Lambda Therapeutic Research.

Sponsor Name:Cipla Limited

MEDICAL SCREENING RECORD FORM

Project No: 0326-17

Subject No: 1026 Subject Initials: KSM

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:	○ YES ◉ NO ○ NAP
Remarks:	

DEMOGRAPHIC DETAILS	
Default	
Consent for Screening Signed:	◉ YES ○ NO
Date of Initiation of Screening:	17-Nov-2017
Sex:	○ MALE ◉ FEMALE
Date Of Birth:	01-Jan-1980
Age In Years (Completed years on the day of screening):	37
Ethnicity:	○ HISPANIC ◉ NON-HISPANIC
Race:	ASIAN
Marital Status:	○ SINGLE ◉ MARRIED ○ WIDOW ○ DIVORCEE
Food Habits:	○ VEGETARIAN ◉ NON-VEGETARIAN ○ EGGETARIAN

PERSONAL HISTORY-SCREENING	
Default	
Has the subject donated blood?:	○ YES ◉ NO
Last date of blood donation:	-
Date of last sample study participated in:	-

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

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

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

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

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

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

Lambda Therapeutic Research Ltd.

Clinical Laboratory Test Report

17060104

LAMBDA
Lambda Therapeutic Research Limited

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**	

CHEMISTRY

[Performed By Reflectance Photometry]

PARAMETER	RESULT	CS/NCS*	REMARK	UNIT	REFERENCE INTERVAL
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 - Study 18-Nov-2017 12:47

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

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CAP ACCREDITED
No. 7183121

M-0232
No. M-0232

Lambda Therapeutic Research Ltd.

Clinical Laboratory Test Report

17060104

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**	

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	**165.78**	NCS	**H**	mL/min	80 - 125
Calculated by Cockcroft Gault method					

Final Remark :- CLINICALLY ACCEPTABLE

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

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Lambda Therapeutic Research Ltd.

Clinical Laboratory Test Report

17060104

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**	

HEMATOLOGY

[Performed By Flowcytometry and Electrical Impedence Method]

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

Final Remark :- CLINICALLY ACCEPTABLE

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

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

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**	

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 10^3/µL	2.0 - 7.0
Calculated			
EOSINOPHILS (ABS)	0.11	X 10^3/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 - Study 18-Nov-2017 12:47

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Lambda Therapeutic Research Ltd.

Clinical Laboratory Test Report

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**	

IMMUNOLOGY

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

Final Remark :- CLINICALLY ACCEPTABLE

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

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No. 7183121

No. M-0232

Lambda Therapeutic Research Ltd.

Clinical Laboratory Test Report

17060104

LAMBDA
Lambda Therapeutic Research Limited

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**	

URINE ANALYSIS

[Performed By Reflectance Photometry]

PARAMETER	RESULT	CS/NCS*	REMARK	UNIT	REFERENCE INTERVAL
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 - Study 18-Nov-2017 12:47

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Lambda Therapeutic Research

Clinical Laboratory Test Report

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 - Study 18-Nov-2017 12:47

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No. 7183121

No. M-0232

Lambda Therapeutic Research Ltd.

17061746

Clinical Laboratory Test Report

LAMBDA
Lambda Therapeutic Research Limited

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

CHEMISTRY

[Performed By Reflectance Photometry]

PARAMETER	RESULT	CS/NCS*	REMARK	UNIT	REFERENCE INTERVAL
CREATININE	0.62			mg/dL	0.5 - 0.9
Enzymatic (Creatine amidohydrolase, IDMS traceable)					
CREATININE CLEARANCE	**160.43**	NCS	**H**	mL/min	80 - 125
Calculated by Cockcroft Gault method					

Final Remark :- clinically acceptable

Reviewed by:- Dr. Sanjaykumar S. Patel - Stud 25-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

Lambda Therapeutic Research Ltd.

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 - Stud 25-Nov-2017 16:24

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No. 7183121

No. M-0232

Lambda Therapeutic Research

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

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 - Stud 25-Nov-2017 16:24

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

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No. 7183121

No. M-0232

Lambda Therapeutic Research Ltd.

17062552

Clinical Laboratory Test Report

LAMBDA
Lambda Therapeutic Research Limited

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

CHEMISTRY

[Performed By Reflectance Photometry]

PARAMETER	RESULT	CS/NCS*	REMARK	UNIT	REFERENCE INTERVAL
CREATININE	0.69			mg/dL	0.5 - 0.9
Enzymatic (Creatine amidohydrolase, IDMS traceable)					
CREATININE CLEARANCE	**144.15**	NCS	**H**	mL/min	80 - 125
Calculated by Cockcroft Gault method					

Final Remark :- CLINICALLY ACCEPTABLE

Reviewed by:- Dr. Sanjaykumar S. Patel - Stud 01-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

Lambda Therapeutic Research Ltd.

