## MEDICAL SCREENING RECORD FORM

Project No: 0326-17



VITAL SIGNS-	SCREENING	
Default		
Height (cm):	156.5	
Weight (Kg):	59.1	
BMI (Kg/m2):	24.13	
Respiratory Rate:	16	
Pulse Rate:	68	
Temperature (°F):	98.6	
Temperature (°C):	37	
Systolic Blood Pressure (Sitting):	120	
Diastolic Blood Pressure (Sitting):	80	
Systolic Blood Pressure (Supine):	120	
Diastolic Blood Pressure (Supine):	80	
Systolic Blood Pressure (Standing):	118	
Diastolic Blood Pressure (Standing):	78	
-		
Orthostatic Hypotension Present:	C YES © NO C NAP	
Remarks:		
DEMOGRAPH	IIC DETAILS	
Default		
Comment for Comming Circuit		
Consent for Screening Signed:	© YES C NO	
Date of Initiation of Screening:	17-Nov-2017	
Sex:	C MALE © FEMALE	
Date Of Birth:	01-Jan-1980	
Age In Years (Completed years on the day of screening):	37	
Ethnicity:	C HISPANIC • NON-HISPANIC	
Race:	ASIAN	
rucc.	NOMIN .	
M 2 10 4	C SINGLE • MARRIED C WIDOW	
Marital Status:		
	C DIVORCEE	
Food Habits:	C © NON- C	
	VEGETARIAN VEGETARIAN EGGETARIAN	
PERSONAL HISTO	DRY-SCREENING	
Default		
Has the subject donated blood?:		
Has the subject donated blood?:		
Last date of blood donation:	-	
Date of last sample study participated in:	-	

## MEDICAL SCREENING RECORD FORM

Project No: 0326-17



History of difficulty in blood donation:	C YES 6 NO C NAP
Smoking:	C CURRENT C PREVIOUS © NEVER
Smoking Details:	
Smoking, If Previous, Stopped since:	
Alcohol:	C CURRENT C PREVIOUS © NEVER
Consumption Details for Alcohol:	
Alcohol, If Previous, Stopped since:	
RECREATIONAL DRUGS (MARIJUANA, OPIATES, AMPHETAMINES, COCAINE, PHENCYCLIDINE, BARBITURATES, BENZODIAZEPINES, METHADONE ETC.):	RECREATIONAL DRUGS (MARIJUANA, OPIATES, AMPHETAMINES, COCAINE, PHENCYCLIDINE, BARBITURATES, BENZODIAZEPINES, METHADONE ETC.)
Recreational Drug:	C CURRENT C PREVIOUS © NEVER
Consumption Details for Recreationl Drug:	
Recreational Drug, If Previous, Stopped since:	
Others:	C CURRENT C PREVIOUS © NEVER
Consumption Details for Other:	
Others, If Previous, Stopped since:	
PHYSICAL EXAMINAT	TION-SCREENING
Default	
Pallor:	C PRESENT G ABSENT
Palpable Nodes:	C PRESENT 6 ABSENT
Nasal Polyp:	C PRESENT G ABSENT
	TRESERT W ADSERT
Icterus:	C PRESENT © ABSENT
Icterus: Edema:	
	C PRESENT 6 ABSENT
Edema:	C PRESENT 6 ABSENT  C PRESENT 6 ABSENT
Edema:  Eczema:	C PRESENT  ABSENT  C PRESENT  ABSENT  C PRESENT  ABSENT
Edema:  Eczema:  Any other (Including skin,head,ear,eye,nose,throat,nails):	C PRESENT  ABSENT  C PRESENT  ABSENT  C PRESENT  ABSENT  NORMAL C ABNORMAL
Edema:  Eczema:  Any other (Including skin,head,ear,eye,nose,throat,nails):  Remarks:	C PRESENT  ABSENT  C PRESENT  ABSENT  C PRESENT  ABSENT  NORMAL C ABNORMAL

## MEDICAL SCREENING RECORD FORM

Project No: 0326-17



Any Infectious Disorder:	C YES © NO
If "Yes", Specify:	
RECENT HISTORY OF MEDICATION (WITHIN LAST 30 DAYS):	RECENT HISTORY OF MEDICATION (WITHIN LAST 30 DAYS)
Recent History of Medication:	C YES 6 NO
If "Yes", Specify:	
HISTORY OF ALLERGY:	HISTORY OF ALLERGY
Allergy to Medicines:	C YES © NO
Allergy to Food:	C YES © NO
Allergy to any other:	C YES © NO
Other, please specify:	
HISTORY OF OTHER DISORDER:	HISTORY OF OTHER DISORDER
Any History of Other Disorder:	C YES • NO
If "Yes", Specify:	
SYSTEMIC EXAMINA	ATION-SCREENING
Cardiovascular System	
Cardiovascular System  Any History of Cardiovascular Disorder:	C YES © NO
	C YES © NO
Any History of Cardiovascular Disorder:	C YES © NO  © REGULAR C IRREGULAR
Any History of Cardiovascular Disorder:  If "Yes",Specify:	
Any History of Cardiovascular Disorder:  If "Yes",Specify:  Pulse Rhythm:	€ REGULAR € IRREGULAR
Any History of Cardiovascular Disorder:  If "Yes",Specify:  Pulse Rhythm:  Pulse Volume:	© REGULAR C IRREGULAR © NORMAL C HIGH C LOW
Any History of Cardiovascular Disorder:  If "Yes",Specify:  Pulse Rhythm:  Pulse Volume:  Inspection (Pericardial area with apex beat):	© REGULAR © IRREGULAR © NORMAL © HIGH © LOW © NORMAL © ABNORMAL
Any History of Cardiovascular Disorder:  If "Yes",Specify:  Pulse Rhythm:  Pulse Volume:  Inspection (Pericardial area with apex beat):  Palpation (Pericardial area with apex beat):	© REGULAR © IRREGULAR © NORMAL © HIGH © LOW © NORMAL © ABNORMAL
Any History of Cardiovascular Disorder:  If "Yes",Specify:  Pulse Rhythm:  Pulse Volume:  Inspection (Pericardial area with apex beat):  Palpation (Pericardial area with apex beat):  Percussion:  Auscultation (Heart sounds):  Remarks if any:	© REGULAR © IRREGULAR © NORMAL © HIGH © LOW © NORMAL © ABNORMAL © NORMAL © ABNORMAL
Any History of Cardiovascular Disorder:  If "Yes",Specify:  Pulse Rhythm:  Pulse Volume:  Inspection (Pericardial area with apex beat):  Palpation (Pericardial area with apex beat):  Percussion:  Auscultation (Heart sounds):	© REGULAR © IRREGULAR  © NORMAL © HIGH © LOW  © NORMAL © ABNORMAL  © NORMAL © ABNORMAL
Any History of Cardiovascular Disorder:  If "Yes",Specify:  Pulse Rhythm:  Pulse Volume:  Inspection (Pericardial area with apex beat):  Palpation (Pericardial area with apex beat):  Percussion:  Auscultation (Heart sounds):  Remarks if any:	© REGULAR © IRREGULAR © NORMAL © HIGH © LOW © NORMAL © ABNORMAL © NORMAL © ABNORMAL

## MEDICAL SCREENING RECORD FORM

Project No: 0326-17



Inspection (Shape of chest):	© NORMAL CABNORMAL
Respiratory Movements(Rhythm,Character,Accessory Muscles,Mediastinum):	© NORMAL C ABNORMAL
Palpation (Tactile Vocal Fremitus, Trachea):	© NORMAL ○ ABNORMAL
Percussion:	♠ NORMAL ← ABNORMAL
Auscultation (Breath sounds,Foreign sounds):	● NORMAL C ABNORMAL
Remarks if any:	
Gastrointestinal System	
Any History of Gastrointestinal Disorder:	C YES © NO
If "Yes",Specify:	
Inspection (Shape of abdomen):	© NORMAL CABNORMAL
Palpation (Tenderness/Rigidity,Liver,Spleen):	
Percussion (Fluid thrill):	© NORMAL C ABNORMAL
Auscultation (Peristaltic Sounds):	© NORMAL € ABNORMAL
Remarks if any:	
Nervous System	
Any History of Nervous System Disorder:	C YES © NO
If "Yes",Specify:	
Higher Functions:	© NORMAL CABNORMAL
Cranial Nerves (except fundoscopy):	© NORMAL CABNORMAL
Motor System (nutrition,power,tone,coordination):	© NORMAL CABNORMAL
Sensory System (Superficial & Deep sensations):	© NORMAL CABNORMAL
Reflexes (Superficial,Deep):	© NORMAL CABNORMAL
Meningeal Signs:	C PRESENT © ABSENT

## MEDICAL SCREENING RECORD FORM

Project No: 0326-17



Abnormal movements:	C PRESENT 6 ABSENT
Remarks if any:	
For Femal	e Only
Last Menstrual Period	
Last Menstrual Period Date:	25-Oct-2017
Regularity:	€ REGULAR € IRREGULAR
Association with Pain:	C PAINFUL © PAINLESS
Obstetric History	
Date of last delivery:	05-Aug-2014
Gravida:	3
Para (Including current status):	3
No. of live children:	3
No. of children died:	0
All children healthy:	© YES CNO CNAP
Remarks:	-
Any spontaneous Abortions or MTP:	-
Date of last abortion or MTP:	
Lactating/Nursing:	C YES © NO
Volunteer is in the child bearing age:	G YES C NO
Family Planing Measures:	☐ PERMANENT ☐ TEMPORARY ☐ POST CONTRACEPTION CONTRACEPTION MENOPAUSAL ☐ NOT APPLICABLE
Details of Permanent Contraception:	
Details of Temporary Contraception:	✓ DOUBLE BARRIER ☐ PILLS ☐ RHYTHM ☐ IUCD ☐ NAP
Remarks:	
SCREENING CLINICAL EXA	MINATION-SCREENING
Default	
Clinically fit:	© YES C NO
Remarks:	
LAB REPORT-S	CREENING
Default	
Lab Report Remark:	

## MEDICAL SCREENING RECORD FORM

Project No: 0326-17



Clinically:	← ACCEPTABLE ← NOT ACCEPTABLE
Remarks,if Repeated:	
Any dietary advice given to subject?:	C YES 6 NO C NAP
Additional Information:	
X-RAY EXAMINATIO	ON-SCREENING
Default	
X-RAY Comments:	
Clinically:	• ACCEPTABLE • NOT ACCEPTABLE
ELECTROCARDIOGR	RAM-SCREENING
Default	
ECG Impression Remark:	WNL
Remarks,if ECG Repeated:	
Clinically:	• ACCEPTABLE • NOT ACCEPTABLE
CLINICAL SCREENING ELI	GIBILITY-SCREENING
Default	
Is Eligible for study?:	© YES C NO
Remarks,In case of re-eligibility:	
OTHER EXAMINATI	ON-SCREENING
Default	
Other Examination-1:	
Clinically-1:	C ACCEPTABLE C NOT ACCEPTABLE
Other Examination-2:	
Clinically-2:	C ACCEPTABLE C NOT ACCEPTABLE
Other Examination-3:	
Clinically-3:	C ACCEPTABLE C NOT ACCEPTABLE
Other Examination-4:	
Clinically-4:	C ACCEPTABLE C NOT ACCEPTABLE
Remarks:	
Screening I	Review
Review History	
Is Eligible Status:	YES
Declare By:	Manishpatel (Study Physician) On 25-Nov-2017 13:47
Remarks:	
Final Review By :	ketulmodi (PI/COI) On 09-Jan-2018 15:25

## MEDICAL SCREENING RECORD FORM

Project No: 0326-17



Remarks:	I have reviewed medical screening record afte r DCF
	icsolution.



# **Clinical Laboratory Test Report**



Lambda Therapeutic Research Limited

Screening AH17-06704 Subject Initial: KSM Subject

Date Of Birth: 01-Jan-1980 Referred By: Dr. Manish Patel

17060104 Lab ID: Sex: Female

Visit : Screening **Sample Collected** Sample Collected At:

Sample Received On: Report Date: Study /Project

17-Nov-2017 18:21 Ahmedabad

17-Nov-2017 18:54 17-Nov-2017 22:40

#### **CHEMISTRY**

[Performed By Reflectance Photometry]

	·	•	, -		
PARAMETER PLASMA RANDOM GLUCOSE	<b>RESULT</b> 92.5	CS/NCS*	REMARK	<b>UNIT</b> R	FERENCE INTERVAL  - WHO CRITERIA FOR DIAGNOSIS OF DIABETES >200 along with symptoms of hyperglycemia suggestive of diabetes
Glucose oxidase	0.33			mg/dL	0.2.4.5
BILIRUBIN TOTAL	0.32			IIIg/uL	0.2 - 1.5
Azobilirubin					
TOTAL PROTEIN	7.54			g/dL	6.9 - 8.6
Biuret					
ALBUMIN	4.14			g/dL	3.9 - 5.2
BCG					
GLOBULIN	3.4			g/dL	2.5 - 3.8
Calculated					
A/G RATIO	1.22				1.2 - 2.2
Calculated					
S.G.O.T. (AST)	21			U/L	15.0 - 46.0
UV WITH P-5-P					
S.G.P.T. (ALT)	31			U/L	11.0 - 58.0
UV WITH P-5-P					
CREATININE	0.60			mg/dL	0.5 - 0.9
Enzymatic (Creatine amidohydrolase, IDMS traceable)					

**CLINICALLY ACCEPTABLE** Final Remark :-

Reviewed by:-Jaimin Chhaganbhai Ahir - Stud 18-Nov-2017 12:47

\*- NCS = Non Clinical Significant, CS = Clinical Significant

This is an Electronically authenticated report

Report Printed On: 16-Feb-2018 11:39 Authenticated By: Dhaval J Patel 17-Nov-2017 20:15







## **Clinical Laboratory Test Report**



Lambda Therapeutic Research Limited

Screening Subject Initial: Subject Date Of Birth: Referred By:	AH17-06704 KSM N/A 01-Jan-1980 Dr. Manish Patel	Lab ID: Sex : Visit :	17060104 Female Screening	Sample Collected Sample Collected At: Sample Received On: Report Date: Study /Project	17-Nov-2017 18:21 Ahmedabad 17-Nov-2017 18:54 17-Nov-2017 22:40
UREA	21.4			mg/dL	15.0 - 36.0
Jrease quinolinium	dye				
SODIUM	140.2			mmol/L	135.6 - 145.9
Direct ISE					
OTASSIUM	4.63			mmol/L	3.8 - 5.4
irect ISE					
HLORIDE	106.1			mmol/L	97.3 - 107.0
irect ISE					
REATININE CLE	ARANCE <b>165.78</b>		NCS	H mL/min	80 - 125
alculated by Cock	croft Gault				

Final Remark :- CLINICALLY ACCEPTABLE

Reviewed by:- Jaimin Chhaganbhai Ahir - Stud

§ 8-Nov-2017 12:47

\*- NCS = Non Clinical Significant, CS = Clinical Significant

This is an Electronically authenticated report

Report Printed On: 16-Feb-2018 11:39 Authenticated By:Dhaval J Patel 17-Nov-2017 20:15



method





## **Clinical Laboratory Test Report**



Lambda Therapeutic Research Limited

Screening AH17-06704 Subject Initial: KSM

Subject Date Of Birth: 01-Jan-1980 Referred By: Dr. Manish Patel

17060104 Lab ID: Sex: Female

Visit : Screening **Sample Collected** Sample Collected At:

Sample Received On: Report Date:

Study /Project

17-Nov-2017 18:21 Ahmedabad

17-Nov-2017 18:54 17-Nov-2017 22:40

#### **HEMATOLOGY**

[Performed By Flowcytometry and Electrical Impedence Method]

PARAMETER	RESULT	CS/NCS*	REMARK		REFERENCE INTERVAL
HAEMOGLOBIN	11.5			g/dL	10.0 - 14.4
SLS-Haemoglobin method					
RBC COUNT	4.16			X 10^6/μL	3.8 - 4.8
Hydro Dynamic focussing method					
HCT	34.6	NCS	L	%	36.0 - 46.0
RBC pulse-height detection method					
MCV	83.2			fL	83.0 - 101.0
Calculated					
MCH	27.6			Pg	27.0 - 32.0
Calculated					
MCHC	33.2			g/dL	31.5 - 34.5
Calculated					
RDW CV	13.2			%	11.6 - 14.0
Calculated					
PLATELET COUNT	343			X 10^3/μL	150 - 410
Hydro dynamic focussing method					
WBC (TOTAL)	6.71			X 10^3/μL	4.0 - 10.0
Flowcytometry method					
NEUTROPHIL %	56.7			%	40 - 80
Flowcytometry method	24.0			%	20 40
LYMPHOCYTES %	34.9			70	20 - 40
Flowcytometry method					

**CLINICALLY ACCEPTABLE** Final Remark :-

Reviewed by:-Jaimin Chhaganbhai Ahir - Stud 18-Nov-2017 12:47

\*- NCS = Non Clinical Significant, CS = Clinical Significant

This is an Electronically authenticated report

Report Printed On: 16-Feb-2018 11:39 Authenticated By: Dipal D Shah 17-Nov-2017 19:56







# **Clinical Laboratory Test Report**



Lambda Therapeutic Research Limited

Screening Subject Initial: Subject Date Of Birth: Referred By:	AH17-06704 KSM N/A 01-Jan-1980 Dr. Manish Patel	Lab ID: Sex : Visit :	17060104 Female Screening	Sample Collected Sample Collected At: Sample Received On: Report Date: Study /Project	17-Nov-2017 18:21 Ahmedabad 17-Nov-2017 18:54 17-Nov-2017 22:40
EOSINOPHILS %	1.6			%	1 - 6
Flowcytometry met	chod 6.7			%	2 - 10
Flowcytometry met BASOPHILS %	thod 0.1			%	0 - 2
Flowcytometry met NEUTROPHILS (A				X 10^3/μL	2.0 - 7.0
Calculated EOSINOPHILS (A	.BS) 0.11			X 10^3/μL	0.02 - 0.5
Calculated BLOOD GROUP	"O" Pos	itive			

Tube Method
Disclaimer: Historic record
check has not been performed
for blood group and that
verification of the sample's
identity and the test results are
strongly recommended.

