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**DM=DEMOGRAPHICS****DS=DISPOSITION**

 <b>ACTIMUS BIO</b>		ACTIMUS BIOSCIENCES PRIVATE LIMITED					Page 1 of 53
		CASE REPORT FORM					
Study No.	PANT-127-22 <b>STUDYID</b>	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-sequence, four-period, fully replicated, cross over 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 fed conditions.

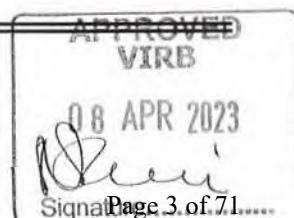
Status of the subject in the Study	<b>NOT SUBMITTED</b>	<input type="checkbox"/> Withdrawn/Dropout	<input type="checkbox"/> NA
Details of withdrawn/dropout	<b>DSTERM</b>		
<b>NOT SUBMITTED</b> subject had any AE/SAE during the study	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> 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
<b>Remarks (If any)</b>			
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	<b>INVNAM</b>	<b>Dr. K. Srinivas</b>
Designation	<b>NOT SUBMITTED</b>	<b>Principal Investigator</b>
Signature & Date	<b>NOT SUBMITTED</b>	

Confidential





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	
<b>VOLUNTEER DEMOGRAPHIC DETAILS</b>			
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	BRTHDT	Age (Years) (as on date) <input type="button" value="AGE"/> <input type="button" value="AGEU"/>	
Height (Me)	VSTEST when VTESTCD= VSORRES/VSORRESU when VTESTCD=	Marital Status <input type="button" value="SCTEST when SCTESTCD=MARISTAT"/> <input type="button" value="SCORRES when SCTESTCD=MARISTAT"/>	
Weight (Kg)	HEIGHT	Gender <input type="checkbox"/> Male <input type="button" value="SEX"/> Female <input type="checkbox"/> Others	
Body Mass Index (BMI) (kg/m <sup>2</sup> )	BMI		
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 <input type="button" value="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**

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

**HISTORY OF HABITS**

Food/Diet	<b>SUPPSC.QVAL when QNAM=DIET</b>	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: <b>SUPPSC.QVAL when QNAM=NVGTYP</b>		
<b>SUPRESP</b>		
Smoking	<input type="checkbox"/> <b>SUOCCUR when SUTRT=CIGARETTE</b>	<input type="checkbox"/> No
Tobacco Chewing	<input type="checkbox"/> <b>SUOCCUR when SUTRT=TOBACCO</b>	<input type="checkbox"/> No
Alcohol	<input type="checkbox"/> <b>SUOCCUR when SUTRT=ALCOHOL</b>	<input type="checkbox"/> Yes
Drugs of Abuse	<input type="checkbox"/> <b>SUOCCUR when SUTRT=DRUGS OF ABUSE</b>	<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	<b>SUDUR when SUTRT=CIGARETTE</b>	Frequency per day	<b>SUDOSFRQ/SUDOSE when SUTRT=CIGARETTE</b>
Past History	If the volunteer had a previous history of smoking, how many days/months/years ago did volunteer quit the same?			<b>SUPPSU.QVAL when QNAM=QUITDUR</b>

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

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

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

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

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

**DM=DEMOGRAPHICS**

<b>ACTIMUS BIOSCIENCES PRIVATE LIMITED</b>		<b>Restricted Circulation</b>
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	<span style="border: 1px solid blue; padding: 2px;">NOT SUBMITTED</span>
RC/designee Sign & Date	<span style="border: 1px solid blue; padding: 2px;">NOT SUBMITTED</span>

Can the volunteer proceed further for screening?

SUPPDM.QVAL when QNAM=SCRSTAT

Comments (if any)	<span style="border: 1px solid blue; padding: 2px;">NOT SUBMITTED</span>
Sign & Date of Investigator/Physician	<span style="border: 1px solid blue; padding: 2px;">NOT SUBMITTED</span>

MH=MEDICAL HISTORY

CM=CONCOMITANT MEDICATIONS



MASTER COPY

RP=REPRODUCTIVE SYSTEM FINDINGS

ACTIMUS BIOSCIENCES PRIVATE LIMITED		Restricted Circulation	
Form Title:	Volunteer Screening Form		
Relevant SOP No.:	CR008-12		
Volunteer Registration No.:	NOT SUBMITTED	Date of Screening	
		MHDTC RPDTC	
<b>MEDICAL HISTORY</b>			
<b>PRESENT MEDICAL HISTORY</b> MHCAT			
Any Present Complaints	MHTERM		
<b>PAST MEDICAL HISTORY</b>			
Any Past Complaints	Yes	No	Remarks
	MHOCCUR		MHTERM SUPPMH.QVAL when QNAM=MHRMK
RECENT OPD VISIT / IPD STAY			
<b>MEDICATION HISTORY (PRESCRIPTION / OTC)</b>			
Name/Type of Drug or Reason for taking Drug	Dosage & Quantity consumed		First & Last dose taken on
CMTRT	CMDOSE	CMDOSU	CMDOSFRQ
			CMSTDTC CMENDTC
<b>SIGNIFICANT FAMILY HISTORY</b> MHCAT			
<b>MHTERM MENSTRUAL AND OBSTETRIC HISTORY</b> <input type="checkbox"/> APPLICABLE or <input type="checkbox"/> NOT APPLICABLE			
LMP	RPTEST when RPTESTCD= RPORRES/RPORRESU when RPTESTCD=		
Obstetric History	LMPSTDTC MENFDUR MENREG SUPPRP.QVAL when QNAM=MENRERMK PREGNN SUPPRP.QVAL when QNAM=OBSRMK BRTHLVN		
Method of Contraception	MENSUR <input type="checkbox"/> Barrier 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		