17062552

Clinical Laboratory Test Report

LAMBDA
Lambda Therapeutic Research Limited

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 - Stud 01-Dec-2017 17:14

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

This is an Electronically authenticated report

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

Lambda Therapeutic Research

17062552

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

Out of Summary Report

PARAMETER	RESULT		UNIT	REFERENCE INTERVAL	COMMENTS
CREATININE CLEARANCE	**144.15**	**H**	mL/min	80 - 125	_____

Final Remark :- CLINICALLY ACCEPTABLE

Reviewed by:- Dr. Sanjaykumar S. Patel - Stud 01-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

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 **24 hrs. clock**
Breath Alcohol Level (BAL):	.000 **%**
Result:	○ Positive ◉ Negative
Start Time of 1st Repeat:	**24 hrs. clock**
Breath Alcohol Level (BAL):	**%**
1st Repeat result:	○ Positive ○ Negative
Start Time of 2nd Repeat:	**24 hrs. clock**
Breath Alcohol Level (BAL):	**%**
2nd Repeat Result:	○ Positive ○ Negative
Final Result:	○ Positive ◉ Negative
For Positive results (if any) Informed to Principal Investigator/Co-Investigator/designate:	○ Yes ○ No ◉ 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:	◉ Yes ○ No ○ NAP
1. URINE SCAN FOR DRUGS ABUSE	
1.1 Urine drug scan tested for:	☑ Amphetamine (AMP) ☑ Barbiturates (BAR) ☑ Benzodiazepines (BZD) ☑ Cocaine (COC) ☑ Morphine (MOR) ☑ Cannabinoids (THC)
1.2 Start time:	13:36 **24 hrs. clock**
1.3 Observation of Results:	○ Positive with one band (Control) ◉ Negative with two band (Control and test) ○ Invalid with No band ○ Invalid with one band (Test)
1.4 Positive for:	☐ Amphetamine (AMP) ☐ Barbiturates (BAR) ☐ Benzodiazepines (BZD) ☐ Cocaine (COC) ☐ Morphine (MOR) ☐ Cannabinoids (THC)
2. URINE SCAN FOR DRUGS ABUSE (1st REPEAT)	

[Authenticated By:Dr. Ketul Modi]
[Authenticated On:29-Dec-2017 17:15 IST (+5:30 GMT)]

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

[Authenticated By:Dr. Ketul Modi]
[Authenticated On:29-Dec-2017 17:15 IST (+5:30 GMT)]

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

[Authenticated By:Dr. Ketul Modi]
[Authenticated On:29-Dec-2017 17:15 IST (+5:30 GMT)]

6.5 Positive for:	☐ Phencyclidine(PCP) ☐ Cotinine(COT) ☐ Methadone(MTD) ☐ Other
6.6 If other then specify:	
Final Result:	○ Positive ○ Negative
Positive for:	☐ Phencyclidine(PCP) ☐ Cotinine(COT) ☐ Methadone(MTD) ☐ Other
If other then specify:	
Remarks (for repeats or any other information):	

CRITERIA FOR SELECTION OF SUBJECTS	Period: 1
Inclusion Criteria	
Non-smoker/ Ex-smoker, healthy, adult, human, volunteers between 18 and 45 years of age (both inclusive):	◉ Yes ○ No
Having a Body Mass Index (BMI) between 18.5 and 29.9 (both inclusive), calculated as weight in kg / height in m2:	◉ Yes ○ 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:	◉ Yes ○ No
Able to understand and comply with the study procedures, in the opinion of the investigator:	◉ Yes ○ No
Able to give voluntary written informed consent for participation in the study:	◉ Yes ○ No
Inclusion Criteria in case of Female subjects	
Surgically sterilized at least 6 months prior to study participation; Or:	○ Yes ○ No ◉ 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:	◉ Yes ○ No ○ NAP
Serum Pregnancy test must be negative:	◉ Yes ○ No ○ NAP
Exclusion criteria	
Known hypersensitivity to Apremilast or any excipients or any related drug or any substance:	○ Yes ◉ No
History or presence of any disease or condition (including Bleeding,) which might compromise the haemopoietic, renal, hepatic, endocrine, pulmonary, central nervous, cardiovascular, immunological, dermatological, gastrointestinal, eye, ear conditions or any other body system:	○ Yes ◉ No
Any history or presence of asthma (including aspirin induced asthma) or nasal polyp or NSAIDs induced urticaria:	○ Yes ◉ No
Difficulty in swallowing solids dosage forms like tablets or capsules:	○ Yes ◉ No
A recent history of harmful use of alcohol (less than 2 years), i.e. alcohol consumption of more than 14 standard drinks per week for men and 07 standard drinks per week for women (A standard drink is defined as 360 ml of beer or 150 ml of wine or 45 ml of 40% distilled spirits, such as rum, whisky, brandy etc):	○ Yes ◉ No
Smokers or who have smoked within last 06 months prior to start of the study:	○ Yes ◉ No

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

The presence of clinically significant abnormal laboratory values during screening:	○ Yes ◉ No
Use of any recreational drugs or history of drug addiction:	○ Yes ◉ No
History of depression and/or suicidal thoughts or behaviour:	○ Yes ◉ No
QTc interval > 450 ms at the time of screening:	○ Yes ◉ No
Subject having CrCL <=50 ml/min at screening:	○ Yes ◉ No
History or presence of psychiatric disorders:	○ Yes ◉ No
A history of difficulty in donating blood:	○ Yes ◉ No
Donation of blood (1 unit or 350 mL) or receipt of an investigational medicinal product or participation in a drug research study within 90 days prior to receiving the first dose of study drug. Elimination half-life of the study drug should be taken into consideration for inclusion of the subject in the study:	○ Yes ◉ No
A positive hepatitis screen including hepatitis B surface antigen and/or HCV antibodies:	○ Yes ◉ No
A positive test result for HIV-I & II antibody:	○ Yes ◉ No
Nursing mothers (females):	○ Yes ◉ No ○ NAP
suitability	
Based on above criterias, Subject is:	◉ Suitable ○ Not-suitable
Criteria to be checked at the time of compliance check	
Ingestion of a medication (Prescribed or Over the counter medicines including 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:	-

