

Lambda Therapeutic Research.

Sponsor Name: Cipla Limited

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Project No: 0326-17

Subject No: 1026 Subject Initials: KSM



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**MEDICAL SCREENING RECORD FORM**

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**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:	<input type="radio"/> YES <input checked="" type="radio"/> NO <input type="radio"/> NAP
Remarks:	

**DEMOGRAPHIC DETAILS**

Default

Consent for Screening Signed:	<input checked="" type="radio"/> YES <input type="radio"/> NO
Date of Initiation of Screening:	17-Nov-2017
Sex:	<input type="radio"/> MALE <input checked="" type="radio"/> FEMALE
Date Of Birth:	01-Jan-1980
Age In Years (Completed years on the day of screening):	37
Ethnicity:	<input type="radio"/> HISPANIC <input checked="" type="radio"/> NON-HISPANIC
Race:	ASIAN
Marital Status:	<input type="radio"/> SINGLE <input checked="" type="radio"/> MARRIED <input type="radio"/> WIDOW <input type="radio"/> DIVORCEE
Food Habits:	<input type="radio"/> VEGETARIAN <input checked="" type="radio"/> NON-VEGETARIAN <input type="radio"/> EGGETARIAN

**PERSONAL HISTORY-SCREENING**

Default

Has the subject donated blood?:	<input type="radio"/> YES <input checked="" type="radio"/> NO
Last date of blood donation:	-
Date of last sample study participated in:	-

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# MEDICAL SCREENING RECORD FORM

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History of difficulty in blood donation:	<input type="radio"/> YES <input checked="" type="radio"/> NO <input type="radio"/> NAP
Smoking:	<input type="radio"/> CURRENT <input type="radio"/> PREVIOUS <input checked="" type="radio"/> NEVER
Smoking Details:	
Smoking, If Previous, Stopped since:	
Alcohol:	<input type="radio"/> CURRENT <input type="radio"/> PREVIOUS <input checked="" type="radio"/> 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:	<input type="radio"/> CURRENT <input type="radio"/> PREVIOUS <input checked="" type="radio"/> NEVER
Consumption Details for Recreationl Drug:	
Recreational Drug, If Previous, Stopped since:	
Others:	<input type="radio"/> CURRENT <input type="radio"/> PREVIOUS <input checked="" type="radio"/> NEVER
Consumption Details for Other:	
Others, If Previous, Stopped since:	

## PHYSICAL EXAMINATION-SCREENING

Default	
Pallor:	<input type="radio"/> PRESENT <input checked="" type="radio"/> ABSENT
Palpable Nodes:	<input type="radio"/> PRESENT <input checked="" type="radio"/> ABSENT
Nasal Polyp:	<input type="radio"/> PRESENT <input checked="" type="radio"/> ABSENT
Icterus:	<input type="radio"/> PRESENT <input checked="" type="radio"/> ABSENT
Edema:	<input type="radio"/> PRESENT <input checked="" type="radio"/> ABSENT
Eczema:	<input type="radio"/> PRESENT <input checked="" type="radio"/> ABSENT
Any other (Including skin,head,ear,eye,nose,throat,nails):	<input checked="" type="radio"/> NORMAL <input type="radio"/> ABNORMAL
Remarks:	

## MEDICAL HISTORY-SCREENING

Default	
HISTORY OF INFECTIOUS DISORDER:	HISTORY OF INFECTIOUS DISORDER

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**MEDICAL SCREENING RECORD FORM**

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Any Infectious Disorder:	<input type="radio"/> YES <input checked="" type="radio"/> NO
If "Yes", Specify:	
RECENT HISTORY OF MEDICATION (WITHIN LAST 30 DAYS):	RECENT HISTORY OF MEDICATION (WITHIN LAST 30 DAYS)
Recent History of Medication:	<input type="radio"/> YES <input checked="" type="radio"/> NO
If "Yes", Specify:	
HISTORY OF ALLERGY:	HISTORY OF ALLERGY
Allergy to Medicines:	<input type="radio"/> YES <input checked="" type="radio"/> NO
Allergy to Food:	<input type="radio"/> YES <input checked="" type="radio"/> NO
Allergy to any other:	<input type="radio"/> YES <input checked="" type="radio"/> NO
Other, please specify:	
HISTORY OF OTHER DISORDER:	HISTORY OF OTHER DISORDER
Any History of Other Disorder:	<input type="radio"/> YES <input checked="" type="radio"/> NO
If "Yes", Specify:	
SYSTEMIC EXAMINATION-SCREENING	
Cardiovascular System	
Any History of Cardiovascular Disorder:	<input type="radio"/> YES <input checked="" type="radio"/> NO
If "Yes",Specify:	
Pulse Rhythm:	<input checked="" type="radio"/> REGULAR <input type="radio"/> IRREGULAR
Pulse Volume:	<input checked="" type="radio"/> NORMAL <input type="radio"/> HIGH <input type="radio"/> LOW
Inspection (Pericardial area with apex beat):	<input checked="" type="radio"/> NORMAL <input type="radio"/> ABNORMAL
Palpation (Pericardial area with apex beat):	<input checked="" type="radio"/> NORMAL <input type="radio"/> ABNORMAL
Percussion:	<input checked="" type="radio"/> NORMAL <input type="radio"/> ABNORMAL
Auscultation (Heart sounds):	<input checked="" type="radio"/> NORMAL <input type="radio"/> ABNORMAL
Remarks if any:	
Respiratory System	
Any History of Respiratory Disorder:	<input type="radio"/> YES <input checked="" type="radio"/> NO
If "Yes",Specify:	



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**MEDICAL SCREENING RECORD FORM**

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

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**MEDICAL SCREENING RECORD FORM**

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Abnormal movements:	<input type="radio"/> PRESENT <input checked="" type="radio"/> ABSENT
Remarks if any:	
For Female Only	
Last Menstrual Period	
Last Menstrual Period Date:	25-Oct-2017
Regularity:	<input checked="" type="radio"/> REGULAR <input type="radio"/> IRREGULAR
Association with Pain:	<input type="radio"/> PAINFUL <input checked="" type="radio"/> 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:	<input checked="" type="radio"/> YES <input type="radio"/> NO <input type="radio"/> NAP
Remarks:	-
Any spontaneous Abortions or MTP:	-
Date of last abortion or MTP:	
Lactating/Nursing:	<input type="radio"/> YES <input checked="" type="radio"/> NO
Volunteer is in the child bearing age:	<input checked="" type="radio"/> YES <input type="radio"/> NO
Family Planing Measures:	<input type="checkbox"/> PERMANENT <input checked="" type="checkbox"/> TEMPORARY <input type="checkbox"/> POST CONTRACEPTION CONTRACEPTION MENOPAUSAL <input type="checkbox"/> NOT APPLICABLE
Details of Permanent Contraception:	
Details of Temporary Contraception:	<input checked="" type="checkbox"/> DOUBLE BARRIER <input type="checkbox"/> PILLS <input type="checkbox"/> RHYTHM <input type="checkbox"/> IUCD <input type="checkbox"/> NAP
Remarks:	
SCREENING CLINICAL EXAMINATION-SCREENING	
Default	
Clinically fit:	<input checked="" type="radio"/> YES <input type="radio"/> NO
Remarks:	
LAB REPORT-SCREENING	
Default	
Lab Report Remark:	

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**MEDICAL SCREENING RECORD FORM**

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Clinically:	<input checked="" type="radio"/> ACCEPTABLE <input type="radio"/> NOT ACCEPTABLE
Remarks,if Repeated:	
Any dietary advice given to subject?:	<input type="radio"/> YES <input checked="" type="radio"/> NO <input type="radio"/> NAP
Additional Information:	
<b>X-RAY EXAMINATION-SCREENING</b>	
Default	
X-RAY Comments:	
Clinically:	<input checked="" type="radio"/> ACCEPTABLE <input type="radio"/> NOT ACCEPTABLE
<b>ELECTROCARDIOGRAM-SCREENING</b>	
Default	
ECG Impression Remark:	WNL
Remarks,if ECG Repeated:	
Clinically:	<input checked="" type="radio"/> ACCEPTABLE <input type="radio"/> NOT ACCEPTABLE
<b>CLINICAL SCREENING ELIGIBILITY-SCREENING</b>	
Default	
Is Eligible for study?:	<input checked="" type="radio"/> YES <input type="radio"/> NO
Remarks,In case of re-eligibility:	
<b>OTHER EXAMINATION-SCREENING</b>	
Default	
Other Examination-1:	
Clinically-1:	<input type="radio"/> ACCEPTABLE <input type="radio"/> NOT ACCEPTABLE
Other Examination-2:	
Clinically-2:	<input type="radio"/> ACCEPTABLE <input type="radio"/> NOT ACCEPTABLE
Other Examination-3:	
Clinically-3:	<input type="radio"/> ACCEPTABLE <input type="radio"/> NOT ACCEPTABLE
Other Examination-4:	
Clinically-4:	<input type="radio"/> ACCEPTABLE <input type="radio"/> NOT ACCEPTABLE
Remarks:	
<b>Screening Review</b>	
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

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**MEDICAL SCREENING RECORD FORM**

Project No: 0326-17

Subject No: 1026 Subject Initials: KSM



Remarks:

I have reviewed medical screening record after DCF resolution.