**VS=VITAL SIGNS**

ACTIMUS BIOSCIENCES PRIVATE LIMITED			Restricted Circulation	
Form Title:	Volunteer Screening Form			
Relevant SOP No.:	CR008-12			
Volunteer Registration No.:	NOT SUBMITTED	Date of Screening	PEDTC VSDTC	
<b>PHYSICAL EXAMINATION</b>				
<b>PECAT GENERAL EXAMINATION</b>				
<b>PETEST</b> when PETESTCD=	Trait	Normal	Abnormal	Describe Abnormalities (if any)
<b>BUILD</b>	Built	<input type="checkbox"/>	<input type="checkbox"/>	PEORRES=Description of abnormality,when examination result is abnormal.
<b>NOURISH</b>	Nourishment	<input type="checkbox"/>	<input type="checkbox"/>	
<b>POSTR</b>	Posture	<input type="checkbox"/>	<input type="checkbox"/>	
<b>PALOR</b>	Trait	Present	Absent	Describe Abnormalities (if any)
	Pallor	<input type="checkbox"/>	<input type="checkbox"/>	
<b>ICTER</b>	Icterus	<input type="checkbox"/>	<input type="checkbox"/>	
<b>CYANO</b>	Cyanosis	<input type="checkbox"/>	<input type="checkbox"/>	
<b>CLUBB</b>	Clubbing	<input type="checkbox"/>	<input type="checkbox"/>	
<b>EDEMA</b>	Edema	<input type="checkbox"/>	<input type="checkbox"/>	
<b>LYMPAH</b>	Lymphadenopathy	<input type="checkbox"/>	<input type="checkbox"/>	
<b>VENIPTR</b>	Signs of Venipuncture	<input type="checkbox"/>	<input type="checkbox"/>	
<b>VITAL SIGNS</b>				
Oral Temperature ( $^{\circ}$ F)/ Body Temperature ( $^{\circ}$ F)	VSTEST when VSTESTCD=	VSORRES/VSORRESU when VSTESTCD=	Respiratory Rate (per min)	PULSE
Blood Pressure (mm of Hg)	SYSBP DIABP		Respiratory Rate (per min)	RESP
Oxygen Saturation- SPO <sub>2</sub> (%)	OXYSAT		Others (if any)	

## PE=PHYSICAL EXAMINATION

ACTIMUS BIOSCIENCES PRIVATE LIMITED				Restricted Circulation
Form Title:	Volunteer Screening Form			
Relevant SOP No.:	CR008-12			Page 3 of 6
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      Applicable <input type="checkbox"/> NOT SUBMITTED <input type="checkbox"/> Not applicable <input type="checkbox"/>					

BREST	Breast	<input type="checkbox"/> PEORRES	<input type="checkbox"/>	<input type="checkbox"/>	NOTE: Populated if any other Examination is Performed
Remarks <input type="checkbox"/> SUPPPE.QVAL when QNAM=PERMK					

	Signature	Date
Screening Performed by	NOT SUBMITTED	NOT SUBMITTED

**LB=LABORATORY RESULTS**

ACTIMUS BIOSCIENCES PRIVATE LIMITED		Restricted Circulation
Form Title:	Volunteer Screening Form	
Relevant SOP No.:	CR008-12	Page 4 of 6
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	Documented by Sign & 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=URSMPC1	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.: **CR008-12**

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Volunteer Registration No.:

**NOT SUBMITTED**

Date of Screening:

**LBDTC MBDTC****PEDTC EGDTC****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					SUPPEG.QVAL when QNAM=EGCLSIG
ECG	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	SUPPEG.QVAL when QNAM=DIAGINFR
PEMETHOD X PETEST when PETESTCD=CHESTPA	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	SUPPEG.QVAL when QNAM=EGRMK
LBCAT Clinical Chemistry	<input type="checkbox"/>	<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"/>	

**In case of females only      Applicable       Not Applicable** 

LBTEST when LBTESTCD=	<b>LBORRES when LBTESTCD=</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<b>SUPPLB.QVAL when QNAM=LBCLSIG</b>
HCG Serum Pregnancy Test	<b>HCG</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
PAPSM Pap Smear Test	<b>PAPSM</b>	<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"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>PETEST when PETESTCD=CHESTPA</b>	<b>PEORRES when PETESTCD=CHESTPA</b>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Chest X-ray-taken on Date:</b>	<b>PEDTC</b>	<input type="checkbox"/>	<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  No

Remarks	<b>NOT SUBMITTED</b>
Evaluated By	<b>NOT SUBMITTED</b>

**For Annotations see CRF page no 11**

<b>ACTIMUS BIOSCIENCES PRIVATE LIMITED</b>					<b>Restricted Circulation</b>
Form Title:	Volunteer Screening Form				
Relevant SOP No.:	CR008-12				Page 6 of 6
<b>Volunteer Registration No.:</b>				<b>Date of Screening:</b>	
<input type="checkbox"/> Applicable <input type="checkbox"/> Not Applicable		<b>Sample Collection for Repeat Investigations</b>			
Sample	Amount collected (ml)	Time of Sample Collection		Remarks	Signature and Date
Blood					
Urine					
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 <input type="checkbox"/> Screening Failed <input type="checkbox"/>					
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	
<b>Screening Evaluation Performed by</b>					

## PE-PHYSICAL EXAMINATION

 ACTIMUS BIO		ACTIMUS BIOSCIENCES PRIVATE LIMITED				Page 2 of 53
		CASE REPORT FORM				
Study No.	PANT-127-22 <b>STUDYID</b>	Version No.	00	Volunteer ID/ Subject No.	<b>NOT SUBMITTED</b>	Period No. <b>VISIT</b>

