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

Project No: 0326-17



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

MEDICAL SCREENING RECORD FORM

Project No: 0326-17



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

MEDICAL SCREENING RECORD FORM

Project No: 0326-17



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

MEDICAL SCREENING RECORD FORM

Project No: 0326-17



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

MEDICAL SCREENING RECORD FORM

Project No: 0326-17



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

MEDICAL SCREENING RECORD FORM

Project No: 0326-17



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

MEDICAL SCREENING RECORD FORM

Project No: 0326-17



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



Clinical Laboratory Test Report



Lambda Therapeutic Research Limited

Screening AH17-06704
Subject Initial: KSM
Subject N/A

Date Of Birth: 01-Jan-1980

Referred By: Dr. Manish Patel

Lab ID: 17060104
Sex: Female
Visit: Screening

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

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

17-Nov-2017 18:21

Study /Project

CHEMISTRY

[Performed By Reflectance Photometry]

| PARAMETER PLASMA RANDOM GLUCOSE Glucose oxidase | RESULT 92.5 | CS/NCS* | REMARK | UNIT mg/dL | - WHO CRITERIA FOR DIAGNOSIS OF DIABETES >200 along with symptoms of hyperglycemia suggestive of diabetes |
|---|-----------------------|---------|--------|----------------------|---|
| BILIRUBIN TOTAL | 0.32 | | | mg/dL | 0.2 - 1.5 |
| DILINODIN TOTAL | 0.32 | | | mg/ac | 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 | 2.4 | | | a /dl | 25 20 |
| 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 - Stud

§ 8-Nov-2017 12:47

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

This is an Electronically authenticated report

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







Clinical Laboratory Test Report



Lambda Therapeutic Research Limited

| Screening Subject Initial: Subject Date Of Birth: Referred By: | AH17-06704 KSM N/A 01-Jan-1980 Dr. Manish Patel | Lab ID: Sex : Visit : | 17060104 Female Screening | Sample Collected Sample Collected At: Sample Received On: Report Date: Study /Project | 17-Nov-2017 18:21 Ahmedabad 17-Nov-2017 18:54 17-Nov-2017 22:40 |
|--|---|-----------------------------|---------------------------------|---|--|
| UREA | 21.4 | | | mg/dL | 15.0 - 36.0 |
| Urease quinolinium 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 CLE | ARANCE 165. | 78 | NCS | H mL/min | 80 - 125 |

Calculated by Cockcroft Gault

method

CLINICALLY ACCEPTABLE Final Remark :-

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

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

This is an Electronically authenticated report

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







Clinical Laboratory Test Report



Lambda Therapeutic Research Limited

Screening AH17-06704 Subject Initial: KSM

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

17060104 Lab ID: Sex: Female

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

Sample Received On: Report Date:

Study /Project

17-Nov-2017 18:21 Ahmedabad

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

HEMATOLOGY

[Performed By Flowcytometry and Electrical Impedence Method]

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

CLINICALLY ACCEPTABLE Final Remark :-

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

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

This is an Electronically authenticated report

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







Clinical Laboratory Test Report



Lambda Therapeutic Research Limited

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

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

Final Remark :- CLINICALLY ACCEPTABLE

Reviewed by:- Jaimin Chhaganbhai Ahir - Stud

§ 8-Nov-2017 12:47

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

This is an Electronically authenticated report

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







Clinical Laboratory Test Report



Lambda Therapeutic Research Limited

Screening AH17-06704 Subject Initial: KSM

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

17060104 Lab ID: Sex: Female Visit :

Screening

Sample Collected Sample Collected At:

Sample Received On: Report Date: Study /Project

17-Nov-2017 18:21

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

Ahmedabad

IMMUNOLOGY

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

ELISA

Anti HIV I&II Non-Reactive Non-Reactive

ELISA

HBsAg Non-Reactive Non-Reactive

FLISA

hCG <0.500 WNL mIU/mL Pre menopausal

females:<4.9

Electrochemiluminescence

CLINICALLY ACCEPTABLE Final Remark :-

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

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







Clinical Laboratory Test Report



Lambda Therapeutic Research Limited

Screening AH17-06704 Subject Initial:

Subject

Referred By:

KSM Date Of Birth:

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

Visit :

17060104 Female

Screening

Sample Collected

Sample Collected At: Sample Received On: Report Date:

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

17-Nov-2017 18:21

Study /Project

URINE ANALYSIS

[Performed By Reflectance Photometry]

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

CLINICALLY ACCEPTABLE Final Remark :-

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

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







Clinical Laboratory Test Report



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

Referred By:

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

Screening

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

Study /Project

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

17-Nov-2017 18:21

Out of Summary Report

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

CLINICALLY ACCEPTABLE Final Remark :-

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

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

This is an Electronically authenticated report

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







Clinical Laboratory Test Report



Lambda Therapeutic Research Limited

Screening AH17-06704 Subject Initial: KSM

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

17061746 Lab ID: Sex: Female

Visit :

PCI1

Sample Collected

Sample Collected At: Sample Received On: Report Date:

25-Nov-2017 12:53 Ahmedabad

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

Study /Project 0326-17

CHEMISTRY

[Performed By Reflectance Photometry]

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

Enzymatic (Creatine amidohydrolase, IDMS

traceable)

H mL/min 160.43 CREATININE CLEARANCE NCS 80 - 125

Calculated by Cockcroft Gault method

clinically acceptable Final Remark :-

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

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

This is an Electronically authenticated report

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







Clinical Laboratory Test Report



Lambda Therapeutic Research Limited

Screening AH17-06704
Subject Initial: KSM
Subject 1026

Date Of Birth: 01-Jan-1980

Referred By: Dr. Manish Patel

Lab ID: 17061746 **Sex :** Female

Visit: PCI1

Sample Collected
Sample Collected At:

Sample Received On:
Report Date:
Study /Project

25-Nov-2017 12:53

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

females: <4.83

0326-17

IMMUNOLOGY

 PARAMETER
 RESULT
 CS/NCS*
 REMARK
 UNIT
 REFERENCE INTERVAL

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

Chemiluminescence

Final Remark :- clinically acceptable

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

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

This is an Electronically authenticated report

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







Clinical Laboratory Test Report



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

Date Of Birth: 01-Jan-1980

Referred By: Dr. Manish Patel

 Lab ID:
 17061746

 Sex :
 Female

 Visit :
 PCI1

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

Study /Project

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

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

Out of Summary Report

PARAMETER RESULT UNIT REFERENCE INTERVAL COMMENTS

CREATININE CLEARANCE 160.43 H mL/min 80 - 125

Final Remark :- clinically acceptable

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

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

This is an Electronically authenticated report

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







Clinical Laboratory Test Report



Lambda Therapeutic Research Limited

Screening AH17-06704 Subject Initial: KSM

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

17062552 Lab ID: Sex: Female

Visit : PCI2 Sample Collected

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

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

01-Dec-2017 15:48

Study /Project 0326-17

CHEMISTRY

[Performed By Reflectance Photometry]

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

Enzymatic (Creatine amidohydrolase, IDMS traceable)

CREATININE CLEARANCE

144.15

NCS

H mL/min

80 - 125

Calculated by Cockcroft Gault

method

CLINICALLY ACCEPTABLE Final Remark :-

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

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

This is an Electronically authenticated report

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







Clinical Laboratory Test Report



Lambda Therapeutic Research Limited

Screening AH17-06704 Subject Initial: KSM Subject

> 01-Jan-1980 Dr. Manish Patel

17062552 Lab ID: Sex: Female Visit :

PCI2

Sample Collected Sample Collected At:

Sample Received On: Report Date: Study /Project

01-Dec-2017 15:48

Ahmedabad

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

0326-17

IMMUNOLOGY

PARAMETER RESULT BETA hCG

<2.39

CS/NCS*

REMARK

WNI

UNIT mIU/mL **REFERENCE INTERVAL**

- Pre menopausal females: <4.83

Chemiluminescence

Date Of Birth:

Referred By:

CLINICALLY ACCEPTABLE Final Remark :-

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

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

This is an Electronically authenticated report

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







Clinical Laboratory Test Report



Screening AH17-06704
Subject Initial: KSM
Subject 1026

CREATININE CLEARANCE

Date Of Birth: 01-Jan-1980

Referred By: Dr. Manish Patel

 Lab ID:
 17062552

 Sex :
 Female

 Visit :
 PCI2

144.15

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

80 - 125

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

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

Out of Summary Report

PARAMETER RESULT UNIT REFERENCE INTERVAL COMMENTS

н

mL/min

Final Remark :- CLINICALLY ACCEPTABLE

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

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

This is an Electronically authenticated report

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





CASE REPORT FORM

Project No: 0326-17



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

Lambda Therapeutic Research.

Sponsor Name:Cipla Limited

CASE REPORT FORM

Project No: 0326-17



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

^{*}This is an electronically authenticated report.

Lambda Therapeutic Research.