Clinical Laboratory Test Report



Lambda Therapeutic Research Limited

<b>Screening</b>	AH17-06704	<b>Lab ID:</b>	17060104	<b>Sample Collected</b>	17-Nov-2017 18:21
<b>Subject Initial:</b>	KSM	<b>Sex :</b>	Female	<b>Sample Collected At:</b>	Ahmedabad
<b>Subject</b>	N/A	<b>Visit :</b>	Screening	<b>Sample Received On:</b>	17-Nov-2017 18:54
<b>Date Of Birth:</b>	01-Jan-1980			<b>Report Date:</b>	17-Nov-2017 22:40
<b>Referred By:</b>	Dr. Manish Patel			<b>Study /Project</b>	

CHEMISTRY

[Performed By Reflectance Photometry]

<u>PARAMETER</u>	<u>RESULT</u>	<u>CS/NCS*</u>	<u>REMARK</u>	<u>UNIT</u>	<u>REFERENCE INTERVAL</u>
PLASMA RANDOM GLUCOSE	92.5			mg/dL	- WHO CRITERIA FOR DIAGNOSIS OF DIABETES >200 along with symptoms of hyperglycemia suggestive of diabetes
Glucose oxidase					
BILIRUBIN TOTAL	0.32			mg/dL	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)					

**Final Remark :-** CLINICALLY ACCEPTABLE

**Reviewed by:-** Jaimin Chhaganbhai Ahir - Stud18-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



No. 7183121

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No. M-0232



Clinical Laboratory Test Report

<b>Screening</b>	AH17-06704	<b>Lab ID:</b>	17060104	<b>Sample Collected</b>	17-Nov-2017 18:21
<b>Subject Initial:</b>	KSM	<b>Sex :</b>	Female	<b>Sample Collected At:</b>	Ahmedabad
<b>Subject</b>	N/A	<b>Visit :</b>	Screening	<b>Sample Received On:</b>	17-Nov-2017 18:54
<b>Date Of Birth:</b>	01-Jan-1980			<b>Report Date:</b>	17-Nov-2017 22:40
<b>Referred By:</b>	Dr. Manish Patel			<b>Study /Project</b>	

UREA	21.4		mg/dL	15.0 - 36.0
Urease quinolinium dye				
SODIUM	140.2		mmol/L	135.6 - 145.9
Direct ISE				
POTASSIUM	4.63		mmol/L	3.8 - 5.4
Direct ISE				
CHLORIDE	106.1		mmol/L	97.3 - 107.0
Direct ISE				
CREATININE CLEARANCE	<b>165.78</b>	NCS	<b>H</b> mL/min	80 - 125

Calculated by Cockcroft Gault method

**Final Remark :-** CLINICALLY ACCEPTABLE

**Reviewed by:-** Jaimin Chhaganbhai Ahir - Stud18-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



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Clinical Laboratory Test Report



Lambda Therapeutic Research Limited

<b>Screening</b>	AH17-06704	<b>Lab ID:</b>	17060104	<b>Sample Collected</b>	17-Nov-2017 18:21
<b>Subject Initial:</b>	KSM	<b>Sex :</b>	Female	<b>Sample Collected At:</b>	Ahmedabad
<b>Subject</b>	N/A	<b>Visit :</b>	Screening	<b>Sample Received On:</b>	17-Nov-2017 18:54
<b>Date Of Birth:</b>	01-Jan-1980			<b>Report Date:</b>	17-Nov-2017 22:40
<b>Referred By:</b>	Dr. Manish Patel			<b>Study /Project</b>	

HEMATOLOGY

[Performed By Flowcytometry and Electrical Impedence Method]

<b>PARAMETER</b>	<b>RESULT</b>	<b>CS/NCS*</b>	<b>REMARK</b>	<b>UNIT</b>	<b>REFERENCE INTERVAL</b>
HAEMOGLOBIN	11.5			g/dL	10.0 - 14.4
SLS-Haemoglobin method					
RBC COUNT	4.16			X 10 <sup>6</sup> /μL	3.8 - 4.8
Hydro Dynamic focussing method					
HCT	<b>34.6</b>	NCS		<b>L</b> %	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 <sup>3</sup> /μL	150 - 410
Hydro dynamic focussing method					
WBC (TOTAL)	6.71			X 10 <sup>3</sup> /μL	4.0 - 10.0
Flowcytometry method					
NEUTROPHIL %	56.7			%	40 - 80
Flowcytometry method					
LYMPHOCYTES %	34.9			%	20 - 40
Flowcytometry method					

**Final Remark :-** CLINICALLY ACCEPTABLE

**Reviewed by:-** Jaimin Chhaganbhai Ahir - Stud18-Nov-2017 12:47

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

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17-Nov-2017 19:56



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No. M-0232



## Clinical Laboratory Test Report

<b>Screening</b>	AH17-06704	<b>Lab ID:</b>	17060104	<b>Sample Collected</b>	17-Nov-2017 18:21
<b>Subject Initial:</b>	KSM	<b>Sex :</b>	Female	<b>Sample Collected At:</b>	Ahmedabad
<b>Subject</b>	N/A	<b>Visit :</b>	Screening	<b>Sample Received On:</b>	17-Nov-2017 18:54
<b>Date Of Birth:</b>	01-Jan-1980			<b>Report Date:</b>	17-Nov-2017 22:40
<b>Referred By:</b>	Dr. Manish Patel			<b>Study /Project</b>	

EOSINOPHILS %	1.6	%	1 - 6
Flowcytometry method			
MONOCYTES %	6.7	%	2 - 10
Flowcytometry method			
BASOPHILS %	0.1	%	0 - 2
Flowcytometry method			
NEUTROPHILS (ABS)	3.80	X 10 <sup>3</sup> /μL	2.0 - 7.0
Calculated			
EOSINOPHILS (ABS)	0.11	X 10 <sup>3</sup> /μL	0.02 - 0.5
Calculated			
BLOOD GROUP	"O" Positive		

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 - Stud18-Nov-2017 12:47

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No. M-0232





Clinical Laboratory Test Report



Lambda Therapeutic Research Limited

<b>Screening</b>	AH17-06704	<b>Lab ID:</b>	17060104	<b>Sample Collected</b>	17-Nov-2017 18:21
<b>Subject Initial:</b>	KSM	<b>Sex :</b>	Female	<b>Sample Collected At:</b>	Ahmedabad
<b>Subject</b>	N/A	<b>Visit :</b>	Screening	<b>Sample Received On:</b>	17-Nov-2017 18:54
<b>Date Of Birth:</b>	01-Jan-1980			<b>Report Date:</b>	17-Nov-2017 22:40
<b>Referred By:</b>	Dr. Manish Patel			<b>Study /Project</b>	

IMMUNOLOGY

<u>PARAMETER</u>	<u>RESULT</u>	<u>CS/NCS*</u>	<u>REMARK</u>	<u>UNIT</u>	<u>REFERENCE INTERVAL</u>
Anti HCV	Non-Reactive				Non-Reactive
ELISA					
Anti HIV I&II	Non-Reactive				Non-Reactive
ELISA					
HBsAg	Non-Reactive				Non-Reactive
ELISA					
hCG	<0.500		WNL	mIU/mL	Pre menopausal females: <4.9
Electrochemiluminescence					

**Final Remark :-** CLINICALLY ACCEPTABLE

**Reviewed by:-** Jaimin Chhaganbhai Ahir - Stud18-Nov-2017 12:47

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

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17-Nov-2017 22:40



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No. M-0232



## Clinical Laboratory Test Report



Lambda Therapeutic Research Limited

<b>Screening</b>	AH17-06704	<b>Lab ID:</b>	17060104	<b>Sample Collected</b>	17-Nov-2017 18:21
<b>Subject Initial:</b>	KSM	<b>Sex :</b>	Female	<b>Sample Collected At:</b>	Ahmedabad
<b>Subject</b>	N/A	<b>Visit :</b>	Screening	<b>Sample Received On:</b>	17-Nov-2017 18:54
<b>Date Of Birth:</b>	01-Jan-1980			<b>Report Date:</b>	17-Nov-2017 22:40
<b>Referred By:</b>	Dr. Manish Patel			<b>Study /Project</b>	

## URINE ANALYSIS

[Performed By Reflectance Photometry]

<u>PARAMETER</u>	<u>RESULT</u>	<u>CS/NCS*</u>	<u>REMARK</u>	<u>UNIT</u>	<u>REFERENCE INTERVAL</u>
Appearance	CLEAR				
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

**Final Remark :-** CLINICALLY ACCEPTABLE**Reviewed by:-** Jaimin Chhaganbhai Ahir - Stud18-Nov-2017 12:47

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

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No. M-0232

## Lambda Therapeutic Research



### Clinical Laboratory Test Report



Lambda Therapeutic Research

Screening	AH17-06704	Lab ID:	17060104	Sample Collected	17-Nov-2017 18:21
Subject Initial:	KSM	Sex :	Female	Sample Collected At:	Ahmedabad
Subject	N/A	Visit :	Screening	Sample Received On:	17-Nov-2017 18:54
Date Of Birth:	01-Jan-1980			Report Date:	17-Nov-2017 22:40
Referred By:	Dr. Manish Patel			Study /Project	

### Out of Summary Report

PARAMETER	RESULT		UNIT	REFERENCE INTERVAL	COMMENTS
CREATININE CLEARANCE	165.78	H	mL/min	80 - 125	
HCT	34.6	L	%	36.0 - 46.0	