## CHECK-IN MEDICAL EXAMINATION

<b>NOT SUBMITTED</b>	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		
		Normal	Abnormal	Not Applicable
		PEORRES when PETESTCD=		
<b>PETEST</b> when PETESTCD=	examined	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>CARDIO</b>	Cardiovascular System	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>RESP</b>	Respiratory System	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>GASTRO</b>	Gastro Intestinal System	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>CNS</b>	Central Nervous System	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>MUSCULO</b>	Musculoskeletal System	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>SKIN</b>	Skin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>PEOTH</b>	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
	<b>NOT SUBMITTED</b>	<b>PEDTC</b>

**VS=VITAL SIGNS****LB=LABORATORY RESULTS**

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**VTEST when VTESTCD=** **HEALTHS AND WELL-BEING QUESTIONNAIRE RECORD****VSORRES/VSORRESU when VTESTCD=**

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

**ALCOHOL TEST**

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

<b>NOT SUBMITTED</b>	<b>Test Interference</b>
<b>Positive</b>	The urine alcohol rapid test dipstick/urine alcohol Cassette colour changes as per the colour provided in kit insert.
<b>Negative</b>	The urine alcohol rapid test dipstick/urine alcohol Cassette colour does not change
<b>Invalid</b>	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

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## URINE DRUG SCREENING

Start time: LBDTC

## Report for Drug of Abuse

LBTEST when LBTESTCD=	Name of the Test	LBORRES		
AMPHET	Amphetamine (AMP)	<input type="checkbox"/> Positive	<input 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
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LBSPEC SERUM ( $\beta$ -HCG) PREGNANCY TEST EVALUATION RECORD

Volume of blood collected (mL)	SUPPLB.QVAL when QNAM=BLDSMPI	Collected by	NOT SUBMITTED
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## Evaluation of Laboratory Investigations

Result	LBORRES	<input type="checkbox"/> Positive	<input type="checkbox"/> Negative	<input type="checkbox"/> Invalid
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## 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 <input type="checkbox"/> Fit <input type="checkbox"/> Unfit for further process of the study.	
Remarks	NOT SUBMITTED	
Concluded by	Signature	Date
	NOT SUBMITTED	NOT SUBMITTED

**IE=INCLUSION/EXCLUSION CRITERIA NOT MET**

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<b>STUDYID</b>						<b>Period No.</b>	<b>NOT SUBMITTED</b>

**INCLUSION CRITERIA AND EXCLUSION CRITERIA**

S.N.O	INCLUSION CRITERIA [ECAT=INCLUSION]	YES	NO	NA
IETEST when IETESTCD=				
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 <sup>2</sup> ?	<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 <sub>2</sub> 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'				

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**IE=INCLUSION/EXCLUSION CRITERIA NOT MET**

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S.No	IETEST when IETESTCD= EXCLUSION CRITERIA IECAT=EXCLUSION	YES	NO	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**

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<b>Conclusion</b>		Based on my medical expertise, clinical and laboratory findings of the subject, I find him/her to be <b>ELIGIBLE</b> <input type="checkbox"/> / <b>NOT ELIGIBLE</b> <input type="checkbox"/> to participate in this bioequivalence study.					
Allotted Subject Number		NOT SUBMITTED					
Evaluated by		Signature			Date		
		NOT SUBMITTED			IEDTC		

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**NOT SUBMITTED**

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**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 <input type="checkbox"/> NA
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)		
<b>Checked By Investigator/Designee</b>	Signature	Date

**NOT SUBMITTED**

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**PRE-DOSE RESTRICTIONS COMPLIANCE**

<b>Restrictions</b>		<b>Compliance</b>		
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 consumption of high fat and high calorie breakfast.		<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
<b>Comments</b>				
<b>Recorded by</b>	<b>Signature</b>		<b>Date</b>	

**POST-DOSE RESTRICTIONS COMPLIANCE**

<b>Restrictions</b>		<b>Compliance</b>		
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
<b>Comments</b>				
<b>Recorded by</b>	<b>Signature</b>		<b>Date</b>	

## EX=EXPOSURE

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## DRUG ADMINISTRATION RECORD

Dosing Station No.: <a href="#">NOT SUBMITTED</a>	Day: Dosing Day <a href="#">NOT SUBMITTED</a>
<b>EXDOSFRM Details of Dosage Form</b>	
<input type="checkbox"/> Tablet <input type="checkbox"/> Capsule <input type="checkbox"/> Suspension <input type="checkbox"/> Pellets with Apple Sauce <input type="checkbox"/> Patches	
Strength: <a href="#">EXDOSE</a> <a href="#">EXDOSU</a> <a href="#">EXDOSTXT</a>	No. of Dosing Unit <a href="#">SUPPEX.QVAL when QNAM=NUMDOSU</a>
<a href="#">SUPPEX.QVAL when QNAM=CONSTYPE</a> <input type="checkbox"/> Chewable	<input type="checkbox"/> Non-Chewable <input type="checkbox"/> NA
Treatment/Treatment code <a href="#">EXTRT</a>	<input type="checkbox"/> Test (T) <input type="checkbox"/> Reference (R)