Final Remark :- CLINICALLY ACCEPTABLE

Reviewed by:- Jaimin Chhaganbhai Ahir - Stud

§ 8-Nov-2017 12:47

\*- NCS = Non Clinical Significant, CS = Clinical Significant

This is an Electronically authenticated report

Report Printed On: 16-Feb-2018 11:39 Authenticated By:Dipal D Shah 17-Nov-2017 19:56







## **Clinical Laboratory Test Report**



Lambda Therapeutic Research Limited

Screening AH17-06704 Subject Initial: KSM

Subject Date Of Birth: 01-Jan-1980 Referred By: Dr. Manish Patel

17060104 Lab ID: Sex: Female Visit :

Screening

Sample Collected Sample Collected At:

Sample Received On: Report Date: Study /Project

17-Nov-2017 18:21

17-Nov-2017 18:54 17-Nov-2017 22:40

Ahmedabad

## **IMMUNOLOGY**

**PARAMETER RESULT** CS/NCS\* **REMARK UNIT REFERENCE INTERVAL** Anti HCV Non-Reactive Non-Reactive

ELISA

Anti HIV I&II Non-Reactive Non-Reactive

ELISA

HBsAg Non-Reactive Non-Reactive

FLISA

hCG <0.500 WNL mIU/mL Pre menopausal

females:<4.9

Electrochemiluminescence

**CLINICALLY ACCEPTABLE** Final Remark :-

Jaimin Chhaganbhai Ahir - Stud 18-Nov-2017 12:47 Reviewed by:-

\*- NCS = Non Clinical Significant, CS = Clinical Significant

This is an Electronically authenticated report

Report Printed On: 16-Feb-2018 11:39 Authenticated By: Dipal D Shah 17-Nov-2017 22:40







## **Clinical Laboratory Test Report**



Lambda Therapeutic Research Limited

Screening AH17-06704 Subject Initial:

Subject

Referred By:

KSM Date Of Birth:

01-Jan-1980 Dr. Manish Patel Lab ID: Sex:

Visit :

17060104 Female

Screening

**Sample Collected** 

Sample Collected At: Sample Received On: Report Date:

Ahmedabad 17-Nov-2017 18:54 17-Nov-2017 22:40

17-Nov-2017 18:21

Study /Project

**URINE ANALYSIS** 

[Performed By Reflectance Photometry]

PARAMETER Appearance	<u>RESULT</u> CLEAR	CS/NCS*	<u>REMARK</u>	<u>UNIT</u>	REFERENCE INTERVAL
Specimen Type	RANDOM				
Colour	Yellow				
Specific Gravity	1.007				1.005 - 1.020
pH	7				5.0 - 8.0
GLUCOSE	Negative				Negative
PROTEIN	Negative				Negative
BILIRUBIN	Negative				Negative
KETONE	Negative				Negative
Urobilinogen	Negative				Negative
ERYTHROCYTES	Negative				Negative
LEUCOCYTES	Negative				Negative
NITRITE	Negative				Negative

**CLINICALLY ACCEPTABLE** Final Remark :-

Reviewed by:-Jaimin Chhaganbhai Ahir - Stud 18-Nov-2017 12:47

\*- NCS = Non Clinical Significant, CS = Clinical Significant

This is an Electronically authenticated report

Report Printed On: 16-Feb-2018 11:39 Authenticated By:Krunalkumar M. Patel 17-Nov-2017 19:32







## **Clinical Laboratory Test Report**



Screening AH17-06704 Subject Initial: **KSM** Subject Date Of Birth:

Referred By:

01-Jan-1980 Dr. Manish Patel Lab ID: 17060104 Sex: Female Visit :

Screening

Sample Collected Sample Collected At: Sample Received On: Report Date:

Study /Project

Ahmedabad 17-Nov-2017 18:54 17-Nov-2017 22:40

17-Nov-2017 18:21

**Out of Summary Report** 

PARAMETER	RESULT		<u>UNIT</u>	REFERENCE INTERVAL	<u>COMMENTS</u>
CREATININE CLEARANCE	165.78	н	mL/min	80 - 125	
НСТ	34.6	L	%	36.0 - 46.0	

**CLINICALLY ACCEPTABLE** Final Remark :-

Jaimin Chhaganbhai Ahir - Stud 18-Nov-2017 12:47 Reviewed by:-

\*- NCS = Non Clinical Significant, CS = Clinical Significant

This is an Electronically authenticated report

Report Printed On: 16-Feb-2018 Authenticated By: Dipal D Shah 17-Nov-2017 19:56 11:39







#### **Clinical Laboratory Test Report**



Lambda Therapeutic Research Limited

Screening AH17-06704 Subject Initial: KSM

Subject 1026 Date Of Birth: 01-Jan-1980 Referred By: Dr. Manish Patel

17061746 Lab ID: Sex: Female

Visit :

PCI1

Sample Collected

Sample Collected At: Sample Received On: Report Date:

25-Nov-2017 12:53 Ahmedabad

25-Nov-2017 13:26 25-Nov-2017 15:24

Study /Project 0326-17

#### **CHEMISTRY**

[Performed By Reflectance Photometry]

**PARAMETER RESULT** CS/NCS\* **REMARK UNIT REFERENCE INTERVAL** mg/dL **CREATININE** 0.62 0.5 - 0.9

Enzymatic (Creatine amidohydrolase, IDMS

traceable)

**H** mL/min 160.43 CREATININE CLEARANCE NCS 80 - 125

Calculated by Cockcroft Gault method

clinically acceptable Final Remark :-

Dr. Sanjaykumar S. Patel - Stud25-Nov-2017 16:24 Reviewed by:-

\*- NCS = Non Clinical Significant, CS = Clinical Significant

This is an Electronically authenticated report

Report Printed On: 16-Feb-2018 11:39 Authenticated By: Dhaval J Patel 25-Nov-2017 15:24







## **Clinical Laboratory Test Report**



Lambda Therapeutic Research Limited

Screening AH17-06704
Subject Initial: KSM
Subject 1026

Date Of Birth: 01-Jan-1980

Referred By: Dr. Manish Patel

**Lab ID:** 17061746 **Sex :** Female

Visit: PCI1

Sample Collected
Sample Collected At:

Sample Received On:
Report Date:
Study /Project

25-Nov-2017 12:53

Ahmedabad 25-Nov-2017 13:26 25-Nov-2017 15:24

females: <4.83

0326-17

## **IMMUNOLOGY**

 PARAMETER
 RESULT
 CS/NCS\*
 REMARK
 UNIT
 REFERENCE INTERVAL

 BETA hCG
 <2.39</td>
 wnl
 mIU/mL
 - Pre menopausal

Chemiluminescence

Final Remark :- clinically acceptable

Reviewed by:- Dr. Sanjaykumar S. Patel - Stud25-Nov-2017 16:24

\*- NCS = Non Clinical Significant, CS = Clinical Significant

This is an Electronically authenticated report

Report Printed On: 16-Feb-2018 11:39 Authenticated By:Hiren D. Patel 25-Nov-2017 15:15







## **Clinical Laboratory Test Report**



Screening AH17-06704
Subject Initial: KSM
Subject 1026
Date Of Birth: 01-Jan-1980

Date Of Birth: 01-Jan-1980

Referred By: Dr. Manish Patel

 Lab ID:
 17061746

 Sex :
 Female

 Visit :
 PCI1

Sample Collected Sample Collected At: Sample Received On: Report Date:

Study /Project

25-Nov-2017 12:53 Ahmedabad 25-Nov-2017 13:26

25-Nov-2017 13:26 25-Nov-2017 15:24 0326-17

# **Out of Summary Report**

PARAMETER RESULT UNIT REFERENCE INTERVAL COMMENTS

CREATININE CLEARANCE 160.43 H mL/min 80 - 125

Final Remark :- clinically acceptable

Reviewed by:- Dr. Sanjaykumar S. Patel - Stud25-Nov-2017 16:24

\*- NCS = Non Clinical Significant, CS = Clinical Significant

This is an Electronically authenticated report

Report Printed On: 16-Feb-2018 11:39 Authenticated By:Dhaval J Patel 25-Nov-2017 15:24







#### **Clinical Laboratory Test Report**



Lambda Therapeutic Research Limited

Screening AH17-06704 Subject Initial: KSM

Subject 1026 Date Of Birth: 01-Jan-1980 Referred By: Dr. Manish Patel

17062552 Lab ID: Sex: Female

Visit : PCI2 Sample Collected

Sample Collected At: Ahmedabad Sample Received On: Report Date:

01-Dec-2017 16:03 01-Dec-2017 17:14

01-Dec-2017 15:48

Study /Project 0326-17

**CHEMISTRY** 

[Performed By Reflectance Photometry]

**PARAMETER RESULT** CS/NCS\* **REMARK UNIT REFERENCE INTERVAL** mg/dL **CREATININE** 0.69 0.5 - 0.9

Enzymatic (Creatine amidohydrolase, IDMS traceable)

CREATININE CLEARANCE

144.15

NCS

**H** mL/min

80 - 125

Calculated by Cockcroft Gault

method

**CLINICALLY ACCEPTABLE** Final Remark :-

Reviewed by:-Dr. Sanjaykumar S. Patel - Studo1-Dec-2017 17:14

\*- NCS = Non Clinical Significant, CS = Clinical Significant

This is an Electronically authenticated report

Report Printed On: 16-Feb-2018 11:39 Authenticated By: Malti Panchal 01-Dec-2017 17:14







# **Clinical Laboratory Test Report**



Lambda Therapeutic Research Limited

Screening AH17-06704
Subject Initial: KSM
Subject 1026

Date Of Birth: 01-Jan-1980
Referred By: Dr. Manish Patel

<2.39

**Lab ID:** 17062552 **Sex :** Female

Visit: PCI2

Sample Collected

Sample Collected At: Sample Received On: Report Date: 01-Dec-2017 15:48 Ahmedabad

01-Dec-2017 16:03 01-Dec-2017 17:14

Study / Project 0326-17

#### **IMMUNOLOGY**

PARAMETER RESULT CS/NCS\* REMARK UNIT REFERENCE INTERVAL

\_\_\_\_\_

Chemiluminescence

BETA hCG

 S\*
 REMARK
 UNIT
 REFERENCE INTERV

 WNI
 mIU/mL
 - Pre menopausal

- Pre menopausal females: <4.83

Final Remark :- CLINICALLY ACCEPTABLE

Reviewed by:- Dr. Sanjaykumar S. Patel - Studo1-Dec-2017 17:14

\*- NCS = Non Clinical Significant, CS = Clinical Significant

This is an Electronically authenticated report

Report Printed On: 16-Feb-2018 11:39 Authenticated By:Nikitaben Jani 01-Dec-2017 17:11







## **Clinical Laboratory Test Report**



Screening AH17-06704
Subject Initial: KSM
Subject 1026

CREATININE CLEARANCE

Date Of Birth: 01-Jan-1980

Referred By: Dr. Manish Patel

 Lab ID:
 17062552

 Sex :
 Female

 Visit :
 PCI2

144.15

Sample Collected Sample Collected At: Sample Received On: Report Date: Study /Project

80 - 125

01-Dec-2017 15:48 Ahmedabad 01-Dec-2017 16:03

01-Dec-2017 16:03 01-Dec-2017 17:14 0326-17

# **Out of Summary Report**

PARAMETER RESULT UNIT REFERENCE INTERVAL COMMENTS

н

mL/min

Final Remark :- CLINICALLY ACCEPTABLE

Reviewed by:- Dr. Sanjaykumar S. Patel - Stud01-Dec-2017 17:14

\*- NCS = Non Clinical Significant, CS = Clinical Significant

This is an Electronically authenticated report

Report Printed On: 16-Feb-2018 11:39 Authenticated By:Malti Panchal 01-Dec-2017 17:14





## CASE REPORT FORM

Project No: 0326-17



CHECK-IN DET	ΓAILS( Period -	1)		
BREATH TEST FOR ALCOHOL CONSUMPTION				Period:
Date:	2:	5-Nov-201	7	
Start Time:	13	3:18 <b>24 h</b>	rs. clock	
Breath Alcohol Level (BAL):	.0	00 %		
Result:	C	Positive	Negative	
Start Time of 1st Repeat:		24 hrs. clo	ock	
Breath Alcohol Level (BAL):		%		
1st Repeat result:	C	Positive	C Negative	
Start Time of 2nd Repeat:		24 hrs. clo	ock	
Breath Alcohol Level (BAL):		%		
2nd Repeat Result:	C	Positive	C Negative	
Final Result:	С	Positive	• Negative	
For Positive results (if any) Informed to Principal Investigator/Co Investigator/designate:	)- C	Yes C N	o <b>©</b> NAP	
Remarks:	-			
URINE SCAN FOR DRUGS OF ABUSE				Period:
SOP reference no:CPMA-26-08				
Date:	25-Nov	<b>-2017</b>		
Refer/Read leaflet before start activity:	<b>€</b> Yes	C No C	NAP	
1. URINE SCAN FOR DRUGS ABUSE				
1.1 Urine drug scan tested for:	Amp (AMP)	ohetamine	■ Barbiturates (BAR)	Benzodiazepines (BZD)
	COC)	aine	Morphine (MOR)	Cannabinoids (THC)
1.2 Start time:	13:36	24 hrs. cl	ock	
1.3 Observation of Results:	one ban (Contro		• Negative wit band (Control a	with No
1.4 Positive for:	□ Am <sub>I</sub> (AMP)	ohetamine	☐ Barbiturates (BAR)	Benzodiazepines (BZD)
	Coca (COC)	aine	☐ Morphine (MOR)	Cannabinoids (THC)

Lambda Therapeutic Research.

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CASE REPORT FORM

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2.1 Urine drug scan tested for:	Amphetamine (AMP)	☐ Barbiturates (BAR)	Benzodiazepines (BZD)
	Cocaine (COC)	☐ Morphine (MOR)	Cannabinoids (THC)
2.2 Start time:	24 hrs. clock		
2.3 Observation of Results:	C Positive with one band (Control) C Invalid with	C Negative wirband (Control a	with No
	one band (Test)		
2.4 Positive for:	Amphetamine (AMP)	☐ Barbiturates (BAR)	Benzodiazepines (BZD)
	Cocaine (COC)	☐ Morphine (MOR)	Cannabinoids (THC)
3. URINE SCAN FOR DRUGS ABUSE (2nd REPEAT)			
3.1 Urine drug scan tested for:	Amphetamine (AMP)	☐ Barbiturates (BAR)	Benzodiazepines (BZD)
	Cocaine (COC)	☐ Morphine (MOR)	Cannabinoids (THC)
	(666)	(MOR)	(IIIe)
3.2 Start time:	24 hrs. clock	(MOR)	(IIIC)
3.2 Start time:  3.3 Observation of Results:	24 hrs. clock C Positive with one band (Control) C Invalid with	C Negative wir	th two C Invalid
	24 hrs. clock C Positive with one band (Control)	C Negative wi	th two C Invalid with No band
	24 hrs. clock C Positive with one band (Control) C Invalid with	C Negative wirband (Control a	th two With No
3.3 Observation of Results:	24 hrs. clock C Positive with one band (Control) C Invalid with one band (Test)  Amphetamine	C Negative wir band (Control a	th two with No band  Benzodiazepines
3.3 Observation of Results:	24 hrs. clock C Positive with one band (Control) C Invalid with one band (Test)  Amphetamine (AMP) Cocaine	C Negative wir band (Control as Barbiturates (BAR)  Morphine (MOR)	th two with No band  Benzodiazepines (BZD)  Cannabinoids
3.3 Observation of Results:  3.4 Positive for:	24 hrs. clock C Positive with one band (Control) C Invalid with one band (Test)  Amphetamine (AMP) Cocaine (COC)	C Negative wir band (Control a Barbiturates (BAR)  Morphine (MOR)	th two with No band  Benzodiazepines (BZD)  Cannabinoids
3.3 Observation of Results:  3.4 Positive for:  Final Result:	24 hrs. clock C Positive with one band (Control) C Invalid with one band (Test)  Amphetamine (AMP) Cocaine (COC) C Positive • Ne	C Negative wir band (Control a Barbiturates (BAR)  Morphine (MOR)  egative	th two and test)  C Invalid with No band  Benzodiazepines (BZD)  Cannabinoids (THC)
3.3 Observation of Results:  3.4 Positive for:  Final Result:	24 hrs. clock C Positive with one band (Control) C Invalid with one band (Test)  Amphetamine (AMP) Cocaine (COC) C Positive © New Amphetamine (AMP)  Cocaine (COC) C Cocaine (COC)	C Negative wir band (Control a band (Control a Barbiturates (BAR)  Morphine (MOR)  gative  Barbiturates (BAR)  Morphine	th two and test)  C Invalid with No band  Benzodiazepines (BZD)  Cannabinoids (THC)  Benzodiazepines (BZD)  Cannabinoids
3.3 Observation of Results:  3.4 Positive for:  Final Result:  Positive for:	24 hrs. clock C Positive with one band (Control) C Invalid with one band (Test)  Amphetamine (AMP) Cocaine (COC) C Positive © New Amphetamine (AMP)  Cocaine (COC) C Cocaine (COC)	C Negative wir band (Control a band (Control a Barbiturates (BAR)  Morphine (MOR)  gative  Barbiturates (BAR)  Morphine	th two and test)  C Invalid with No band  Benzodiazepines (BZD)  Cannabinoids (THC)  Benzodiazepines (BZD)  Cannabinoids
3.3 Observation of Results:  3.4 Positive for:  Final Result:  Positive for:  Remarks (for repeats or any other information):	24 hrs. clock C Positive with one band (Control) C Invalid with one band (Test)  Amphetamine (AMP) Cocaine (COC) C Positive © New Amphetamine (AMP)  Cocaine (COC) C Cocaine (COC)	C Negative wirband (Control a  Barbiturates (BAR)  Morphine (MOR)  gative  Barbiturates (BAR)  Morphine (MOR)	th two and test)  C Invalid with No band  Benzodiazepines (BZD)  Cannabinoids (THC)  Benzodiazepines (BZD)  Cannabinoids

<sup>\*</sup>This is an electronically authenticated report.

