investigation (s): CNS: Clinically Not Significant, CS: Clinically Significant.

* See the lab reports attached herewith for individual test reports/results.

 Volunteer is: *Screening Passed Screening Failed

Note: *The "Screening Passed" Volunteer is eligible to take part in the study only within the next 28 days of screening (Excluding the day of screening and day of study check-in or as per protocol).

If "Screening Failed" mention the reason.		
---	--	--

Signature	Date
Screening Evaluation Performed by	

PE=PHYSICAL EXAMINATION

 ACTIMUS BIO		ACTIMUS BIOSCIENCES PRIVATE LIMITED				Page 2 of 29
		CASE REPORT FORM				
Study No.	PANT-126-22 STUDYID	Version No.	00	Volunteer ID/ Subject No.	NOT SUBMITTED	Period No.
						VISIT

CHECK-IN MEDICAL EXAMINATION

NOT SUBMITTED Is the volunteer fit for admission procedure based on the Checklist for COVID-19 Testing in Actimus Bio sciences private limited? (SOP GL017-XX)?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Did the volunteer given consent on Informed Consent Document?	<input type="checkbox"/> Yes <input type="checkbox"/> No

Any Present Complaints	SUPPPE.QVAL when QNAM=PRECOMPL			
	If Yes, Please Describe:			
	Normal	Abnormal	Not Applicable	Describe Abnormality
PETEST when PETESTCD= examined	PEORRES when PETESTCD=			
CARDIO Cardiovascular System	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	SUPPPE.QVAL when QNAM=ABNORM
RESP Respiratory System	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
GASTRO Gastro Intestinal System	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
CNS Central Nervous System	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
MUSCULO Musculoskeletal System	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
SKIN Skin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
PEOTH Others	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Comments (if any)

SUPPPE.QVAL when QNAM=PERMK

Well-being	<input type="checkbox"/> Well	<input type="checkbox"/> Unwell	SUPPPE.QVAL when QNAM=MEDWELL
Volunteer is Clinically Fit	<input type="checkbox"/> Yes	<input type="checkbox"/> No	SUPPPE.QVAL when QNAM=VOLCLFIT
Subject can be proceeded further for check-in procedures	SUPPPE.QVAL when QNAM=MEDFIT NA		

Performed by	Signature	Date
	NOT SUBMITTED	PEDTC

VS=VITAL SIGNS

LB=LABORATORY RESULTS

		ACTIMUS BIOSCIENCES PRIVATE LIMITED				Page 3 of 29
CASE REPORT FORM						
Study No.	PANT-126-22	Version No.	00	Volunteer ID/ Subject No.	NOT SUBMITTED	Period No.
						VISIT

VTEST when VTESTCD=

VSORRES/VSORRESU when VTESTCD= WELL-BEING QUESTIONNAIRE RECORD

Body temperature (°F)	TEMP	Pulse Rate (per minute)	PULSE
SpO ₂ (%)	OXYSAT	Blood Pressure (mm of Hg)	SYSBP DIABP
Well-being Assessment	SUPPVS.QVAL when QNAM=WELBENG		
Other(s)	NOT SUBMITTED		
Comments	SUPPVS.QVAL when QNAM=VSRMK		
Performed time	Performed by sign & date		
VSDTC			

ALCOHOL TEST

Method used for	NOT SUBMITTED	<input type="checkbox"/> Urine Sample	<input type="checkbox"/> Blood Sample	<input type="checkbox"/> Breath Analyzer
Start time:	LBDTC			
Amount of sample Collected (mL)	SUPPLB.QVAL when QNAM=URSMPCL			
Test Result	LBTEST when LBTESTCD=ETHANOL			
If Positive; % of Alcohol:	LBORRES/LBORRESU when LBTESTCD=ETHANOL			
End time:	NOT SUBMITTED			
Comments	SUPPVS.QVAL when QNAM=LBRMK			
Performed by:	Date:			

NOT SUBMITTED	Test Interference
Positive	The urine alcohol rapid test dipstick/urine alcohol Cassette colour changes as per the colour provided in kit insert.
Negative	The urine alcohol rapid test dipstick/urine alcohol Cassette colour does not change
Invalid	A result where the outer edges of the colour pad produce a slight but majority of the pad remains colourless the test shall be considered invalid and repeat the test.

LB=LABORATORY RESULTS

 ACTIMUS BIO		ACTIMUS BIOSCIENCES PRIVATE LIMITED CASE REPORT FORM				Page 4 of 29
Study No.	PANT-126-22 STUDYID	Version No.	00	Volunteer ID/ Subject No.	NOT SUBMITTED	Period No. VISIT

URINE DRUG SCREENING

Start time: **LBDTC**

Report for Drug of Abuse

LBTEST when LBTESTCD=	Name of the Test	Results		
AMPHET	Amphetamine (AMP)	<input type="checkbox"/> Positive	<input checked="" type="checkbox"/> Negative	<input type="checkbox"/> Invalid
BARB	Barbiturates (BAR)	<input type="checkbox"/> Positive	<input type="checkbox"/> Negative	<input type="checkbox"/> Invalid
BNZDZPN	Benzodiazepine (BZO)	<input type="checkbox"/> Positive	<input type="checkbox"/> Negative	<input type="checkbox"/> Invalid
COCAINE	Cocaine (COC)	<input type="checkbox"/> Positive	<input type="checkbox"/> Negative	<input type="checkbox"/> Invalid
OPIATE	Morphine/ Opiates/ Heroin (OPI)	<input type="checkbox"/> Positive	<input type="checkbox"/> Negative	<input type="checkbox"/> Invalid
CANNAB	Cannabinoids/ Marijuana/ THC	<input type="checkbox"/> Positive	<input type="checkbox"/> Negative	<input type="checkbox"/> Invalid

End time: **LBDTC**

Comments (if any)

SUPPLB.QVAL when QNAM=LBRMK

Performed by	Signature	Date

LBSPEC SERUM (β -HCG) PREGNANCY TEST EVALUATION RECORD

Volume of blood collected (mL)	SUPPLB.QVAL when QNAM=BLDSMPI	Collected by	NOT SUBMITTED
--------------------------------	-------------------------------	--------------	----------------------

Evaluation of Laboratory Investigations

Result	LBORRES	<input type="checkbox"/> Positive	<input type="checkbox"/> Negative	<input type="checkbox"/> Invalid
--------	----------------	-----------------------------------	-----------------------------------	----------------------------------

Comments (if any)

SUPPLB.QVAL when QNAM=LBRMK

Evaluated by	Signature	Date
	NOT SUBMITTED	NOT SUBMITTED

Conclusion Based on my medical expertise, I found the volunteer Fit Unfit for further process of the study.

Remarks	NOT SUBMITTED
---------	----------------------

Concluded by	Signature	Date
	NOT SUBMITTED	NOT SUBMITTED

IE=INCLUSION/EXCLUSION CRITERIA NOT MET

 ACTIMUS BIO		ACTIMUS BIOSCIENCES PRIVATE LIMITED CASE REPORT FORM				Page 5 of 29	
Study No.	PANT-126-22 STUDYID	Version No.	00	Volunteer ID/ Subject No.	NOT SUBMITTED	Period No.	NOT SUBMITTED