<b>Details of Drug Administration</b>		<a href="#">SUPPEX.QVAL when QNAM=POSTUR</a>		
State of Administration <a href="#">EXFAST</a>		<input type="checkbox"/> Fasting	Dosing Posture	<input type="checkbox"/> Sitting <input type="checkbox"/> Supine
Subject identified <a href="#">SUPPEX.QVAL when QNAM=SBJIDENT</a>		<input type="checkbox"/> Yes <input type="checkbox"/> No		
Verified Treatment Code <a href="#">SUPPEX.QVAL when QNAM=VRFTRTCD</a>		<input type="checkbox"/> Yes <input type="checkbox"/> No		
Fasting hours maintained as per protocol <a href="#">SUPPEX.QVAL when QNAM=FSTHPP</a>		<input type="checkbox"/> Yes <input type="checkbox"/> No		
Dosing procedure explained to the subject <a href="#">SUPPEX.QVAL when QNAM=PROCEXP</a>		<input type="checkbox"/> Yes <input type="checkbox"/> No		
Instructed the subject to swallow the given dosage form along with the protocol specified water <a href="#">SUPPEX.QVAL when QNAM=INSTRU</a>		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA		
Dosing done under yellow monochromatic light <a href="#">SUPPEX.QVAL when QNAM=YMONLGT</a>		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA		
Dosing Time		Quantity of Water (mL)	No. of Units Administered	<a href="#">SUPPEX.QVAL when QNAM=NUMADM</a>
Schedule	Actual	Recommended	Consumed	Administered
<a href="#">NOT SUBMITTED</a>	<a href="#">EXSTDTC</a> <a href="#">EXENDTC</a>	<a href="#">SUPPEX.QVAL when QNAM=WTRCONS</a>	<a href="#">SUPPEX.QVAL when QNAM=WTRRCOM</a>	Unit Check Done <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA
<a href="#">SUPPEX.QVAL when QNAM=EXPIRDAT</a>		<a href="#">SUPPEX.QVAL when QNAM=MFGDAT</a>		
<a href="#">EXLOT</a> <a href="#">SUPPEX.QVAL when QNAM=STORCNDNS</a>		Paste the Unit Dose Label <a href="#">NOT SUBMITTED</a>		
Signature of the Subject				

## Comments:

[SUPPEX.QVAL when QNAM=EXRMK](#)

	Signature	Date
Administered by	<a href="#">NOT SUBMITTED</a>	<a href="#">NOT SUBMITTED</a>
Witnessed by QA	<a href="#">NOT SUBMITTED</a>	<a href="#">NOT SUBMITTED</a>
Checked by Investigator	<a href="#">NOT SUBMITTED</a>	<a href="#">NOT SUBMITTED</a>

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**BLOOD SAMPLE COLLECTION RECORD**

<b>SUPPPC.QVAL when QNAM=SMPAMT</b> Amount of sample (mL):		Anticoagulant used:		<b>SUPPPC.QVAL when QNAM=ANTICOAG</b> Total No. of Samples as per Protocol:		
Sample Collected Under:		<b>SUPPPC.QVAL when QNAM=SAMPLIGT</b>		Aromatic Light		<input type="checkbox"/> Others
Dosing date: <b>NOT SUBMITTED</b>		Dosing Time: <b>NOT SUBMITTED</b>				
Cannula Insertion Time	Done by (Sign& Date)	Cannula Removal Time	Done By (Sign& Date)	Remarks		
<b>NOT SUBMITTED</b>	<b>NOT SUBMITTED</b>	<b>NOT SUBMITTED</b>	<b>NOT SUBMITTED</b>	<b>NOT SUBMITTED</b>		

**BLOOD SAMPLE COLLECTION DETAIL** **SUPPPC.QVAL when QNAM=REASON**

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.	<b>PCDT</b>	<b>PCTPT 0.00</b>	<b>NOT SUBMITTED</b>		<b>PCDT</b>	<b>SUPPPC.QVAL when QNAM=COLINTM</b>		<b>NOT SUBMITTED</b>
2.		0.50	<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.		2.00	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
5.		3.00	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
6.		3.33	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
7.		3.67	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
8.		4.00	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
9.		4.33	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
10.		4.67	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
11.		5.00	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
12.		5.33	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
13.		5.67	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
14.		6.00	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
15.		6.50	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
16.		7.00	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
17.		8.00	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		

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For Annotations see CRF page 22

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<b>BLOOD SAMPLE COLLECTION DETAILS</b>									
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.		9.00	<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			
<b>Total No. of samples collected:</b> <span style="border: 1px solid blue; padding: 2px;">SUPPPC.QVAL when QNAM=NUMSAMP</span>									
<b>In case of any reason for delay in the sample collection use below codes</b>									
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			
		<span style="border: 1px solid blue; padding: 2px;">NOT SUBMITTED</span>				<span style="border: 1px solid blue; padding: 2px;">NOT SUBMITTED</span>			

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## VS=VITAL SIGNS

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## VITALS AND WELL BEING QUESTIONNAIRE RECORD

Date of Dosing: NOT SUBMITTED			Dosing Time: NOT SUBMITTED						
Time Point	Time of Vitals & SWBQ VTEST when VTESTCD= VSORRES/VSORRESU when VTESTCD=	Body Temp (°F)	Pulse Rate (per minute)	SpO <sub>2</sub> (%)	Blood Pressure (mm of Hg)	Well Being		Remarks	Sign & Date
						VSREASND when VSSTAT="NOT DONE"	Ye		
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 <sub>2</sub> (%)	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						
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Checked By Investigator:	Signature			Date			
	NOT SUBMITTED			NOT SUBMITTED			

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**MEAL CONSUMPTION RECORD**

Date of Dosing:	NOT SUBMITTED	Dosing Time:	NOT SUBMITTED
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Particulars	Schedule Time & Date	Consumption time (hrs)		Completely	Remarks	Monitored By
		Start	End			
MLPTPT <b>Dinner</b> (11.00 hrs Pre-dose)	MLTRT NOT SUBMITTED	MLSTDTC	MLENDTC	MLDOSE = 100 when CONSUMED = Yes <input type="checkbox"/> YES <input type="checkbox"/> NO	MLREASND when MLSTAT="NOT DONE"	↑
<b>Breakfast</b> 0.50 hrs Pre-dose High fat and high calorie breakfast				<input type="checkbox"/> Yes <input type="checkbox"/> No		
<b>Lunch</b> (4.00 hrs Post-dose)				<input type="checkbox"/> Yes <input type="checkbox"/> No		
<b>Snacks</b> (9.00 hrs Post-dose)				<input type="checkbox"/> Yes <input type="checkbox"/> No		
<b>Dinner</b> (13.00 hrs Post-dose)				<input type="checkbox"/> Yes <input type="checkbox"/> No		