COMPLIANCE CHECK-PI	Period: 1
Demographic Details	
Age in Years (Completed as of Screening Date):	37
Subject Reporting And Consent Procedure Record	
Date of reporting to the clinical facility:	25-Nov-2017
Presentation of ICF & obtained the consent on ICF:	◉ Yes ○ No
If 'Yes', mention pagination number of ICF:	29
Protocol Compliance Assessment	
Criteria Check Complete:	◉ Yes ○ No ○ NAP
Urine scan for drugs of abuse tested negative:	◉ Yes ○ No
Breath test for alcohol consumption tested negative:	◉ Yes ○ No
Date of last menstruation period (for female subject):	21-NOV-2017

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

Complaints of any illness:	(•) No ( ) Yes
If YES, provide details:	-
General Physical examination:	(•) Normal ( ) Abnormal
Oral Body Temperature:	98.6 **°F**
Blood Pressure (Systolic):	122 **mmHg**
Blood Pressure (Diastolic):	80 **mmHg**
Radial Pulse Rate:	84 **beats/min**
Cardiovascular System Examination:	(•) Normal ( ) Abnormal
Respiratory System Examination:	(•) Normal ( ) Abnormal
Central Nervous System Examination:	(•) Normal ( ) Abnormal
Per Abdomen Examination:	(•) Normal ( ) Abnormal
Any other Significant finding:	-
Any investigations recommended:	-
Vein puncture site:	(•) Normal ( ) Abnormal
Subject well-being:	(•) Well ( ) Unwell
If 'Abnormal' in any of the above-mentioned sections, please enter details.:	-
Remark if Any:	-
Subject is fit:	(•) Yes ( ) 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?:	(•) Yes ( ) 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:	(•) Well ( ) Unwell
If unwell then specify:	-
Remarks:	-

0.000 HRS PRE DOSE PK SAMPLE COLLECTION	Period: 1
Date and Time of Dosing:	

Date of sample collection:	26-Nov-2017
Scheduled date and Time of sample collection (for post dose only):	
Actual Time of sample collection:	07:30 **24 hrs. clock**
Remarks:	
PK Sample ID:	PK17862931
Remarks if any other reason:	

IMP ADMINISTRATION	Period: 1
DATE:	26-Nov-2017
IS SUBJECT COMPLIANT TO ALL PREDOSE REQUIREMENTS AS PER PROTOCOL?:	(•) Yes ( ) No ( ) NA
TIME:	08:24 **24 hrs. clock**
MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA:	(•) Yes ( ) No ( ) NA
ML OF WATER ADMINISTERED WITH IP:	240
LABEL:	0000250430
PRODUCT CODE/ TYPE:	Reference
DOSING DONE BY:	kanarampatel (Dosing)
DOSING SUPERVISION DONE BY:	ankitkpatel (Dosing)
REMARKS:	Subject spilled out approx 02 to 03 drops of dosing water during IMP administration.

STUDY DRUG ADMINISTRATION-COMPLIANCE	Period: 1
Has the subject compliant to 02 hour post dose water restriction?:	(•) Yes ( ) No
Has the subject compliant to postural restriction for 04 hours post dose in sitting posture? (unless medically necessary due to adverse event or procedurally required or natural exigency):	(•) Yes ( ) No
Has the subject compliant to 04 hours post dose fasting condition?:	(•) Yes ( ) No
Remark If any:	-

0.250 HRS POST DOSE PK SAMPLE COLLECTION	Period: 1
Date and Time of Dosing:	26-Nov-2017 08:24
Date of sample collection:	26-Nov-2017
Scheduled date and Time of sample collection (for post dose only):	26-Nov-2017 08:39
Actual Time of sample collection:	08:39 **24 hrs. clock**
Remarks:	
PK Sample ID:	PK17863003
Remarks if any other reason:	

0.500 HRS POST DOSE PK SAMPLE COLLECTION	Period: 1
Date and Time of Dosing:	26-Nov-2017 08:24
Date of sample collection:	26-Nov-2017
Scheduled date and Time of sample collection (for post dose only):	26-Nov-2017 08:54
Actual Time of sample collection:	08:54 **24 hrs. clock**
Remarks:	
PK Sample ID:	PK17863075
Remarks if any other reason:	

0.750 HRS POST DOSE PK SAMPLE COLLECTION	Period: 1

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Date and Time of Dosing:	26-Nov-2017 08:24
Date of sample collection:	26-Nov-2017
Scheduled date and Time of sample collection (for post dose only):	26-Nov-2017 09:09
Actual Time of sample collection:	09:09 **24 hrs. clock**
Remarks:	
PK Sample ID:	PK17863147
Remarks if any other reason:	