INCLUSION CRITERIA AND EXCLUSION CRITERIA

S.No. IETEST when IETESTCD=	INCLUSION CRITERIA [ECAT=INCLUSION]	YES	NO	NA
INCL01	1. Is the subject able to understand and provide written informed consent?	<input type="checkbox"/>	<input checked="" type="checkbox"/> IEORRES	<input type="checkbox"/>
INCL02	2. Is the subject healthy, adult, human being within 18-45 years of age (both inclusive) weighing at least 50 kgs?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
INCL03	3. Is the subject's Body Mass Index (BMI) in between 18.50 and 24.90 (both inclusive), calculated as weight in Kg/height in m ² ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
INCL04	4. Is the subject of normal health as determined by medical history and physical examination performed within 28 days prior to the drug administration (excluding screening day and period-I check-in day)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
INCL05	5. Is the subject having normal ECG, chest X-ray and vital signs [body temperature 95.0°F (35°C) to 98.6°F (37°C), pulse rate 60 to 100 per minute, systolic blood pressure 100 to 140 mm/Hg, diastolic blood pressure 60 to 90 mm/Hg, respiratory rate 14 to 20 per min and SpO ₂ levels-95% to 100%]?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
INCL06	6. Are the subject's screening laboratory values being within normal limits or laboratory abnormalities considered by the investigator to be of no clinical significance?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
INCL07	7. Whether the subject would be available for the entire study period and is willing to adhere to the protocol requirements as evidenced by written informed consent?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
INCL08	8. Is the male volunteer being willing to follow approved birth control methods (a double barrier method) for the duration of the study as judged by the investigator(s), such as condom with spermicide, condom with diaphragm, or abstinence, vasectomized and willing not to donate sperm during this time?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
INCL09	9. Is the female volunteer of child bearing potential, practicing an acceptable method of birth control at the time of study initiation as judged by the investigator(s), such as condoms, foams, jellies, diaphragm, intrauterine device (IUD) or abstinence or is postmenopausal for at least 1 year or is surgically sterile (bilateral tubal ligation, bilateral oophorectomy or undergone hysterectomy)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
INCL10	10. Is serum pregnancy test "negative" for the female subject at screening and check-in of period-I?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Exclude the volunteer if any one of the given above inclusion criteria is Ticked (✓) as 'NO'				

Confidential

IE=INCLUSION/EXCLUSION CRITERIA NOT MET

 ACTIMUS BIO		ACTIMUS BIOSCIENCES PRIVATE LIMITED CASE REPORT FORM				Page 6 of 29	
Study No.	PANT-126-22	Version No.	00	Volunteer ID/ Subject No.	NOT SUBMITTED		Period No.

S.No.	IETEST when IETESTCD=	EXCLUSION CRITERIA [ECAT=EXCLUSION]	YES	IRES	NA
EXCL01	1.	Whether the subject has any history of hypersensitivity or idiosyncratic reaction to Pantoprazole or any other related drugs?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EXCL02	2.	Is subject had any history or presence of significant cardiovascular, pulmonary, hepatic, renal, gastrointestinal, endocrine, immunological, dermatological, neurological, urogenital or psychiatric disease or disorder?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EXCL03	3.	Is the subject positive for HIV antibody, HCV, Hepatitis B surface antigen or RPR?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EXCL04	4.	Does the subject have history of chronic alcoholism, chronic smoking (more than 10 units per day of cigarettes, bidis, or any other form) or chronic consumption of gutkha, pan masala and tobacco products?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EXCL05	5.	Did the subject consumed alcohol, gutkha, pan masala and tobacco products 48.00 hours prior to period-I check-in?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EXCL06	6.	Does the subject have taken any xanthine containing food or beverages (like tea, coffee, chocolates or cola drinks) 24.00 hours prior to Period-I check-in?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EXCL07	7.	Did the subject consumed grapefruit or its products 03 days prior to the initiation of the study?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EXCL08	8.	Did the subject had taken over the counter (OTC) or enzyme modifying medication or any prescribed medications (including herbal preparation) during the last 07 days of study initiation?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EXCL09	9.	Did the subject participated in any other clinical investigation using experimental drug or had blood loss of more than 350 mL at single occasion in the past 90 days?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EXCL10	10.	Is the subject with positive alcohol test and positive urine screen for drugs of abuse at the time of check-in?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EXCL11	11.	Is the subject suffering from diarrhea in the last 24.00 hours which leads to dehydration?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EXCL12	12.	Is the female subject being pregnant or planning (women with child bearing potential) to become pregnant during the study (if applicable)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EXCL13	13.	Is the female subject in lactation period at the time of study admission (if applicable)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Exclude the volunteer if any one of the above-mentioned exclusion criteria ticked (✓) as 'YES'

IE=INCLUSION/EXCLUSION CRITERIA NOT MET

 ACTIMUS BIO		ACTIMUS BIOSCIENCES PRIVATE LIMITED				Page 7 of 29
CASE REPORT FORM						
Study No.	PANT-126-22	Version No.	00	Volunteer ID/ Subject No.		Period No.
Conclusion		Based on my medical expertise, clinical and laboratory findings of the subject, I find him/her to be ELIGIBLE <input type="checkbox"/> / NOT ELIGIBLE <input type="checkbox"/> <input type="checkbox"/> to participate in this bioequivalence study.				
Allotted Subject Number		NOT SUBMITTED				
Evaluated by		Signature			Date	
		NOT SUBMITTED			IEDTC	

Confidential

NOT SUBMITTED

 ACTIMUS BIO		ACTIMUS BIOSCIENCES PRIVATE LIMITED					Page 8 of 29
		CASE REPORT FORM					
Study No.	PANT-126-22	Version No.	00	Volunteer ID/ Subject No.		Period No.	

SUBJECT CHECK-IN RECORD

Volunteers meet the recommended inclusion and exclusion criteria as per the study protocol	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Baggage check performed	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Frisking performed	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Allotted Subject Number	<input type="checkbox"/> Yes	<input type="checkbox"/> No
#Items issued	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Allotted Locker Number	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Allotted Bed Number	<input type="checkbox"/> Yes	<input type="checkbox"/> No

#ID card, Uniform, Towel, Foot wear and Toiletries

Subject Signature	Check-in time	Performed by Signature and Date

Comments (if any)

Checked By Investigator/Designee	Signature	Date

NOT SUBMITTED

 ACTIMUS BIO		ACTIMUS BIOSCIENCES PRIVATE LIMITED				Page 9 of 29	
		CASE REPORT FORM					
Study No.	PANT-126-22	Version No.	00	Volunteer ID/ Subject No.		Period No.	

PRE-DOSE RESTRICTIONS COMPLIANCE

Restrictions		Compliance		
Housed at least 11.00 hours prior to dosing.		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA		
At least 10.00 hours fasting complied prior to dosing.		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA		
At least 01.00 hour water restriction complied before dosing.		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA		
Comments				
Recorded by	Signature		Date	

POST-DOSE RESTRICTIONS COMPLIANCE

Restrictions		Compliance		
At least 01.00 hour water restriction complied after dosing.		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA		
At least 2.00 hours sitting or semi-inclined position complied after dosing.		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA		
At least 04.00 hours fasting restriction complied after dosing.		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA		
Comments				
Recorded by	Signature		Date	

Confidential

EX=EXPOSURE

 ACTIMUS BIO		ACTIMUS BIOSCIENCES PRIVATE LIMITED					Page 10 of 29
		CASE REPORT FORM					
Study No.	PANT-126-22 STUDYID	Version No.	00	Volunteer ID/ Subject No.	NOT SUBMITTED	Period No.	VISIT

DRUG ADMINISTRATION RECORD

Dosing Station No.: NOT SUBMITTED	Day: Dosing Day NOT SUBMITTED
--	--------------------------------------

EXDOSFRM**Details of Dosage Form**

Tablet Capsule Suspension Pellets with Apple Sauce Patches

Strength: **EXDOSE EXDOSU EXDOSTXT** No. of Dosing Units **SUPPEX.QVAL when QNAM=NUMDOSU**

SUPPEX.QVAL when QNAM=CONSTYPE In-Chewable NA

Treatment/Treatment code **EXTRT** Test (T) Reference (R)

Details of Drug Administration

SUPPEX.QVAL when QNAM=POSTUR

State of Administration EXFAST	<input type="checkbox"/> Fasting	Dosing Posture	<input type="checkbox"/> Sitting	<input type="checkbox"/> Supine
---------------------------------------	----------------------------------	----------------	----------------------------------	---------------------------------

Subject identified SUPPEX.QVAL when QNAM=SBJIDENT	<input type="checkbox"/> Yes	<input type="checkbox"/> No
--	------------------------------	-----------------------------

Verified Treatment Code SUPPEX.QVAL when QNAM=VRFRTCD	<input type="checkbox"/> Yes	<input type="checkbox"/> No
--	------------------------------	-----------------------------

Fasting hours maintained as per protocol SUPPEX.QVAL when QNAM=FSTHPP	<input type="checkbox"/> Yes	<input type="checkbox"/> No
--	------------------------------	-----------------------------

Dosing procedure explained to the sub SUPPEX.QVAL when QNAM=PROCEXP	<input type="checkbox"/> Yes	<input type="checkbox"/> No
--	------------------------------	-----------------------------