Comments	SUPPML.QVAL when QNAM=MLRMK	
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Checked By	Signature	Date
	NOT SUBMITTED	NOT SUBMITTED

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#### **CHECK OUT MEDICAL EXAMINATION**

<b>Any Present Complaints</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No		<b>If Yes, Please Describe:</b>		
<b>Body system examined</b>	<b>Normal</b>	<b>Abnormal</b>	<b>Not Applicable</b>	<b>Describe Abnormality</b>	
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"/>		
<b>Comments</b>					
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

<b>Performed by</b>	<b>Signature</b>	<b>Date</b>

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**NOT SUBMITTED**

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**SUBJECT CHECK-OUT RECORD**

<b>Details</b>		
Subject in normal health/ vitals	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Items returned ( <b>ID card, Uniform, Towel and Foot wear</b> )	<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

<b>Subject Signature</b>	<b>Check-out time</b>	<b>Performed by Signature and Date</b>

<b>Remarks</b>	
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<b>Checked By Investigator</b>	<b>Signature</b>	<b>Date</b>

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### **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)?				<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>Any Present Complaints</b>		<input type="checkbox"/> Yes	<input type="checkbox"/> No	<b>If Yes, Please Describe:</b>
<b>Subject reported any illness during washout period</b>		<a href="#">SUPPPE.QVAL when QNAM=ANYILL</a>		
<b>Body system examined</b>	<b>Normal</b>	<b>Abnormal</b>	<b>Not Applicable</b>	<b>Describe Abnormality</b>
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"/>	
<b>Comments (if any)</b>				
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				

<b>Performed by</b>	<b>Signature</b>	<b>Date</b>

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## VITALS AND WELL-BEING QUESTIONNAIRE RECORD

Body temperature (°F)		Pulse Rate (per minute)	
SpO <sub>2</sub> (%)		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.

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**URINE DRUG SCREENING**

<b>Start time:</b>						
<b>Report for Drug of Abuse</b>						
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		
<b>End time:</b>						
Comments (if any)						
Performed by	Signature			Date		

<b>SERUM (<math>\beta</math>-HCG) PREGNANCY TEST EVALUATION RECORD</b>						
Volume of blood collected (mL)				Collected by		
<b>Evaluation of Laboratory Investigations</b>						
Result	<input type="checkbox"/> Positive		<input type="checkbox"/> Negative	<input type="checkbox"/> Invalid		
Comments (if any)						
Evaluated by	Signature			Date		

<b>Conclusion</b>	Based on my medical expertise, I found the volunteer <input type="checkbox"/> Fit <input type="checkbox"/> Unfit for further process of the study.					
<b>Remarks</b>						
<b>Concluded by</b>	Signature			Date		

**NOT SUBMITTED**

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**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 ( <b>ID card, Uniform, Towel, Foot ware and Toiletries</b> )	<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

<b>Comments</b>		
	<b>Signature</b>	<b>Date</b>
<b>Checked by</b>		

**NOT SUBMITTED**

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#### 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 consumption of high fat and high caloric breakfast.		<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		
<b>Comments</b>				
<b>Recorded by</b>		<b>Signature</b>	<b>Date</b>	

#### 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		
<b>Comments</b>				
<b>Recorded by</b>		<b>Signature</b>	<b>Date</b>	

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## DRUG ADMINISTRATION RECORD

Dosing Station No.:		Day: Dosing Day						
<b>Details of Dosage Form</b>								
<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)					
<b>Details of Drug Administration</b>								
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					
				Mouth Check Done	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA	
Paste the Unit Dose Label								
				Signature of the Subject				

**Comments:**

	Signature	Date
Administered by		
Witnessed by QA		
Checked by Investigator		

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### 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.		2.00	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
5.		3.00	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
6.		3.33	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
7.		3.67	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
8.		4.00	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
9.		4.33	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
10.		4.67	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
11.		5.00	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
12.		5.33	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
13.		5.67	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
14.		6.00	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
15.		6.50	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
16.		7.00	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
17.		8.00	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		

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## 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.		9.00	<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		

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### 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 <sub>2</sub> (%)	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"/>		
<b>If Required</b>										
Actual Time (hrs)	Temp (°F)	Pulse Rate (per minute)	SpO <sub>2</sub> (%)	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.

<b>Comments</b>							
<b>Checked By Investigator:</b>	<b>Signature</b>				<b>Date</b>		

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## MEAL CONSUMPTION RECORD

Date of Dosing:	Dosing Time:		
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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		
Breakfast 0.50 hrs Pre-dose High fat and high calorie breakfast				<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			
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Checked By	Signature	Date

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#### CHECK OUT MEDICAL EXAMINATION

<b>Any Present Complaints</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No		<b>If Yes, Please Describe:</b>		
<b>Body system examined</b>	<b>Normal</b>	<b>Abnormal</b>	<b>Not Applicable</b>	<b>Describe Abnormality</b>	
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"/>		
<b>Comments</b>					
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

<b>Performed by</b>	<b>Signature</b>	<b>Date</b>

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### SUBJECT CHECK-OUT RECORD

<b>Details</b>		
Subject in normal health/ vitals	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Items returned ( <b>ID card, Uniform, Towel and Foot wear</b> )	<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

<b>Subject Signature</b>	<b>Check-out time</b>	<b>Performed by Signature and Date</b>

<b>Remarks</b>	
----------------	--

<b>Checked By Investigator</b>	<b>Signature</b>	<b>Date</b>

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**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)?	<input type="checkbox"/> Yes <input type="checkbox"/> No
---	--

<b>Any Present Complaints</b>	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<b>If Yes, Please Describe:</b>	
<b>Subject reported any illness during washout period</b>			<a href="#">SUPPPE.QVAL when QNAM=ANYILL</a>	
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"/>	
<b>Comments (if any)</b>				
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	

<b>Performed by</b>	<b>Signature</b>	<b>Date</b>

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### VITALS AND WELL-BEING QUESTIONNAIRE RECORD

Body temperature (°F)		Pulse Rate (per minute)	
SpO <sub>2</sub> (%)		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

<b>Positive</b>	The urine alcohol rapid test dipstick/urine alcohol. Cassette colour changes as per the colour provided in kit insert.
<b>Negative</b>	The urine alcohol rapid test dipstick/urine alcohol Cassette colour does not change
<b>Invalid</b>	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.