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Sponsor Name: Cipla Limited

CASE REPORT FORM

Project No: 0326-17

Subject No: 1026 Subject Initials: KSM

4477	Phencyclidine(PCP) Cotinine(COT) Methadone(MTD)
4.1 Urine drug scan tested for:	Other
4010 4 4 10	1 Other
4.2 If other then specify:	241,
4.3 Start Time:	24 hrs. clock
4.4 Observation of Results:	C Positive with one band (Control and test)  C Negative with two band (Control and test)  C Invalid with No band
	C Invalid with one band (Test)
4.5 Positive for:	Phencyclidine(PCP) Cotinine(COT) Methadone(MTD)
	☐ Other
4.6 If other then specify:	
5. URINE SCAN FOR DRUGS ABUSE ADDITIONAL (1st REPEAT)	
5.1 Urine drug scan tested for:	Phencyclidine(PCP) Cotinine(COT) Methadone(MTD)
	☐ Other
5.2 If other then specify:	
5.3 Start Time:	24 hrs. clock
5.4 Observation of Results:	C Positive with one band (Control and test)  C Negative with two band (Control and test)  C Invalid with No band
	C Invalid with one band (Test)
5.5 Positive for:	Phencyclidine(PCP) Cotinine(COT) Methadone(MTD)
	Other
5.6 If other then specify:	
6. URINE SCAN FOR DRUGS ABUSE ADDITIONAL (2nd REPEAT)	
6.1 Urine drug scan tested for:	Phencyclidine(PCP) Cotinine(COT) Methadone(MTD)
	☐ Other
6.2 If other then specify:	
6.3 Start Time:	24 hrs. clock
6.4 Observation of Results:	C Positive with one band (Control and test)  C Negative with two band (Control and test)  C Invalid with No band
	C Invalid with one band (Test)

Lambda Therapeutic Research. Sponsor Name:Cipla Limited CASE REPORT FORM

Subject No: 1026



Project No: 0326-17 Subject Initials: KSM

6.5 Positive for:	Phencyclidine(PCP) Cotinine(COT) Methadone(MTD)
6.6 If other then specify:	
Final Result:	C Positive C Negative
Positive for:	Phencyclidine(PCP) Cotinine(COT) Methadone(MTD)  Other
If other then specify:	
Remarks (for repeats or any other information):	
CRITERIA FOR SELECTION OF SUBJECTS	Period: 1
Inclusion Criteria	
Non-smoker/ Ex-smoker, healthy, adult, human, volunteers between 18 an years of age (both inclusive):	d 45 G Yes C No
Having a Body Mass Index (BMI) between 18.5 and 29.9 (both inclusive) calculated as weight in kg / height in m2:	Yes C No
Not having any significant diseases or clinically significant abnormal finding during screening, medical history, clinical examination, laboratory evaluation 12-lead ECG and X-ray chest (Postero-anterior view) recordings:	
Able to understand and comply with the study procedures, in the opinion the investigator:	of Yes C No
Able to give voluntary written informed consent for participation in the s	tudy: • Yes • No
Inclusion Criteria in case of Female subjects	
Surgically sterilized at least 6 months prior to study participation; Or:	C Yes C No G NAP
If of child bearing potential is willing to use a suitable and effective double barrier contraceptive method or intra uterine device during the study. and:	G Yes C No C NAP
Serum Pregnancy test must be negative:	© Yes C No C NAP
Exclusion criteria	
Known hypersensitivity to Apremilast or any excipients or any related dror any substance:	Ug C Yes © No
History or presence of any disease or condition (including Bleeding,) which might compromise the haemopoietic, renal, hepatic, endocrine, pulmonary, central nervous, cardiovascular, immunological, dermatological, gastrointest eye, ear conditions or any other body system:	C Ves G No
Any history or presence of asthma (including aspirin induced asthma) or a polyp or NSAIDs induced urticaria:	C Yes © No
Difficulty in swallowing solids dosage forms like tablets or capsules:	C Yes © No
A recent history of harmful use of alcohol (less than 2 years), i.e. alcohol consumption of more than 14 standard drinks per week for men and 07 standard drinks per week for women (A standard drink is defined as 360 m beer or 150 ml of wine or 45 ml of 40% distilled spirits, such as rum, whis brandy etc):	
Smokers or who have smoked within last 06 months prior to start of the study:	C Yes © No

## CASE REPORT FORM

Project No: 0326-17



screening:	C Yes © No
Use of any recreational drugs or history of drug addiction:	C Yes 6 No
History of depression and/or suicidal thoughts or behaviour:	C Yes • No
QTc interval > 450 ms at the time of screening:	C Yes 6 No
Subject having CrCL <=50 ml/min at screening:	C Yes 6 No
History or presence of psychiatric disorders:	C Yes 6 No
A history of difficulty in donating blood:	C Yes • No
Donation of blood (1 unit or 350 mL) or receipt of an investigational medicinal product or participation in a drug research study within 90 days prior to receiving the first dose of study drug. Elimination half-life of the study drug should be taken into consideration for inclusion of the subject in the study:	C Yes 6 No
A positive hepatitis screen including hepatitis B surface antigen and/or HCV antibodies:	C Yes 6 No
A positive test result for HIV-I & II antibody:	C Yes © No
Nursing mothers (females):	C Yes 6 No C NAP
suitability	
Based on above criterias, Subject is:	© Suitable © Not-suitable
Criteria to be checked at the time of compliance check	
Ingestion of a medication (Prescribed or Over the counter medicines including h inducers, rifampin, phenobarbital, carbamazepine, phenytoin) at any time in 14 for whatever reason (e.g. low-sodium), for four weeks prior to receiving the IMI be at the discretion of the Principal Investigator.	days prior to dosing of period-I and an unusual diet,
Consumption of grapefruits or grapefruit products within a period of 72 hours	prior to check-in of period-I.
Consumption of alcohol or alcoholic products within 48 hours prior to check-in	of period-I.
Testing positive in pre-study drug scans.	
Remarks:	-
COMPLIANCE CHECK-PI	Period: 1
Demographic Details	
Age in Years (Completed as of Screening Date):	37
<b>Subject Reporting And Consent Procedure Record</b>	
Date of reporting to the clinical facility:	25-Nov-2017
Presentation of ICF & obtained the consent on ICF:	• Yes C No
If 'Yes', mention pagination number of ICF:	29
Protocol Compliance Assessment	
Criteria Check Complete:	G Yes C No C NAP
Urine scan for drugs of abuse tested negative:	€ Yes C No
Breath test for alcohol consumption tested negative:	• Yes C No
Date of last menstruation period (for female subject):	21-NOV-2017

## CASE REPORT FORM

Project No: 0326-17



Result of serum pregnancy test:	C NAP (For Male Positive Negative subject)
Prohibitions	
Are you suffering from any illness since the last visit (Including allergic reaction, itching, rash on your skin):	C Yes 6 No
Have you consumed any xanthine containing food or beverages (like tea, coffee, chocolates or cola drinks) for 24 hours prior to check-in?:	C Yes • No
Have you consumed tobacco, tobacco containing products (Gutkha, Pan/Pan masala or any other) for 24 hours prior to check-in?:	C Yes € No
Have you consumed recreational products, alcohol or alcoholic products for 48 hours prior to check-in?:	C Yes O No
Have you consumed grapefruit or grapefruit products, for 72 hours prior to check-in?:	C Yes • No
Any history of smoking for 6 months prior to start of the study?:	C Yes 6 No
Ingestion of a medication (Prescribed or Over the counter medicines including herbal remedies, strong cytochrome P450 enzyme inducers, rifampin, phenobarbital, carbamazepine, phenytoin) at any time in 14 days prior to dosing?:	C Yes € No
Have you consumed an unusual diet, for whatever reason (e.g. low-sodium), for four weeks prior to dosing?:	C Yes 6 No
Has the subject been instructed not to participate in other clinical trial or donate blood anywhere else during the study?:	• Yes C No
Is subject compliant to all above restrictions/requirement?:	• Yes C No
Remark If any:	-
Subject Eligibility	
Compliance check reviewed By:	C PI G Co-I C Study Physician
Subject eligible:	• Yes C No
Remarks,If any:	-
LABORATORY ASSESSMENT-PRIOR TO CHECK IN OF (PERIOD I)	Period: 1
Note: For Estimation of CrCl (Creatinine Clearance).	
Has the blood sample been collected as per protocol?:	€ Yes C No
Date of blood sample collection:	25-Nov-2017
Lab report clinically acceptable:	G Yes C No C NAP
Comments (if any):	-
CHECK-IN B&B	Period: 1
Baggage and Body Search done:	G Yes C No
Date of Check In:	25-Nov-2017
Time of Check-in:	19:41 <b>24 hrs. clock</b>
Remarks:	-
CLINICAL EXAMINATION - CHECK IN	Period: 1
Date of clinical examination:	25-Nov-2017
Start Time of Clinical Examination:	20:16 24 hrs. clock

## CASE REPORT FORM

Project No: 0326-17



Complaints of any illness:	© No C Yes
If YES, provide details:	-
General Physical examination:	© Normal C Abnormal
Oral Body Temperature:	98.6 °F
Blood Pressure (Systolic):	122 mmHg
Blood Pressure (Diastolic):	80 mmHg
Radial Pulse Rate:	84 beats/min
Cardiovascular System Examination:	€ Normal C Abnormal
Respiratory System Examination:	€ Normal € Abnormal
Central Nervous System Examination:	€ Normal € Abnormal
Per Abdomen Examination:	<b>⊙</b> Normal <b>○</b> Abnormal
Any other Significant finding:	-
Any investigations recommended:	-
Vein puncture site:	<b>⊙</b> Normal <b>○</b> Abnormal
Subject well-being:	• Well C Unwell
If 'Abnormal' in any of the above-mentioned sections, please enter details.:	-
Remark if Any:	-
Subject is fit:	€ Yes C No
DINNER CHECK-IN (DAY-1)	Period: 1
Date of meal distribution:	25-Nov-2017
	25-Nov-2017 20:24 <b>24 hrs. clock</b>
Date of meal distribution:	
Date of meal distribution: Start Time:	20:24 24 hrs. clock
Date of meal distribution: Start Time: End Time:	20:24 <b>24 hrs. clock</b> 20:40 <b>24 hrs. clock</b>
Date of meal distribution:  Start Time:  End Time:  Has subject consumed meal completely?:	20:24 24 hrs. clock 20:40 24 hrs. clock  • Yes • No
Date of meal distribution:  Start Time:  End Time:  Has subject consumed meal completely?:  Details of meal left (Approximate Quantity):	20:24 24 hrs. clock 20:40 24 hrs. clock  • Yes • No  -
Date of meal distribution:  Start Time:  End Time:  Has subject consumed meal completely?:  Details of meal left (Approximate Quantity):  Remarks:	20:24 24 hrs. clock 20:40 24 hrs. clock  • Yes • No  od - 1)
Date of meal distribution:  Start Time:  End Time:  Has subject consumed meal completely?:  Details of meal left (Approximate Quantity):  Remarks:  HOUSING DETAILS( Period	20:24 24 hrs. clock 20:40 24 hrs. clock  • Yes • No  od - 1)
Date of meal distribution:  Start Time:  End Time:  Has subject consumed meal completely?:  Details of meal left (Approximate Quantity):  Remarks:  HOUSING DETAILS( Period 0.00 HRS PRE DOSE VITAL SIGNS AND WELL-BEING RECORD	20:24 24 hrs. clock 20:40 24 hrs. clock  • Yes • No  od - 1)  Period:
Date of meal distribution:  Start Time:  End Time:  Has subject consumed meal completely?:  Details of meal left (Approximate Quantity):  Remarks:  HOUSING DETAILS( Periodon)  0.00 HRS PRE DOSE VITAL SIGNS AND WELL-BEING RECORD  Position:	20:24 24 hrs. clock 20:40 24 hrs. clock  • Yes • No
Date of meal distribution:  Start Time: End Time: Has subject consumed meal completely?: Details of meal left (Approximate Quantity): Remarks:  HOUSING DETAILS( Period O.00 HRS PRE DOSE VITAL SIGNS AND WELL-BEING RECORD Position: Date of vital measurement:	20:24 24 hrs. clock 20:40 24 hrs. clock  • Yes • No  od - 1)  Period:  Sitting 26-Nov-2017
Date of meal distribution:  Start Time:  End Time:  Has subject consumed meal completely?:  Details of meal left (Approximate Quantity):  Remarks:  HOUSING DETAILS( Period O.00 HRS PRE DOSE VITAL SIGNS AND WELL-BEING RECORD Position:  Date of vital measurement:  Start Time of vital measurement:	20:24 24 hrs. clock 20:40 24 hrs. clock  • Yes • No  od - 1)  Period:  Sitting  26-Nov-2017  07:04 24 hrs. clock
Date of meal distribution:  Start Time:  End Time:  Has subject consumed meal completely?:  Details of meal left (Approximate Quantity):  Remarks:  HOUSING DETAILS( Period O.00 HRS PRE DOSE VITAL SIGNS AND WELL-BEING RECORD Position:  Date of vital measurement:  Start Time of vital measurement:  Systolic Blood Pressure:	20:24 24 hrs. clock 20:40 24 hrs. clock  • Yes • No  Sitting 26-Nov-2017 07:04 24 hrs. clock 116 mmHg 76 mmHg 84 beats/min
Date of meal distribution:  Start Time:  End Time:  Has subject consumed meal completely?:  Details of meal left (Approximate Quantity):  Remarks:  HOUSING DETAILS( Period O.00 HRS PRE DOSE VITAL SIGNS AND WELL-BEING RECORD Position:  Date of vital measurement:  Start Time of vital measurement:  Systolic Blood Pressure:  Diastolic Blood Pressure:	20:24 24 hrs. clock 20:40 24 hrs. clock  • Yes • No  od - 1)  Period: 1  Sitting  26-Nov-2017  07:04 24 hrs. clock  116 mmHg  76 mmHg
Date of meal distribution:  Start Time:  End Time:  Has subject consumed meal completely?:  Details of meal left (Approximate Quantity):  Remarks:  HOUSING DETAILS( Periodon On the Present of Management of Manage	20:24 24 hrs. clock 20:40 24 hrs. clock  • Yes • No  Sitting 26-Nov-2017 07:04 24 hrs. clock 116 mmHg 76 mmHg 84 beats/min
Date of meal distribution:  Start Time: End Time: Has subject consumed meal completely?:  Details of meal left (Approximate Quantity): Remarks:  HOUSING DETAILS( Period O.00 HRS PRE DOSE VITAL SIGNS AND WELL-BEING RECORD Position: Date of vital measurement: Start Time of vital measurement: Systolic Blood Pressure: Diastolic Blood Pressure: Radial Pulse: Oral Body Temperature:	20:24 24 hrs. clock 20:40 24 hrs. clock  • Yes • No  od - 1)  Period: 1  Sitting  26-Nov-2017  07:04 24 hrs. clock  116 mmHg  76 mmHg  84 beats/min  98.0 °F
Date of meal distribution:  Start Time:  End Time:  Has subject consumed meal completely?:  Details of meal left (Approximate Quantity):  Remarks:  HOUSING DETAILS( Period O.00 HRS PRE DOSE VITAL SIGNS AND WELL-BEING RECORD Position:  Date of vital measurement:  Start Time of vital measurement:  Systolic Blood Pressure:  Diastolic Blood Pressure:  Radial Pulse:  Oral Body Temperature:  Well-being:	20:24 24 hrs. clock 20:40 24 hrs. clock  • Yes • No  od - 1)  Period: 1  Sitting  26-Nov-2017  07:04 24 hrs. clock  116 mmHg  76 mmHg  84 beats/min  98.0 °F  • Well • Unwell
Date of meal distribution:  Start Time: End Time: Has subject consumed meal completely?:  Details of meal left (Approximate Quantity): Remarks:  HOUSING DETAILS( Period O.00 HRS PRE DOSE VITAL SIGNS AND WELL-BEING RECORD Position: Date of vital measurement: Start Time of vital measurement: Systolic Blood Pressure: Diastolic Blood Pressure: Radial Pulse: Oral Body Temperature: Well-being: If unwell then specify:	20:24 24 hrs. clock 20:40 24 hrs. clock  • Yes C No  od - 1)  Period: 1  Sitting 26-Nov-2017 07:04 24 hrs. clock 116 mmHg 76 mmHg 84 beats/min 98.0 °F  • Well C Unwell -