1.000 HRS POST DOSE PK SAMPLE COLLECTION	Period: 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 **24 hrs. clock**
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 **24 hrs. clock**
Systolic Blood Pressure:	112 **mmHg**
Diastolic Blood Pressure:	78 **mmHg**
Radial Pulse:	76 **beats/min**
Well-being:	(•) Well ( ) Unwell
If unwell then specify:	-
Remarks:	-

1.333 HRS POST DOSE PK SAMPLE COLLECTION	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 **24 hrs. clock**
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 **24 hrs. clock**
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

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 **24 hrs. clock**
Remarks:	
PK Sample ID:	PK17863350
Remarks if any other reason:	

2.333 HRS POST DOSE PK SAMPLE COLLECTION	Period: 1
Date and Time of Dosing:	26-Nov-2017 08:24
Date of sample collection:	26-Nov-2017
Scheduled date and Time of sample collection (for post dose only):	26-Nov-2017 10:44
Actual Time of sample collection:	10:44 **24 hrs. clock**
Remarks:	
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 **24 hrs. clock**
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 **24 hrs. clock**
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 **24 hrs. clock**
Systolic Blood Pressure:	114 **mmHg**
Diastolic Blood Pressure:	74 **mmHg**
Radial Pulse:	72 **beats/min**
Well-being:	(•) Well ( ) Unwell
If unwell then specify:	-
Remarks:	-

3.333 HRS POST DOSE PK SAMPLE COLLECTION	Period: 1
Date and Time of Dosing:	26-Nov-2017 08:24
Date of sample collection:	26-Nov-2017

Scheduled date and Time of sample collection (for post dose only):	26-Nov-2017 11:44
Actual Time of sample collection:	11:44 **24 hrs. clock**
Remarks:	
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 **24 hrs. clock**
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 **24 hrs. clock**
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 **24 hrs. clock**
End Time:	12:42 **24 hrs. clock**
Has subject consumed meal completely?:	(•) Yes ( ) 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 **24 hrs. clock**
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 **24 hrs. clock**
Remarks:	
PK Sample ID:	PK17863854

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 **24 hrs. clock**
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 **24 hrs. clock**
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 **24 hrs. clock**
Systolic Blood Pressure:	110 **mmHg**
Diastolic Blood Pressure:	70 **mmHg**
Radial Pulse:	68 **beats/min**
Well-being:	(•) Well ( ) 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 **24 hrs. clock**
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 **24 hrs. clock**
End Time:	16:33 **24 hrs. clock**
Has subject consumed meal completely?:	(•) Yes ( ) No
Details of meal left (Approximate Quantity):	-
Remarks:	-

10.000 HRS POST DOSE PK SAMPLE COLLECTION	Period: 1

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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 **24 hrs. clock**
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 **24 hrs. clock**
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 **24 hrs. clock**
End Time:	20:45 **24 hrs. clock**
Has subject consumed meal completely?:	(•) Yes ( ) 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 **24 hrs. clock**
Systolic Blood Pressure:	108 **mmHg**
Diastolic Blood Pressure:	68 **mmHg**
Radial Pulse:	72 **beats/min**
Well-being:	(•) Well ( ) 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 **24 hrs. clock**
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

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:	○ Positive ◉ Negative
Start Time of 1st Repeat:	**24 hrs. clock**
Breath Alcohol Level (BAL):	**%**
1st Repeat result:	○ Positive ○ Negative
Start Time of 2nd Repeat:	**24 hrs. clock**
Breath Alcohol Level (BAL):	**%**
2nd Repeat Result:	○ Positive ○ Negative
Final Result:	○ Positive ◉ Negative
For Positive results (if any) Informed to Principal Investigator/Co-Investigator/designate:	○ Yes ○ No ◉ NAP
Remarks:	-

36.000 HRS AMBULATORY PK SAMPLE COLLECTION (DAY 2)	Period: 1
Date and Time of Dosing:	26-Nov-2017 08:24
Date of sample collection:	27-Nov-2017
Scheduled date and Time of sample collection (for post dose only):	27-Nov-2017 20:24
Actual Time of sample collection:	20:25 **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?:	○ Yes ◉ No
Have you donated blood anywhere else or participated in other clinical trial since last visit?:	○ Yes ◉ No
If Yes, Remarks:	-
Well Being at the Time of Ambulatory	
Date of well being:	27-Nov-2017

Start Time of well being:	20:36 **24 hrs. clock**
Well-Being at the time of ambulatory sample:	(•) Well ( ) Unwell
Remarks if Unwell:	-
Remark if any:	-

BREATH TEST FOR ALCOHOL CONSUMPTION (48.000 HRS AMBULATORY VISIT)	Period: 1
Date:	28-Nov-2017
Start Time:	09:57 **24 hrs. clock**
Breath Alcohol Level (BAL):	.000 **%**
Result:	( ) Positive (•) Negative
Start Time of 1st Repeat:	**24 hrs. clock**
Breath Alcohol Level (BAL):	**%**
1st Repeat result:	( ) Positive ( ) Negative
Start Time of 2nd Repeat:	**24 hrs. clock**
Breath Alcohol Level (BAL):	**%**
2nd Repeat Result:	( ) Positive ( ) Negative
Final Result:	( ) Positive (•) Negative
For Positive results (if any) Informed to Principal Investigator/Co-Investigator/designate:	( ) Yes ( ) No (•) 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 **24 hrs. clock**
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?:	( ) Yes (•) No
Have you donated blood anywhere else or participated in other clinical trial since last visit?:	( ) Yes (•) No
If Yes, Remarks:	-
Well Being at the Time of Ambulatory	
Date of well being:	28-Nov-2017