Final Remark :- CLINICALLY ACCEPTABLE

Reviewed by:- Jaimin Chhaganbhai Ahir - Stud18-Nov-2017 12:47

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

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No. M-0232



## Clinical Laboratory Test Report

<b>Screening</b>	AH17-06704	<b>Lab ID:</b>	17061746	<b>Sample Collected</b>	25-Nov-2017 12:53
<b>Subject Initial:</b>	KSM	<b>Sex :</b>	Female	<b>Sample Collected At:</b>	Ahmedabad
<b>Subject</b>	1026	<b>Visit :</b>	PCI1	<b>Sample Received On:</b>	25-Nov-2017 13:26
<b>Date Of Birth:</b>	01-Jan-1980			<b>Report Date:</b>	25-Nov-2017 15:24
<b>Referred By:</b>	Dr. Manish Patel			<b>Study /Project</b>	0326-17

## CHEMISTRY

[Performed By Reflectance Photometry]

<u>PARAMETER</u>	<u>RESULT</u>	<u>CS/NCS*</u>	<u>REMARK</u>	<u>UNIT</u>	<u>REFERENCE INTERVAL</u>
CREATININE	0.62			mg/dL	0.5 - 0.9
Enzymatic (Creatine amidohydrolase, IDMS traceable)					
CREATININE CLEARANCE	<b>160.43</b>	NCS		<b>H</b> mL/min	80 - 125

Calculated by Cockcroft Gault  
method**Final Remark :-** clinically acceptable**Reviewed by:-** Dr. Sanjaykumar S. Patel - Stud25-Nov-2017 16:24

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

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Report Printed On: 16-Feb-2018 11:39

Authenticated By: Dhaval J Patel

25-Nov-2017 15:24



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No. M-0232



## Clinical Laboratory Test Report

Screening	AH17-06704	Lab ID:	17061746	Sample Collected	25-Nov-2017 12:53
Subject Initial:	KSM	Sex :	Female	Sample Collected At:	Ahmedabad
Subject	1026	Visit :	PCI1	Sample Received On:	25-Nov-2017 13:26
Date Of Birth:	01-Jan-1980			Report Date:	25-Nov-2017 15:24
Referred By:	Dr. Manish Patel			Study /Project	0326-17

## IMMUNOLOGY

PARAMETER	RESULT	CS/NCS*	REMARK	UNIT	REFERENCE INTERVAL
BETA hCG	<2.39		wnl	mIU/mL	- Pre menopausal females: <4.83
Chemiluminescence					

Final Remark :- clinically acceptable

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

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

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Authenticated By:Hiren D. Patel

25-Nov-2017 15:15



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No. M-0232

# Lambda Therapeutic Research



## Clinical Laboratory Test Report



Lambda Therapeutic Research

Screening	AH17-06704	Lab ID:	17061746	Sample Collected	25-Nov-2017 12:53
Subject Initial:	KSM	Sex :	Female	Sample Collected At:	Ahmedabad
Subject	1026	Visit :	PCI1	Sample Received On:	25-Nov-2017 13:26
Date Of Birth:	01-Jan-1980			Report Date:	25-Nov-2017 15:24
Referred By:	Dr. Manish Patel			Study /Project	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

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25-Nov-2017 15:24



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No. M-0232



Clinical Laboratory Test Report

<b>Screening</b>	AH17-06704	<b>Lab ID:</b>	17062552	<b>Sample Collected</b>	01-Dec-2017 15:48
<b>Subject Initial:</b>	KSM	<b>Sex :</b>	Female	<b>Sample Collected At:</b>	Ahmedabad
<b>Subject</b>	1026	<b>Visit :</b>	PCI2	<b>Sample Received On:</b>	01-Dec-2017 16:03
<b>Date Of Birth:</b>	01-Jan-1980			<b>Report Date:</b>	01-Dec-2017 17:14
<b>Referred By:</b>	Dr. Manish Patel			<b>Study /Project</b>	0326-17

CHEMISTRY

[Performed By Reflectance Photometry]

<u>PARAMETER</u>	<u>RESULT</u>	<u>CS/NCS*</u>	<u>REMARK</u>	<u>UNIT</u>	<u>REFERENCE INTERVAL</u>
CREATININE	0.69			mg/dL	0.5 - 0.9
Enzymatic (Creatine amidohydrolase, IDMS traceable)					
CREATININE CLEARANCE	<b>144.15</b>	NCS		<b>H</b> mL/min	80 - 125

Calculated by Cockcroft Gault  
method

**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



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No. M-0232



Clinical Laboratory Test Report

Screening	AH17-06704	Lab ID:	17062552	Sample Collected	01-Dec-2017 15:48
Subject Initial:	KSM	Sex :	Female	Sample Collected At:	Ahmedabad
Subject	1026	Visit :	PCI2	Sample Received On:	01-Dec-2017 16:03
Date Of Birth:	01-Jan-1980			Report Date:	01-Dec-2017 17:14
Referred By:	Dr. Manish Patel			Study /Project	0326-17

IMMUNOLOGY

PARAMETER	RESULT	CS/NCS*	REMARK	UNIT	REFERENCE INTERVAL
BETA hCG	<2.39		WNL	mIU/mL	- Pre menopausal females: <4.83
Chemiluminescence					

Final Remark :- CLINICALLY ACCEPTABLE

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

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

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01-Dec-2017 17:11



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No. M-0232



## Lambda Therapeutic Research



### Clinical Laboratory Test Report



Lambda Therapeutic Research

Screening	AH17-06704	Lab ID:	17062552	Sample Collected	01-Dec-2017 15:48
Subject Initial:	KSM	Sex :	Female	Sample Collected At:	Ahmedabad
Subject	1026	Visit :	PCI2	Sample Received On:	01-Dec-2017 16:03
Date Of Birth:	01-Jan-1980			Report Date:	01-Dec-2017 17:14
Referred By:	Dr. Manish Patel			Study /Project	0326-17

### Out of Summary Report

<u>PARAMETER</u>	<u>RESULT</u>	<u>UNIT</u>	<u>REFERENCE INTERVAL</u>	<u>COMMENTS</u>
CREATININE CLEARANCE	144.15	H mL/min	80 - 125	

**Final Remark :-** CLINICALLY ACCEPTABLE

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

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01-Dec-2017 17:14



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No. M-0232

Lambda Therapeutic Research.

Sponsor Name:Cipla Limited

# CASE REPORT FORM

Project No: 0326-17

Subject No: 1026 Subject Initials: KSM



## CHECK-IN DETAILS( Period - 1)

BREATH TEST FOR ALCOHOL CONSUMPTION		Period: 1
Date:	25-Nov-2017	
Start Time:	13:18 <b>24 hrs. clock</b>	
Breath Alcohol Level (BAL):	.000 %	
Result:	<input type="radio"/> Positive <input checked="" type="radio"/> Negative	
Start Time of 1st Repeat:	<b>24 hrs. clock</b>	
Breath Alcohol Level (BAL):	%	
1st Repeat result:	<input type="radio"/> Positive <input type="radio"/> Negative	
Start Time of 2nd Repeat:	<b>24 hrs. clock</b>	
Breath Alcohol Level (BAL):	%	
2nd Repeat Result:	<input type="radio"/> Positive <input type="radio"/> Negative	
Final Result:	<input type="radio"/> Positive <input checked="" type="radio"/> Negative	
For Positive results (if any) Informed to Principal Investigator/Co-Investigator/designate:	<input type="radio"/> Yes <input type="radio"/> No <input checked="" type="radio"/> NAP	
Remarks:	-	

URINE SCAN FOR DRUGS OF ABUSE		Period: 1
SOP reference no:CPMA-26-08		
Date:	25-Nov-2017	
Refer/Read leaflet before start activity:	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NAP	
1. URINE SCAN FOR DRUGS ABUSE		
1.1 Urine drug scan tested for:	<input checked="" type="checkbox"/> Amphetamine (AMP) <input checked="" type="checkbox"/> Barbiturates (BAR) <input checked="" type="checkbox"/> Benzodiazepines (BZD) <input checked="" type="checkbox"/> Cocaine (COC) <input checked="" type="checkbox"/> Morphine (MOR) <input checked="" type="checkbox"/> Cannabinoids (THC)	
1.2 Start time:	13:36 <b>24 hrs. clock</b>	
1.3 Observation of Results:	<input type="radio"/> Positive with one band (Control) <input checked="" type="radio"/> Negative with two band (Control and test) <input type="radio"/> Invalid with No band <input type="radio"/> Invalid with one band (Test)	
1.4 Positive for:	<input type="checkbox"/> Amphetamine (AMP) <input type="checkbox"/> Barbiturates (BAR) <input type="checkbox"/> Benzodiazepines (BZD) <input type="checkbox"/> Cocaine (COC) <input type="checkbox"/> Morphine (MOR) <input type="checkbox"/> Cannabinoids (THC)	
2. URINE SCAN FOR DRUGS ABUSE (1st REPEAT)		

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Page 1 of 32

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[Authenticated On:29-Dec-2017 17:15 IST (+5:30 GMT)]

Lambda Therapeutic Research.