Instructed the subject to swallow the given dosage form along with the protocol specified water SUPPEX.QVAL when QNAM=INSTRU	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA
---	------------------------------	-----------------------------	-----------------------------

Dosing done under yellow monochro SUPPEX.QVAL when QNAM=YMONLGT	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA
--	------------------------------	-----------------------------	-----------------------------

Dosing Time	Quantity of Water (mL)		No. of Units	SUPPEX.QVAL when QNAM=NUMADM		
-------------	------------------------	--	--------------	-------------------------------------	--	--

Schedule	Actual	Recommended	Consumed	No. of Units Administered		
NOT SUBMITTED	EXSTDTC	SUPPEX.QVAL when QNAM=WTRCONS	SUPPEX.QVAL when QNAM=WTRRCOM	Unit Check Done	SUPPEX.QVAL when QNAM=MTHCHK	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA
	EXENDTC					

SUPPEX.QVAL when QNAM=EXPIRDAT	SUPPEX.QVAL when QNAM=MFGDAT
---------------------------------------	-------------------------------------

EXLOT	SUPPEX.QVAL when QNAM=STORCNDS
--------------	---------------------------------------

Paste the Unit Dose Label

NOT SUBMITTED

Signature of the Subject

Comments: **SUPPEX.QVAL when QNAM=EXRMK**

	Signature	Date
Administered by	NOT SUBMITTED	NOT SUBMITTED
Witnessed by QA	NOT SUBMITTED	NOT SUBMITTED
Checked by Investigator	NOT SUBMITTED	NOT SUBMITTED

 ACTIMUS BIO		ACTIMUS BIOSCIENCES PRIVATE LIMITED					Page 11 of 29
		CASE REPORT FORM					
Study No.	PANT-126-22 STUDYID	Version No.	00	Volunteer ID/ Subject No.	NOT SUBMITTED	Period No.	VISIT

BLOOD SAMPLE COLLECTION RECORD

SUPPPC.QVAL when QNAM=SMPAMT		Amount of sample (mL):		Anticoagulant used:		SUPPPC.QVAL when QNAM=ANTICOAG	
						pl:	
Sample Collected Under:		SUPPPC.QVAL when QNAM=SAMPLIGT		Chromatic Light		<input type="checkbox"/> Others	
Dosing date: NOT SUBMITTED				Dosing Time: NOT SUBMITTED			
Cannula Insertion Time	Done by (Sign& Date)	Cannula Removal Time	Done By (Sign& Date)	Remarks			
NOT SUBMITTED	NOT SUBMITTED	NOT SUBMITTED	NOT SUBMITTED	NOT SUBMITTED			

BLOOD SAMPLE COLLECTION DETAILS

S. No.	Date	Sample Time Point (hrs)	Verified the Vacutainer for Subject No. & Time Point	Schedule Time of sample collection (hrs)	Actual Time of sample collection (hrs)	Sample collected within scheduled time	If no, Reason	Collected by Sign& Date
1.	PCDT	PCTPT 0.00	NOT SUBMITTED		PCDT	SUPPPC.QVAL when QNAM=COLINTM	<input type="checkbox"/> Yes <input type="checkbox"/> No	NOT SUBMITTED
2.		0.50	<input type="checkbox"/> Yes <input type="checkbox"/> No	SUPPPC.QVAL when QNAM=SCHTM			<input type="checkbox"/> Yes <input type="checkbox"/> No	
3.		1.00	<input type="checkbox"/> Yes <input type="checkbox"/> No				<input type="checkbox"/> Yes <input type="checkbox"/> No	
4.		1.50	<input type="checkbox"/> Yes <input type="checkbox"/> No				<input type="checkbox"/> Yes <input type="checkbox"/> No	
5.		2.00	<input type="checkbox"/> Yes <input type="checkbox"/> No				<input type="checkbox"/> Yes <input type="checkbox"/> No	
6.		2.25	<input type="checkbox"/> Yes <input type="checkbox"/> No				<input type="checkbox"/> Yes <input type="checkbox"/> No	
7.		2.50	<input type="checkbox"/> Yes <input type="checkbox"/> No				<input type="checkbox"/> Yes <input type="checkbox"/> No	
8.		2.75	<input type="checkbox"/> Yes <input type="checkbox"/> No				<input type="checkbox"/> Yes <input type="checkbox"/> No	
9.		3.00	<input type="checkbox"/> Yes <input type="checkbox"/> No				<input type="checkbox"/> Yes <input type="checkbox"/> No	
10.		3.33	<input type="checkbox"/> Yes <input type="checkbox"/> No				<input type="checkbox"/> Yes <input type="checkbox"/> No	
11.		3.67	<input type="checkbox"/> Yes <input type="checkbox"/> No				<input type="checkbox"/> Yes <input type="checkbox"/> No	
12.		4.00	<input type="checkbox"/> Yes <input type="checkbox"/> No				<input type="checkbox"/> Yes <input type="checkbox"/> No	
13.		4.50	<input type="checkbox"/> Yes <input type="checkbox"/> No				<input type="checkbox"/> Yes <input type="checkbox"/> No	
14.		5.00	<input type="checkbox"/> Yes <input type="checkbox"/> No				<input type="checkbox"/> Yes <input type="checkbox"/> No	
15.		5.50	<input type="checkbox"/> Yes <input type="checkbox"/> No				<input type="checkbox"/> Yes <input type="checkbox"/> No	
16.		6.00	<input type="checkbox"/> Yes <input type="checkbox"/> No				<input type="checkbox"/> Yes <input type="checkbox"/> No	
17.		7.00	<input type="checkbox"/> Yes <input type="checkbox"/> No				<input type="checkbox"/> Yes <input type="checkbox"/> No	

For Annotations see CRF page 22

 ACTIMUS BIO		ACTIMUS BIOSCIENCES PRIVATE LIMITED						Page 12 of 29
		CASE REPORT FORM						
Study No.	PANT-126-22	Version No.	00	Volunteer ID/ Subject No.			Period No.	
BLOOD SAMPLE COLLECTION DETAILS								
S. No.	Date	Sample Time Point (hrs)	Verified the Vacutainer for Subject No. & Time Point	Schedule Time of sample collection (hrs)	Actual Time of sample collection (hrs)	Sample collected within scheduled time	If no, Reason	Collected by Sign& Date
18.		8.00	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
19.		10.00	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
20.		12.00*	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
21.		16.00	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
22.		24.00	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
Total No. of samples collected: SUPPPC.QVAL when QNAM=NUMSAMP								
In case of any reason for delay in the sample collection use below codes								
Codes		Reason for delay in the sample collection						
A	Cannula Block							
B	Direct Vein puncture due to Cannula Block							
C	Delayed Sampling due to late arrival of Subject							
D	Delayed due to medical checkup because of ADR/AE							
E	Slow Blood Flow							
F	Delay due to Meal Consumption							
*	Cannula to be removed							
0.5 mL of normal saline will be injected in to the cannula after each sample withdrawal till 10.00 hours post-dose sample and 0.5 mL of saline mixed blood will be discarded from the cannula till 12.00 hours post-dose sample.								
In-house blood samples will be collected within +2 minutes from scheduled time.								
Schedule time of sample collection (hrs) will be as per the dosing time of subject. Differences from the above will be noted as protocol deviations.								
Comments (if any)								
Checked By Investigator		Signature			Date			
		NOT SUBMITTED			NOT SUBMITTED			

VS=VITAL SIGNS

 ACTIMUS BIO		ACTIMUS BIOSCIENCES PRIVATE LIMITED CASE REPORT FORM							Page 13 of 29
		Study No.	PANT-126-22	Version No.	00	Volunteer ID/ Subject No	NOT SUBMITTED	Period No.	
	STUDYID								

VITALS AND WELL BEING QUESTIONNAIRE RECORD

Date of Dosing: NOT SUBMITTED				Dosing Time: NOT SUBMITTED							
Time Pt	Time of Vitals & SWBQ VTEST when VTESTCD= VSORRES/VSORRESU when VTESTCD=	Body Temp (°F)	Pulse Rate (per minute)	SpO ₂ (%)	Blood Pressure (mm of Hg)	VSREASND when VSSTAT="NOT DONE"	W.B.D. No	Remarks	Sign & Date		
									VSPT	VSDTC	TEMP
0.00 Pre-dose	VSTPT		VSDTC	TEMP	PULSE	OXYSAT	SYSBP	DIABP	<input type="checkbox"/>	<input type="checkbox"/>	SUPPVS.QVAL when QNAM=VSRMK
1.00 Post-dose									<input type="checkbox"/>	<input type="checkbox"/>	
3.00 Post-dose									<input type="checkbox"/>	<input type="checkbox"/>	
6.00 Post-dose									<input type="checkbox"/>	<input type="checkbox"/>	
10.00 Post-dose									<input type="checkbox"/>	<input type="checkbox"/>	
24.00 Check-out									<input type="checkbox"/>	<input type="checkbox"/>	

If Required

Actual Time (hrs)	Temp (°F)	Pulse Rate (per minute)	SpO ₂ (%)	Blood Pressure (mm of Hg)	Well Being		Remarks	Done by Sign & Date
					Yes	No		
					<input type="checkbox"/>	<input type="checkbox"/>		
					<input type="checkbox"/>	<input type="checkbox"/>		

Note: Vitals shall be performed within a window period of \pm 45 min. for in-house except for Pre-dose and check out. If vitals are out of range, AE form will be filled and followed up.