Start Time of well being:	10:02 **24 hrs. clock**
Well-Being at the time of ambulatory sample:	(•) Well ( ) Unwell
Remarks if Unwell:	-
Remark if any:	-

CHECK-OUT DETAILS(Period - 1)

CLINICAL EXAMINATION-CHECK OUT	Period: 1
Date of Clinical Examination:	27-Nov-2017
Start Time of Clinical Examination:	07:25 **24 hrs. clock**
Complaint of any illness:	(•) No ( ) Yes
If YES, provide details:	-
General Physical examination:	(•) Normal ( ) Abnormal
Oral Body Temperature:	97.8 **°F**
Radial Pulse Rate:	76 **beats/min**
Blood Pressure(Systolic):	112 **mmHg**
Blood Pressure(Diastolic):	78 **mmHg**
Cardiovascular System Examination:	(•) Normal ( ) Abnormal
Respiratory System Examination:	(•) Normal ( ) Abnormal
Central Nervous System Examination:	(•) Normal ( ) Abnormal
Per Abdomen Examination:	(•) Normal ( ) Abnormal
Any other Significant finding:	-
Any investigations recommended:	-
If 'Abnormal' in any of the above-mentioned sections, please enter details:	-
To be performed at the time of check-out	
Vein puncture site:	(•) Normal ( ) Abnormal
Subject well-being:	(•) Well ( ) Unwell
Comments:	-
Subject is fit for Check-out:	(•) Yes ( ) 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:	( ) Medical Event ( ) Adverse Event ( ) Discontinuation ( ) Safety Assessment (•) Subject Not reported for scheduled visit ( ) others
If Others, Specify:	-

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Date:	01-Dec-2017
Mode of communication:	Telephone
Detail of Discussion:	Subject was contacted telephonically and info rmed 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:	○ Positive ◉ Negative
Start Time of 1st Repeat:	**24 hrs. clock**
Breath Alcohol Level (BAL):	**%**
1st Repeat result:	○ Positive ○ Negative
Start Time of 2nd Repeat:	**24 hrs. clock**
Breath Alcohol Level (BAL):	**%**
2nd Repeat Result:	○ Positive ○ Negative
Final Result:	○ Positive ◉ Negative
For Positive results (if any) Informed to Principal Investigator/Co-Investigator/designate:	○ Yes ○ No ◉ 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:	◉ Yes ○ No ○ NAP
1. URINE SCAN FOR DRUGS ABUSE	
1.1 Urine drug scan tested for:	☑ Amphetamine (AMP) ☑ Barbiturates (BAR) ☑ Benzodiazepines (BZD) ☑ Cocaine (COC) ☑ Morphine (MOR) ☑ Cannabinoids (THC)
1.2 Start time:	16:45 **24 hrs. clock**
1.3 Observation of Results:	○ Positive with one band (Control) ◉ Negative with two band (Control and test) ○ Invalid with No band ○ Invalid with one band (Test)
1.4 Positive for:	☐ Amphetamine (AMP) ☐ Barbiturates (BAR) ☐ Benzodiazepines (BZD) ☐ Cocaine (COC) ☐ Morphine (MOR) ☐ Cannabinoids (THC)

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

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

6.5 Positive for:	☐ Phencyclidine(PCP) ☐ Cotinine(COT) ☐ Methadone(MTD) ☐ Other
6.6 If other then specify:	
Final Result:	○ Positive ○ Negative
Positive for:	☐ Phencyclidine(PCP) ☐ Cotinine(COT) ☐ Methadone(MTD) ☐ Other
If other then specify:	
Remarks (for repeats or any other information):	

COMPLIANCE CHECK-PII	Period: 2
Demographic Details	
Age in Years (Completed as of Screening Date):	37
Subject Reporting Record	
Date of reporting to the clinical facility:	01-Dec-2017
Protocol Compliance Assessment	
Urine scans for drugs of abuse tested negative:	◉ Yes ○ No
Breath test for alcohol consumption tested negative:	◉ Yes ○ No
Date of last menstruation period (For Female subject):	21-NOV-2017
Result of serum pregnancy test:	○ Positive ◉ Negative ○ NAP (For Male subject)
Prohibitions	
Are you suffering from any illness since the last visit (Including allergic reaction, itching, rash on your skin)?:	○ Yes ◉ No
Have you consumed any xanthine containing food or beverages (like tea, coffee, chocolates or cola drinks) for 24 hours prior to check-in?:	○ Yes ◉ No
Have you consumed tobacco, tobacco containing products (Gutkha, Pan/Pan masala or any other) for 24 hours prior to check-in?:	○ Yes ◉ No
Have you consumed recreational products, alcohol or alcoholic products since last PK sample collection of Period I?:	○ Yes ◉ No
Have you consumed grapefruit or grapefruit products since last PK sample collection of Period I?:	○ Yes ◉ No
Have you smoked since last PK sample collection of Period I?:	○ Yes ◉ 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?:	○ Yes ◉ No
Have you consumed an unusual diet, for whatever reason (e.g. low-sodium) since last PK sample collection of Period I?:	○ Yes ◉ No
Have you donated blood anywhere else or participated in other clinical trial since last PK sample collection of Period I?:	○ Yes ◉ No
Is subject compliant to all above restrictions/requirement?:	◉ Yes ○ 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?:	(•) Yes ( ) No
Date of blood sample collection:	01-Dec-2017
Lab report clinically acceptable:	(•) Yes ( ) No ( ) NAP
Comments (if any):	-