Sponsor Name:Cipla Limited

# CASE REPORT FORM

Project No: 0326-17

Subject No: 1026 Subject Initials: KSM



2.1 Urine drug scan tested for:	<input type="checkbox"/> Amphetamine (AMP) <input type="checkbox"/> Barbiturates (BAR) <input type="checkbox"/> Benzodiazepines (BZD) <input type="checkbox"/> Cocaine (COC) <input type="checkbox"/> Morphine (MOR) <input type="checkbox"/> Cannabinoids (THC)
2.2 Start time:	<b>24 hrs. clock</b>
2.3 Observation of Results:	<input type="radio"/> Positive with one band (Control) <input type="radio"/> Negative with two band (Control and test) <input type="radio"/> Invalid with No band <input type="radio"/> Invalid with one band (Test)
2.4 Positive for:	<input type="checkbox"/> Amphetamine (AMP) <input type="checkbox"/> Barbiturates (BAR) <input type="checkbox"/> Benzodiazepines (BZD) <input type="checkbox"/> Cocaine (COC) <input type="checkbox"/> Morphine (MOR) <input type="checkbox"/> Cannabinoids (THC)
<b>3. URINE SCAN FOR DRUGS ABUSE (2nd REPEAT)</b>	
3.1 Urine drug scan tested for:	<input type="checkbox"/> Amphetamine (AMP) <input type="checkbox"/> Barbiturates (BAR) <input type="checkbox"/> Benzodiazepines (BZD) <input type="checkbox"/> Cocaine (COC) <input type="checkbox"/> Morphine (MOR) <input type="checkbox"/> Cannabinoids (THC)
3.2 Start time:	<b>24 hrs. clock</b>
3.3 Observation of Results:	<input type="radio"/> Positive with one band (Control) <input type="radio"/> Negative with two band (Control and test) <input type="radio"/> Invalid with No band <input type="radio"/> Invalid with one band (Test)
3.4 Positive for:	<input type="checkbox"/> Amphetamine (AMP) <input type="checkbox"/> Barbiturates (BAR) <input type="checkbox"/> Benzodiazepines (BZD) <input type="checkbox"/> Cocaine (COC) <input type="checkbox"/> Morphine (MOR) <input type="checkbox"/> Cannabinoids (THC)
Final Result:	<input type="radio"/> Positive <input checked="" type="radio"/> Negative
Positive for:	<input type="checkbox"/> Amphetamine (AMP) <input type="checkbox"/> Barbiturates (BAR) <input type="checkbox"/> Benzodiazepines (BZD) <input type="checkbox"/> Cocaine (COC) <input type="checkbox"/> Morphine (MOR) <input type="checkbox"/> Cannabinoids (THC)
Remarks (for repeats or any other information):	-
Date:	
Refer/Read leaflet before start activity:	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NAP
<b>4. URINE SCAN FOR DRUGS ABUSE ADDITIONAL</b>	

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**CASE REPORT FORM**

Project No: 0326-17

Subject No: 1026 Subject Initials: KSM



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

Lambda Therapeutic Research.

Sponsor Name:Cipla Limited

# CASE REPORT FORM

Project No: 0326-17

Subject No: 1026 Subject Initials: KSM



6.5 Positive for:	<input type="checkbox"/> Phencyclidine(PCP) <input type="checkbox"/> Cotinine(COT) <input type="checkbox"/> Methadone(MTD) <input type="checkbox"/> Other
6.6 If other then specify:	
Final Result:	<input type="radio"/> Positive <input type="radio"/> Negative
Positive for:	<input type="checkbox"/> Phencyclidine(PCP) <input type="checkbox"/> Cotinine(COT) <input type="checkbox"/> Methadone(MTD) <input type="checkbox"/> 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 and 45 years of age (both inclusive):	<input checked="" type="radio"/> Yes <input type="radio"/> No
Having a Body Mass Index (BMI) between 18.5 and 29.9 (both inclusive), calculated as weight in kg / height in m2:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Not having any significant diseases or clinically significant abnormal findings during screening, medical history, clinical examination, laboratory evaluations, 12-lead ECG and X-ray chest (Postero-anterior view) recordings:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Able to understand and comply with the study procedures, in the opinion of the investigator:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Able to give voluntary written informed consent for participation in the study:	<input checked="" type="radio"/> Yes <input type="radio"/> No

### Inclusion Criteria in case of Female subjects

Surgically sterilized at least 6 months prior to study participation; Or:	<input type="radio"/> Yes <input type="radio"/> No <input checked="" type="radio"/> 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:	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NAP
Serum Pregnancy test must be negative:	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NAP

### Exclusion criteria

Known hypersensitivity to Apremilast or any excipients or any related drug or any substance:	<input type="radio"/> Yes <input checked="" type="radio"/> 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, gastrointestinal, eye, ear conditions or any other body system:	<input type="radio"/> Yes <input checked="" type="radio"/> No
Any history or presence of asthma (including aspirin induced asthma) or nasal polyp or NSAIDs induced urticaria:	<input type="radio"/> Yes <input checked="" type="radio"/> No
Difficulty in swallowing solids dosage forms like tablets or capsules:	<input type="radio"/> Yes <input checked="" type="radio"/> 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 ml of beer or 150 ml of wine or 45 ml of 40% distilled spirits, such as rum, whisky, brandy etc):	<input type="radio"/> Yes <input checked="" type="radio"/> No
Smokers or who have smoked within last 06 months prior to start of the study:	<input type="radio"/> Yes <input checked="" type="radio"/> No

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The presence of clinically significant abnormal laboratory values during screening:	<input type="radio"/> Yes <input checked="" type="radio"/> No
Use of any recreational drugs or history of drug addiction:	<input type="radio"/> Yes <input checked="" type="radio"/> No
History of depression and/or suicidal thoughts or behaviour:	<input type="radio"/> Yes <input checked="" type="radio"/> No
QTc interval > 450 ms at the time of screening:	<input type="radio"/> Yes <input checked="" type="radio"/> No
Subject having CrCL <=50 ml/min at screening:	<input type="radio"/> Yes <input checked="" type="radio"/> No
History or presence of psychiatric disorders:	<input type="radio"/> Yes <input checked="" type="radio"/> No
A history of difficulty in donating blood:	<input type="radio"/> Yes <input checked="" type="radio"/> 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:	<input type="radio"/> Yes <input checked="" type="radio"/> No
A positive hepatitis screen including hepatitis B surface antigen and/or HCV antibodies:	<input type="radio"/> Yes <input checked="" type="radio"/> No
A positive test result for HIV-I & II antibody:	<input type="radio"/> Yes <input checked="" type="radio"/> No
Nursing mothers (females):	<input type="radio"/> Yes <input checked="" type="radio"/> No <input type="radio"/> NAP
<b>suitability</b>	
Based on above criterias, Subject is:	<input checked="" type="radio"/> Suitable <input type="radio"/> Not-suitable
<b>Criteria to be checked at the time of compliance check</b>	
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 of period-I and an unusual diet, for whatever reason (e.g. low-sodium), for four weeks prior to receiving the IMP in Period-I. In any such case subject selection will be at the discretion of the Principal Investigator.	
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:	-
<b>COMPLIANCE CHECK-PI</b> <span style="float: right;">Period: 1</span>	
<b>Demographic Details</b>	
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:	<input checked="" type="radio"/> Yes <input type="radio"/> No
If 'Yes', mention pagination number of ICF:	29
<b>Protocol Compliance Assessment</b>	
Criteria Check Complete:	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NAP
Urine scan for drugs of abuse tested negative:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Breath test for alcohol consumption tested negative:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Date of last menstruation period (for female subject):	21-NOV-2017

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

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Project No: 0326-17

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Complaints of any illness:	<input checked="" type="radio"/> No <input type="radio"/> Yes
If YES, provide details:	-
General Physical examination:	<input checked="" type="radio"/> Normal <input type="radio"/> 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:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Respiratory System Examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Central Nervous System Examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Per Abdomen Examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Any other Significant finding:	-
Any investigations recommended:	-
Vein puncture site:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Subject well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If 'Abnormal' in any of the above-mentioned sections, please enter details.:	-
Remark if Any:	-
Subject is fit:	<input checked="" type="radio"/> Yes <input type="radio"/> No

## DINNER CHECK-IN (DAY-1) Period: 1

Date of meal distribution:	25-Nov-2017
Start Time:	20:24 24 hrs. clock
End Time:	20:40 24 hrs. clock
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-

## HOUSING DETAILS( Period - 1)

### 0.00 HRS PRE DOSE VITAL SIGNS AND WELL-BEING RECORD Period: 1

Position:	Sitting
Date of vital measurement:	26-Nov-2017
Start Time of vital measurement:	07:04 24 hrs. clock
Systolic Blood Pressure:	116 mmHg
Diastolic Blood Pressure:	76 mmHg
Radial Pulse:	84 beats/min
Oral Body Temperature:	98.0 °F
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-

### 0.000 HRS PRE DOSE PK SAMPLE COLLECTION Period: 1

Date and Time of Dosing:	
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# CASE REPORT FORM

Project No: 0326-17

Subject No: 1026 Subject Initials: KSM



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 <b>24 hrs. clock</b>
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?:	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NA	
TIME:	08:24 <b>24 hrs. clock</b>	
MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA:	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> 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?:	<input checked="" type="radio"/> Yes <input type="radio"/> 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):	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Has the subject compliant to 04 hours post dose fasting condition?:	<input checked="" type="radio"/> Yes <input type="radio"/> 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 <b>24 hrs. clock</b>	
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 <b>24 hrs. clock</b>	
Remarks:		
PK Sample ID:	PK17863075	
Remarks if any other reason:		

0.750 HRS POST DOSE PK SAMPLE COLLECTION		Period: 1
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Subject No: 1026 Subject Initials: KSM