Comments	SUPPVS.QVAL when QNAM=VSRMK						
----------	-----------------------------	--	--	--	--	--	--

Checked By Investigator:	Signature			Date			
	NOT SUBMITTED			NOT SUBMITTED			

 Confidential

ML=MEAL CONSUMPTION

 ACTIMUS BIO		ACTIMUS BIOSCIENCES PRIVATE LIMITED				Page 14 of 29
		CASE REPORT FORM				
Study No.	PANT-126-22 STUDYID	Version No.	00	Volunteer ID/ Subject No.	NOT SUBMITTED	Period No. VISIT

MEAL CONSUMPTION RECORD

Date of Dosing: NOT SUBMITTED	Dosing Time: NOT SUBMITTED
-------------------------------	----------------------------

Particulars	Schedule Time & Date	Consumption time (hrs)		Completely		Remarks	Monitored By
		Start	End	MLDOSE = 100 when CONSUMED = Yes	MLDOSE = '<100' when CONSUMED = No		
MLPTPT Dinner (11.00 hrs Pre-dose)	MLTRT NOT SUBMITTED	MLSTDTC	MLENDTC	<input type="checkbox"/> Yes	<input type="checkbox"/> No		
Lunch (4.00 hrs Post-dose)				<input type="checkbox"/> Yes	<input type="checkbox"/> No		
Snacks (9.00 hrs Post-dose)				<input type="checkbox"/> Yes	<input type="checkbox"/> No		
Dinner (13.00 hrs Post-dose)				<input type="checkbox"/> Yes	<input type="checkbox"/> No		

Comments	SUPPML.QVAL when QNAM=MLRMK
----------	-----------------------------

Checked By	Signature	Date
	NOT SUBMITTED	NOT SUBMITTED

For Annotations see CRF page 13

 ACTIMUS BIO		ACTIMUS BIOSCIENCES PRIVATE LIMITED					Page 15 of 29
		CASE REPORT FORM					
Study No.	PANT-126-22	Version No.	00	Volunteer ID/ Subject No.		Period No.	

CHECK OUT MEDICAL EXAMINATION

Any Present Complaints		<input type="checkbox"/> Yes	<input type="checkbox"/> No	If Yes, Please Describe:			
Body system examined		Normal	Abnormal	Not Applicable	Describe Abnormality		
Cardiovascular System		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
Respiratory System		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
Gastro Intestinal System		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
Central Nervous System		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
Musculoskeletal System		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
Skin		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
Others		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
Comments							
Well-being		<input type="checkbox"/> Well	<input type="checkbox"/> Unwell				
Volunteer is Clinically Fit		<input type="checkbox"/> Yes	<input type="checkbox"/> No				
Subject can be proceeded further for check-out procedures					<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA
Performed by		Signature			Date		

NOT SUBMITTED

 ACTIMUS BIO		ACTIMUS BIOSCIENCES PRIVATE LIMITED					Page 16 of 29
		CASE REPORT FORM					
Study No.	PANT-126-22	Version No.	00	Volunteer ID/ Subject No.		Period No.	

SUBJECT CHECK-OUT RECORD

Details			
Subject in normal health/ vitals	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
Items returned (ID card, Uniform, Towel and Foot wear)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
Subject belongings returned	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
Compensation recommended	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA
Instructed subject not to consume alcohol and tobacco throughout study completion	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA
Instructed subject not to take any xanthine containing food or beverages (like tea, coffee, chocolates or cola drinks)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA
Instructed subjects not to consume grapefruit products	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA
Instructed subject should not to consume pan or pan masala, gutkha, masala containing tobacco and supari (betel nut)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA
Instructed subject should not consume prescribed medications within 7 days and enzyme modifying medication or any systemic medication (either prescribed or over-the-counter Including Herbal Preparation) and Monoamine Oxidase Inhibitor (MAOI)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA
Instructed about subsequent period Check-In	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA

Subject Signature	Check-out time	Performed by Signature and Date
Remarks		
Checked By Investigator	Signature	Date

For Annotations see CRF page 13

 ACTIMUS BIO		ACTIMUS BIOSCIENCES PRIVATE LIMITED				Page 17 of 29
		CASE REPORT FORM				
Study No.	PANT-126-22	Version No.	00	Volunteer ID/ Subject No.		Period No.

CHECK-IN MEDICAL EXAMINATION

Is the volunteer fit for admission procedure based on the Checklist for COVID-19 Testing in Actimus Bio sciences private limited? (SOP GL017-XX). Yes No

Any Present Complaints	<input type="checkbox"/> Yes	<input type="checkbox"/> No	If Yes, Please Describe:	
Subject reported any illness during washout period			SUPPPE.QVAL when QNAM=ANYILL	
Body system examined	Normal	Abnormal	Not Applicable	Describe Abnormality
Cardiovascular System	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Respiratory System	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Gastro Intestinal System	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Central Nervous System	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Musculoskeletal System	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Skin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Others	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Comments (if any)				

Well-being	<input type="checkbox"/> Well	<input type="checkbox"/> Unwell	
Volunteer is Clinically Fit	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
Subject can be proceeded further for check-in procedures	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA

Performed by	Signature	Date

 ACTIMUS BIO	ACTIMUS BIOSCIENCES PRIVATE LIMITED					Page 18 of 29
	CASE REPORT FORM					
Study No.	PANT-126-22	Version No.	00	Volunteer ID/ Subject No.		Period No.

VITALS AND WELL-BEING QUESTIONNAIRE RECORD

Body temperature (°F)		Pulse Rate (per minute)	
SpO ₂ (%)		Blood Pressure (mm of Hg)	
Well-being Assessment	<input type="checkbox"/> Well <input type="checkbox"/> Unwell		
Other(s)			
Comments			
Performed time	Performed by sign & date		

ALCOHOL TEST

Method used for Alcohol test:	<input type="checkbox"/> Urine Sample	<input type="checkbox"/> Blood Sample	<input type="checkbox"/> Breath Analyzer
Start time:			
Amount of sample Collected (mL)			
Test Result	<input type="checkbox"/> Positive	<input type="checkbox"/> Negative	<input type="checkbox"/> Invalid
If Positive; % of Alcohol:			
End time:			
Comments			
Performed by:	Date:		

Test Interference

Positive	The urine alcohol rapid test dipstick/urine alcohol. Cassette colour changes as per the colour provided in kit insert.
Negative	The urine alcohol rapid test dipstick/urine alcohol Cassette colour does not change
Invalid	A result where the outer edges of the colour pad produce a slight but majority of the pad remains colourless the test shall be considered invalid and repeat the test.

 ACTIMUS BIO		ACTIMUS BIOSCIENCES PRIVATE LIMITED				Page 19 of 29
CASE REPORT FORM						
Study No.	PANT-126-22	Version No.	00	Volunteer ID/ Subject No.		Period No.