## CASE REPORT FORM

Project No: 0326-17



Date of sample collection:	26-Nov-2017
Scheduled date and Time of sample collection (for post dose only):	
Actual Time of sample collection:	07:30 24 hrs. clock
Remarks:	
PK Sample ID:	PK17862931
Remarks if any other reason:	
IMP ADMINISTRATION	Period: 1
DATE:	26-Nov-2017
IS SUBJECT COMPLIANT TO ALL PREDOSE REQUIREMENTS AS	
PER PROTOCOL?:	© Yes C No C NA
TIME:	08:24 24 hrs. clock
MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA:	€ Yes C No C NA
ML OF WATER ADMINISTERED WITH IP:	240
LABEL:	0000250430
PRODUCT CODE/ TYPE:	Reference
DOSING DONE BY:	kanarampatel (Dosing)
DOSING SUPERVISION DONE BY:	ankitkpatel (Dosing)
REMARKS:	Subject spilled out approx 02 to 03 drops of
	dosing water during IMP administration.
STUDY DRUG ADMINISTRATION-COMPLIANCE	Period: 1
Has the subject compliant to 02 hour post dose water restriction?:	• Yes C No
Has the subject compliant to postural restriction for 04 hours post dose in sitting posture? (unless medically necessary due to adverse event or procedurally required or natural exigency):	€ Yes C No
Has the subject compliant to 04 hours post dose fasting condition?:	€ Yes C No
Remark If any:	-
0.250 HRS POST DOSE PK SAMPLE COLLECTION	Period: 1
Date and Time of Dosing:	26-Nov-2017 08:24
Date of sample collection:	26-Nov-2017
Scheduled date and Time of sample collection (for post dose only):	26-Nov-2017 08:39
Actual Time of sample collection:	08:39 24 hrs. clock
Remarks:	
PK Sample ID:	PK17863003
Remarks if any other reason:	
0.500 HRS POST DOSE PK SAMPLE COLLECTION	Period: 1
Date and Time of Dosing:	26-Nov-2017 08:24
Date of sample collection:	26-Nov-2017
Scheduled date and Time of sample collection (for post dose only):	26-Nov-2017 08:54
Actual Time of sample collection:	08:54 24 hrs. clock
Remarks:	
PK Sample ID:	PK17863075
Remarks if any other reason:	
0.750 HRS POST DOSE PK SAMPLE COLLECTION	Period: 1

<sup>\*</sup>This is an electronically authenticated report.

Sponsor Name:Cipla Limited

## CASE REPORT FORM

Project No: 0326-17



Date and Time of Dosing:	26-Nov-2017 08:24
Date of sample collection:	26-Nov-2017
Scheduled date and Time of sample collection (for post dose only):	26-Nov-2017 09:09
Actual Time of sample collection:	09:09 24 hrs. clock
Remarks:	
PK Sample ID:	PK17863147
Remarks if any other reason:	
1.000 HRS POST DOSE PK SAMPLE COLLECTION	Period
Date and Time of Dosing:	26-Nov-2017 08:24
Date of sample collection:	26-Nov-2017
Scheduled date and Time of sample collection (for post dose only):	26-Nov-2017 09:24
Actual Time of sample collection:	09:24 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK17863219
Remarks if any other reason:	
1.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD	Perioc
Position:	Sitting
Date of vital measurement:	26-Nov-2017
Start Time of vital measurement:	08:56 24 hrs. clock
Systolic Blood Pressure:	112 mmHg
Diastolic Blood Pressure:	78 mmHg
Radial Pulse:	76 beats/min
Well-being:	• Well • Unwell
If unwell then specify:	-
Remarks:	-
1.333 HRS POST DOSE PK SAMPLE COLLECTION	Perioc
Date and Time of Dosing:	26-Nov-2017 08:24
Date of sample collection:	26-Nov-2017
Scheduled date and Time of sample collection (for post dose only):	26-Nov-2017 09:44
Actual Time of sample collection:	09:44 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK17863278
Remarks if any other reason:	
1.667 HRS POST DOSE PK SAMPLE COLLECTION	Period
Date and Time of Dosing:	26-Nov-2017 08:24
Date of sample collection:	26-Nov-2017
Scheduled date and Time of sample collection (for post dose only):	26-Nov-2017 10:04
Actual Time of sample collection:	10:04 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK17863314
Remarks if any other reason:	
2.000 HRS POST DOSE PK SAMPLE COLLECTION	Perioc

Sponsor Name:Cipla Limited

## CASE REPORT FORM

Project No: 0326-17



Date of sample collection:	26-Nov-2017
Scheduled date and Time of sample collection (for post dose only):	26-Nov-2017 10:24
Actual Time of sample collection:	10:24 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK17863350
Remarks if any other reason:	
2.333 HRS POST DOSE PK SAMPLE COLLECTION	Period: 1
Date and Time of Dosing:	26-Nov-2017 08:24
Date of sample collection:	26-Nov-2017
Scheduled date and Time of sample collection (for post dose only):	26-Nov-2017 10:44
Actual Time of sample collection:	10:44 24 hrs. clock
Remarks:	10000 210000
PK Sample ID:	PK17863386
Remarks if any other reason:	1117003300
2.667 HRS POST DOSE PK SAMPLE COLLECTION	Period: 1
Date and Time of Dosing:	
Date of sample collection:	26-Nov-2017
Scheduled date and Time of sample collection (for post dose only):	26-Nov-2017 11:04
Actual Time of sample collection:	11:04 24 hrs. clock
Remarks:	PV15072422
PK Sample ID:	PK17863423
Remarks if any other reason:	
3.000 HRS POST DOSE PK SAMPLE COLLECTION	Period: 1
Date and Time of Dosing:	26-Nov-2017 08:24
Date of sample collection:	26-Nov-2017
Scheduled date and Time of sample collection (for post dose only):	26-Nov-2017 11:24
Actual Time of sample collection:	11:24 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK17863495
Remarks if any other reason:	
3.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD	Period: 1
Position:	Sitting
Date of vital measurement:	26-Nov-2017
Start Time of vital measurement:	10:48 <b>24 hrs. clock</b>
Systolic Blood Pressure:	114 mmHg
Diastolic Blood Pressure:	74 mmHg
Radial Pulse:	72 beats/min
Well-being:	€ Well € Unwell
If unwell then specify:	-
Remarks:	-
3.333 HRS POST DOSE PK SAMPLE COLLECTION	Period: 1
Date and Time of Dosing:	26-Nov-2017 08:24
Date of sample collection:	26-Nov-2017 00:24 26-Nov-2017
Date of sample collection:	/D- NOV-/UL/

<sup>\*</sup>This is an electronically authenticated report.

Sponsor Name:Cipla Limited

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Scheduled date and Time of sample collection (for post dose only):	26-Nov-2017 11:44
Actual Time of sample collection:	11:44 24 hrs. clock
Remarks:	11:44 24 Hrs. clock
PK Sample ID:	PK17863567
Remarks if any other reason:	FK1/603307
•	
3.667 HRS POST DOSE PK SAMPLE COLLECTION	Period:
Date and Time of Dosing:	26-Nov-2017 08:24
Date of sample collection:	26-Nov-2017
Scheduled date and Time of sample collection (for post dose only):	26-Nov-2017 12:04
Actual Time of sample collection:	12:04 24 hrs. clock
Remarks:	
PK Sample ID:	PK17863638
Remarks if any other reason:	
4.000 HRS POST DOSE PK SAMPLE COLLECTION	Period:
Date and Time of Dosing:	26-Nov-2017 08:24
Date of sample collection:	26-Nov-2017
Scheduled date and Time of sample collection (for post dose only):	26-Nov-2017 12:24
Actual Time of sample collection:	12:24 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK17863710
Remarks if any other reason:	
LIDIGII (4.00 LIDG POCT POCT) (PANA)	
LUNCH (4.00 HRS POST DOSE) (DAY 1)	Period:
Date of meal distribution:	Period: 26-Nov-2017
Date of meal distribution:	26-Nov-2017
Date of meal distribution: Start Time:	26-Nov-2017 12:26 <b>24 hrs. clock</b>
Date of meal distribution: Start Time: End Time:	26-Nov-2017 12:26 24 hrs. clock 12:42 24 hrs. clock
Date of meal distribution:  Start Time:  End Time:  Has subject consumed meal completely?:	26-Nov-2017  12:26 24 hrs. clock  12:42 24 hrs. clock  •• Yes © No
Date of meal distribution:  Start Time:  End Time:  Has subject consumed meal completely?:  Details of meal left (Approximate Quantity):  Remarks:	26-Nov-2017  12:26 24 hrs. clock  12:42 24 hrs. clock  •• Yes © No
Date of meal distribution:  Start Time:  End Time:  Has subject consumed meal completely?:  Details of meal left (Approximate Quantity):  Remarks:  4.500 HRS POST DOSE PK SAMPLE COLLECTION	26-Nov-2017  12:26 24 hrs. clock  12:42 24 hrs. clock  • Yes C No  Period:
Date of meal distribution:  Start Time:  End Time:  Has subject consumed meal completely?:  Details of meal left (Approximate Quantity):  Remarks:  4.500 HRS POST DOSE PK SAMPLE COLLECTION  Date and Time of Dosing:	26-Nov-2017  12:26 24 hrs. clock  12:42 24 hrs. clock  • Yes • No  Period:  26-Nov-2017 08:24
Date of meal distribution:  Start Time:  End Time:  Has subject consumed meal completely?:  Details of meal left (Approximate Quantity):  Remarks:  4.500 HRS POST DOSE PK SAMPLE COLLECTION  Date and Time of Dosing:  Date of sample collection:	26-Nov-2017  12:26 24 hrs. clock  12:42 24 hrs. clock  • Yes © No  Period:  26-Nov-2017 08:24  26-Nov-2017
Date of meal distribution:  Start Time:  End Time:  Has subject consumed meal completely?:  Details of meal left (Approximate Quantity):  Remarks:  4.500 HRS POST DOSE PK SAMPLE COLLECTION  Date and Time of Dosing:  Date of sample collection:  Scheduled date and Time of sample collection (for post dose only):	26-Nov-2017  12:26 24 hrs. clock  12:42 24 hrs. clock  © Yes © No   Period:  26-Nov-2017 08:24  26-Nov-2017  26-Nov-2017 12:54
Date of meal distribution:  Start Time:  End Time:  Has subject consumed meal completely?:  Details of meal left (Approximate Quantity):  Remarks:  4.500 HRS POST DOSE PK SAMPLE COLLECTION  Date and Time of Dosing:  Date of sample collection:  Scheduled date and Time of sample collection (for post dose only):  Actual Time of sample collection:	26-Nov-2017  12:26 24 hrs. clock  12:42 24 hrs. clock  • Yes © No  Period:  26-Nov-2017 08:24  26-Nov-2017
Date of meal distribution:  Start Time:  End Time:  Has subject consumed meal completely?:  Details of meal left (Approximate Quantity):  Remarks:  4.500 HRS POST DOSE PK SAMPLE COLLECTION  Date and Time of Dosing:  Date of sample collection:  Scheduled date and Time of sample collection (for post dose only):  Actual Time of sample collection:  Remarks:	26-Nov-2017  12:26 24 hrs. clock  12:42 24 hrs. clock  • Yes © No   Period:  26-Nov-2017 08:24  26-Nov-2017  26-Nov-2017 12:54  12:54 24 hrs. clock
Date of meal distribution:  Start Time:  End Time:  Has subject consumed meal completely?:  Details of meal left (Approximate Quantity):  Remarks:  4.500 HRS POST DOSE PK SAMPLE COLLECTION  Date and Time of Dosing:  Date of sample collection:  Scheduled date and Time of sample collection (for post dose only):  Actual Time of sample collection:  Remarks:  PK Sample ID:	26-Nov-2017  12:26 24 hrs. clock  12:42 24 hrs. clock  © Yes © No   Period:  26-Nov-2017 08:24  26-Nov-2017  26-Nov-2017 12:54
Date of meal distribution:  Start Time:  End Time:  Has subject consumed meal completely?:  Details of meal left (Approximate Quantity):  Remarks:  4.500 HRS POST DOSE PK SAMPLE COLLECTION  Date and Time of Dosing:  Date of sample collection:  Scheduled date and Time of sample collection (for post dose only):  Actual Time of sample collection:  Remarks:  PK Sample ID:  Remarks if any other reason:	26-Nov-2017  12:26 24 hrs. clock  12:42 24 hrs. clock  • Yes © No   Period:  26-Nov-2017 08:24  26-Nov-2017 12:54  12:54 24 hrs. clock  PK17863782
Date of meal distribution:  Start Time:  End Time:  Has subject consumed meal completely?:  Details of meal left (Approximate Quantity):  Remarks:  4.500 HRS POST DOSE PK SAMPLE COLLECTION  Date and Time of Dosing:  Date of sample collection:  Scheduled date and Time of sample collection (for post dose only):  Actual Time of sample collection:  Remarks:  PK Sample ID:  Remarks if any other reason:  5.000 HRS POST DOSE PK SAMPLE COLLECTION	26-Nov-2017  12:26 24 hrs. clock  12:42 24 hrs. clock  FYes C No  Period:  26-Nov-2017 08:24  26-Nov-2017  26-Nov-2017 12:54  12:54 24 hrs. clock  PK17863782  Period:
Date of meal distribution:  Start Time:  End Time:  Has subject consumed meal completely?:  Details of meal left (Approximate Quantity):  Remarks:  4.500 HRS POST DOSE PK SAMPLE COLLECTION  Date and Time of Dosing:  Date of sample collection:  Scheduled date and Time of sample collection (for post dose only):  Actual Time of sample collection:  Remarks:  PK Sample ID:  Remarks if any other reason:  5.000 HRS POST DOSE PK SAMPLE COLLECTION  Date and Time of Dosing:	26-Nov-2017  12:26 24 hrs. clock  12:42 24 hrs. clock  Feriod:  26-Nov-2017 08:24  26-Nov-2017 12:54  12:54 24 hrs. clock  PK17863782  Period:  26-Nov-2017 08:24
Date of meal distribution:  Start Time:  End Time:  Has subject consumed meal completely?:  Details of meal left (Approximate Quantity):  Remarks:  4.500 HRS POST DOSE PK SAMPLE COLLECTION  Date and Time of Dosing:  Date of sample collection:  Scheduled date and Time of sample collection (for post dose only):  Actual Time of sample collection:  Remarks:  PK Sample ID:  Remarks if any other reason:  5.000 HRS POST DOSE PK SAMPLE COLLECTION  Date and Time of Dosing:  Date of sample collection:	26-Nov-2017  12:26 24 hrs. clock  12:42 24 hrs. clock  • Yes © No   Period:  26-Nov-2017 08:24  26-Nov-2017 12:54  12:54 24 hrs. clock  PK17863782  Period:  26-Nov-2017 08:24  26-Nov-2017 08:24
Date of meal distribution:  Start Time:  End Time:  Has subject consumed meal completely?:  Details of meal left (Approximate Quantity):  Remarks:  4.500 HRS POST DOSE PK SAMPLE COLLECTION  Date and Time of Dosing:  Date of sample collection:  Scheduled date and Time of sample collection (for post dose only):  Actual Time of sample collection:  Remarks:  PK Sample ID:  Remarks if any other reason:  5.000 HRS POST DOSE PK SAMPLE COLLECTION  Date and Time of Dosing:  Date of sample collection:  Scheduled date and Time of sample collection (for post dose only):	26-Nov-2017  12:26 24 hrs. clock  12:42 24 hrs. clock  FYES O NO   Period:  26-Nov-2017 08:24  26-Nov-2017 12:54  12:54 24 hrs. clock  PK17863782  Period:  26-Nov-2017 08:24  26-Nov-2017 13:24
Date of meal distribution:  Start Time:  End Time:  Has subject consumed meal completely?:  Details of meal left (Approximate Quantity):  Remarks:  4.500 HRS POST DOSE PK SAMPLE COLLECTION  Date and Time of Dosing:  Date of sample collection:  Scheduled date and Time of sample collection (for post dose only):  Actual Time of sample collection:  Remarks:  PK Sample ID:  Remarks if any other reason:  5.000 HRS POST DOSE PK SAMPLE COLLECTION  Date and Time of Dosing:  Date of sample collection:  Scheduled date and Time of sample collection (for post dose only):  Actual Time of sample collection:	26-Nov-2017  12:26 24 hrs. clock  12:42 24 hrs. clock  • Yes © No   Period:  26-Nov-2017 08:24  26-Nov-2017 12:54  12:54 24 hrs. clock  PK17863782  Period:  26-Nov-2017 08:24  26-Nov-2017 08:24
Date of meal distribution:  Start Time:  End Time:  Has subject consumed meal completely?:  Details of meal left (Approximate Quantity):  Remarks:  4.500 HRS POST DOSE PK SAMPLE COLLECTION  Date and Time of Dosing:  Date of sample collection:  Scheduled date and Time of sample collection (for post dose only):  Actual Time of sample collection:  Remarks:  PK Sample ID:  Remarks if any other reason:  5.000 HRS POST DOSE PK SAMPLE COLLECTION  Date and Time of Dosing:  Date of sample collection:  Scheduled date and Time of sample collection (for post dose only):	26-Nov-2017  12:26 24 hrs. clock  12:42 24 hrs. clock  FYES O NO   Period:  26-Nov-2017 08:24  26-Nov-2017 12:54  12:54 24 hrs. clock  PK17863782  Period:  26-Nov-2017 08:24  26-Nov-2017 13:24

<sup>\*</sup>This is an electronically authenticated report.