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### URINE DRUG SCREENING

<b>Start time:</b>						
<b>Report for Drug of Abuse</b>						
<b>Name of the Test</b>			<b>Results</b>			
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	
<b>End time:</b>						
<b>Comments (if any)</b>						
<b>Performed by</b>	<b>Signature</b>			<b>Date</b>		

<b>SERUM (<math>\beta</math>-HCG) PREGNANCY TEST EVALUATION RECORD</b>						
<b>Volume of blood collected (mL)</b>			<b>Collected by</b>			
<b>Evaluation of Laboratory Investigations</b>						
<b>Result</b>	<input type="checkbox"/> Positive			<input type="checkbox"/> Negative	<input type="checkbox"/> Invalid	
<b>Comments (if any)</b>						
<b>Evaluated by</b>	<b>Signature</b>			<b>Date</b>		

<b>Conclusion</b>	Based on my medical expertise, I found the volunteer <input type="checkbox"/> <b>Fit</b> <input type="checkbox"/> <b>Unfit</b> for further process of the study.		
<b>Remarks</b>			
<b>Concluded by</b>	<b>Signature</b>		
	<b>Date</b>		

**NOT SUBMITTED**

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**SUBJECT CHECK-IN RECORD**

Details	<b>Yes</b>	<b>No</b>	<b>NA</b>
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 ( <b>ID card, Uniform, Towel, Foot ware and Toiletries</b> )	<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		
<b>Checked by</b>	Signature	Date

**NOT SUBMITTED**

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#### 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 consumption of high fat and high calorie breakfast.		<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		
<b>Comments</b>				
<b>Recorded by</b>	<b>Signature</b>		<b>Date</b>	

#### 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		
<b>Comments</b>				
<b>Recorded by</b>	<b>Signature</b>		<b>Date</b>	

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**DRUG ADMINISTRATION RECORD**

Dosing Station No.:		Day: Dosing Day					
<b>Details of Dosage Form</b>							
<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)					
<b>Details of Drug Administration</b>							
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	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA		
Schedule	Actual	Recommended	Consumed				
				Mouth Check Done	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA		
Paste the Unit Dose Label				Signature of the Subject			
<b>Comments:</b>							
		Signature			Date		
Administered by							
Witnessed by QA							
Checked by Investigator							

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### 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.		2.00	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
5.		3.00	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
6.		3.33	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
7.		3.67	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
8.		4.00	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
9.		4.33	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
10.		4.67	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
11.		5.00	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
12.		5.33	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
13.		5.67	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
14.		6.00	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
15.		6.50	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
16.		7.00	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
17.		8.00	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		

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<b>BLOOD SAMPLE COLLECTION DETAILS</b>								
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.		9.00	<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.		<b>12.00*</b>	<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		
<b>Total No. of samples collected:</b>								
<b>In case of any reason for delay in the sample collection use below codes</b>								
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			

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### VITALS AND WELL BEING QUESTIONNAIRE RECORD

<b>Date of Dosing:</b>				<b>Dosing Time:</b>						
<b>Time Point (hrs)</b>	<b>Time of Vitals &amp; SWBQ</b>		<b>Body Temp (°F)</b>	<b>Pulse Rate (per minute)</b>	<b>SpO<sub>2</sub> (%)</b>	<b>Blood Pressure (mm of Hg)</b>	<b>Well Being</b>		<b>Remarks</b>	<b>Done by Sign &amp; Date</b>
	<b>Schedule</b>	<b>Actual</b>					<b>Yes</b>	<b>No</b>		
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

<b>Actual Time (hrs)</b>	<b>Temp (°F)</b>	<b>Pulse Rate (per minute)</b>	<b>SpO<sub>2</sub> (%)</b>	<b>Blood Pressure (mm of Hg)</b>	<b>Well Being</b>		<b>Remarks</b>	<b>Done by Sign &amp; Date</b>
					<b>Yes</b>	<b>No</b>		
					<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.

<b>Comments</b>			
<b>Checked By Investigator:</b>	<b>Signature</b>		<b>Date</b>

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### MEAL CONSUMPTION RECORD

Date of Dosing:	Dosing Time:		
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Particulars	Schedule Time & Date	Consumption time (hrs)		Completely consumed		Remarks	Monitored By
		Start	End	<input type="checkbox"/> Yes	<input type="checkbox"/> No		
<b>Dinner</b> (11.00 hrs Pre-dose)				<input type="checkbox"/> Yes	<input type="checkbox"/> No		
<b>Breakfast</b> 0.50 hrs Pre-dose High fat and high calorie breakfast				<input type="checkbox"/> Yes	<input type="checkbox"/> No		
<b>Lunch</b> (4.00 hrs Post-dose)				<input type="checkbox"/> Yes	<input type="checkbox"/> No		
<b>Snacks</b> (9.00 hrs Post-dose)				<input type="checkbox"/> Yes	<input type="checkbox"/> No		
<b>Dinner</b> (13.00 hrs Post-dose)				<input type="checkbox"/> Yes	<input type="checkbox"/> No		

Comments			
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<b>Checked By</b>	<b>Signature</b>	<b>Date</b>