URINE DRUG SCREENING

Start time:						
Report for Drug of Abuse						
Name of the Test		Results				
Amphetamine (AMP)		<input type="checkbox"/> Positive	<input type="checkbox"/> Negative	<input type="checkbox"/> Invalid		
Barbiturates (BAR)		<input type="checkbox"/> Positive	<input type="checkbox"/> Negative	<input type="checkbox"/> Invalid		
Benzodiazepine (BZO)		<input type="checkbox"/> Positive	<input type="checkbox"/> Negative	<input type="checkbox"/> Invalid		
Cocaine (COC)		<input type="checkbox"/> Positive	<input type="checkbox"/> Negative	<input type="checkbox"/> Invalid		
Morphine/ Opiates/ Heroin (OPI)		<input type="checkbox"/> Positive	<input type="checkbox"/> Negative	<input type="checkbox"/> Invalid		
Cannabinoids/ Marijuana/ THC		<input type="checkbox"/> Positive	<input type="checkbox"/> Negative	<input type="checkbox"/> Invalid		
End time:						
Comments (if any)						
Performed by	Signature		Date			

SERUM (β-HCG) PREGNANCY TEST EVALUATION RECORD						
Volume of blood collected (mL)			Collected by			
Evaluation of Laboratory Investigations						
Result	<input type="checkbox"/> Positive		<input type="checkbox"/> Negative	<input type="checkbox"/> Invalid		
Comments (if any)						
Evaluated by	Signature		Date			
Conclusion	Based on my medical expertise, I found the volunteer <input type="checkbox"/> Fit <input type="checkbox"/> Unfit for further process of the study.					
Remarks						
Concluded by	Signature		Date			

NOT SUBMITTED

 ACTIMUS BIO		ACTIMUS BIOSCIENCES PRIVATE LIMITED					Page 20 of 29
		CASE REPORT FORM					
Study No.	PANT-126-22	Version No.	00	Volunteer ID/ Subject No.		Period No.	

SUBJECT CHECK-IN RECORD

Details	Yes	No	NA
Did the subject had abnormal vitals as per vitals and well-being form?			
Did the subject had diarrhea in the last 24 hrs which leads to dehydration?			
Did the subject consume grapefruit during washout period			
Did the subject had any xanthine containing food or beverages (like tea, coffee, chocolates or cola drinks) during washout period			
Did the subject consume pan or pan masala, gutkha, masala containing tobacco and supari (betel nut) during washout period			
Concomitant medication taken by the subject during washout period?			
If yes: a) Details of the drug (if any)			
b) Any drug interaction with the study drug			
Did the subject had positive results for alcohol analysis test			
Did the subject had positive results for UDS (urine drug screen)			
Is the female subject found positive for serum pregnancy test?			
Did the subject donated blood during washout period			
Did the subject had any illness during the washout period			
Whether the investigator / Physician has raised any objection for the volunteer to be included into the study.			
If Yes, mention the reason			

Exclude the subject, if any one of the above is ticked 'yes'.

Baggage check performed	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA
Frisking performed	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
Items issued (ID card, Uniform, Towel, Foot ware and Toiletries)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
Allotted Bed Number	<input type="checkbox"/> Yes	<input type="checkbox"/> No	

Subject Signature	Check-in time	Performed by Signature and Date

Comments		
Checked by	Signature	Date

Confidential

NOT SUBMITTED

 ACTIMUS BIO		ACTIMUS BIOSCIENCES PRIVATE LIMITED					Page 21 of 29
		CASE REPORT FORM					
Study No.	PANT-126-22	Version No.	00	Volunteer ID/ Subject No.		Period No.	

PRE-DOSE RESTRICTIONS COMPLIANCE

Restrictions		Compliance		
Housed at least 11.00 hours prior to dosing.		<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA
At least 10.00 hours fasting complied prior to dosing.		<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA
At least 01.00 hour water restriction complied before dosing.		<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA
Comments				
Recorded by	Signature		Date	

POST-DOSE RESTRICTIONS COMPLIANCE

Restrictions		Compliance		
At least 01.00 hour water restriction complied after dosing.		<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA
At least 2.00 hours sitting or semi-inclined position complied after dosing.		<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA
At least 04.00 hours fasting restriction complied after dosing.		<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA
Comments				
Recorded by	Signature		Date	

 ACTIMUS BIO	ACTIMUS BIOSCIENCES PRIVATE LIMITED					Page 22 of 29
	CASE REPORT FORM					
Study No.	PANT-126-22	Version No.	00	Volunteer ID/ Subject No.		Period No.

DRUG ADMINISTRATION RECORD

Dosing Station No.:		Day: Dosing Day				
Details of Dosage Form						
<input type="checkbox"/> Tablet <input type="checkbox"/> Capsule <input type="checkbox"/> Suspension <input type="checkbox"/> Pellets with Apple Sauce		<input type="checkbox"/> Patches				
Strength:		No. of Dosing Units:				
<input type="checkbox"/> Chewable <input type="checkbox"/> Non-Chewable		<input type="checkbox"/> NA				
Treatment/Treatment code		<input type="checkbox"/> Test (T) <input type="checkbox"/> Reference (R)				
Details of Drug Administration						
State of Administration		<input type="checkbox"/> Fed <input type="checkbox"/> Fasting	Dosing Posture	<input type="checkbox"/> Sitting <input type="checkbox"/> Supine		
Subject identified		<input type="checkbox"/> Yes <input type="checkbox"/> No				
Verified Treatment Code		<input type="checkbox"/> Yes <input type="checkbox"/> No				
Fasting hours maintained as per protocol		<input type="checkbox"/> Yes <input type="checkbox"/> No				
Dosing procedure explained to the subject		<input type="checkbox"/> Yes <input type="checkbox"/> No				
Instructed the subject to swallow the given dosage form along with the protocol specified water		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA				
Dosing done under yellow monochromatic light		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA				
Dosing Time		Quantity of Water (mL)		No. of Units Administered		
Schedule	Actual	Recommended	Consumed		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA	Mouth Check Done
Paste the Unit Dose Label						
				Signature of the Subject		

Comments:

	Signature	Date
Administered by		
Witnessed by QA		
Checked by Investigator		

 ACTIMUS BIO		ACTIMUS BIOSCIENCES PRIVATE LIMITED					Page 23 of 29
		CASE REPORT FORM					
Study No.	PANT-126-22	Version No.	00	Volunteer ID/ Subject No.			Period No.

BLOOD SAMPLE COLLECTION RECORD

Amount of sample (mL):	Anticoagulant used:	Total No. of Samples as per Protocol:		
Sample Collected Under:		<input type="checkbox"/> Luminous Light	<input type="checkbox"/> Monochromatic Light	<input type="checkbox"/> Others
Dosing date:		Dosing Time:		
Cannula Insertion Time	Done by (Sign& Date)	Cannula Removal Time	Done By (Sign& Date)	Remarks

BLOOD SAMPLE COLLECTION DETAILS

S. No.	Date	Sample Time Point (hrs)	Verified the Vacutainer for Subject No. & Time Point	Schedule Time of sample collection (hrs)	Actual Time of sample collection (hrs)	Sample collected within scheduled time	If no, Reason	Collected by Sign& Date
1.		0.00	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
2.		0.50	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
3.		1.00	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
4.		1.50	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
5.		2.00	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
6.		2.25	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
7.		2.50	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
8.		2.75	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
9.		3.00	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
10.		3.33	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
11.		3.67	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
12.		4.00	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
13.		4.50	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
14.		5.00	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
15.		5.50	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
16.		6.00	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
17.		7.00	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		

Confidential

 ACTIMUS BIO		ACTIMUS BIOSCIENCES PRIVATE LIMITED						Page 24 of 29
		CASE REPORT FORM						
Study No.	PANT-126-22	Version No.	00	Volunteer ID/ Subject No.			Period No.	

BLOOD SAMPLE COLLECTION DETAILS

S. No.	Date	Sample Time Point (hrs)	Verified the Vacutainer for Subject No. & Time Point	Schedule Time of sample collection (hrs)	Actual Time of sample collection (hrs)	Sample collected within scheduled time	If no, Reason	Collected by Sign& Date
18.		8.00	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
19.		10.00	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
20.		12.00*	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
21.		16.00	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
22.		24.00	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		

Total No. of samples collected:

In case of any reason for delay in the sample collection use below codes

Codes	Reason for delay in the sample collection
A	Cannula Block
B	Direct Vein puncture due to Cannula Block
C	Delayed Sampling due to late arrival of Subject
D	Delayed due to medical checkup because of ADR/AE
E	Slow Blood Flow
F	Delay due to Meal Consumption
*	Cannula to be removed

0.5 mL of normal saline will be injected in to the cannula after each sample withdrawal till 10.00 hours post-dose sample and 0.5 mL of saline mixed blood will be discarded from the cannula till 12.00 hours post-dose sample.