Sponsor Name:Cipla Limited

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Remarks if any other reason:		
5.500 HRS POST DOSE PK SAMPLE COLLECTION		Period: 1
Date and Time of Dosing:	26-Nov-2017 08:24	
Date of sample collection:	26-Nov-2017	
Scheduled date and Time of sample collection (for post dose only):	26-Nov-2017 13:54	
Actual Time of sample collection:	13:54 <b>24 hrs. clock</b>	
Remarks:		
PK Sample ID:	PK17863926	
Remarks if any other reason:		
6.000 HRS POST DOSE PK SAMPLE COLLECTION Perio		
Date and Time of Dosing:	26-Nov-2017 08:24	
Date of sample collection:	26-Nov-2017	
Scheduled date and Time of sample collection (for post dose only):	26-Nov-2017 14:24	
Actual Time of sample collection:	14:24 <b>24 hrs. clock</b>	
Remarks:		
PK Sample ID:	PK17863998	
Remarks if any other reason:		
6.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD		Period:
Position:	Sitting	
Date of vital measurement:	26-Nov-2017	
Start Time of vital measurement:	13:50 24 hrs. clock	
Systolic Blood Pressure:	110 mmHg	
Diastolic Blood Pressure:	70 <b>mmHg</b>	
Radial Pulse:	68 beats/min	
Well-being:	© Well C Unwell	
If unwell then specify:	-	
Remarks:	-	
8.000 HRS POST DOSE PK SAMPLE COLLECTION		Period:
Date and Time of Dosing:	26-Nov-2017 08:24	
Date of sample collection:	26-Nov-2017	
Scheduled date and Time of sample collection (for post dose only):	26-Nov-2017 16:24	
Actual Time of sample collection:	16:24 <b>24 hrs. clock</b>	
Remarks:		
PK Sample ID:	PK17864070	
Remarks if any other reason:		
SNACKS (DAY 1)		Period:
Date of meal distribution:	26-Nov-2017	
Start Time:	16:25 <b>24 hrs. clock</b>	
End Time:	16:33 24 hrs. clock	
Has subject consumed meal completely?:	€ Yes C No	
Details of meal left (Approximate Quantity):	-	
Remarks:	-	
10.000 HRS POST DOSE PK SAMPLE COLLECTION		Period:
TOWN THE TOOT DOOL IT OF MIT EL COLLECTION		T CHOU.

<sup>\*</sup>This is an electronically authenticated report.

Sponsor Name:Cipla Limited

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Project No: 0326-17

Subject No: 1026 Subject Initials: KSM



D . 177 CD .	26.37 20.17.00.24
Date and Time of Dosing:	26-Nov-2017 08:24
Date of sample collection:	26-Nov-2017
Scheduled date and Time of sample collection (for post dose only):	26-Nov-2017 18:24
Actual Time of sample collection:	18:24 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK17864142
Remarks if any other reason:	
12.000 HRS POST DOSE PK SAMPLE COLLECTION	Period
Date and Time of Dosing:	26-Nov-2017 08:24
Date of sample collection:	26-Nov-2017
Scheduled date and Time of sample collection (for post dose only):	26-Nov-2017 20:24
Actual Time of sample collection:	20:25 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK17864214
Remarks if any other reason:	
DINNER (DAY 1)	Period
Date of meal distribution:	26-Nov-2017
Start Time:	20:27 <b>24 hrs. clock</b>
End Time:	20:45 24 hrs. clock
Has subject consumed meal completely?:	G Yes C No
Details of meal left (Approximate Quantity):	-
Remarks:	-
12.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD	Period
Position:	Sitting
Date of vital measurement:	26-Nov-2017
Start Time of vital measurement:	19:45 24 hrs. clock
Systolic Blood Pressure:	108 mmHg
-	100
Diasione Blood Pressure:	68 mmHg
Diastolic Blood Pressure:  Radial Pulse:	68 mmHg 72 heats/min
Diastolic Blood Pressure:  Radial Pulse:  Well-being:	68 mmHg 72 beats/min  • Well • Unwell
Radial Pulse: Well-being:	72 beats/min  • Well • Unwell
Radial Pulse: Well-being: If unwell then specify:	72 beats/min  • Well • Unwell  -
Radial Pulse:  Well-being:  If unwell then specify:  Remarks:	72 beats/min  • Well • Unwell  -
Radial Pulse:  Well-being:  If unwell then specify:  Remarks:  16.000 HRS POST DOSE PK SAMPLE COLLECTION	72 beats/min  • Well • Unwell  Period
Radial Pulse:  Well-being:  If unwell then specify:  Remarks:  16.000 HRS POST DOSE PK SAMPLE COLLECTION  Date and Time of Dosing:	72 beats/min  • Well • Unwell  26-Nov-2017 08:24
Radial Pulse:  Well-being:  If unwell then specify: Remarks:  16.000 HRS POST DOSE PK SAMPLE COLLECTION  Date and Time of Dosing: Date of sample collection:	72 beats/min  • Well • Unwell  26-Nov-2017 08:24 27-Nov-2017
Radial Pulse:  Well-being:  If unwell then specify:  Remarks:  16.000 HRS POST DOSE PK SAMPLE COLLECTION  Date and Time of Dosing:  Date of sample collection:  Scheduled date and Time of sample collection (for post dose only):	72 beats/min  • Well • Unwell  26-Nov-2017 08:24  27-Nov-2017  27-Nov-2017 00:24
Radial Pulse:  Well-being:  If unwell then specify:  Remarks:  16.000 HRS POST DOSE PK SAMPLE COLLECTION  Date and Time of Dosing:  Date of sample collection:  Scheduled date and Time of sample collection (for post dose only):  Actual Time of sample collection:	72 beats/min  • Well • Unwell  26-Nov-2017 08:24 27-Nov-2017
Radial Pulse:  Well-being:  If unwell then specify:  Remarks:  16.000 HRS POST DOSE PK SAMPLE COLLECTION  Date and Time of Dosing:  Date of sample collection:  Scheduled date and Time of sample collection (for post dose only):  Actual Time of sample collection:  Remarks:	72 beats/min  • Well • Unwell  -  -  26-Nov-2017 08:24  27-Nov-2017  27-Nov-2017 00:24  00:24 24 hrs. clock
Radial Pulse:  Well-being:  If unwell then specify:  Remarks:  16.000 HRS POST DOSE PK SAMPLE COLLECTION  Date and Time of Dosing:  Date of sample collection:  Scheduled date and Time of sample collection (for post dose only):  Actual Time of sample collection:  Remarks:  PK Sample ID:	72 beats/min  • Well • Unwell  26-Nov-2017 08:24  27-Nov-2017  27-Nov-2017 00:24
Radial Pulse:  Well-being:  If unwell then specify: Remarks:  16.000 HRS POST DOSE PK SAMPLE COLLECTION  Date and Time of Dosing: Date of sample collection: Scheduled date and Time of sample collection (for post dose only): Actual Time of sample collection: Remarks: PK Sample ID: Remarks if any other reason:	72 beats/min  • Well • Unwell  -  -  -  Period  26-Nov-2017 08:24  27-Nov-2017  27-Nov-2017 00:24  00:24 24 hrs. clock  PK17864286
Radial Pulse:  Well-being:  If unwell then specify:  Remarks:  16.000 HRS POST DOSE PK SAMPLE COLLECTION  Date and Time of Dosing:  Date of sample collection:  Scheduled date and Time of sample collection (for post dose only):  Actual Time of sample collection:  Remarks:  PK Sample ID:	72 beats/min  • Well • Unwell  -  -  26-Nov-2017 08:24  27-Nov-2017  27-Nov-2017 00:24  00:24 24 hrs. clock
Radial Pulse:  Well-being:  If unwell then specify: Remarks:  16.000 HRS POST DOSE PK SAMPLE COLLECTION  Date and Time of Dosing: Date of sample collection: Scheduled date and Time of sample collection (for post dose only): Actual Time of sample collection: Remarks: PK Sample ID: Remarks if any other reason:	72 beats/min  • Well • Unwell  -  -  -  Period  26-Nov-2017 08:24  27-Nov-2017  27-Nov-2017 00:24  00:24 24 hrs. clock  PK17864286

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27-Nov-2017

Date of sample collection:

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Scheduled date and Time of sample collection (for post dose only):	27-Nov-2017 08:24	
Actual Time of sample collection:	08:24 24 hrs. clock	
Remarks:		
PK Sample ID:	PK17864358	
Remarks if any other reason:		
BREATH TEST FOR ALCOHOL CONSUMPTION (36.000 HRS AMBULATORY VISIT)  Period:		
Date:	27-Nov-2017	
Start Time:	20:05 24 hrs. clock	
Breath Alcohol Level (BAL):	.000 %	
Result:	C Positive • Negative	
Start Time of 1st Repeat:	24 hrs. clock	
Breath Alcohol Level (BAL):	%	
1st Repeat result:	C Positive C Negative	
Start Time of 2nd Repeat:	24 hrs. clock	
Breath Alcohol Level (BAL):	%	
2nd Repeat Result:	C Positive C Negative	
Final Result:	C Positive • Negative	
For Positive results (if any) Informed to Principal Investigator/Co-Investigator/designate:	C Yes C No @ NAP	
Remarks:	-	
36.000 HRS AMBULATORY PK SAMPLE COLLECTION (DAY 2)	Period: 1	
Date and Time of Dosing:	26-Nov-2017 08:24	
Date of sample collection:	27-Nov-2017	
Scheduled date and Time of sample collection (for post dose only):	27-Nov-2017 20:24	
Actual Time of sample collection:	20:25 <b>24 hrs. clock</b>	
Remarks:		
PK Sample ID:	PK17864430	
Remarks if any other reason:		
$36.000~\mathrm{HRS}$ COMPLIANCE AND WELL BEING AT THE TIME OF AMBU (DAY 2)	ULATORY SAMPLE Period: 1	
Compliance at the Time of Ambulatory		
Date of compliance at the time of ambulatory sample:	27-Nov-2017	
Have you consumed any medication (Prescribed or Over the counter medicines including herbal remedies, strong cytochrome P450 enzyme inducers, rifampin, phenobarbital, carbamazepine, phenytoin), xanthine containing food or		
beverages (like tea, coffee, chocolates or cola drinks), tobacco, tobacco containing products (Gutkha, Pan/Pan masala or any other), recreational products, alcohol or alcoholic products, grapefruit or grapefruit products, an unusual diet, for whatever reason (e.g. low-sodium) or smoked since last visit?:		
Have you donated blood anywhere else or participated in other clinical trial since last visit?:	C Yes • No	
If Yes, Remarks:	-	
Well Being at the Time of Ambulatory		
Date of well being:	27-Nov-2017	
*This is an alecturaries flavorable action to discount	Da == 14 a f 22	

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Start Time of well being:	20:36 24 hrs. clock
Well-Being at the time of ambulatory sample:	• Well • Unwell
Remarks if Unwell:	-
Remark if any:	-
BREATH TEST FOR ALCOHOL CONSUMPTION (48.000 HRS AMBULA'	TORY VISIT) Period: 1
Date:	28-Nov-2017
Start Time:	09:57 24 hrs. clock
Breath Alcohol Level (BAL):	.000 %
Result:	C Positive • Negative
Start Time of 1st Repeat:	24 hrs. clock
Breath Alcohol Level (BAL):	%
1st Repeat result:	C Positive C Negative
Start Time of 2nd Repeat:	24 hrs. clock
Breath Alcohol Level (BAL):	%
2nd Repeat Result:	C Positive C Negative
	_
Final Result:	C Positive • Negative
For Positive results (if any) Informed to Principal Investigator/Co-Investigator/designate:	C Yes C No 6 NAP
Remarks:	
48.000 HRS AMBULATORY PK SAMPLE COLLECTION (DAY 3)	Period: 1
Date and Time of Dosing:	26-Nov-2017 08:24
Date of sample collection:	28-Nov-2017
Scheduled date and Time of sample collection (for post dose only):	28-Nov-2017 08:24
Actual Time of sample collection:	10:01 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK17864484
Remarks if any other reason:	
48.000 HRS COMPLIANCE AND WELL BEING AT THE TIME OF AMBU	JLATORY SAMPLE Period: 1
(DAY 3)	Terrod. 1
Compliance at the Time of Ambulatory	
Date of compliance at the time of ambulatory sample:	28-Nov-2017
Have you consumed any medication (Prescribed or Over the counter medicines	
including herbal remedies, strong cytochrome P450 enzyme inducers, rifampin,	
phenobarbital, carbamazepine, phenytoin), xanthine containing food or beverages (like tea, coffee, chocolates or cola drinks), tobacco, tobacco	C Yes © No
containing products (Gutkha, Pan/Pan masala or any other), recreational	16 15 10
products, alcohol or alcoholic products, grapefruit or grapefruit products, an	
unusual diet, for whatever reason (e.g. low-sodium) or smoked since last visit?:	
Have you donated blood anywhere else or participated in other clinical trial	C.:. C.:
since last visit?:	C Yes © No
If Yes, Remarks:	-
Well Being at the Time of Ambulatory	<u></u>
Date of well being:	28-Nov-2017
Dute of won being.	20 1104-2017

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Start Time of well being:	10:02 24 hrs. clock			
Well-Being at the time of ambulatory sample:	• Well • Unwell			
Remarks if Unwell:	-			
Remark if any:	-			
CHECK-OUT DETAILS( Period - 1)				
CLINICAL EXAMINATION-CHECK OUT	Period: 1			
Date of Clinical Examination:	27-Nov-2017			
Start Time of Clinical Examination:	07:25 <b>24 hrs. clock</b>			
Complaint of any illness:	€ No C Yes			
If YES, provide details:	-			
General Physical examination:	♠ Normal C Abnormal			
Oral Body Temperature:	97.8 °F			
Radial Pulse Rate:	76 beats/min			
Blood Pressure(Systolic):	112 mmHg			
Blood Pressure(Diastolic):	78 mmHg			
Cardiovascular System Examination:	♠ Normal C Abnormal			
Respiratory System Examination:	♠ Normal C Abnormal			
Central Nervous System Examination:	♠ Normal C Abnormal			
Per Abdomen Examination:	♠ Normal C Abnormal			
Any other Significant finding:	-			
Any investigations recommended:	-			
If 'Abnormal' in any of the above-mentioned sections, please enter deta	ails: -			
To be performed at the time of check-out				
Vein puncture site:	● Normal C Abnormal			
Subject well-being:	• Well • Unwell			
Comments:	-			
Subject is fit for Check-out:	€ Yes C No			
Remark If any:	-			
CHECK-OUT B&B	Period: 1			
Date of check out:	27-Nov-2017			
Time of Check-out:	09:00 24 hrs. clock			
Remarks:	-			
SUBJECT FOLLOW UP DETAILS	Period: 1			
Period No.:	II			
Purpose:	C Medical Event  C Adverse Event  C Safety Assessment  C Safety Assessment  C Subject Not reported for scheduled visit  C Others			
If Others, Specify:	-			
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Date:		01-Dec-201	7	
Mode of communication:		Telephone		
Detail of Discussion:			contacted telephone check in day o	onically and info rmed of period II.
Remark if any:		-		
CHECK-IN DETAILS(	Perio	d - 2)		
BREATH TEST FOR ALCOHOL CONSUMPTION				Period: 2
Date:		01-Dec-201	7	
Start Time:		16:39 <b>24 h</b>	rs. clock	
Breath Alcohol Level (BAL):		.000 %		
Result:		C Positive	Negative	
Start Time of 1st Repeat:		24 hrs. clo	ock	
Breath Alcohol Level (BAL):		%		
1st Repeat result:		C Positive	O Negative	
Start Time of 2nd Repeat:		24 hrs. clo	ock	
Breath Alcohol Level (BAL):		%		
2nd Repeat Result:		C Positive	O Negative	
Final Result:		C Positive	Negative	
For Positive results (if any) Informed to Principal Investigator/Co- Investigator/designate:		O Yes O No	o <b>(</b> NAP	
Remarks:		-		
URINE SCAN FOR DRUGS OF ABUSE				Period: 2
SOP reference no:CPMA-26-08				
Date:	01-	Dec-2017		
Refer/Read leaflet before start activity:	<b>⊙</b> 7	Tes C No C	NAP	
1. URINE SCAN FOR DRUGS ABUSE				
1.1 Urine drug scan tested for:	(AM	•	Barbiturates (BAR)	Benzodiazepines (BZD)
	(CO	Cocaine (C)	Morphine (MOR)	Cannabinoids (THC)
1.2 Start time:	16:4	45 <b>24 hrs. cl</b>	ock	
1.3 Observation of Results:	one (Con	Positive with band ntrol) nvalid with band (Test)	© Negative wit band (Control a	with No
1.4 Positive for:	(AM	<b>Л</b> Р)	Barbiturates (BAR)	Benzodiazepines (BZD)
		Cocaine (C)	☐ Morphine (MOR)	Cannabinoids (THC)

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2. URINE SCAN FOR DRUGS ABUSE (1st REPEAT)			
2.1 Urine drug scan tested for:	Amphetamine (AMP)	☐ Barbiturates (BAR)	Benzodiazepines (BZD)
	Cocaine (COC)	Morphine (MOR)	Cannabinoids (THC)
2.2 Start time:	24 hrs. clock		
2.3 Observation of Results:	C Positive with one band (Control) C Invalid with one band (Test)	C Negative with band (Control and	with No
2.4 Positive for:	Amphetamine (AMP)	Barbiturates (BAR)	Benzodiazepines (BZD)
	Cocaine (COC)	☐ Morphine (MOR)	Cannabinoids (THC)
3. URINE SCAN FOR DRUGS ABUSE (2nd REPEAT)			
3.1 Urine drug scan tested for:	Amphetamine (AMP)	☐ Barbiturates (BAR)	Benzodiazepines (BZD)
	Cocaine (COC)	☐ Morphine (MOR)	Cannabinoids (THC)
3.2 Start time:	24 hrs. clock		
3.3 Observation of Results:	C Positive with one band (Control)	C Negative with band (Control and	with No
	C Invalid with one band (Test)		
3.4 Positive for:	Amphetamine (AMP)	Barbiturates (BAR)	Benzodiazepines (BZD)
	Cocaine (COC)	Morphine (MOR)	Cannabinoids (THC)
Final Result:	C Positive C Ne	gative	
Positive for:	Amphetamine (AMP)	Barbiturates (BAR)	Benzodiazepines (BZD)
	Cocaine (COC)	☐ Morphine (MOR)	Cannabinoids (THC)
Remarks (for repeats or any other information):	-		
Date:			

<sup>\*</sup>This is an electronically authenticated report.