CHECK-IN B&B	Period: 2
Baggage and Body Search done:	(•) Yes ( ) No
Date of Check In:	01-Dec-2017
Time of Check-in:	18:06 **24 hrs. clock**
Remarks:	-

CLINICAL EXAMINATION - CHECK IN	Period: 2
Date of clinical examination:	01-Dec-2017
Start Time of Clinical Examination:	18:37 **24 hrs. clock**
Complaints of any illness:	(•) No ( ) Yes
If YES, provide details:	-
General Physical examination:	(•) Normal ( ) Abnormal
Oral Body Temperature:	98.2 **°F**
Blood Pressure (Systolic):	116 **mmHg**
Blood Pressure (Diastolic):	82 **mmHg**
Radial Pulse Rate:	72 **beats/min**
Cardiovascular System Examination:	(•) Normal ( ) Abnormal
Respiratory System Examination:	(•) Normal ( ) Abnormal
Central Nervous System Examination:	(•) Normal ( ) Abnormal
Per Abdomen Examination:	(•) Normal ( ) Abnormal
Any other Significant finding:	-
Any investigations recommended:	-
Vein puncture site:	(•) Normal ( ) Abnormal
Subject well-being:	(•) Well ( ) Unwell
If 'Abnormal' in any of the above-mentioned sections, please enter details.:	-
Remark if Any:	-
Subject is fit:	(•) Yes ( ) No

DINNER CHECK-IN (DAY-1)	Period: 2
Date of meal distribution:	01-Dec-2017
Start Time:	20:28 **24 hrs. clock**
End Time:	20:47 **24 hrs. clock**
Has subject consumed meal completely?:	(•) Yes ( ) No
Details of meal left (Approximate Quantity):	-

Remarks:	-

HOUSING DETAILS(Period - 2)

0.00 HRS PRE DOSE VITAL SIGNS AND WELL-BEING RECORD	Period: 2
Position:	Sitting
Date of vital measurement:	02-Dec-2017
Start Time of vital measurement:	05:54 **24 hrs. clock**
Systolic Blood Pressure:	116 **mmHg**
Diastolic Blood Pressure:	78 **mmHg**
Radial Pulse:	76 **beats/min**
Oral Body Temperature:	97.8 **°F**
Well-being:	(•) Well ( ) Unwell
If unwell then specify:	-
Remarks:	-

0.000 HRS PRE DOSE PK SAMPLE COLLECTION	Period: 2
Date and Time of Dosing:	
Date of sample collection:	02-Dec-2017
Scheduled date and Time of sample collection (for post dose only):	
Actual Time of sample collection:	07:34 **24 hrs. clock**
Remarks:	
PK Sample ID:	PK17879834
Remarks if any other reason:	

IMP ADMINISTRATION	Period: 2
DATE:	02-Dec-2017
IS SUBJECT COMPLIANT TO ALL PREDOSE REQUIREMENTS AS PER PROTOCOL?:	(•) Yes ( ) No ( ) NA
TIME:	08:24 **24 hrs. clock**
MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA:	(•) Yes ( ) No ( ) 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?:	(•) Yes ( ) No
Has the subject compliant to postural restriction for 04 hours post dose in sitting posture? (unless medically necessary due to adverse event or procedurally required or natural exigency):	( ) Yes (•) No
Has the subject compliant to 04 hours post dose fasting condition?:	(•) Yes ( ) 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

Date of sample collection:	02-Dec-2017
Scheduled date and Time of sample collection (for post dose only):	02-Dec-2017 08:39
Actual Time of sample collection:	08:39 **24 hrs. clock**
Remarks:	
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 **24 hrs. clock**
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 **24 hrs. clock**
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 **24 hrs. clock**
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 **24 hrs. clock**
Systolic Blood Pressure:	116 **mmHg**
Diastolic Blood Pressure:	72 **mmHg**
Radial Pulse:	68 **beats/min**
Well-being:	(•) Well ( ) 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

Scheduled date and Time of sample collection (for post dose only):	02-Dec-2017 09:44
Actual Time of sample collection:	09:44 **24 hrs. clock**
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 **24 hrs. clock**
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 **24 hrs. clock**
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 **24 hrs. clock**
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 **24 hrs. clock**
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 **24 hrs. clock**
Remarks:	
PK Sample ID:	PK17880194

Remarks if any other reason:	