In-house blood samples will be collected within +2 minutes from scheduled time.

Schedule time of sample collection (hrs) will be as per the dosing time of subject. Differences from the above will be noted as protocol deviations.

Comments (if any)		
	Signature	Date
Checked By Investigator		

For Annotations see CRF page 24

 ACTIMUS BIO		ACTIMUS BIOSCIENCES PRIVATE LIMITED CASE REPORT FORM							Page 25 of 29
		Study No.	PANT-126-22	Version No.	00	Volunteer ID/ Subject No.		Period No.	

VITALS AND WELL BEING QUESTIONNAIRE RECORD

Date of Dosing:				Dosing Time:						
Time Point (hrs)	Time of Vitals & SWBQ		Body Temp (°F)	Pulse Rate (per minute)	SpO ₂ (%)	Blood Pressure (mm of Hg)	Well Being		Remarks	Done by Sign & Date
	Schedule	Actual				Yes	No			
0.00 Pre-dose							<input type="checkbox"/>	<input type="checkbox"/>		
1.00 Post-dose							<input type="checkbox"/>	<input type="checkbox"/>		
3.00 Post-dose							<input type="checkbox"/>	<input type="checkbox"/>		
6.00 Post-dose							<input type="checkbox"/>	<input type="checkbox"/>		
10.00 Post-dose							<input type="checkbox"/>	<input type="checkbox"/>		
24.00 Check-out							<input type="checkbox"/>	<input type="checkbox"/>		

If Required

Actual Time (hrs)	Temp (°F)	Pulse Rate (per minute)	SpO ₂ (%)	Blood Pressure (mm of Hg)	Well Being		Remarks	Done by Sign & Date
					Yes	No		
					<input type="checkbox"/>	<input type="checkbox"/>		
					<input type="checkbox"/>	<input type="checkbox"/>		

Note: Vitals shall be performed within a window period of \pm 45 min. for in-house except for Pre-dose and check out. If vitals are out of range, AE form will be filled and followed up.

Comments			
Checked By Investigator:	Signature	Date	

Confidential

 ACTIMUS BIO	ACTIMUS BIOSCIENCES PRIVATE LIMITED						Page 26 of 29
	CASE REPORT FORM						
Study No.	PANT-126-22	Version No.	00	Volunteer ID/ Subject No.			Period No.

MEAL CONSUMPTION RECORD

Date of Dosing:	Dosing Time:		
-----------------	--------------	--	--

Particulars	Schedule Time & Date	Consumption time (hrs)		Completely consumed		Remarks	Monitored By
		Start	End	<input type="checkbox"/> Yes	<input type="checkbox"/> No		
Dinner (11.00 hrs Pre-dose)				<input type="checkbox"/> Yes	<input type="checkbox"/> No		
Lunch (4.00 hrs Post-dose)				<input type="checkbox"/> Yes	<input type="checkbox"/> No		
Snacks (9.00 hrs Post-dose)				<input type="checkbox"/> Yes	<input type="checkbox"/> No		
Dinner (13.00 hrs Post-dose)				<input type="checkbox"/> Yes	<input type="checkbox"/> No		

Comments	
----------	--

Checked By	Signature	Date

Confidential

NOT SUBMITTED

 ACTIMUS BIO		ACTIMUS BIOSCIENCES PRIVATE LIMITED				Page 27 of 29
		CASE REPORT FORM				
Study No.	PANT-126-22	Version No.	00	Volunteer ID/ Subject No.		Period No.

SUBJECT CHECK-OUT RECORD

Details		
Subject in normal health/ vitals	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Items returned (ID card, Uniform, Towel and Foot wear)	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Subject belongings returned	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Compensation recommended	<input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> NA
Instructed subject not to consume alcohol and tobacco throughout study completion	<input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> NA
Instructed subject not to take any xanthine containing food or beverages (like tea, coffee, chocolates or cola drinks)	<input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> NA
Instructed subjects not to consume grapefruit products	<input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> NA
Instructed subject should not to consume pan or pan masala, gutkha, masala containing tobacco and supari (betel nut)	<input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> NA
Instructed subject should not consume prescribed medications within 7 days and enzyme modifying medication or any systemic medication (either prescribed or over-the-counter Including Herbal Preparation) and Monoamine Oxidase Inhibitor (MAOI)	<input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> NA

Subject Signature	Check-out time	Performed by Signature and Date
Remarks		
Checked By Investigator	Signature	Date

Confidential

DS=DISPOSITION

ACTIMUS BIOSCIENCES PRIVATE LIMITED		Restricted Circulation												
Form title:	Subject Drop-Out Record													
Relevant SOP No:	CR036-13													
SUBJECT DROP-OUT RECORD														
Subject No.	NOT SUBMITTED	Period No.												
Date of Drop-out: DSSTDTC														
Reason	Tick (✓)	Remarks												
Reason for Drop-out														
<table border="0" style="width: 100%;"> <tr> <td style="width: 15%;">DSTERM</td> <td colspan="2"></td> </tr> <tr> <td>1. Voluntarily withdrawn</td> <td colspan="2">DSDECOD=WITHDRAWL BY SUBJECT</td> </tr> <tr> <td>2. Absent for subsequent check-in</td> <td colspan="2">DSDECOD=WITHDRAWL BY SUBJECT</td> </tr> <tr> <td>3. Others: (specify if any)</td> <td colspan="2">DSDECOD=OTHER</td> </tr> </table>			DSTERM			1. Voluntarily withdrawn	DSDECOD=WITHDRAWL BY SUBJECT		2. Absent for subsequent check-in	DSDECOD=WITHDRAWL BY SUBJECT		3. Others: (specify if any)	DSDECOD=OTHER	
DSTERM														
1. Voluntarily withdrawn	DSDECOD=WITHDRAWL BY SUBJECT													
2. Absent for subsequent check-in	DSDECOD=WITHDRAWL BY SUBJECT													
3. Others: (specify if any)	DSDECOD=OTHER													
If subject voluntarily withdrawn, Signature & Date of the Subject		DSSTDTC												
Is the subject eligible to participate in the subsequent period(s) SUPPDS.QVAL when QNAM=ELIGNSP A <input type="checkbox"/>														
Recommendation/ Comments		SUPPDS.QVAL when QNAM=DSRMK												
Compensation Recommended (Tick the applicable)	As per SOP / Protocol Recommendations	NOT SUBMITTED <input type="checkbox"/> NA <input type="checkbox"/>												
Reason for drop-out was Informed to Sponsor		NOT SUBMITTED <input type="checkbox"/> NA <input type="checkbox"/>												
Reason for drop-out was Informed to Ethics committee		NOT SUBMITTED <input type="checkbox"/> NA <input type="checkbox"/>												
Note: Sponsor and EC will be notified for the reason of the Subject drop-out in the sponsor updates and EC periodic review reports respectively through PI. (NA- Not Applicable)														
Remarks	SUPPDS.QVAL when QNAM=DSRMK													
Complied by Investigator (Sign & Date)		NOT SUBMITTED												
Verified by Principal Investigator (Sign & Date)		NOT SUBMITTED												

DS=DISPOSITION

ACTIMUS BIOSCIENCES PRIVATE LIMITED		Restricted Circulation
Form title:	Subject Withdrawal Record	
Relevant SOP No:	CR036-13	

SUBJECT WITHDRAWAL RECORD

Subject No.	NOT SUBMITTED	Period No.	NOT SUBMITTED
Date of withdrawal:	DSSTDTC	Time of withdrawal:	DSSTDTC DSDTC
Reason	Tick (✓)	Remarks	
Reason for Withdrawal			
1. Adverse event	DSDECOD=ADVERSE EVENT		
2. Failure to comply with the requirements of the study	DSDECOD=FAILURE TO MEET CONTINUATION CRITERIA		
3. Erroneous Inclusion in the study	DSDECOD=PROTOCOL-SPECIFIED WITHDRAWAL CRITERIA MET		
4. Meet the Exclusion in the study	DSDECOD=OTHER		
5. Willful withholding of information by the subject	DSDECOD=OTHER		
6. Additional Subject	DSDECOD=OTHER		
7. Others (Specify if any):	DSDECOD=OTHER		