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Subject No: 1026 Subject Initials: KSM	ystems

4. URINE SCAN FOR DRUGS ABUSE ADDITIONAL	
4.1 Urine drug scan tested for:	Phencyclidine(PCP) Cotinine(COT) Methadone(MTD)  Other
4.2 If other then specify:	
4.3 Start Time:	24 hrs. clock
4.4 Observation of Results:	C Positive with one band (Control) C Invalid with No band (Control and test) C Invalid with No band (Test)
4.5 Positive for:	Phencyclidine(PCP) Cotinine(COT) Methadone(MTD)  Other
4.6 If other then specify:	
5. URINE SCAN FOR DRUGS ABUSE ADDITIONAL (1st REPEAT)	
5.1 Urine drug scan tested for:	Phencyclidine(PCP) Cotinine(COT) Methadone(MTD)  Other
5.2 If other then specify:	
5.3 Start Time:	24 hrs. clock
5.4 Observation of Results:	C Positive with one band (Control) C Invalid with one band (Test) C Negative with two band (Control and test) C Invalid with No band
5.5 Positive for:	Phencyclidine(PCP) Cotinine(COT) Methadone(MTD)  Other
5.6 If other then specify:	
6. URINE SCAN FOR DRUGS ABUSE ADDITIONAL (2nd REPEAT)	
6.1 Urine drug scan tested for:	Phencyclidine(PCP) Cotinine(COT) Methadone(MTD)  Other
6.2 If other then specify:	
6.3 Start Time:	24 hrs. clock
6.4 Observation of Results:	C Positive with one band (Control)  C Negative with two band (Control and test)  C Invalid with No band  C Invalid with No band
	one band (Test)

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6.5 Positive for:	Phencyclidine(PCP) Cotinine(COT) Methadone(MTD)  Other
6.6 If other then specify:	
Final Result:	C Positive C Negative
Positive for:	Phencyclidine(PCP) Cotinine(COT) Methadone(MTD)  Other
If other then specify:	
Remarks (for repeats or any other information):	
COMPLIANCE CHECK-PII	Period: 2
Demographic Details	
Age in Years (Completed as of Screening Date):	37
Subject Reporting Record	
Date of reporting to the clinical facility:	01-Dec-2017
Protocol Compliance Assessment	
Urine scans for drugs of abuse tested negative:	© Yes C No
Breath test for alcohol consumption tested negative:	€ Yes C No
Date of last menstruation period (For Female subject):	21-NOV-2017
Result of serum pregnancy test:	C O NAP (For Male Positive Negative subject)
Prohibitions	
Are you suffering from any illness since the last visit (Including allergic reaction, itching, rash on your skin)?:	C Yes • No
Have you consumed any xanthine containing food or beverages (like tea, coffee, chocolates or cola drinks) for 24 hours prior to check-in?:	C Yes • No
Have you consumed tobacco, tobacco containing products (Gutkha, Pan/F masala or any other) for 24 hours prior to check-in?:	C Yes • No
Have you consumed recreational products, alcohol or alcoholic products s last PK sample collection of Period I?:	C Yes • No
Have you consumed grapefruit or grapefruit products since last PK sample collection of Period I?:	C Yes • No
Have you smoked since last PK sample collection of Period I?:	C Yes • No
Ingestion of a medication (Prescribed or Over the counter medicines included herbal remedies, strong cytochrome P450 enzyme inducers, rifampin, phenobarbital, carbamazepine, phenytoin) at any time since last PK sample collection of Period I?:	C Vec 6 No
Have you consumed an unusual diet, for whatever reason (e.g. low-sodiun since last PK sample collection of Period I?:	n) C Yes • No
Have you donated blood anywhere else or participated in other clinical trissince last PK sample collection of Period I?:	al C Yes • No
Is subject compliant to all above restrictions/requirement?:	€ Yes C No
Remark If any:	-

<sup>\*</sup>This is an electronically authenticated report.

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LABORATORY ASSESSMENT-PRIOR TO CHECK IN OF (PERIOD II)  Per	
Note: For Estimation of CrCl (Creatinine Clearance).	
Has the blood sample been collected as per protocol?:	• Yes C No
Date of blood sample collection:	01-Dec-2017
Lab report clinically acceptable:	© Yes C No C NAP
Comments (if any):	-
CHECK-IN B&B	Period: 2
Baggage and Body Search done:	€ Yes C No
Date of Check In:	01-Dec-2017
Time of Check-in:	18:06 24 hrs. clock
Remarks:	-
CLINICAL EXAMINATION - CHECK IN	Period: 2
Date of clinical examination:	01-Dec-2017
Start Time of Clinical Examination:	18:37 24 hrs. clock
Complaints of any illness:	© No C Yes
If YES, provide details:	-
General Physical examination:	€ Normal C Abnormal
Oral Body Temperature:	98.2 °F
Blood Pressure (Systolic):	116 mmHg
Blood Pressure (Diastolic):	82 mmHg
Radial Pulse Rate:	72 beats/min
Cardiovascular System Examination:	© Normal C Abnormal
Respiratory System Examination:	€ Normal C Abnormal
Central Nervous System Examination:	© Normal C Abnormal
Per Abdomen Examination:	© Normal C Abnormal
Any other Significant finding:	-
Any investigations recommended:	-
Vein puncture site:	• Normal C Abnormal
Subject well-being:	€ Well C Unwell
If 'Abnormal' in any of the above-mentioned sections, please enter details.:	-
Remark if Any:	-
Subject is fit:	€ Yes C No
DINNER CHECK-IN (DAY-1)	Period: 2
Date of meal distribution:	01-Dec-2017
Start Time:	20:28 <b>24 hrs. clock</b>
End Time:	20:47 <b>24 hrs. clock</b>
Has subject consumed meal completely?:	€ Yes C No
Details of meal left (Approximate Quantity):	-

<sup>\*</sup>This is an electronically authenticated report.

### CASE REPORT FORM

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Remarks:	-		
HOUSING DETAILS( Period - 2)			
0.00 HRS PRE DOSE VITAL SIGNS AND WELL-BEING RECORD	Period: 2		
Position:	Sitting		
Date of vital measurement:	02-Dec-2017		
Start Time of vital measurement:	05:54 24 hrs. clock		
Systolic Blood Pressure:	116 mmHg		
Diastolic Blood Pressure:	78 mmHg		
Radial Pulse:	76 beats/min		
Oral Body Temperature:	97.8 °F		
Well-being:	€ Well € Unwell		
If unwell then specify:	-		
Remarks:	-		
0.000 HRS PRE DOSE PK SAMPLE COLLECTION	Period: 2		
Date and Time of Dosing:			
Date of sample collection:	02-Dec-2017		
Scheduled date and Time of sample collection (for post dose only):			
Actual Time of sample collection:	07:34 24 hrs. clock		
Remarks:			
PK Sample ID:	PK17879834		
Remarks if any other reason:			
IMP ADMINISTRATION	Period: 2		
-	Period: 2 02-Dec-2017		
IMP ADMINISTRATION			
IMP ADMINISTRATION  DATE: IS SUBJECT COMPLIANT TO ALL PREDOSE REQUIREMENTS AS	02-Dec-2017		
IMP ADMINISTRATION  DATE:  IS SUBJECT COMPLIANT TO ALL PREDOSE REQUIREMENTS AS PER PROTOCOL?:	02-Dec-2017  • Yes C No C NA		
IMP ADMINISTRATION  DATE:  IS SUBJECT COMPLIANT TO ALL PREDOSE REQUIREMENTS AS PER PROTOCOL?:  TIME:	02-Dec-2017  • Yes C No C NA  08:24 24 hrs. clock		
IMP ADMINISTRATION  DATE: IS SUBJECT COMPLIANT TO ALL PREDOSE REQUIREMENTS AS PER PROTOCOL?:  TIME: MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA:	02-Dec-2017  • Yes C No C NA  08:24 24 hrs. clock • Yes C No C NA		
IMP ADMINISTRATION  DATE:  IS SUBJECT COMPLIANT TO ALL PREDOSE REQUIREMENTS AS PER PROTOCOL?:  TIME:  MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA:  ML OF WATER ADMINISTERED WITH IP:	02-Dec-2017  • Yes O No O NA  08:24 24 hrs. clock • Yes O No O NA  240		
IMP ADMINISTRATION  DATE:  IS SUBJECT COMPLIANT TO ALL PREDOSE REQUIREMENTS AS PER PROTOCOL?:  TIME:  MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA:  ML OF WATER ADMINISTERED WITH IP:  LABEL:	02-Dec-2017  • Yes C No C NA  08:24 24 hrs. clock • Yes C No C NA  240  0000251825		
IMP ADMINISTRATION  DATE:  IS SUBJECT COMPLIANT TO ALL PREDOSE REQUIREMENTS AS PER PROTOCOL?:  TIME:  MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA:  ML OF WATER ADMINISTERED WITH IP:  LABEL:  PRODUCT CODE/ TYPE:	02-Dec-2017  • Yes C No C NA  08:24 24 hrs. clock • Yes C No C NA  240  0000251825  Test		
IMP ADMINISTRATION  DATE:  IS SUBJECT COMPLIANT TO ALL PREDOSE REQUIREMENTS AS PER PROTOCOL?:  TIME:  MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA:  ML OF WATER ADMINISTERED WITH IP:  LABEL:  PRODUCT CODE/ TYPE:  DOSING DONE BY:	02-Dec-2017  • Yes O No O NA  08:24 24 hrs. clock • Yes O No O NA  240  0000251825  Test  ankitkpatel (Dosing)		
IMP ADMINISTRATION  DATE:  IS SUBJECT COMPLIANT TO ALL PREDOSE REQUIREMENTS AS PER PROTOCOL?:  TIME:  MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA:  ML OF WATER ADMINISTERED WITH IP:  LABEL:  PRODUCT CODE/ TYPE:  DOSING DONE BY:  DOSING SUPERVISION DONE BY:	02-Dec-2017  • Yes O No O NA  08:24 24 hrs. clock • Yes O No O NA  240  0000251825  Test  ankitkpatel (Dosing)  kanarampatel (Dosing)		
IMP ADMINISTRATION  DATE:  IS SUBJECT COMPLIANT TO ALL PREDOSE REQUIREMENTS AS PER PROTOCOL?:  TIME:  MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA:  ML OF WATER ADMINISTERED WITH IP:  LABEL:  PRODUCT CODE/ TYPE:  DOSING DONE BY:  DOSING SUPERVISION DONE BY:  REMARKS:	02-Dec-2017  • Yes O No O NA  08:24 24 hrs. clock • Yes O No O NA  240  0000251825  Test  ankitkpatel (Dosing)  kanarampatel (Dosing)		
IMP ADMINISTRATION  DATE:  IS SUBJECT COMPLIANT TO ALL PREDOSE REQUIREMENTS AS PER PROTOCOL?:  TIME:  MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA:  ML OF WATER ADMINISTERED WITH IP:  LABEL:  PRODUCT CODE/ TYPE:  DOSING DONE BY:  DOSING SUPERVISION DONE BY:  REMARKS:  STUDY DRUG ADMINISTRATION-COMPLIANCE	02-Dec-2017  • Yes C No C NA  08:24 24 hrs. clock • Yes C No C NA  240  0000251825  Test  ankitkpatel (Dosing)  kanarampatel (Dosing)		
IMP ADMINISTRATION  DATE:  IS SUBJECT COMPLIANT TO ALL PREDOSE REQUIREMENTS AS PER PROTOCOL?:  TIME:  MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA:  ML OF WATER ADMINISTERED WITH IP:  LABEL:  PRODUCT CODE/ TYPE:  DOSING DONE BY:  DOSING SUPERVISION DONE BY:  REMARKS:  STUDY DRUG ADMINISTRATION-COMPLIANCE  Has the subject compliant to 02 hour post dose water restriction?:  Has the subject compliant to postural restriction for 04 hours post dose in sitting posture? (unless medically necessary due to adverse event or	02-Dec-2017  • Yes C No C NA  08:24 24 hrs. clock • Yes C No C NA  240  0000251825  Test  ankitkpatel (Dosing)  kanarampatel (Dosing)  Period: 2		
IMP ADMINISTRATION  DATE:  IS SUBJECT COMPLIANT TO ALL PREDOSE REQUIREMENTS AS PER PROTOCOL?:  TIME:  MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA:  ML OF WATER ADMINISTERED WITH IP:  LABEL:  PRODUCT CODE/ TYPE:  DOSING DONE BY:  DOSING SUPERVISION DONE BY:  REMARKS:  STUDY DRUG ADMINISTRATION-COMPLIANCE  Has the subject compliant to 02 hour post dose water restriction?:  Has the subject compliant to postural restriction for 04 hours post dose in sitting posture? (unless medically necessary due to adverse event or procedurally required or natural exigency):	02-Dec-2017  • Yes C No C NA  08:24 24 hrs. clock • Yes C No C NA  240  0000251825  Test  ankitkpatel (Dosing)  kanarampatel (Dosing)  Period: 2		
IMP ADMINISTRATION  DATE:  IS SUBJECT COMPLIANT TO ALL PREDOSE REQUIREMENTS AS PER PROTOCOL?:  TIME:  MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA:  ML OF WATER ADMINISTERED WITH IP:  LABEL:  PRODUCT CODE/ TYPE:  DOSING DONE BY:  DOSING SUPERVISION DONE BY:  REMARKS:  STUDY DRUG ADMINISTRATION-COMPLIANCE  Has the subject compliant to 02 hour post dose water restriction?:  Has the subject compliant to postural restriction for 04 hours post dose in sitting posture? (unless medically necessary due to adverse event or procedurally required or natural exigency):  Has the subject compliant to 04 hours post dose fasting condition?:	© Yes C No C NA  08:24 24 hrs. clock © Yes C No C NA  240  0000251825  Test  ankitkpatel (Dosing)  kanarampatel (Dosing)  Period: 2  © Yes C No  C Yes C No		

<sup>\*</sup>This is an electronically authenticated report.