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**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"/>		
<b>Comments</b>						
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

<b>Performed by</b>	<b>Signature</b>	<b>Date</b>

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**SUBJECT CHECK-OUT RECORD**

Details		
Subject in normal health/ vitals	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Items returned ( <b>ID card, Uniform, Towel and Foot wear</b> )	<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

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### 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)?				<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>Any Present Complaints</b>		<input type="checkbox"/> Yes	<input type="checkbox"/> No	<b>If Yes, Please Describe:</b>
<b>Subject reported any illness during washout period</b>		<a href="#">SUPPPE.QVAL when QNAM=ANYILL</a>		
<b>Body system examined</b>	<b>Normal</b>	<b>Abnormal</b>	<b>Not Applicable</b>	<b>Describe Abnormality</b>
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"/>	
<b>Comments (if any)</b>				
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

<b>Performed by</b>	<b>Signature</b>	<b>Date</b>

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### **VITALS AND WELL-BEING QUESTIONNAIRE RECORD**

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

### **ALCOHOL TEST**

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

### **Test Interference**

<b>Positive</b>	The urine alcohol rapid test dipstick/urine alcohol. Cassette colour changes as per the colour provided in kit insert.
<b>Negative</b>	The urine alcohol rapid test dipstick/urine alcohol Cassette colour does not change
<b>Invalid</b>	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.

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**URINE DRUG SCREENING**

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

<b>SERUM (<math>\beta</math>-HCG) PREGNANCY TEST EVALUATION RECORD</b>			
<b>Volume of blood collected (mL)</b>		<b>Collected by</b>	
<b>Evaluation of Laboratory Investigations</b>			
<b>Result</b>	<input type="checkbox"/> Positive	<input type="checkbox"/> Negative	<input type="checkbox"/> Invalid
<b>Comments (if any)</b>			
<b>Evaluated by</b>	<b>Signature</b>		<b>Date</b>

<b>Conclusion</b>	Based on my medical expertise, I found the volunteer <input type="checkbox"/> <b>Fit</b> <input type="checkbox"/> <b>Unfit</b> for further process of the study.		
<b>Remarks</b>			
<b>Concluded by</b>	<b>Signature</b>		<b>Date</b>

**NOT SUBMITTED**

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**SUBJECT CHECK-IN RECORD**

Details	<b>Yes</b>	<b>No</b>	<b>NA</b>
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 ( <b>ID card, Uniform, Towel, Foot ware and Toiletries</b> )	<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

<b>Comments</b>		
<b>Checked by</b>	<b>Signature</b>	<b>Date</b>

**NOT SUBMITTED**

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#### 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 consumption of high fat and high calorie breakfast.		<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		
<b>Comments</b>				
<b>Recorded by</b>	<b>Signature</b>		<b>Date</b>	

#### 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		
<b>Comments</b>				
<b>Recorded by</b>	<b>Signature</b>		<b>Date</b>	

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### DRUG ADMINISTRATION RECORD

Dosing Station No.:		Day: Dosing Day					
<b>Details of Dosage Form</b>							
<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)					
<b>Details of Drug Administration</b>							
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				
				Mouth Check Done	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA		
Paste the Unit Dose Label							
				Signature of the Subject			
<b>Comments:</b>							
		Signature			Date		
Administered by							
Witnessed by QA							
Checked by Investigator							

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## 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.		2.00	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
5.		3.00	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
6.		3.33	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
7.		3.67	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
8.		4.00	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
9.		4.33	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
10.		4.67	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
11.		5.00	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
12.		5.33	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
13.		5.67	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
14.		6.00	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
15.		6.50	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
16.		7.00	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		
17.		8.00	<input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Yes <input type="checkbox"/> No		

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## 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.		9.00	<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		

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### 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 <sub>2</sub> (%)	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 <sub>2</sub> (%)	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			
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Checked By Investigator:	Signature	Date

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### MEAL CONSUMPTION RECORD

Date of Dosing:	Dosing Time:		
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Particulars	Schedule Time & Date	Consumption time (hrs)		Completely consumed	Remarks	Monitored By
		Start	End			
<b>Dinner</b> (11.00 hrs Pre-dose)				<input type="checkbox"/> Yes	<input type="checkbox"/> No	
<b>Breakfast</b> 0.50 hrs Pre-dose High fat and high calorie breakfast				<input type="checkbox"/> Yes	<input type="checkbox"/> No	
<b>Lunch</b> (4.00 hrs Post-dose)				<input type="checkbox"/> Yes	<input type="checkbox"/> No	
<b>Snacks</b> (9.00 hrs Post-dose)				<input type="checkbox"/> Yes	<input type="checkbox"/> No	
<b>Dinner</b> (13.00 hrs Post-dose)				<input type="checkbox"/> Yes	<input type="checkbox"/> No	

Comments		
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Checked By	Signature	Date

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**SUBJECT CHECK-OUT RECORD**

Details		
Subject in normal health/ vitals		<input type="checkbox"/> Yes <input type="checkbox"/> No
Items returned ( <b>ID card, Uniform, Towel and Foot wear</b> )		<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		<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	
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Checked By Investigator	Signature	Date

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## POST 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	SpO2 (%)	Well-Being	Remarks	Done by Sign& <span style="background-color: yellow;">SUPPVS.QVAL when QNAM=WELBENG</span>
			SYSBP				
VSDTC	TEMP	PULSE	DIABP	OXYSAT			<span style="background-color: yellow;">SUPPVS.QVAL when QNAM=VSRMK</span>

Does the subject have any abnormality in post study Assessments?