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 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK17863147
Remarks if any other reason:	

## 1.000 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 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 Period: 1

Position:	Sitting
Date of vital measurement:	26-Nov-2017
Start Time of vital measurement:	08:56 <b>24 hrs. clock</b>
Systolic Blood Pressure:	112 <b>mmHg</b>
Diastolic Blood Pressure:	78 <b>mmHg</b>
Radial Pulse:	76 <b>beats/min</b>
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-

## 1.333 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 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: 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 10:04
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 Period: 1

Date and Time of Dosing:	26-Nov-2017 08:24
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Project No: 0326-17

Subject No: 1026 Subject Initials: KSM



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 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK17863386
Remarks if any other reason:	

## 2.667 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 11:04
Actual Time of sample collection:	11:04 <b>24 hrs. clock</b>
Remarks:	
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 <b>mmHg</b>
Diastolic Blood Pressure:	74 <b>mmHg</b>
Radial Pulse:	72 <b>beats/min</b>
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> 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

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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 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK17863567
Remarks if any other reason:	

## 3.667 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 12:04
Actual Time of sample collection:	12:04 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK17863638
Remarks if any other reason:	

## 4.000 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 12:24
Actual Time of sample collection:	12:24 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK17863710
Remarks if any other reason:	

## LUNCH (4.00 HRS POST DOSE) (DAY 1) Period: 1

Date of meal distribution:	26-Nov-2017
Start Time:	12:26 <b>24 hrs. clock</b>
End Time:	12:42 <b>24 hrs. clock</b>
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-

## 4.500 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 12:54
Actual Time of sample collection:	12:54 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK17863782
Remarks if any other reason:	

## 5.000 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 13:24
Actual Time of sample collection:	13:24 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK17863854

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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 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 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: 1

Position:	Sitting
Date of vital measurement:	26-Nov-2017
Start Time of vital measurement:	13:50 <b>24 hrs. clock</b>
Systolic Blood Pressure:	110 <b>mmHg</b>
Diastolic Blood Pressure:	70 <b>mmHg</b>
Radial Pulse:	68 <b>beats/min</b>
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-

## 8.000 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 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: 1

Date of meal distribution:	26-Nov-2017
Start Time:	16:25 <b>24 hrs. clock</b>
End Time:	16:33 <b>24 hrs. clock</b>
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-

## 10.000 HRS POST DOSE PK SAMPLE COLLECTION Period: 1

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Subject No: 1026 Subject Initials: KSM



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: 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 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: 1

Date of meal distribution:	26-Nov-2017
Start Time:	20:27 <b>24 hrs. clock</b>
End Time:	20:45 <b>24 hrs. clock</b>
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-

## 12.00 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:	19:45 <b>24 hrs. clock</b>
Systolic Blood Pressure:	108 <b>mmHg</b>
Diastolic Blood Pressure:	68 <b>mmHg</b>
Radial Pulse:	72 <b>beats/min</b>
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-

## 16.000 HRS POST DOSE PK SAMPLE COLLECTION 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 00:24
Actual Time of sample collection:	00:24 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK17864286
Remarks if any other reason:	

## 24.000 HRS POST DOSE PK SAMPLE COLLECTION Period: 1

Date and Time of Dosing:	26-Nov-2017 08:24
Date of sample collection:	27-Nov-2017

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# CASE REPORT FORM

Project No: 0326-17

Subject No: 1026 Subject Initials: KSM



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: 1

Date:	27-Nov-2017
Start Time:	20:05 24 hrs. clock
Breath Alcohol Level (BAL):	.000 %
Result:	<input type="radio"/> Positive <input checked="" type="radio"/> Negative
Start Time of 1st Repeat:	24 hrs. clock
Breath Alcohol Level (BAL):	%
1st Repeat result:	<input type="radio"/> Positive <input type="radio"/> Negative
Start Time of 2nd Repeat:	24 hrs. clock
Breath Alcohol Level (BAL):	%
2nd Repeat Result:	<input type="radio"/> Positive <input type="radio"/> Negative
Final Result:	<input type="radio"/> Positive <input checked="" type="radio"/> Negative
For Positive results (if any) Informed to Principal Investigator/Co-Investigator/designate:	<input type="radio"/> Yes <input type="radio"/> No <input checked="" type="radio"/> 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 24 hrs. clock
Remarks:	
PK Sample ID:	PK17864430
Remarks if any other reason:	

## 36.000 HRS COMPLIANCE AND WELL BEING AT THE TIME OF AMBULATORY SAMPLE (DAY 2) 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?:	<input type="radio"/> Yes <input checked="" type="radio"/> No
Have you donated blood anywhere else or participated in other clinical trial since last visit?:	<input type="radio"/> Yes <input checked="" type="radio"/> No
If Yes, Remarks:	-

### Well Being at the Time of Ambulatory

Date of well being:	27-Nov-2017
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Project No: 0326-17

Subject No: 1026 Subject Initials: KSM



Start Time of well being:	20:36 <b>24 hrs. clock</b>
Well-Being at the time of ambulatory sample:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
Remarks if Unwell:	-
Remark if any:	-

## BREATH TEST FOR ALCOHOL CONSUMPTION (48.000 HRS AMBULATORY VISIT) Period: 1

Date:	28-Nov-2017
Start Time:	09:57 <b>24 hrs. clock</b>
Breath Alcohol Level (BAL):	.000 %
Result:	<input type="radio"/> Positive <input checked="" type="radio"/> Negative
Start Time of 1st Repeat:	<b>24 hrs. clock</b>
Breath Alcohol Level (BAL):	%
1st Repeat result:	<input type="radio"/> Positive <input type="radio"/> Negative
Start Time of 2nd Repeat:	<b>24 hrs. clock</b>
Breath Alcohol Level (BAL):	%
2nd Repeat Result:	<input type="radio"/> Positive <input type="radio"/> Negative
Final Result:	<input type="radio"/> Positive <input checked="" type="radio"/> Negative
For Positive results (if any) Informed to Principal Investigator/Co-Investigator/designate:	<input type="radio"/> Yes <input type="radio"/> No <input checked="" type="radio"/> 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 AMBULATORY SAMPLE (DAY 3) Period: 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 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?:	<input type="radio"/> Yes <input checked="" type="radio"/> No
Have you donated blood anywhere else or participated in other clinical trial since last visit?:	<input type="radio"/> Yes <input checked="" type="radio"/> No
If Yes, Remarks:	-

### Well Being at the Time of Ambulatory

Date of well being:	28-Nov-2017
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Project No: 0326-17

Subject No: 1026 Subject Initials: KSM

Start Time of well being:	10:02 24 hrs. clock
Well-Being at the time of ambulatory sample:	<input checked="" type="radio"/> Well <input type="radio"/> 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 24 hrs. clock	
Complaint of any illness:	<input checked="" type="radio"/> No <input type="radio"/> Yes	
If YES, provide details:	-	
General Physical examination:	<input checked="" type="radio"/> Normal <input type="radio"/> 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:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal	
Respiratory System Examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal	
Central Nervous System Examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal	
Per Abdomen Examination:	<input checked="" type="radio"/> Normal <input type="radio"/> 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:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal	
Subject well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell	
Comments:	-	
Subject is fit for Check-out:	<input checked="" type="radio"/> Yes <input type="radio"/> 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:	<input type="radio"/> Medical Event <input type="radio"/> Adverse Event <input type="radio"/> Discontinuation <input type="radio"/> Safety Assessment <input checked="" type="radio"/> Subject Not reported for scheduled visit <input type="radio"/> others	
If Others, Specify:	-	

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# CASE REPORT FORM

Project No: 0326-17

Subject No: 1026 Subject Initials: KSM



Date:	01-Dec-2017
Mode of communication:	Telephone
Detail of Discussion:	Subject was contacted telephonically and informed to report on the check in day of period II.
Remark if any:	-

## CHECK-IN DETAILS( Period - 2)

BREATH TEST FOR ALCOHOL CONSUMPTION		Period: 2
Date:	01-Dec-2017	
Start Time:	16:39 24 hrs. clock	
Breath Alcohol Level (BAL):	.000 %	
Result:	<input type="radio"/> Positive <input checked="" type="radio"/> Negative	
Start Time of 1st Repeat:	24 hrs. clock	
Breath Alcohol Level (BAL):	%	
1st Repeat result:	<input type="radio"/> Positive <input type="radio"/> Negative	
Start Time of 2nd Repeat:	24 hrs. clock	
Breath Alcohol Level (BAL):	%	
2nd Repeat Result:	<input type="radio"/> Positive <input type="radio"/> Negative	
Final Result:	<input type="radio"/> Positive <input checked="" type="radio"/> Negative	
For Positive results (if any) Informed to Principal Investigator/Co-Investigator/designate:	<input type="radio"/> Yes <input type="radio"/> No <input checked="" type="radio"/> 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:	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NAP	
1. URINE SCAN FOR DRUGS ABUSE		
1.1 Urine drug scan tested for:	<input checked="" type="checkbox"/> Amphetamine (AMP) <input checked="" type="checkbox"/> Barbiturates (BAR) <input checked="" type="checkbox"/> Benzodiazepines (BZD) <input checked="" type="checkbox"/> Cocaine (COC) <input checked="" type="checkbox"/> Morphine (MOR) <input checked="" type="checkbox"/> Cannabinoids (THC)	
1.2 Start time:	16:45 24 hrs. clock	
1.3 Observation of Results:	<input type="radio"/> Positive with one band (Control) <input checked="" type="radio"/> Negative with two band (Control and test) <input type="radio"/> Invalid with No band <input type="radio"/> Invalid with one band (Test)	
1.4 Positive for:	<input type="checkbox"/> Amphetamine (AMP) <input type="checkbox"/> Barbiturates (BAR) <input type="checkbox"/> Benzodiazepines (BZD) <input type="checkbox"/> Cocaine (COC) <input type="checkbox"/> Morphine (MOR) <input type="checkbox"/> Cannabinoids (THC)	