Sponsor Name:Cipla Limited

### CASE REPORT FORM

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Date of sample collection:	02-Dec-2017	
Scheduled date and Time of sample collection (for post dose only):	02-Dec-2017 08:39	
Actual Time of sample collection:	08:39 24 hrs. clock	
Remarks:	ooley 21 may elden	
PK Sample ID:	PK17879870	
Remarks if any other reason:	1121,0,50,0	
0.500 HRS POST DOSE PK SAMPLE COLLECTION		Period: 2
Date and Time of Dosing:	02-Dec-2017 08:24	renou. 2
Date of sample collection:	02-Dec-2017 02-Dec-2017	
Scheduled date and Time of sample collection (for post dose only):	02-Dec-2017 02-Dec-2017 08:54	
Actual Time of sample collection:	08:54 24 hrs. clock	
Remarks:	06.34 <b>24 HTS. CIOCK</b>	
PK Sample ID:	PK17879906	
	PK1/8/9900	
Remarks if any other reason:		
0.750 HRS POST DOSE PK SAMPLE COLLECTION		Period: 2
Date and Time of Dosing:	02-Dec-2017 08:24	
Date of sample collection:	02-Dec-2017	
Scheduled date and Time of sample collection (for post dose only):	02-Dec-2017 09:09	
Actual Time of sample collection:	09:09 <b>24 hrs. clock</b>	
Remarks:		
PK Sample ID:	PK17879942	
Remarks if any other reason:		
1.000 HRS POST DOSE PK SAMPLE COLLECTION		Period: 2
•	02-Dec-2017 08:24	Period: 2
1.000 HRS POST DOSE PK SAMPLE COLLECTION	02-Dec-2017 08:24 02-Dec-2017	Period: 2
1.000 HRS POST DOSE PK SAMPLE COLLECTION  Date and Time of Dosing:		Period: 2
1.000 HRS POST DOSE PK SAMPLE COLLECTION  Date and Time of Dosing:  Date of sample collection:	02-Dec-2017	Period: 2
1.000 HRS POST DOSE PK SAMPLE COLLECTION  Date and Time of Dosing:  Date of sample collection:  Scheduled date and Time of sample collection (for post dose only):	02-Dec-2017 02-Dec-2017 09:24	Period: 2
1.000 HRS POST DOSE PK SAMPLE COLLECTION  Date and Time of Dosing:  Date of sample collection:  Scheduled date and Time of sample collection (for post dose only):  Actual Time of sample collection:	02-Dec-2017 02-Dec-2017 09:24	Period: 2
1.000 HRS POST DOSE PK SAMPLE COLLECTION  Date and Time of Dosing:  Date of sample collection:  Scheduled date and Time of sample collection (for post dose only):  Actual Time of sample collection:  Remarks:	02-Dec-2017 02-Dec-2017 09:24 09:24 24 hrs. clock	Period: 2
1.000 HRS POST DOSE PK SAMPLE COLLECTION  Date and Time of Dosing:  Date of sample collection:  Scheduled date and Time of sample collection (for post dose only):  Actual Time of sample collection:  Remarks:  PK Sample ID:	02-Dec-2017 02-Dec-2017 09:24 09:24 <b>24 hrs. clock</b>	
1.000 HRS POST DOSE PK SAMPLE COLLECTION  Date and Time of Dosing:  Date of sample collection:  Scheduled date and Time of sample collection (for post dose only):  Actual Time of sample collection:  Remarks:  PK Sample ID:  Remarks if any other reason:	02-Dec-2017 02-Dec-2017 09:24 09:24 <b>24 hrs. clock</b>	
1.000 HRS POST DOSE PK SAMPLE COLLECTION  Date and Time of Dosing:  Date of sample collection:  Scheduled date and Time of sample collection (for post dose only):  Actual Time of sample collection:  Remarks:  PK Sample ID:  Remarks if any other reason:  1.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD	02-Dec-2017 02-Dec-2017 09:24 09:24 24 hrs. clock PK17879978	
1.000 HRS POST DOSE PK SAMPLE COLLECTION  Date and Time of Dosing:  Date of sample collection:  Scheduled date and Time of sample collection (for post dose only):  Actual Time of sample collection:  Remarks:  PK Sample ID:  Remarks if any other reason:  1.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD Position:	02-Dec-2017 02-Dec-2017 09:24 09:24 24 hrs. clock PK17879978	
1.000 HRS POST DOSE PK SAMPLE COLLECTION  Date and Time of Dosing:  Date of sample collection:  Scheduled date and Time of sample collection (for post dose only):  Actual Time of sample collection:  Remarks:  PK Sample ID:  Remarks if any other reason:  1.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD Position:  Date of vital measurement:	02-Dec-2017  02-Dec-2017 09:24  09:24 24 hrs. clock  PK17879978  Sitting  02-Dec-2017	
1.000 HRS POST DOSE PK SAMPLE COLLECTION  Date and Time of Dosing:  Date of sample collection:  Scheduled date and Time of sample collection (for post dose only):  Actual Time of sample collection:  Remarks:  PK Sample ID:  Remarks if any other reason:  1.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD  Position:  Date of vital measurement:  Start Time of vital measurement:	02-Dec-2017 02-Dec-2017 09:24 09:24 24 hrs. clock  PK17879978  Sitting 02-Dec-2017 09:15 24 hrs. clock	
1.000 HRS POST DOSE PK SAMPLE COLLECTION  Date and Time of Dosing:  Date of sample collection:  Scheduled date and Time of sample collection (for post dose only):  Actual Time of sample collection:  Remarks:  PK Sample ID:  Remarks if any other reason:  1.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD  Position:  Date of vital measurement:  Start Time of vital measurement:  Systolic Blood Pressure:	02-Dec-2017 02-Dec-2017 09:24 09:24 24 hrs. clock  PK17879978  Sitting 02-Dec-2017 09:15 24 hrs. clock 116 mmHg	
1.000 HRS POST DOSE PK SAMPLE COLLECTION  Date and Time of Dosing:  Date of sample collection:  Scheduled date and Time of sample collection (for post dose only):  Actual Time of sample collection:  Remarks:  PK Sample ID:  Remarks if any other reason:  1.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD  Position:  Date of vital measurement:  Start Time of vital measurement:  Systolic Blood Pressure:  Diastolic Blood Pressure:	02-Dec-2017 02-Dec-2017 09:24 09:24 24 hrs. clock  PK17879978  Sitting 02-Dec-2017 09:15 24 hrs. clock 116 mmHg 72 mmHg	
1.000 HRS POST DOSE PK SAMPLE COLLECTION  Date and Time of Dosing:  Date of sample collection:  Scheduled date and Time of sample collection (for post dose only):  Actual Time of sample collection:  Remarks:  PK Sample ID:  Remarks if any other reason:  1.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD  Position:  Date of vital measurement:  Start Time of vital measurement:  Systolic Blood Pressure:  Diastolic Blood Pressure:  Radial Pulse:  Well-being:	02-Dec-2017 02-Dec-2017 09:24 09:24 24 hrs. clock  PK17879978  Sitting 02-Dec-2017 09:15 24 hrs. clock 116 mmHg 72 mmHg 68 beats/min	
1.000 HRS POST DOSE PK SAMPLE COLLECTION  Date and Time of Dosing:  Date of sample collection:  Scheduled date and Time of sample collection (for post dose only):  Actual Time of sample collection:  Remarks:  PK Sample ID:  Remarks if any other reason:  1.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD  Position:  Date of vital measurement:  Start Time of vital measurement:  Systolic Blood Pressure:  Diastolic Blood Pressure:  Radial Pulse:  Well-being:  If unwell then specify:	02-Dec-2017  02-Dec-2017 09:24  09:24 24 hrs. clock  PK17879978  Sitting  02-Dec-2017  09:15 24 hrs. clock  116 mmHg  72 mmHg  68 beats/min  € Well € Unwell	
1.000 HRS POST DOSE PK SAMPLE COLLECTION  Date and Time of Dosing:  Date of sample collection:  Scheduled date and Time of sample collection (for post dose only):  Actual Time of sample collection:  Remarks:  PK Sample ID:  Remarks if any other reason:  1.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD  Position:  Date of vital measurement:  Start Time of vital measurement:  Systolic Blood Pressure:  Diastolic Blood Pressure:  Radial Pulse:  Well-being:  If unwell then specify:  Remarks:	02-Dec-2017 02-Dec-2017 09:24 09:24 24 hrs. clock  PK17879978  Sitting 02-Dec-2017 09:15 24 hrs. clock 116 mmHg 72 mmHg 68 beats/min  • Well C Unwell	Period: 2
1.000 HRS POST DOSE PK SAMPLE COLLECTION  Date and Time of Dosing:  Date of sample collection:  Scheduled date and Time of sample collection (for post dose only):  Actual Time of sample collection:  Remarks:  PK Sample ID:  Remarks if any other reason:  1.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD  Position:  Date of vital measurement:  Start Time of vital measurement:  Systolic Blood Pressure:  Diastolic Blood Pressure:  Radial Pulse:  Well-being:  If unwell then specify:  Remarks:  1.333 HRS POST DOSE PK SAMPLE COLLECTION	02-Dec-2017 02-Dec-2017 09:24 09:24 24 hrs. clock  PK17879978  Sitting 02-Dec-2017 09:15 24 hrs. clock 116 mmHg 72 mmHg 68 beats/min  © Well © Unwell -	Period: 2
1.000 HRS POST DOSE PK SAMPLE COLLECTION  Date and Time of Dosing:  Date of sample collection:  Scheduled date and Time of sample collection (for post dose only):  Actual Time of sample collection:  Remarks:  PK Sample ID:  Remarks if any other reason:  1.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD  Position:  Date of vital measurement:  Start Time of vital measurement:  Systolic Blood Pressure:  Diastolic Blood Pressure:  Radial Pulse:  Well-being:  If unwell then specify:  Remarks:	02-Dec-2017 02-Dec-2017 09:24 09:24 24 hrs. clock  PK17879978  Sitting 02-Dec-2017 09:15 24 hrs. clock 116 mmHg 72 mmHg 68 beats/min  • Well C Unwell	Period: 2  Period: 2

<sup>\*</sup>This is an electronically authenticated report.

Sponsor Name:Cipla Limited

### CASE REPORT FORM

Project No: 0326-17



Actual Time of sample collection:   PK17880014   PK17880014	Scheduled date and Time of sample collection (for post dose only):	02-Dec-2017 09:44
PK Sample ID:         PK17880014           Remarks if any other reason:         Perod. 2           1.667 HRS POST DOSE PK SAMPLE COLLECTION         Q2-Dec-2017 08:24           Date of Sample collection:         Q2-Dec-2017 10:04           Scheduled date and Time of sample collection (for post dose only):         Q2-Dec-2017 10:04           Actual Time of sample collection:         10:04 24 hrs. clock           Remarks:         PK Sample ID:           PK Sample ID:         PK 17880050           Remarks if any other reason:         PEROd. 2           2009 HRS POST DOSE PK SAMPLE COLLECTION         Perod. 2           Date and Time of Dosing:         Q2-Dec-2017 08:24           Date of sample collection:         Q2-Dec-2017 10:24           Scheduled date and Time of sample collection (for post dose only):         Q2-Dec-2017 10:24           Actual Time of sample collection:         PK 17880086           Remarks:         PK 17880086           PK Sample ID:         PK 17880086           Remarks if any other reason:         Perod. 2           2.333 HRS POSI DOSE PK SAMPLE COLLECTION         Perod. 2           Date and Time of Dosing:         Q2-Dec-2017 08:24           Date of sample collection:         Q2-Dec-2017 08:24           Scheduled date and Time of sample collection (for post dose only):	Actual Time of sample collection:	09:44 24 hrs. clock
Remarks if any other reason:	Remarks:	
Date and Time of Dosing:   02-Dec-2017 08:24	PK Sample ID:	PK17880014
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Date and Time of Dosing:  Date of sample collection:  O2-Dec-2017  Scheduled date and Time of sample collection (for post dose only):  Actual Time of sample collection:  Remarks:  O2-Dec-2017  11:24  24 hrs. clock	Remarks if any other reason:	
Date of sample collection:  Scheduled date and Time of sample collection (for post dose only):  Actual Time of sample collection:  Remarks:  102-Dec-2017  11:24  24 hrs. clock	3.000 HRS POST DOSE PK SAMPLE COLLECTION	Period: 2
Scheduled date and Time of sample collection (for post dose only):  Actual Time of sample collection:  Remarks:  02-Dec-2017 11:24  24 hrs. clock	Date and Time of Dosing:	02-Dec-2017 08:24
Actual Time of sample collection: 11:24 24 hrs. clock  Remarks:	Date of sample collection:	02-Dec-2017
Remarks:	Scheduled date and Time of sample collection (for post dose only):	02-Dec-2017 11:24
	Actual Time of sample collection:	11:24 24 hrs. clock
777.0	Remarks:	
PK Sample ID:   PK17880194	PK Sample ID:	PK17880194

<sup>\*</sup>This is an electronically authenticated report.

Sponsor Name:Cipla Limited

### CASE REPORT FORM

Project No: 0326-17



Remarks if any other reason:		
3.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD Period: 2		
Position:	Sitting	
Date of vital measurement:	02-Dec-2017	
Start Time of vital measurement:	10:56 24 hrs. clock	
Systolic Blood Pressure:	112 <b>mmHg</b>	
Diastolic Blood Pressure:	74 mmHg	
Radial Pulse:	68 beats/min	
Well-being:	Well C Unwell	
If unwell then specify:	-	
Remarks:	-	
LUNCH (4.00 HRS POST DOSE) (DAY 1)	Period: 2	
Date of meal distribution:	02-Dec-2017	
Start Time:	12:27 <b>24 hrs. clock</b>	
End Time:	12:34 24 hrs. clock	
Has subject consumed meal completely?:	C Yes 6 No	
Details of meal left (Approximate Quantity):	03 Nos Roti. 1/2 Qty Of Daal. 1/2 Qty Of Ca bbage Vegetable. 1/2 Qty Of Rice. 1/2 Qty O f Khaman Dhokla.	
Remarks:	-	
6.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD	Period: 2	
Position:	Sitting	
Date of vital measurement:	02-Dec-2017	
Start Time of vital measurement:	13:59 24 hrs. clock	
Systolic Blood Pressure:	114 mmHg	
Diastolic Blood Pressure:	74 mmHg	
Radial Pulse:	72 beats/min	
Well-being:	• Well C Unwell	
If unwell then specify:	-	
Remarks:	-	
SNACKS (DAY 1)	Period: 2	
Date of meal distribution:	02-Dec-2017	
Start Time:	16:24 24 hrs. clock	
End Time:	16:31 24 hrs. clock	
Has subject consumed meal completely?:	<b>⊙</b> Yes <b>○</b> No	
Details of meal left (Approximate Quantity):	-	
Remarks:	-	
DINNER (DAY 1)	Period: 2	
Date of meal distribution:	02-Dec-2017	
Start Time:	20:21 24 hrs. clock	
End Time:	20:33 24 hrs. clock	
Has subject consumed meal completely?:	€ Yes C No	

<sup>\*</sup>This is an electronically authenticated report.

### CASE REPORT FORM

Project No: 0326-17



Details of meal left (Approximate Quantity):	-
Remarks:	-
12.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING REG	CORD Period: 2
Position:	Sitting
Date of vital measurement:	02-Dec-2017
Start Time of vital measurement:	19:45 <b>24 hrs. clock</b>
Systolic Blood Pressure:	116 <b>mmHg</b>
Diastolic Blood Pressure:	76 <b>mmHg</b>
Radial Pulse:	80 beats/min
Well-being:	• Well C Unwell
If unwell then specify:	-
Remarks:	-
CHECK-OUT DET	TAILS( Period - 2)
CLINICAL EXAMINATION-CHECK OUT	Period: 2
Date of Clinical Examination:	03-Dec-2017
Start Time of Clinical Examination:	07:45 <b>24 hrs. clock</b>
Complaint of any illness:	<b>⊙</b> No C Yes
If YES, provide details:	-
General Physical examination:	♠ Normal ♠ Abnormal
Oral Body Temperature:	98.2 °F
Radial Pulse Rate:	64 beats/min
Blood Pressure(Systolic):	112 <b>mmHg</b>
Blood Pressure(Diastolic):	72 mmHg
Cardiovascular System Examination:	♠ Normal
Respiratory System Examination:	
Central Nervous System Examination:	
Per Abdomen Examination:	♠ Normal ♠ Abnormal
Any other Significant finding:	-
Any investigations recommended:	
If 'Abnormal' in any of the above-mentioned sections, please enter	details: -
To be performed at the time of check-out	
Vein puncture site:	Normal C Abnormal
Subject well-being:	• Well C Unwell
Comments:	-
Subject is fit for Check-out:	€ Yes C No
Remark If any:	-
CHECK-OUT B&B	Period: 2
Date of check out:	03-Dec-2017
Time of Check-out:	08:52 24 hrs. clock
Remarks:	-

<sup>\*</sup>This is an electronically authenticated report.

### CASE REPORT FORM

Project No: 0326-17



CLINICAL EXAMINATION - END OF STUDY	Period: 2
Date of clinical examination:	05-Dec-2017
Start time of clinical examination:	11:49 <b>24 hrs. clock</b>
Complaints of any illness:	€ No C Yes
If YES, provide details:	-
General Physical examination:	• Normal C Abnormal
Oral Body Temperature:	98.0 °F
Systolic Blood Pressure:	108 mmHg
Diastolic Blood Pressure:	68 mmHg
Radial Pulse Rate:	72 beats/min
Cardiovascular System Examination:	• Normal C Abnormal
Respiratory System Examination:	• Normal C Abnormal
Central Nervous System Examination:	© Normal C Abnormal
Per Abdomen Examination:	© Normal C Abnormal
Any other Significant finding:	-
Any investigations recommended:	-
Vein puncture site:	© Normal C Abnormal
Subject well-being:	€ Well € Unwell
If 'Abnormal' in any of the above-mentioned sections, please enter the details:	-
Subject is fit:	€ Yes C No
Remark If any:	-
ECG EXAMINATION-END OF STUDY	Period: 2
ECG EXAMINATION	
Date Of ECG:	11-Dec-2017
Time of ECG:	11:10 24 hrs. clock
Was ECG Repeated:	C Yes 6 No
If Yes, Date of Repeat ECG:	
ECG Impression:	WNL
	© C Not Clinically C Clinically
Overall Assessment:	Normal Significant Significant
Remark, If any:	-
END STUDY LABORATORY ASSESSMENT AND STUDY COMPLETION	
Note: For Estimation of Hematology, Biochemistry (except random glucose and	l sodium, potassium, chloride).
Post study safety sample collected as per protocol?:	€ Yes C No
Date of safety sample collection:	05-Dec-2017
Lab report clinically acceptable:	• Yes C No C NAP
Result of serum pregnancy test:	C NAP (For Male Positive Negative subject)
Remarks If Any:	-
*This is an alastocking the authority of a local	Dana 27 af 22

<sup>\*</sup>This is an electronically authenticated report.