3.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD	Period: 2
Position:	Sitting
Date of vital measurement:	02-Dec-2017
Start Time of vital measurement:	10:56 **24 hrs. clock**
Systolic Blood Pressure:	112 **mmHg**
Diastolic Blood Pressure:	74 **mmHg**
Radial Pulse:	68 **beats/min**
Well-being:	(•) Well ( ) 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 **24 hrs. clock**
End Time:	12:34 **24 hrs. clock**
Has subject consumed meal completely?:	( ) Yes (•) 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 O f Khaman Dhokla.
Remarks:	-

6.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD	Period: 2
Position:	Sitting
Date of vital measurement:	02-Dec-2017
Start Time of vital measurement:	13:59 **24 hrs. clock**
Systolic Blood Pressure:	114 **mmHg**
Diastolic Blood Pressure:	74 **mmHg**
Radial Pulse:	72 **beats/min**
Well-being:	(•) Well ( ) Unwell
If unwell then specify:	-
Remarks:	-

SNACKS (DAY 1)	Period: 2
Date of meal distribution:	02-Dec-2017
Start Time:	16:24 **24 hrs. clock**
End Time:	16:31 **24 hrs. clock**
Has subject consumed meal completely?:	(•) Yes ( ) No
Details of meal left (Approximate Quantity):	-
Remarks:	-

DINNER (DAY 1)	Period: 2
Date of meal distribution:	02-Dec-2017
Start Time:	20:21 **24 hrs. clock**
End Time:	20:33 **24 hrs. clock**
Has subject consumed meal completely?:	(•) Yes ( ) No

[Authenticated By:Dr. Ketul Modi]
[Authenticated On:29-Dec-2017 17:15 IST (+5:30 GMT)]

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 **24 hrs. clock**
Systolic Blood Pressure:	116 **mmHg**
Diastolic Blood Pressure:	76 **mmHg**
Radial Pulse:	80 **beats/min**
Well-being:	(•) Well ( ) 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 **24 hrs. clock**
Complaint of any illness:	(•) No ( ) Yes
If YES, provide details:	-
General Physical examination:	(•) Normal ( ) Abnormal
Oral Body Temperature:	98.2 **°F**
Radial Pulse Rate:	64 **beats/min**
Blood Pressure(Systolic):	112 **mmHg**
Blood Pressure(Diastolic):	72 **mmHg**
Cardiovascular System Examination:	(•) Normal ( ) Abnormal
Respiratory System Examination:	(•) Normal ( ) Abnormal
Central Nervous System Examination:	(•) Normal ( ) Abnormal
Per Abdomen Examination:	(•) Normal ( ) Abnormal
Any other Significant finding:	-
Any investigations recommended:	--
If 'Abnormal' in any of the above-mentioned sections, please enter details:	-
To be performed at the time of check-out	
Vein puncture site:	(•) Normal ( ) Abnormal
Subject well-being:	(•) Well ( ) Unwell
Comments:	-
Subject is fit for Check-out:	(•) Yes ( ) No
Remark If any:	-

CHECK-OUT B&B	Period: 2
Date of check out:	03-Dec-2017
Time of Check-out:	08:52 **24 hrs. clock**
Remarks:	-

CLINICAL EXAMINATION - END OF STUDY	Period: 2
Date of clinical examination:	05-Dec-2017
Start time of clinical examination:	11:49 **24 hrs. clock**
Complaints of any illness:	(•) No ( ) Yes
If YES, provide details:	-
General Physical examination:	(•) Normal ( ) Abnormal
Oral Body Temperature:	98.0 **°F**
Systolic Blood Pressure:	108 **mmHg**
Diastolic Blood Pressure:	68 **mmHg**
Radial Pulse Rate:	72 **beats/min**
Cardiovascular System Examination:	(•) Normal ( ) Abnormal
Respiratory System Examination:	(•) Normal ( ) Abnormal
Central Nervous System Examination:	(•) Normal ( ) Abnormal
Per Abdomen Examination:	(•) Normal ( ) Abnormal
Any other Significant finding:	-
Any investigations recommended:	-
Vein puncture site:	(•) Normal ( ) Abnormal
Subject well-being:	(•) Well ( ) Unwell
If 'Abnormal' in any of the above-mentioned sections, please enter the details:	-
Subject is fit:	(•) Yes ( ) No
Remark If any:	-

ECG EXAMINATION-END OF STUDY	Period: 2
ECG EXAMINATION	
Date Of ECG:	11-Dec-2017
Time of ECG:	11:10 **24 hrs. clock**
Was ECG Repeated:	( ) Yes (•) No
If Yes, Date of Repeat ECG:	
ECG Impression:	WNL
Overall Assessment:	(•) Normal ( ) Not Clinically Significant ( ) 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?:	(•) Yes ( ) No
Date of safety sample collection:	05-Dec-2017
Lab report clinically acceptable:	(•) Yes ( ) No ( ) NAP
Result of serum pregnancy test:	( ) Positive (•) Negative ( ) NAP (For Male subject)
Remarks If Any:	-

STUDY COMPLETION STATUS	
Has the subject completed the study?:	○ Yes ◉ No
If "No", please refer:	○ Pre dose discontinued form ◉ Post dose discontinued form
If "Yes", then any protocol or sampling deviation reported for subject?:	○ Yes ○ No
If "Yes", then select appropriate option:	☐ Protocol deviation ☐ Sampling Deviation
Remarks:	-