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2. URINE SCAN FOR DRUGS ABUSE (1st REPEAT)		
2.1 Urine drug scan tested for:	<input type="checkbox"/> Amphetamine (AMP) <input type="checkbox"/> Barbiturates (BAR) <input type="checkbox"/> Benzodiazepines (BZD) <input type="checkbox"/> Cocaine (COC) <input type="checkbox"/> Morphine (MOR) <input type="checkbox"/> Cannabinoids (THC)	
2.2 Start time:	24 hrs. clock	
2.3 Observation of Results:	<input type="radio"/> Positive with one band (Control) <input type="radio"/> Negative with two band (Control and test) <input type="radio"/> Invalid with No band <input type="radio"/> Invalid with one band (Test)	
2.4 Positive for:	<input type="checkbox"/> Amphetamine (AMP) <input type="checkbox"/> Barbiturates (BAR) <input type="checkbox"/> Benzodiazepines (BZD) <input type="checkbox"/> Cocaine (COC) <input type="checkbox"/> Morphine (MOR) <input type="checkbox"/> Cannabinoids (THC)	
3. URINE SCAN FOR DRUGS ABUSE (2nd REPEAT)		
3.1 Urine drug scan tested for:	<input type="checkbox"/> Amphetamine (AMP) <input type="checkbox"/> Barbiturates (BAR) <input type="checkbox"/> Benzodiazepines (BZD) <input type="checkbox"/> Cocaine (COC) <input type="checkbox"/> Morphine (MOR) <input type="checkbox"/> Cannabinoids (THC)	
3.2 Start time:	24 hrs. clock	
3.3 Observation of Results:	<input type="radio"/> Positive with one band (Control) <input type="radio"/> Negative with two band (Control and test) <input type="radio"/> Invalid with No band <input type="radio"/> Invalid with one band (Test)	
3.4 Positive for:	<input type="checkbox"/> Amphetamine (AMP) <input type="checkbox"/> Barbiturates (BAR) <input type="checkbox"/> Benzodiazepines (BZD) <input type="checkbox"/> Cocaine (COC) <input type="checkbox"/> Morphine (MOR) <input type="checkbox"/> Cannabinoids (THC)	
Final Result:	<input type="radio"/> Positive <input checked="" type="radio"/> Negative	
Positive for:	<input type="checkbox"/> Amphetamine (AMP) <input type="checkbox"/> Barbiturates (BAR) <input type="checkbox"/> Benzodiazepines (BZD) <input type="checkbox"/> Cocaine (COC) <input type="checkbox"/> Morphine (MOR) <input type="checkbox"/> Cannabinoids (THC)	
Remarks (for repeats or any other information):	-	
Date:		
Refer/Read leaflet before start activity:	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NAP	

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

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6.5 Positive for:	<input type="checkbox"/> Phencyclidine(PCP) <input type="checkbox"/> Cotinine(COT) <input type="checkbox"/> Methadone(MTD) <input type="checkbox"/> Other
6.6 If other then specify:	
Final Result:	<input checked="" type="radio"/> Positive <input type="radio"/> Negative
Positive for:	<input type="checkbox"/> Phencyclidine(PCP) <input type="checkbox"/> Cotinine(COT) <input type="checkbox"/> Methadone(MTD) <input type="checkbox"/> 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:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Breath test for alcohol consumption tested negative:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Date of last menstruation period (For Female subject):	21-NOV-2017
Result of serum pregnancy test:	<input type="radio"/> Positive <input checked="" type="radio"/> Negative <input type="radio"/> NAP (For Male subject)

### Prohibitions

Are you suffering from any illness since the last visit (Including allergic reaction, itching, rash on your skin)?:	<input type="radio"/> Yes <input checked="" type="radio"/> No
Have you consumed any xanthine containing food or beverages (like tea, coffee, chocolates or cola drinks) for 24 hours prior to check-in?:	<input type="radio"/> Yes <input checked="" type="radio"/> No
Have you consumed tobacco, tobacco containing products (Gutkha, Pan/Pan masala or any other) for 24 hours prior to check-in?:	<input type="radio"/> Yes <input checked="" type="radio"/> No
Have you consumed recreational products, alcohol or alcoholic products since last PK sample collection of Period I?:	<input type="radio"/> Yes <input checked="" type="radio"/> No
Have you consumed grapefruit or grapefruit products since last PK sample collection of Period I?:	<input type="radio"/> Yes <input checked="" type="radio"/> No
Have you smoked since last PK sample collection of Period I?:	<input type="radio"/> Yes <input checked="" type="radio"/> 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 since last PK sample collection of Period I?:	<input type="radio"/> Yes <input checked="" type="radio"/> No
Have you consumed an unusual diet, for whatever reason (e.g. low-sodium) since last PK sample collection of Period I?:	<input type="radio"/> Yes <input checked="" type="radio"/> No
Have you donated blood anywhere else or participated in other clinical trial since last PK sample collection of Period I?:	<input type="radio"/> Yes <input checked="" type="radio"/> No
Is subject compliant to all above restrictions/requirement?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Remark If any:	-

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## LABORATORY ASSESSMENT-PRIOR TO CHECK IN OF (PERIOD II) Period: 2

Note: For Estimation of CrCl (Creatinine Clearance).

Has the blood sample been collected as per protocol?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Date of blood sample collection:	01-Dec-2017
Lab report clinically acceptable:	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NAP
Comments (if any):	-

## CHECK-IN B&B Period: 2

Baggage and Body Search done:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Date of Check In:	01-Dec-2017
Time of Check-in:	18:06 <b>24 hrs. clock</b>
Remarks:	-

## CLINICAL EXAMINATION - CHECK IN Period: 2

Date of clinical examination:	01-Dec-2017
Start Time of Clinical Examination:	18:37 <b>24 hrs. clock</b>
Complaints of any illness:	<input checked="" type="radio"/> No <input type="radio"/> Yes
If YES, provide details:	-
General Physical examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Oral Body Temperature:	98.2 <b>°F</b>
Blood Pressure (Systolic):	116 <b>mmHg</b>
Blood Pressure (Diastolic):	82 <b>mmHg</b>
Radial Pulse Rate:	72 <b>beats/min</b>
Cardiovascular System Examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Respiratory System Examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Central Nervous System Examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Per Abdomen Examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Any other Significant finding:	-
Any investigations recommended:	-
Vein puncture site:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Subject well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If 'Abnormal' in any of the above-mentioned sections, please enter details.:	-
Remark if Any:	-
Subject is fit:	<input checked="" type="radio"/> Yes <input type="radio"/> 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?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-

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# CASE REPORT FORM

Project No: 0326-17

Subject No: 1026 Subject Initials: KSM



Remarks:	-
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## 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 <b>24 hrs. clock</b>
Systolic Blood Pressure:	116 <b>mmHg</b>
Diastolic Blood Pressure:	78 <b>mmHg</b>
Radial Pulse:	76 <b>beats/min</b>
Oral Body Temperature:	97.8 <b>°F</b>
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> 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 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK17879834
Remarks if any other reason:	

### IMP ADMINISTRATION Period: 2

DATE:	02-Dec-2017
IS SUBJECT COMPLIANT TO ALL PREDOSE REQUIREMENTS AS PER PROTOCOL?:	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NA
TIME:	08:24 <b>24 hrs. clock</b>
MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA:	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NA
ML OF WATER ADMINISTERED WITH IP:	240
LABEL:	0000251825
PRODUCT CODE/ TYPE:	Test
DOSING DONE BY:	ankitkpatel (Dosing)
DOSING SUPERVISION DONE BY:	kanarampatel (Dosing)
REMARKS:	

### STUDY DRUG ADMINISTRATION-COMPLIANCE Period: 2

Has the subject compliant to 02 hour post dose water restriction?:	<input checked="" type="radio"/> Yes <input type="radio"/> 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):	<input type="radio"/> Yes <input checked="" type="radio"/> No
Has the subject compliant to 04 hours post dose fasting condition?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Remark If any:	refer AER from biznet.

### 0.250 HRS POST DOSE PK SAMPLE COLLECTION Period: 2

Date and Time of Dosing:	02-Dec-2017 08:24
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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 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK17879870
Remarks if any other reason:	

## 0.500 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 08:54
Actual Time of sample collection:	08:54 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK17879906
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

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 09:24
Actual Time of sample collection:	09:24 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK17879978
Remarks if any other reason:	

## 1.00 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:	09:15 <b>24 hrs. clock</b>
Systolic Blood Pressure:	116 <b>mmHg</b>
Diastolic Blood Pressure:	72 <b>mmHg</b>
Radial Pulse:	68 <b>beats/min</b>
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-

## 1.333 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

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[Authenticated On:29-Dec-2017 17:15 IST (+5:30 GMT)]



Lambda Therapeutic Research.