### CASE REPORT FORM

Project No: 0326-17



STUDY COMPLETION STATUS				
Has the subject completed the study?:	C Yes • No			
If "No", please refer:	C Pre dose G Post dose discontinued form			
If "Yes", then any protocol or sampling deviation reported for subject?:	C Yes C No			
If "Yes", then select appropriate option:	☐ Protocol deviation ☐ Sampling Deviation			
Remarks:	-			
ADVERSE EVENT/ MEDICAL EVENT RECORDING	Period: 2			
Is it Adverse Event or Medical Event?:	€ Adverse Event C Medical Event			
Period:	02			
Subject No:	1026			
Subject Initials:	KSM			
Date of Birth:	01-Jan-1980			
Date of onset:	02-Dec-2017			
Time of Onset:	11:44 24 hrs. clock			
Date of reporting or Obseved on:	02-Dec-2017			
Time of Reporting or observed at:	11:45 24 hrs. clock			
Date of Recording the AE/ME:	02-Dec-2017			
Time of recording the AE/ME:	11:49 <b>24 hrs. clock</b>			
1.0 Description of the event with associated symptoms, onset, duration,	, progress of the event:			
1.1 Details:	Subject had single episode of vomiting at app roximately 1144 hrs, 02-Dec-2017. Vomiting la sted for 01 minute. Vomitus was approximately 100 ml in amount and contained fluid with fo od particles. He has no any other complaint a t present.			
Adverse Event Term (If required by protocol):	Vomiting			
1.2 Nature of Onset:	© Sudden C Gradual C Unknown			
1.3 Occurrence:	C Continuous C Intermittent © Single Episode			
1.4 Severity:	• Mild C Moderate C Severe			
2.0 Clinical Examination				
2.1 Temperature:	98.0 °F			
2.2 Systolic Blood Pressure:	120 mmHg			
2.3 Diastolic Blood Pressure:	82 mmHg			
2.4 Pulse Rate:	68 beats/min			
2.5 General Physical Examination:	Normal			
2.6 Systemic Examination:	Normal			
2.7 Cardiovascular System:	Normal			
2.8 Central Nervous System:	Normal			
2.9 Respiratory System:	Normal			
2.10 Per Abdomen:	Normal			
2.11 If abnormal in any of above, please specify:	-			
Has the PI/ Designate been informed?:	Yes			

<sup>\*</sup>This is an electronically authenticated report.

### CASE REPORT FORM

Project No: 0326-17



Remarks:	-
Checked By:	Dr Anshul Attrey
3.0 Follow up details including examination:	
3.1 Physician's notes:	As per PI's advice subject is discontinued fr om
•	study on emesis ground.
3.1 Advise / Treatment:	Rest Reassurance Follow Up
3.1 Checked by:	Dr Anshul Attrey
3.2 Physicians notes:	Subject had another episode of vomiting of ab out 200ml food mixed watery content at 1515 h rs on 02-Dec-17. Vomiting was lasted for 1 mi nute. On examination- Temp 98.0'F Puls e-68/min BP-112/72 mmHg S/E- NAD
3.2 Advise / Treatment:	Subject was given Inj. Emeset 2ml IV stat at 1525 hrs followed by ORS powder which was dis solved in 1 liter of water and 250ml given at 1527 hrs. rest reassurance continue fo llow-up
3.2 Checked By:	Dr Anshul Attrey
3.3 Physicians notes:	2145 hrs 02-Dec-2017 Subject was followed up, he is feeling well and he has no complaint of vomiting or any complaint at present. O n examination- Temp 98.2'F Pulse-72/min BP-116/78 mmHg S/E- NAD
3.3 Advise / Treatment:	rest reassurance follow-up
3.3 Checked By:	Dr Anshul Attrey
3.4 Physicians notes:	0725 hrs 03-Dec-2017 Subject was followed up, She is feeling well and She has no further e pisode of vomiting .She has no any complaint at present. On examination- Temp 98.0°F Pu lse-76/min BP-110/74 mmHg S/E- NAD Hence t his AE of Vomiting is considered to be resolv ed since 1527 hrs,02-Dec-2017.
3.4 Advise / Treatment:	-
3.4 Checked By:	Dr Anshul Attrey
3.5 Physicians notes:	
3.5 Advise / Treatment:	
3.5 Checked By:	
Remarks:	
CONCOMITANT MEDICATION FORM	Period: 2
Medication Name or Therapy:	Emeset
Medication Code:	vDrugName=Emeset
Medication for AE#:	01
Dose:	Inj. Emeset (Ondansetron 2 mg/ml) total 02 ml
Dosage form/Unit:	Milliliter
If 'Other' (Dosage form/Unit), please specify:	
Frequency:	Other
If 'Other' (Frequency), please specify:	Stat
Route:	Intravenous

### CASE REPORT FORM

Project No: 0326-17



If 'Other' (Route), please specify:	
Start date:	02-Dec-2017
Start time:	15:25 24 hrs. clock
End date:	
End time:	24 hrs. clock
Ongoing:	C Yes © No
Remark, if any:	-

CONCOMITANT MEDICATION FORM, Repetition: 2	Period: 2
Medication Name or Therapy:	Electral
Medication Code:	vDrugName=Electral
Medication for AE#:	01
Dose:	Electral Powder (Nacl 2.6 g, KCL 1.5 g, Na Ci trate 2.9 g, Dextrose 13.5 g) powder is disso lved in 1 liter of water,out of it 250 ml of water given 01 times.
Dosage form/Unit:	Milliliter
If 'Other' (Dosage form/Unit), please specify:	
Frequency:	Other
If 'Other' (Frequency), please specify:	Stat
Route:	Oral
If 'Other' (Route), please specify:	
Start date:	02-Dec-2017
Start time:	15:27 24 hrs. clock
End date:	
End time:	24 hrs. clock
Ongoing:	C Yes © No
Remark, if any:	-

ADVERSE EVENT UPDATE FORM Per					
Adverse event Term:	Vomiting				
Adverse event Code:	llt_name=Vomiting## pt_name=Vomit	llt_name=Vomiting## pt_name=Vomiting## vMeddraVersion=MedDRA201			
AE number:	01	01			
Time of last IMP administration:	08:24 <b>24 hrs. clock</b>				
Date of last IMP administration:	02-Dec-2017				
Time of AE onset:	11:44 <b>24 hrs. clock</b>				
Date of AE onset:	02-DEC-2017				
Time of AE Resolution:	15:27 24 hrs. clock				
Date of AE Resolution:	02-DEC-2017				
Severity:	• MILD C MODERATE C SEVER	E			
m : 4 1	<b>©</b> GRADE 1:MILD AE	C GRADE 2:MODERATE AE	C GRADE 3:SEVERE AE		
Toxicity grade:	C GRADE 4:LIFE-THREATENING OR DISABLING AE	C GRADE 5:DEATH RELATED TO AE	C NOT APPLICABLE		
Serious?:	C YES © NO				

<sup>\*</sup>This is an electronically authenticated report.

### CASE REPORT FORM

Project No: 0326-17



Is it significant?:	C YES © NO			
If Conicous Conicousmoss suitonico	CONGENITAL ANOMALY I	SIGNIFICANT DISABILITY	□ DEATH	
If Serious, Seriousness criteria:	LI HOSPITALIZATION	□ LIFE THREATENING	OTHER MED	
Unexpected adverse drug reaction?:	C YES ONO C NAP			
Relationship to Study Treatment:	C NOT RELATED C UNLIKELY C RELATED C NAP	Y RELATED <b>©</b> PO	SSIBLY RELATED	)
Action Taken with Study Treatment:	C DOSE INCREASED C DO C DRUG INTERRUPTED © DE C UNKNOWN	OSE NOT CHANG RUG WITHDRAW		
Outcome:	C NOT RECOVERED/NOT G RESOLVED REC	COVERED/RESOLV	C RECOVERED WITH SEQUI	
	C RECOVERING/RESOLVING	UNKNOWN	C FATAL	
Caused study discontinuation:	€ YES C NO			
Concomitant treatment/Therapy given:	• YES C NO			
Does given concomitant medication has drug-drug interaction along with study drug?:	C YES © NO C NAP			
If Yes, then Specify:	-			
Remarks if, any:	-			
POST-DOSE SUBJECT DISCONTINUA	TION RECORD			Period: 2
SOP reference no: CPMA-17-12				
Status of Discontinuation				
Date of Discontinuation:		02-Dec-2017		
Time of last IMP administered:		08:24 <b>24 hrs. clo</b>	ock	
Date of last IMP administered:		02-Dec-2017		
Reason for discontinuation		T		_
Reasons:		C On his/her own accord	• On the grounds of Emesis	C On medical grounds
reasons.	C For having withheld critical Information	C On grounds of protocol non-compliance	C Any other (please specify)	
If any other:		-		
Description of Event:		Subject had single roximately 1144 hrs for 01 minute. Von in amount and cont He had no any other	nitus was approximation ained fluid with fo	miting la sted ately 100 ml

### CASE REPORT FORM

Project No: 0326-17



Management of Event:	Subject was discontinued from the study from emesis ground in consultation with principal investigator.
Checked By:	Dr. Ketul Modi
Communication of the Event	
Informed to IEC:	05-Dec-2017
Informed to Sponsor:	05-Dec-2017
Informed to concerned departments:	05-Dec-2017
Other Event related Information	
Post study safety assessment done:	€ Yes C No
Compensation paid:	€ Yes C No
If 'NO' in any of the above sections, please specify:	-
Comments By PI:	Subject was discontinued from the study on me dical ground. However he was followed-up till resolution of AE and his end study safety as sessment and found clinically acceptable.
Checked By:	Dr. Ketul Modi



## **Clinical Laboratory Test Report**



Lambda Therapeutic Research Limited

05-Dec-2017 11:33

05-Dec-2017 11:47

Screening AH17-06704 Subject Initial: KSM

Subject Date Of Birth: 01-Jan-1980 Referred By: Dr. Manish Patel

17063193 Lab ID: Sex: Female

Visit :

**Sample Collected** 

Sample Collected At: Sample Received On:

Report Date: 05-Dec-2017 20:50 Study /Project

0326-17

Ahmedabad

#### **CHEMISTRY**

[Performed By Reflectance Photometry]

<u>PARAMETER</u>	RESULT	CS/NCS*	REMARK	UNIT	REFERENCE INTERVAL
BILIRUBIN TOTAL	0.36			mg/dL	0.2 - 1.5
Azobilirubin					
TOTAL PROTEIN	7.83			g/dL	6.9 - 8.6
Biuret					
ALBUMIN	4.62			g/dL	3.9 - 5.2
	1102			3, -	3.5 3.2
BCG					
GLOBULIN	3.2			g/dL	2.5 - 3.8
Calculated					
A/G RATIO	1.44				1.2 - 2.2
Calculated					
S.G.O.T. (AST)	23			U/L	15.0 - 46.0
					20.0
UV WITH P-5-P					
S.G.P.T. (ALT)	28			U/L	11.0 - 58.0
UV WITH P-5-P					
CREATININE	0.61			mg/dL	0.5 - 0.9
Enzymatic (Creatine					
amidohydrolase, IDMS					
traceable)	17.0			mg/dL	15.0 26.0
UREA	17.8			mg/aL	15.0 - 36.0
Urease quinolinium dye					
CREATININE CLEARANCE	163.06	NCS		<b>H</b> mL/min	80 - 125
Calculated by Cockcroft Gault method					

clinically acceptable Final Remark :-

Reviewed by:-Dr. Sanjaykumar S. Patel - Studo7-Dec-2017 11:38

\*- NCS = Non Clinical Significant, CS = Clinical Significant

This is an Electronically authenticated report

Report Printed On: 16-Feb-2018 11:40 Authenticated By: Dhaval J Patel 05-Dec-2017 20:50







### **Clinical Laboratory Test Report**



Lambda Therapeutic Research Limited

05-Dec-2017 11:33

Ahmedabad

Screening AH17-06704 Subject Initial: KSM

Subject Date Of Birth: 01-Jan-1980 Referred By: Dr. Manish Patel

17063193 Lab ID: Sex: Female

Visit :

**Sample Collected** 

Sample Collected At: Sample Received On:

05-Dec-2017 11:47 Report Date: 05-Dec-2017 20:50 Study /Project

0326-17

#### **HEMATOLOGY**

[Performed By Flowcytometry and Electrical Impedence Method]

<u>PARAMETER</u>	RESULT	CS/NCS*	REMARK	UNIT I	REFERENCE INTERVAL
HAEMOGLOBIN	12.3			g/dL	10.0 - 14.4
SLS-Haemoglobin method					
RBC COUNT	4.44			Χ 10^6/μL	3.8 - 4.8
Hydro Dynamic focussing					
method	26.0			%	26.0 46.0
HCT	36.8			%	36.0 - 46.0
RBC pulse-height detection					
method MCV	82.9	NCS	L	fL	83.0 - 101.0
Coloulated					
Calculated MCH	27.7			Pg	27.0 - 32.0
MCH	27.7			. 9	27.0 - 32.0
Calculated					
MCHC	33.4			g/dL	31.5 - 34.5
Calculated					
RDW CV	13.2			%	11.6 - 14.0
Calculated					
PLATELET COUNT	364			X 10^3/μL	150 - 410
Hydro dynamic focussing method					
WBC (TOTAL)	7.57			X 10^3/μL	4.0 - 10.0
Flowcytometry method					
NEUTROPHIL %	66.0			%	40 - 80
Classes the markers are at head					
Flowcytometry method LYMPHOCYTES %	25.9			%	20 - 40
LIPHINOCITES /0	<i>23.3</i>			· <del>-</del>	20 70
Flowcytometry method					

Final Remark :-

clinically acceptable

Reviewed by:-

Dr. Sanjaykumar S. Patel - Studo7-Dec-2017 11:38

\*- NCS = Non Clinical Significant, CS = Clinical Significant

This is an Electronically authenticated report

Report Printed On: 16-Feb-2018 11:40 Authenticated By: Amit K. Barot 05-Dec-2017 12:15







## **Clinical Laboratory Test Report**



Lambda Therapeutic Research Limited

Screening Subject Initial: Subject Date Of Birth: Referred By:	AH17-06704 KSM 1026 01-Jan-1980 Dr. Manish Patel	Lab ID: Sex : Visit :	17063193 Female PS	Sample Collected Sample Collected At: Sample Received On: Report Date: Study /Project	05-Dec-2017 11:33 Ahmedabad 05-Dec-2017 11:47 05-Dec-2017 20:50 0326-17
OSINOPHILS %	1.6			%	1 - 6
Flowcytometry met					
10NOCYTES %	6.2			%	2 - 10
lowcytometry met	thod				
ASOPHILS %	0.3			%	0 - 2
lowcytometry met	thod				
EUTROPHILS (A	ABS) 5.00			X 10^3/μL	2.0 - 7.0
Calculated					
OSINOPHILS (A	ABS) 0.12			X 10^3/μL	0.02 - 0.5
alculated					

Final Remark :- clinically acceptable

**Reviewed by:-** Dr. Sanjaykumar S. Patel - Studo7-Dec-2017 11:38

\*- NCS = Non Clinical Significant, CS = Clinical Significant

This is an Electronically authenticated report

Report Printed On: 16-Feb-2018 11:40 Authenticated By:Amit K. Barot 05-Dec-2017 12:15







# **Clinical Laboratory Test Report**



Lambda Therapeutic Research Limited

Screening AH17-06704
Subject Initial: KSM
Subject 1026

Date Of Birth: 01-Jan-1980

Referred By: Dr. Manish Patel

**Lab ID:** 17063193 **Sex :** Female

Visit: PS

Sample Collected
Sample Collected At:

Study /Project

Sample Collected At: Sample Received On: Report Date:

mIU/mL

05-Dec-2017 11:33

Ahmedabad 05-Dec-2017 11:47 05-Dec-2017 20:50

0326-17

### **IMMUNOLOGY**

wnl

PARAMETER RESULT CS/NCS\* REMARK UNIT REFERENCE INTERVAL

<2.39

Chemiluminescence

BETA hCG

- Pre menopausal females: <4.83

Final Remark :- clinically acceptable

Reviewed by:- Dr. Sanjaykumar S. Patel - Studo7-Dec-2017 11:38

\*- NCS = Non Clinical Significant, CS = Clinical Significant

This is an Electronically authenticated report

Report Printed On: 16-Feb-2018 11:40 Authenticated By:Dipal D Shah 05-Dec-2017 16:58







### **Clinical Laboratory Test Report**



Screening AH17-06704
Subject Initial: KSM
Subject 1026
Date Of Birth: 01-Jan-1980

Referred By:

01-Jan-1980 Dr. Manish Patel 

 Lab ID:
 17063193

 Sex :
 Female

 Visit :
 PS

Sample Collected Sample Collected At: Sample Received On: Report Date: Study /Project 05-Dec-2017 11:33 Ahmedabad 05-Dec-2017 11:47

05-Dec-2017 11:47 05-Dec-2017 20:50 0326-17

## **Out of Summary Report**

PARAMETER	RESULT		<u>UNIT</u>	REFERENCE INTERVAL	<b>COMMENTS</b>
CREATININE CLEARANCE	163.06	н	mL/min	80 - 125	
MCV	82.9	L	fL	83.0 - 101.0	

Final Remark :- clinically acceptable

Reviewed by:- Dr. Sanjaykumar S. Patel - Stud07-Dec-2017 11:38

\*- NCS = Non Clinical Significant, CS = Clinical Significant

This is an Electronically authenticated report

Report Printed On: 16-Feb-2018 11:40 Authenticated By:Amit K. Barot 05-Dec-2017 12:15