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

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

CONCOMITANT MEDICATION FORM	Period: 2
Medication Name or Therapy:	Emeset
Medication Code:	vDrugName=Emeset
Medication for AE#:	01
Dose:	Inj. Emeset (Ondansetron 2 mg/ml) total 02 ml
Dosage form/Unit:	Milliliter
If 'Other' (Dosage form/Unit), please specify:	
Frequency:	Other
If 'Other' (Frequency), please specify:	Stat
Route:	Intravenous

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:	○ Yes ◉ No
Remark, if any:	-

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

ADVERSE EVENT UPDATE FORM	Period: 2
Adverse event Term:	Vomiting
Adverse event Code:	llt_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:	◉ MILD ○ MODERATE ○ SEVERE
Toxicity grade:	◉ GRADE 1:MILD AE ○ GRADE 2:MODERATE AE ○ GRADE 3:SEVERE AE ○ GRADE 4:LIFE-THREATENING OR DISABLING AE ○ GRADE 5:DEATH RELATED TO AE ○ NOT APPLICABLE
Serious?:	○ YES ◉ NO

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Is it significant?:	○ YES ◉ NO
If Serious, Seriousness criteria:	☐ CONGENITAL ANOMALY OR BIRTH DEFECT ☐ SIGNIFICANT DISABILITY ☐ DEATH ☐ HOSPITALIZATION ☐ LIFE THREATENING ☐ OTHER MEDICALLY IMPORTANT EVENT
Unexpected adverse drug reaction?:	○ YES ◉ NO ○ NAP
Relationship to Study Treatment:	○ NOT RELATED ○ UNLIKELY RELATED ◉ POSSIBLY RELATED ○ RELATED ○ NAP
Action Taken with Study Treatment:	○ DOSE INCREASED ○ DOSE NOT CHANGED ○ DOSE REDUCED ○ DRUG INTERRUPTED ◉ DRUG WITHDRAWN ○ NOT APPLICABLE ○ UNKNOWN
Outcome:	○ NOT RECOVERED/NOT RESOLVED ◉ RECOVERED/RESOLVED ○ RECOVERED/RESOLVED WITH SEQUELAE ○ RECOVERING/RESOLVING ○ UNKNOWN ○ FATAL
Caused study discontinuation:	◉ YES ○ NO
Concomitant treatment/Therapy given:	◉ YES ○ NO
Does given concomitant medication has drug-drug interaction along with study drug?:	○ YES ◉ NO ○ 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 **24 hrs. clock**
Date of last IMP administered:	02-Dec-2017
Reason for discontinuation	
Reasons:	○ On his/her own accord ◉ On the grounds of Emesis ○ On medical grounds ○ For having withheld critical Information ○ On grounds of protocol non-compliance ○ Any other (please specify)
If any other:	-
Description of Event:	Subject had single episode of vomiting at app roximately 1144 hrs, 02-Dec-2017. Vomiting la sted for 01 minute. Vomitus was approximately 100 ml in amount and contained fluid with fo od particles. He had no any other complaint.

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

[Authenticated By:Dr. Ketul Modi]
[Authenticated On:29-Dec-2017 17:15 IST (+5:30 GMT)]

Lambda Therapeutic Research Ltd.

17063193

Clinical Laboratory Test Report

LAMBDA
Lambda Therapeutic Research Limited

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

CHEMISTRY

[Performed By Reflectance Photometry]

PARAMETER	RESULT	CS/NCS*	REMARK	UNIT	REFERENCE INTERVAL
BILIRUBIN TOTAL	0.36			mg/dL	0.2 - 1.5
Azobilirubin					
TOTAL PROTEIN	7.83			g/dL	6.9 - 8.6
Biuret					
ALBUMIN	4.62			g/dL	3.9 - 5.2
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	**163.06**	NCS	**H**	mL/min	80 - 125
Calculated by Cockcroft Gault method					

Final Remark :- clinically acceptable

Reviewed by:- Dr. Sanjaykumar S. Patel - Stud 07-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

Lambda Therapeutic Research Ltd.

17063193

Clinical Laboratory Test Report

LAMBDA
Lambda Therapeutic Research Limited

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

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 10^6/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 10^3/µL	150 - 410
Hydro dynamic focussing method					
WBC (TOTAL)	7.57			X 10^3/µL	4.0 - 10.0
Flowcytometry method					
NEUTROPHIL %	66.0			%	40 - 80
Flowcytometry method					
LYMPHOCYTES %	25.9			%	20 - 40
Flowcytometry method					

Final Remark :- clinically acceptable

Reviewed by:- Dr. Sanjaykumar S. Patel - Stud 07-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

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

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 10^3/µL	2.0 - 7.0
Calculated			
EOSINOPHILS (ABS)	0.12	X 10^3/µL	0.02 - 0.5
Calculated			

Final Remark :- clinically acceptable

Reviewed by:- Dr. Sanjaykumar S. Patel - Stud 07-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

Lambda Therapeutic Research Ltd.

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 - Stud 07-Dec-2017 11:38

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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. 7183121

No. M-0232

Lambda Therapeutic Research

17063193

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

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 - Stud 07-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