Yes (Abnormality Detected) SUPPPE.QVAL when QNAM=ABNORMYN (Abnormality Detected-NAD)

If "Yes" Specify the abnormality SUPPPE.QVAL when QNAM=PSABNORM

(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  YES  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  Normal  Abnormal  Not applicable

ECG Comments (in any) SUPPPE.QVAL when QNAM=POSTECGC

Signature of the Investigator	NOT SUBMITTED	NOT SUBMITTED

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### POST STUDY LABORATORY EVALUATION RECORD

<b>1. Sample Collection</b>						
Nature of Sample	Amount Collected (ml)	Time of sample collected		Collected by Signature & date		
Blood						
Urine						
Others:						
<b>2. Evaluation of Lab investigations</b>						
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:		<input type="checkbox"/> Normal	<input type="checkbox"/> Abnormal	<input type="checkbox"/> NA		
CS:		<input type="checkbox"/> Normal	<input type="checkbox"/> Abnormal	<input type="checkbox"/> NA		
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

**DS=DISPOSITION**

<b>ACTIMUS BIOSCIENCES PRIVATE LIMITED</b>		<b>Restricted Circulation</b>
Form title:	Subject Drop-Out Record	
Relevant SOP No.:	CR036-13	
<b>SUBJECT DROP-OUT RECORD</b>		
<b>Subject No.</b>	<b>NOT SUBMITTED</b>	<b>Period No.</b>
<b>Date of Drop-out:</b> DSSTDTC		
<b>Reason</b>	<b>Tick (✓)</b>	<b>Remarks</b>
<b>Reason for Drop-out</b>		
1. Voluntarily withdrawn	DSDECOD=WITHDRAWL BY SUBJECT	
2. Absent for subsequent check-in	DSDECOD=WITHDRAWL BY SUBJECT	
3. Others: (specify if any)	DSDECOD=OTHER	
<b>If subject voluntarily withdrawn, Signature &amp;</b> DSSTDTC <b>Date of the Subject</b>		
Is the subject eligible to participate in the subsequent period(s) SUPPDS.QVAL when QNAM=ELIGNSP NA <input type="checkbox"/>		
<b>Recommendation/ Comments</b> 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"/>		
<b>Note:</b> 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)		
<b>Remarks</b>	SUPPDS.QVAL when QNAM=DSRMK	
<b>Complied by Investigator (Sign &amp; Date)</b>	NOT SUBMITTED	
<b>Verified by Principal Investigator (Sign &amp; Date)</b>	NOT SUBMITTED	

**DS=DISPOSITION**

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

**SUBJECT WITHDRAWAL RECORD**

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

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

<b>NOT SUBMITTED</b>	<b>Recommendation/ Comments</b>		
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)			
<b>Remarks</b>	<b>SUPPDS.QVAL when QNAM=DSRMK</b>		
<b>Complied by Investigator (Sign &amp; Date)</b>		<b>NOT SUBMITTED</b>	
<b>Verified by Principal Investigator (Sign &amp; Date)</b>		<b>NOT SUBMITTED</b>	

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

**AE=ADVERSE EVENTS**

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

Severity	Relationship to IMP	Seriousness
<b>AESEV</b>	<input type="checkbox"/> Definite <b>AEREL</b>	<b>AESER</b>
<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** plicable

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)	<b>SUPPAE.QVAL when QNAM=AERMK</b>
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Investigator/Designee Sign & Date	<b>NOT SUBMITTED</b>
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Checked by Sign & Date (PI/Co-Investigator)	<b>NOT SUBMITTED</b>
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**For Annotations see CRF page 67, 68**

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

<b>Follow-up Details</b>			
<b>Study No.:</b>	<b>Period No.:</b>	<b>Subject No.:</b>	
Follow up Number			
Date and Time			
Description of Event			
General Examination			
Medical Examination			
<b>Body Temperature (°F)</b>	<b>Pulse Rate/ min.</b>	<b>Blood Pressure (mm/Hg)</b>	<b>Respiratory Rate/ min.</b>
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			
<b>Body Temperature (°F)</b>	<b>Pulse Rate/ min.</b>	<b>Blood Pressure (mm/Hg)</b>	<b>Respiratory Rate/ min.</b>
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)			

**DD=DEATH DETAILS**

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

For Annotations see CRF page 11  
Applicable  Not Applicable

<b>Nature of Sample</b>	<b>Amount Collected (ml)</b>	<b>Time of collection</b>	<b>Remarks</b>	<b>Sign &amp; Date</b>

**Evaluation of Lab investigations**

<b>Lab investigations</b>	<b>(Tick ✓ the relevant)</b>		
	<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 <b>AEOUD</b>	Resolved Date : <b>AEENDTC</b>	Resolved Time : <b>AEENDTC</b>
	<input type="checkbox"/> Recovered without sequela <b>AEOUD</b>	<input type="checkbox"/> Recovered with sequelae <b>AEOUF</b>

**Duration of the Event:** (Onset time of event to Resolution time of event)

Note: Duration of in-house adverse event shall be mentioned in hours & Post study adverse events in days)

**AEDUR**

<input type="checkbox"/> If Ongoing <b>AEENRF</b>	Condition worsening	<input type="checkbox"/> Condition Recovering
<input type="checkbox"/> If Died	Date of death: <b>DTHDTC</b>	Time of death: <b>DTHDTC</b>
	Subject autopsy was done? <b>DDTEST</b> when <b>DDTESTCD = AUTOPIND</b>	<b>DDORRES</b>
	Give cause of the death: <b>DDTEST</b> when <b>DDTESTCD = PRCDT</b>	<b>DDORRES</b>
<input type="checkbox"/> If Unknown	<b>NOT SUBMITTED</b>	
Final Diagnosis	<b>AETERM</b>	
Comments (If any)	<b>SUPPAE.QVAL</b> when <b>QNAM=AERMK</b>	
Investigator/Designee Sign & Date	<b>NOT SUBMITTED</b>	
Principal/Co-Investigator Sign & Date	<b>NOT SUBMITTED</b>	

**CM=CONCOMITANT MEDICATION**

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