Subject withdrawal decision taken by:	SUPPDS.QVAL when QNAM=DISWTSPI	Principal Investigator <input type="checkbox"/>
In case, withdrawal decision is taken by physician / Investigator whether discussed with PI prior to withdrawal?	SUPPDS.QVAL when ONAM=DECSBY	
Is the subject eligible to participate in the subsequent period(s)	SUPPDS.QVAL when QNAM=ELIGNSP	
Reason for withdrawal is informed to the subject	SUPPDS.QVAL when QNAM=RSNINF	

NOT SUBMITTED	Recommendation/ Comments		
Compensation Recommended (Tick the applicable)	As per SOP / Protocol Recommendations		Yes <input type="checkbox"/> NA <input type="checkbox"/>
	As per EC Recommendation (In case of SAE Only)		Yes <input type="checkbox"/> NA <input type="checkbox"/>
	Any Insurance Claim Process required (In case of SAE Only)		Yes <input type="checkbox"/> NA <input type="checkbox"/>
Informed to Sponsor (In case of SAE only)	Yes <input type="checkbox"/>	No <input type="checkbox"/>	NA <input type="checkbox"/>
Informed to EC (In case of SAE only)	Yes <input type="checkbox"/>	No <input type="checkbox"/>	NA <input type="checkbox"/>
Informed to regulatory bodies (In case of SAE only)	Yes <input type="checkbox"/>	No <input type="checkbox"/>	NA <input type="checkbox"/>
Note: Sponsor and EC will be notified for the reason of the Subject withdrawal in the sponsor updates and EC periodic review reports respectively through PI. (NA-Not Applicable)			

Remarks	SUPPDS.QVAL when QNAM=DSRMK
Complied by Investigator (Sign & Date)	NOT SUBMITTED
Verified by Principal Investigator (Sign & Date)	NOT SUBMITTED

VS=VITAL SIGNS

 ACTIMUS BIO		ACTIMUS BIOSCIENCES PRIVATE LIMITED				Page 28 of 29
		CASE REPORT FORM				
Study No.	PANT-126-22	Version No.	00	Volunteer ID/ Subject No.		Period No. VISIT

For Annotations see CRF page 13

STUDY MEDICAL EXAMINATION RECORD

Any present complaints? Yes No If "Yes", please describe:Female staff nurse present (in case of female subjects) Yes No NA (Not applicable in case of female physician or male subjects).

Systems	Examination	Normal	Abnormal
Cardiovascular System	Inspection: Palpation: Auscultation: Percussion	<input type="checkbox"/>	<input type="checkbox"/>
Respiratory System	Inspection: Palpation: Auscultation: Percussion	<input type="checkbox"/>	<input type="checkbox"/>
Abdomen Inspection	Inspection: Palpation: Auscultation: Percussion	<input type="checkbox"/>	<input type="checkbox"/>
Central Nervous System	Motor system and Sensory system	<input type="checkbox"/>	<input type="checkbox"/>
Skin	Inspection: Palpation: Auscultation	<input type="checkbox"/>	<input type="checkbox"/>

Any other System Examination performed: (As per the investigator or as per the protocol):

[VTEST when VTESTCD=](#)[VSORRES/VSORRESU when VTESTCD=](#)

POST STUDY VITALS

Actual Time (hrs)	Body Temp (°F)	Pulse Rate (per minute)	Blood Pressure (mm of SYSBP)	SpO2 (%)	Well-Being	Remarks	Done by Sign&
							SUPPVS.QVAL when QNAM=WELBENG
VSDTC	TEMP	PULSE	DIABP	OXYSAT			SUPPVS.QVAL when QNAM=VSRMK
Does the subject have any abn?							
<input type="checkbox"/> Yes (Abnormality Detected) SUPPPE.QVAL when QNAM=PSABNORM (Abnormality Detected-NAD)							
If "Yes" Specify the abnormality:							
(If CS, record the same in Adverse Event Form. If CNS, send the volunteer for further procedures.)							
If "No" Volunteer will be sent for further procedures.							
Subject shall be sent for further procedures of post study laboratory investigations as per the protocol SUPPPE.QVAL when QNAM=POSTSAMP							<input type="checkbox"/> YES <input type="checkbox"/> NO
(CNS: Clinically not significant CS: Clinically significant, NA – Not applicable)							
Post Study ECG (if any)		SUPPPE.QVAL when QNAM=POSTECG] Not applicable					
ECG Evaluation		<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> Not applicable					
ECG Comments (in any)		SUPPPE.QVAL when QNAM=POSTECGC					

Signature of the Investigator	Signature	Date
	NOT SUBMITTED	NOT SUBMITTED

Confidential

For Annotations see CRF page 10, 11

 ACTIMUS BIO		ACTIMUS BIOSCIENCES PRIVATE LIMITED				Page 29 of 29
		CASE REPORT FORM				
Study No.	PANT-126-22	Version No.	00	Volunteer ID/ Subject No.		Period No.

POST STUDY LABORATORY EVALUATION RECORD

1. Sample Collection				
Nature of Sample	Amount Collected (ml)	Time of sample collected	Collected by Signature & date	
Blood				
Urine				
Others:				
2. Evaluation of Lab investigations				
Lab investigations		(Tick ✓ the relevant)		
Clinical chemistry investigations		<input type="checkbox"/> Normal	<input type="checkbox"/> Abnormal	<input type="checkbox"/> NA
Hematology		<input type="checkbox"/> Normal	<input type="checkbox"/> Abnormal	<input type="checkbox"/> NA
Pregnancy test (Urine/ Serum)		<input type="checkbox"/> Normal	<input type="checkbox"/> Abnormal	<input type="checkbox"/> NA
Other (s)		<input type="checkbox"/> Normal	<input type="checkbox"/> Abnormal	<input type="checkbox"/> NA
CNS:				
CS:				
CS Parameters to be repeated after _____ Days / _____ weeks.				
CNS: Clinically Not Significant; CS: Clinically significant.				
See the lab reports attached here with for individual test reports/ results.				
All the laboratory investigations are within acceptable Limits: <input type="checkbox"/> Yes <input type="checkbox"/> No				
(If 'No' Refer Adverse Event Forms)				
Remarks				

Signature of Investigator	Signature	Date

Confidential

AE=ADVERSE EVENTS**VS=VITAL SIGNS**

MASTER COPY

PE=PHYSICAL EXAMINATION

ACTIMUS BIOSCIENCES PRIVATE LIMITED			Restricted Circulation	
Form title:	Adverse Event Recording Form		-	
Relevant SOP	CR027-14		Page 1 of 2	
Study No.: STUDYID	Subject No.: NOT SUBMITTED	Period No.: VISIT		
<input type="checkbox"/> SUPPAE.QVAL when QNAM=AEOCCUR <input type="checkbox"/> Wash-out period <input type="checkbox"/> Post Study <input type="checkbox"/> Others:				
Onset of the event SUPPAE.QVAL when QNAM=ONSEVENT	Date	Time		
		AESTDTC		
Recording of the event NOT SUBMITTED	Date	Time		
		NOT SUBMITTED		
Last Dose received Treatment Code: SUPPAE.QVAL when QNAM=LSTRTCD	Date	Time		
Reporting Method	NOT SUBMITTED	<input type="checkbox"/> Observed	<input type="checkbox"/> By Lab Report	<input type="checkbox"/> Others:
Clinical Examination of the Subject: NOT SUBMITTED			<input type="checkbox"/> Not Applicable	
Description of Event	SUPPAE.QVAL when QNAM=SUBCOMPL			
General Examination	NOT SUBMITTED			
Body Temperature (°F)	Pulse Rate/ min.	Blood Pressure (mm/Hg)	Respiratory Rate/ min.	
TEMP	PULSE	SYSBP DIABP	RESP	
Systemic Examination	PETEST when PETESTCD= PHYSAPER			
(Note: Clinical Examination of the subject is not applicable for clinically significant Post study Laboratory investigations)				
Provisional/ Final Diagnosis	AETERM			
Action Taken with respect to A	AEACN	<input type="checkbox"/> Increased Surveillance <input type="checkbox"/> AECONTRT	<input type="checkbox"/> Concomitant Medication	
	AEHOSP	<input type="checkbox"/> Shift to Hospital	<input type="checkbox"/> Others: AEACNOTH	