Sponsor Name:Cipla Limited

**CASE REPORT FORM**

Project No: 0326-17

Subject No: 1026 Subject Initials: KSM



Scheduled date and Time of sample collection (for post dose only):	02-Dec-2017 09:44
Actual Time of sample collection:	09:44 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK17880014
Remarks if any other reason:	

**1.667 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 10:04
Actual Time of sample collection:	10:04 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK17880050
Remarks if any other reason:	

**2.000 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 10:24
Actual Time of sample collection:	10:24 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK17880086
Remarks if any other reason:	

**2.333 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 10:44
Actual Time of sample collection:	10:44 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK17880122
Remarks if any other reason:	

**2.667 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 11:04
Actual Time of sample collection:	11:04 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK17880158
Remarks if any other reason:	

**3.000 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 11:24
Actual Time of sample collection:	11:24 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK17880194

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Sponsor Name:Cipla Limited

# CASE REPORT FORM

Project No: 0326-17

Subject No: 1026 Subject Initials: KSM



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 <b>24 hrs. clock</b>
Systolic Blood Pressure:	112 <b>mmHg</b>
Diastolic Blood Pressure:	74 <b>mmHg</b>
Radial Pulse:	68 <b>beats/min</b>
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> 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 <b>24 hrs. clock</b>
Has subject consumed meal completely?:	<input type="radio"/> Yes <input checked="" type="radio"/> No
Details of meal left (Approximate Quantity):	03 Nos Roti. 1/2 Qty Of Daal. 1/2 Qty Of Cabbage Vegetable. 1/2 Qty Of Rice. 1/2 Qty Of 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 <b>24 hrs. clock</b>
Systolic Blood Pressure:	114 <b>mmHg</b>
Diastolic Blood Pressure:	74 <b>mmHg</b>
Radial Pulse:	72 <b>beats/min</b>
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-

## SNACKS (DAY 1) Period: 2

Date of meal distribution:	02-Dec-2017
Start Time:	16:24 <b>24 hrs. clock</b>
End Time:	16:31 <b>24 hrs. clock</b>
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-

## DINNER (DAY 1) Period: 2

Date of meal distribution:	02-Dec-2017
Start Time:	20:21 <b>24 hrs. clock</b>
End Time:	20:33 <b>24 hrs. clock</b>
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No

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Sponsor Name:Cipla Limited

### CASE REPORT FORM

Project No: 0326-17

Subject No: 1026 Subject Initials: KSM



Details of meal left (Approximate Quantity):	-
Remarks:	-

#### 12.00 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:	19:45 <b>24 hrs. clock</b>
Systolic Blood Pressure:	116 <b>mmHg</b>
Diastolic Blood Pressure:	76 <b>mmHg</b>
Radial Pulse:	80 <b>beats/min</b>
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-

#### CHECK-OUT DETAILS( 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:	<input checked="" type="radio"/> No <input type="radio"/> Yes
If YES, provide details:	-
General Physical examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Oral Body Temperature:	98.2 <b>°F</b>
Radial Pulse Rate:	64 <b>beats/min</b>
Blood Pressure(Systolic):	112 <b>mmHg</b>
Blood Pressure(Diastolic):	72 <b>mmHg</b>
Cardiovascular System Examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Respiratory System Examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Central Nervous System Examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Per Abdomen Examination:	<input checked="" type="radio"/> Normal <input type="radio"/> 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:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Subject well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
Comments:	-
Subject is fit for Check-out:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Remark If any:	-

#### CHECK-OUT B&B Period: 2

Date of check out:	03-Dec-2017
Time of Check-out:	08:52 <b>24 hrs. clock</b>
Remarks:	-

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# CASE REPORT FORM

Project No: 0326-17

Subject No: 1026 Subject Initials: KSM



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:	<input checked="" type="radio"/> No <input type="radio"/> Yes	
If YES, provide details:	-	
General Physical examination:	<input checked="" type="radio"/> Normal <input type="radio"/> 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:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal	
Respiratory System Examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal	
Central Nervous System Examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal	
Per Abdomen Examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal	
Any other Significant finding:	-	
Any investigations recommended:	-	
Vein puncture site:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal	
Subject well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell	
If 'Abnormal' in any of the above-mentioned sections, please enter the details:	-	
Subject is fit:	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Remark If any:	-	
ECG EXAMINATION-END OF STUDY		Period: 2
<b>ECG EXAMINATION</b>		
Date Of ECG:	11-Dec-2017	
Time of ECG:	11:10 <b>24 hrs. clock</b>	
Was ECG Repeated:	<input type="radio"/> Yes <input checked="" type="radio"/> No	
If Yes, Date of Repeat ECG:		
ECG Impression:	WNL	
Overall Assessment:	<input checked="" type="radio"/> Normal <input type="radio"/> Not Clinically Significant <input type="radio"/> Clinically Significant	
Remark, If any:	-	
END STUDY LABORATORY ASSESSMENT AND STUDY COMPLETION STATUS		Period: 2
Note: For Estimation of Hematology, Biochemistry (except random glucose and sodium, potassium, chloride).		
Post study safety sample collected as per protocol?:	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Date of safety sample collection:	05-Dec-2017	
Lab report clinically acceptable:	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NAP	
Result of serum pregnancy test:	<input type="radio"/> Positive <input checked="" type="radio"/> Negative <input type="radio"/> NAP (For Male subject)	
Remarks If Any:	-	

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### CASE REPORT FORM

Project No: 0326-17

Subject No: 1026 Subject Initials: KSM



STUDY COMPLETION STATUS	
Has the subject completed the study?:	<input type="radio"/> Yes <input checked="" type="radio"/> No
If "No", please refer:	<input type="radio"/> Pre dose discontinued form <input checked="" type="radio"/> Post dose discontinued form
If "Yes", then any protocol or sampling deviation reported for subject?:	<input type="radio"/> Yes <input type="radio"/> No
If "Yes", then select appropriate option:	<input type="checkbox"/> Protocol deviation <input type="checkbox"/> Sampling Deviation
Remarks:	-

### ADVERSE EVENT/ MEDICAL EVENT RECORDING Period: 2

Is it Adverse Event or Medical Event?:	<input checked="" type="radio"/> Adverse Event <input type="radio"/> 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 <b>24 hrs. clock</b>
Date of reporting or Observed on:	02-Dec-2017
Time of Reporting or observed at:	11:45 <b>24 hrs. clock</b>
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 approximately 1144 hrs, 02-Dec-2017. Vomiting lasted for 01 minute. Vomitus was approximately 100 ml in amount and contained fluid with food particles. He has no any other complaint at present.
Adverse Event Term (If required by protocol):	Vomiting
1.2 Nature of Onset:	<input checked="" type="radio"/> Sudden <input type="radio"/> Gradual <input type="radio"/> Unknown
1.3 Occurrence:	<input type="radio"/> Continuous <input type="radio"/> Intermittent <input checked="" type="radio"/> Single Episode
1.4 Severity:	<input checked="" type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe

#### 2.0 Clinical Examination

2.1 Temperature:	98.0 <b>°F</b>
2.2 Systolic Blood Pressure:	120 <b>mmHg</b>
2.3 Diastolic Blood Pressure:	82 <b>mmHg</b>
2.4 Pulse Rate:	68 <b>beats/min</b>
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

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Sponsor Name:Cipla Limited

# CASE REPORT FORM

Project No: 0326-17

Subject No: 1026 Subject Initials: KSM



Remarks:	-
Checked By:	Dr Anshul Attrey
<b>3.0 Follow up details including examination:</b>	
3.1 Physician's notes:	As per PI's advice subject is discontinued from 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 about 200ml food mixed watery content at 1515 hrs on 02-Dec-17. Vomiting was lasted for 1 minute. 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 dissolved in 1 liter of water and 250ml given at 1527 hrs. rest reassurance continue follow-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. On 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 episode of vomiting .She has no any complaint at present. On examination- Temp.- 98.0°F Pulse-76/min BP- 110/74 mmHg S/E- NAD Hence this AE of Vomiting is considered to be resolved 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

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# CASE REPORT FORM



Project No: 0326-17

Subject No: 1026 Subject Initials: KSM

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:	<input type="radio"/> Yes <input checked="" type="radio"/> 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:	<input type="radio"/> Yes <input checked="" type="radio"/> No
Remark, if any:	-

## ADVERSE EVENT UPDATE FORM Period: 2

Adverse event Term:	Vomiting		
Adverse event Code:	lIt_name=Vomiting## pt_name=Vomiting## vMeddraVersion=MedDRA201		
AE number:	01		
Time of last IMP administration:	08:24 24 hrs. clock		
Date of last IMP administration:	02-Dec-2017		
Time of AE onset:	11:44 24 hrs. clock		
Date of AE onset:	02-DEC-2017		
Time of AE Resolution:	15:27 24 hrs. clock		
Date of AE Resolution:	02-DEC-2017		
Severity:	<input checked="" type="radio"/> MILD <input type="radio"/> MODERATE <input type="radio"/> SEVERE		
Toxicity grade:	<input checked="" type="radio"/> GRADE 1:MILD AE <input type="radio"/> GRADE 2:MODERATE AE <input type="radio"/> GRADE 3:SEVERE AE <input type="radio"/> GRADE 4:LIFE-THREATENING OR DISABLING AE <input type="radio"/> GRADE 5:DEATH RELATED TO AE <input type="radio"/> NOT APPLICABLE		
Serious?:	<input type="radio"/> YES <input checked="" type="radio"/> NO		

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# CASE REPORT FORM

Project No: 0326-17

Subject No: 1026 Subject Initials: KSM



Is it significant?:	<input type="radio"/> YES <input checked="" type="radio"/> NO
If Serious, Seriousness criteria:	<input type="checkbox"/> CONGENITAL ANOMALY OR BIRTH DEFECT <input type="checkbox"/> SIGNIFICANT DISABILITY <input type="checkbox"/> DEATH <input type="checkbox"/> HOSPITALIZATION <input type="checkbox"/> LIFE THREATENING <input type="checkbox"/> OTHER MEDICALLY IMPORTANT EVENT
Unexpected adverse drug reaction?:	<input type="radio"/> YES <input checked="" type="radio"/> NO <input type="radio"/> NAP
Relationship to Study Treatment:	<input type="radio"/> NOT RELATED <input type="radio"/> UNLIKELY RELATED <input checked="" type="radio"/> POSSIBLY RELATED <input type="radio"/> RELATED <input type="radio"/> NAP
Action Taken with Study Treatment:	<input type="radio"/> DOSE INCREASED <input type="radio"/> DOSE NOT CHANGED <input type="radio"/> DOSE REDUCED <input type="radio"/> DRUG INTERRUPTED <input checked="" type="radio"/> DRUG WITHDRAWN <input type="radio"/> NOT APPLICABLE <input type="radio"/> UNKNOWN
Outcome:	<input type="radio"/> NOT RECOVERED/NOT RESOLVED <input checked="" type="radio"/> RECOVERED/RESOLVED <input type="radio"/> RECOVERED/RESOLVED WITH SEQUELAE <input type="radio"/> RECOVERING/RESOLVING <input type="radio"/> UNKNOWN <input type="radio"/> FATAL
Caused study discontinuation:	<input checked="" type="radio"/> YES <input type="radio"/> NO
Concomitant treatment/Therapy given:	<input checked="" type="radio"/> YES <input type="radio"/> NO
Does given concomitant medication has drug-drug interaction along with study drug?:	<input type="radio"/> YES <input checked="" type="radio"/> NO <input type="radio"/> NAP
If Yes, then Specify:	-
Remarks if, any:	-

## POST-DOSE SUBJECT DISCONTINUATION 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. clock</b>
Date of last IMP administered:	02-Dec-2017

### Reason for discontinuation

Reasons:	<input type="radio"/> On his/her own accord <input checked="" type="radio"/> On the grounds of Emesis <input type="radio"/> On medical grounds <input type="radio"/> For having withheld critical Information <input type="radio"/> On grounds of protocol non-compliance <input type="radio"/> Any other (please specify)
If any other:	-
Description of Event:	Subject had single episode of vomiting at approximately 1144 hrs, 02-Dec-2017. Vomiting lasted for 01 minute. Vomitus was approximately 100 ml in amount and contained fluid with food particles. He had no any other complaint.

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**CASE REPORT FORM**

Project No: 0326-17

Subject No: 1026 Subject Initials: KSM



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



Clinical Laboratory Test Report

<b>Screening</b>	AH17-06704	<b>Lab ID:</b>	17063193	<b>Sample Collected</b>	05-Dec-2017 11:33
<b>Subject Initial:</b>	KSM	<b>Sex :</b>	Female	<b>Sample Collected At:</b>	Ahmedabad
<b>Subject</b>	1026	<b>Visit :</b>	PS	<b>Sample Received On:</b>	05-Dec-2017 11:47
<b>Date Of Birth:</b>	01-Jan-1980			<b>Report Date:</b>	05-Dec-2017 20:50
<b>Referred By:</b>	Dr. Manish Patel			<b>Study /Project</b>	0326-17

CHEMISTRY

[Performed By Reflectance Photometry]

<u>PARAMETER</u>	<u>RESULT</u>	<u>CS/NCS*</u>	<u>REMARK</u>	<u>UNIT</u>	<u>REFERENCE INTERVAL</u>
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
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
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)					
UREA	17.8			mg/dL	15.0 - 36.0
Urease quinolinium dye					
CREATININE CLEARANCE	<b>163.06</b>	NCS		<b>H</b> mL/min	80 - 125
Calculated by Cockcroft Gault method					

**Final Remark :-** clinically acceptable

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

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

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Report Printed On: 16-Feb-2018 11:40

Authenticated By: Dhaval J Patel

05-Dec-2017 20:50



No. 7183121

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No. M-0232



Clinical Laboratory Test Report

<b>Screening</b>	AH17-06704	<b>Lab ID:</b>	17063193	<b>Sample Collected</b>	05-Dec-2017 11:33
<b>Subject Initial:</b>	KSM	<b>Sex :</b>	Female	<b>Sample Collected At:</b>	Ahmedabad
<b>Subject</b>	1026	<b>Visit :</b>	PS	<b>Sample Received On:</b>	05-Dec-2017 11:47
<b>Date Of Birth:</b>	01-Jan-1980			<b>Report Date:</b>	05-Dec-2017 20:50
<b>Referred By:</b>	Dr. Manish Patel			<b>Study /Project</b>	0326-17

HEMATOLOGY

[Performed By Flowcytometry and Electrical Impedence Method]

PARAMETER	RESULT	CS/NCS*	REMARK	UNIT	REFERENCE INTERVAL
HAEMOGLOBIN	12.3			g/dL	10.0 - 14.4
SLS-Haemoglobin method					
RBC COUNT	4.44			X 10 <sup>6</sup> /μL	3.8 - 4.8
Hydro Dynamic focussing method					
HCT	36.8			%	36.0 - 46.0
RBC pulse-height detection method					
MCV	82.9	NCS		L fL	83.0 - 101.0
Calculated					
MCH	27.7			Pg	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 <sup>3</sup> /μL	150 - 410
Hydro dynamic focussing method					
WBC (TOTAL)	7.57			X 10 <sup>3</sup> /μL	4.0 - 10.0
Flowcytometry method					
NEUTROPHIL %	66.0			%	40 - 80
Flowcytometry method					
LYMPHOCYTES %	25.9			%	20 - 40
Flowcytometry method					

**Final Remark :-** clinically acceptable

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

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

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Authenticated By:Amit K. Barot

05-Dec-2017 12:15



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No. M-0232



# Clinical Laboratory Test Report

Lambda Therapeutic Research Limited

<b>Screening</b>	AH17-06704	<b>Lab ID:</b>	17063193	<b>Sample Collected</b>	05-Dec-2017 11:33
<b>Subject Initial:</b>	KSM	<b>Sex :</b>	Female	<b>Sample Collected At:</b>	Ahmedabad
<b>Subject</b>	1026	<b>Visit :</b>	PS	<b>Sample Received On:</b>	05-Dec-2017 11:47
<b>Date Of Birth:</b>	01-Jan-1980			<b>Report Date:</b>	05-Dec-2017 20:50
<b>Referred By:</b>	Dr. Manish Patel			<b>Study /Project</b>	0326-17

EOSINOPHILS %	1.6	%	1 - 6
Flowcytometry method			
MONOCYTES %	6.2	%	2 - 10
Flowcytometry method			
BASOPHILS %	0.3	%	0 - 2
Flowcytometry method			
NEUTROPHILS (ABS)	5.00	X 10 <sup>3</sup> /μL	2.0 - 7.0
Calculated			
EOSINOPHILS (ABS)	0.12	X 10 <sup>3</sup> /μL	0.02 - 0.5
Calculated			

**Final Remark :-** clinically acceptable

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

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

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Report Printed On: 16-Feb-2018 11:40

Authenticated By:Amit K. Barot

05-Dec-2017 12:15



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No. M-0232



Clinical Laboratory Test Report

Screening	AH17-06704	Lab ID:	17063193	Sample Collected	05-Dec-2017 11:33
Subject Initial:	KSM	Sex :	Female	Sample Collected At:	Ahmedabad
Subject	1026	Visit :	PS	Sample Received On:	05-Dec-2017 11:47
Date Of Birth:	01-Jan-1980			Report Date:	05-Dec-2017 20:50
Referred By:	Dr. Manish Patel			Study /Project	0326-17

IMMUNOLOGY

PARAMETER	RESULT	CS/NCS*	REMARK	UNIT	REFERENCE INTERVAL
BETA hCG	<2.39		wnl	mIU/mL	- Pre menopausal females: <4.83
Chemiluminescence					

Final Remark :- clinically acceptable

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

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

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Report Printed On: 16-Feb-2018 11:40

Authenticated By:Dipal D Shah

05-Dec-2017 16:58



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No. M-0232

## Lambda Therapeutic Research



### Clinical Laboratory Test Report



Lambda Therapeutic Research

Screening	AH17-06704	Lab ID:	17063193	Sample Collected	05-Dec-2017 11:33
Subject Initial:	KSM	Sex :	Female	Sample Collected At:	Ahmedabad
Subject	1026	Visit :	PS	Sample Received On:	05-Dec-2017 11:47
Date Of Birth:	01-Jan-1980			Report Date:	05-Dec-2017 20:50
Referred By:	Dr. Manish Patel			Study /Project	0326-17

### Out of Summary Report

PARAMETER	RESULT		UNIT	REFERENCE INTERVAL	COMMENTS
CREATININE CLEARANCE	163.06	H	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

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Authenticated By:Amit K. Barot

05-Dec-2017 12:15



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No. M-0232