AE=ADVERSE EVENTS

ACTIMUS BIOSCIENCES PRIVATE LIMITED		Restricted Circulation
Form title:	Adverse Event Recording Form	
Relevant SOP	CR027-14	Page 2 of 2

Severity	Relationship to IMP	Seriousness
AESEV	<input type="checkbox"/> Definite AEREL	AESER
<input type="checkbox"/> Mild	<input type="checkbox"/> Probable	<input type="checkbox"/> Yes
<input type="checkbox"/> Moderate	<input type="checkbox"/> Possible	<input type="checkbox"/> No
<input type="checkbox"/> Severe	<input type="checkbox"/> Unlikely	(If yes, complete SAE form)
	<input type="checkbox"/> Not Related	

NOT SUBMITTED

 Any Investigations advised: Yes No

Sample collection: <input type="checkbox"/> Applicable <input type="checkbox"/> Not Applicable				
Nature of Sample	Amount Collected (ml)	Time of Collection	Remarks	Collected by Sign & Date

 Subject continued in the study **SUPPAE.QVAL when QNAM=SUBCONT** applicable

 If 'No' mention the reason **SUPPAE.QVAL when QNAM=NCONTRS**

If Adverse Event is related to laboratory investigations will be repeated after _____ days/weeks.	
Comments (if any)	SUPPAE.QVAL when QNAM=AERMK
Investigator/Designee Sign & Date	NOT SUBMITTED
Checked by Sign & Date (PI/Co-Investigator)	NOT SUBMITTED

For Annotations see CRF page 43, 44

ACTIMUS BIOSCIENCES PRIVATE LIMITED		Restricted Circulation
Form title:	Adverse Event Follow Up Form	
Relevant SOP	CR027-14	Page 1 of 2

Follow-up Details			
Study No.:	Period No.:	Subject No.:	
Follow up Number			
Date and Time			
Description of Event			
General Examination			
Medical Examination			
Body Temperature (°F)	Pulse Rate/ min.	Blood Pressure (mm/Hg)	Respiratory Rate/ min.
Medical advice if any			
Any Investigations advised			
Action Taken with respect to AE	<input type="checkbox"/> Increased Surveillance <input type="checkbox"/> Shift to Hospital	<input type="checkbox"/> Concomitant Medication <input type="checkbox"/> Others:	
Follow-up done by (Sign & Date)			

Follow up Number			
Date and Time			
Description of Event			
General Examination			
Medical Examination			
Body Temperature (°F)	Pulse Rate/ min.	Blood Pressure (mm/Hg)	Respiratory Rate/ min.
Medical advice if any			
Any Investigations advised			
Action Taken with respect to AE	<input type="checkbox"/> Increased Surveillance <input type="checkbox"/> Shift to Hospital	<input type="checkbox"/> Concomitant Medication <input type="checkbox"/> Others:	
Follow-up done by (Sign & Date)			

AE=ADVERSE EVENTS

DM=DEMOGRAPHICS

ACTIMUS BIO

MASTER COPY

DD=DEATH DETAILS

ACTIMUS BIOSCIENCES PRIVATE LIMITED		Restricted Circulation
Form title:	Adverse Event Follow Up Form	
Relevant SOP	CR027-14	Page 2 of 2

For Annotations see CRF page 11

 Applicable Not Applicable

Nature of Sample	Amount Collected (ml)	Time of collection	Remarks	Sign & Date

Evaluation of Lab investigations

Lab investigations	(Tick ✓ the relevant)		
	<input type="checkbox"/> Normal	<input type="checkbox"/> Abnormal	<input type="checkbox"/> NA
	<input type="checkbox"/> Normal	<input type="checkbox"/> Abnormal	<input type="checkbox"/> NA
	<input type="checkbox"/> Normal	<input type="checkbox"/> Abnormal	<input type="checkbox"/> NA
	<input type="checkbox"/> Normal	<input type="checkbox"/> Abnormal	<input type="checkbox"/> NA

CNS:

CS:

Repeat sample required: Yes No NA

If repeat sample required, after how many days sample to be collected approximately _____ days.

Evaluated by (Sign & Date):

Outcome of Adverse Event

<input type="checkbox"/> If Resolved AEOUT	Resolved Date : AEENDTC	Resolved Time : AEENDTC
	<input type="checkbox"/> Recovered without sequelae AEOUT	<input type="checkbox"/> Recovered with sequelae AEOUT
Duration of the Event: (Onset time of event to Resolution time of event)		AEDUR
Note: Duration of in-house adverse event shall be mentioned in hours & Post study adverse events in days)		
<input type="checkbox"/> If Ongoing AEENRF condition worsening		<input type="checkbox"/> Condition Recovering
<input type="checkbox"/> If Died	Date of death: DTHDT	Time of death: DTHDT
	Subject autopsy was done? DDTEST when DDTESTCD = AUTOPIND DDORRES	
	Give cause of the death: DDTEST when DDTESTCD = PRCDT DDORRES	
<input type="checkbox"/> If Unknown	NOT SUBMITTED	
Final Diagnosis	AETERM	
Comments (If any)	SUPPAE.QVAL when QNAM=AERMK	
Investigator/Designee Sign & Date	NOT SUBMITTED	
Principal/Co-Investigator Sign & Date	NOT SUBMITTED	

CM=CONCOMITANT MEDICATION

ACTIMUS BIOSCIENCES PRIVATE LIMITED		Restricted Circulation
Form title:	Concomitant Medication Form	
Relevant SOP	CR027-14	
Study No.:	STUDYID	Subject No.: NOT SUBMITTED
Period No.:	VISIT	
Concomitant details Number		
Brand Name & Drug Name	SUPPCM.QVAL when QNAM=COMPSTN CMTRT SUPPCM.QVAL when QNAM=TRTBRAND	
Strength	SUPPCM.QVAL when QNAM=TRTBRACH SUPPCM.QVAL when QNAM=TRTSTRNG	
Dose given	CMDOSE	CMDOSU CMDOSFRM CMDOSTXT CMDOSFRQ
Route of Administration	CMROUTE	
Date of Administration	CMSTDTC	Time of Administration: CMENDTC
Administered by	NOT SUBMITTED	Verified by: NOT SUBMITTED
Concomitant details Number		
Brand Name & Drug Name	SUPPCM.QVAL when QNAM=COMPSTN CMTRT SUPPCM.QVAL when QNAM=TRTBRAND	
Strength	SUPPCM.QVAL when QNAM=TRTBRACH SUPPCM.QVAL when QNAM=TRTSTRNG	
Dose given	CMDOSE	CMDOSU CMDOSFRM CMDOSTXT CMDOSFRQ
Route of Administration	CMROUTE	
Date of Administration	CMSTDTC	Time of Administration: CMENDTC
Administered by sign& date	NOT SUBMITTED	Verified by: NOT SUBMITTED
Concomitant details Number		
Brand Name & Drug Name	SUPPCM.QVAL when QNAM=COMPSTN CMTRT SUPPCM.QVAL when QNAM=TRTBRAND	
Strength	SUPPCM.QVAL when QNAM=TRTBRACH SUPPCM.QVAL when QNAM=TRTSTRNG	
Dose given	CMDOSE	CMDOSU CMDOSFRM CMDOSTXT CMDOSFRQ
Route of Administration	CMROUTE	
Date of Administration	CMSTDTC	Time of Administration: CMENDTC
Administered by sign& date	NOT SUBMITTED	Verified by: NOT SUBMITTED
Concomitant details Number		
Brand Name & Drug Name	SUPPCM.QVAL when QNAM=COMPSTN CMTRT SUPPCM.QVAL when QNAM=TRTBRAND	
Strength	SUPPCM.QVAL when QNAM=TRTBRACH SUPPCM.QVAL when QNAM=TRTSTRNG	
Dose given	CMDOSE	CMDOSU CMDOSFRM CMDOSTXT CMDOSFRQ
Route of Administration	CMROUTE	
Date of Administration	CMSTDTC	Time of Administration: CMENDTC
Administered by sign& date	NOT SUBMITTED	Verified by: NOT SUBMITTED
Remarks (if any)	SUPPCM.QVAL when QNAM=CMRMK	
Checked by (PI/Designee)	NOT SUBMITTED	