Sponsor Name: Cipla Limited

CASE REPORT FORM

Project No: 0326-17

Subject No: 1026 Subject Initials: KSM

| 4477 | Phencyclidine(PCP) Cotinine(COT) Methadone(MTD) | | | | |
|---|--|--|--|--|--|
| 4.1 Urine drug scan tested for: | Other | | | | |
| 4010 4 4 16 | 1 Other | | | | |
| 4.2 If other then specify: | 241, | | | | |
| 4.3 Start Time: | 24 hrs. clock | | | | |
| 4.4 Observation of Results: | C Positive with one band (Control and test) C Negative with two band (Control and test) C Invalid with No band | | | | |
| | C Invalid with one band (Test) | | | | |
| | | | | | |
| | Phencyclidine(PCP) Cotinine(COT) Methadone(MTD | | | | |
| | ☐ Other | | | | |
| 4.6 If other then specify: | | | | | |
| 5. URINE SCAN FOR DRUGS ABUSE ADDITIONAL (1st REPEAT) | | | | | |
| | | | | | |
| 5.1 Urine drug scan tested for: | Phencyclidine(PCP) Cotinine(COT) Methadone(MTD) | | | | |
| | Other | | | | |
| 5.2 If other then specify: | | | | | |
| 5.3 Start Time: | 24 hrs. clock | | | | |
| 5.4 Observation of Results: | C Positive with one band (Control and test) C Negative with two band (Control and test) C Invalid with No band | | | | |
| | C Invalid with one band (Test) | | | | |
| | | | | | |
| 5.5 Positive for: | Phencyclidine(PCP) Cotinine(COT) Methadone(MTD) | | | | |
| | Other | | | | |
| 5.6 If other then specify: | | | | | |
| 6. URINE SCAN FOR DRUGS ABUSE ADDITIONAL (2nd REPEAT) | | | | | |
| | | | | | |
| 6.1 Urine drug scan tested for: | Phencyclidine(PCP) Cotinine(COT) Methadone(MTD) | | | | |
| | ☐ Other | | | | |
| 6.2 If other then specify: | | | | | |
| 6.3 Start Time: | 24 hrs. clock | | | | |
| 6.4 Observation of Results: | C Positive with one band (Control and test) C Negative with two band (Control and test) C Invalid with No band | | | | |
| | C Invalid with one band (Test) | | | | |

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

Subject No: 1026



Project No: 0326-17 Subject Initials: KSM

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

CASE REPORT FORM

Project No: 0326-17



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

CASE REPORT FORM

Project No: 0326-17



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

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| Complaints of any illness: | © No C Yes |
|--|---|
| If YES, provide details: | - |
| General Physical examination: | • Normal C Abnormal |
| Oral Body Temperature: | 98.6 °F |
| Blood Pressure (Systolic): | 122 mmHg |
| Blood Pressure (Diastolic): | 80 mmHg |
| Radial Pulse Rate: | 84 beats/min |
| Cardiovascular System Examination: | € Normal € 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 C Unwell |
| If 'Abnormal' in any of the above-mentioned sections, please enter details.: | - |
| Remark if Any: | - |
| Subject is fit: | € Yes C No |
| | |
| DINNER CHECK-IN (DAY-1) | Period: 1 |
| DINNER CHECK-IN (DAY-1) Date of meal distribution: | Period: 1 25-Nov-2017 |
| | |
| Date of meal distribution: | 25-Nov-2017 |
| Date of meal distribution: Start Time: | 25-Nov-2017 20:24 24 hrs. clock |
| Date of meal distribution: Start Time: End Time: | 25-Nov-2017 20:24 24 hrs. clock 20:40 24 hrs. clock |
| Date of meal distribution: Start Time: End Time: Has subject consumed meal completely?: | 25-Nov-2017 20:24 24 hrs. clock 20:40 24 hrs. clock • Yes • No |
| Date of meal distribution: Start Time: End Time: Has subject consumed meal completely?: Details of meal left (Approximate Quantity): | 25-Nov-2017 20:24 24 hrs. clock 20:40 24 hrs. clock • Yes • No |
| Date of meal distribution: Start Time: End Time: Has subject consumed meal completely?: Details of meal left (Approximate Quantity): Remarks: | 25-Nov-2017 20:24 24 hrs. clock 20:40 24 hrs. clock • Yes • No od - 1) |
| Date of meal distribution: Start Time: End Time: Has subject consumed meal completely?: Details of meal left (Approximate Quantity): Remarks: HOUSING DETAILS(Period | 25-Nov-2017 20:24 24 hrs. clock 20:40 24 hrs. clock • Yes • No od - 1) |
| Date of meal distribution: Start Time: End Time: Has subject consumed meal completely?: Details of meal left (Approximate Quantity): Remarks: HOUSING DETAILS(Period 0.00 HRS PRE DOSE VITAL SIGNS AND WELL-BEING RECORD | 25-Nov-2017 20:24 24 hrs. clock 20:40 24 hrs. clock • Yes • No Dd - 1) Period: |
| Date of meal distribution: Start Time: End Time: Has subject consumed meal completely?: Details of meal left (Approximate Quantity): Remarks: HOUSING DETAILS(Periodon On the Property of the Property | 25-Nov-2017 20:24 24 hrs. clock 20:40 24 hrs. clock • Yes • No od - 1) Period: 3 |
| Date of meal distribution: Start Time: End Time: Has subject consumed meal completely?: Details of meal left (Approximate Quantity): Remarks: HOUSING DETAILS(Period O.00 HRS PRE DOSE VITAL SIGNS AND WELL-BEING RECORD Position: Date of vital measurement: | 25-Nov-2017 20:24 24 hrs. clock 20:40 24 hrs. clock • Yes • No Sitting 26-Nov-2017 |
| Date of meal distribution: Start Time: End Time: Has subject consumed meal completely?: Details of meal left (Approximate Quantity): Remarks: HOUSING DETAILS(Period O.00 HRS PRE DOSE VITAL SIGNS AND WELL-BEING RECORD Position: Date of vital measurement: Start Time of vital measurement: | 25-Nov-2017 20:24 24 hrs. clock 20:40 24 hrs. clock • Yes • No od - 1) Period: Sitting 26-Nov-2017 07:04 24 hrs. clock |
| Date of meal distribution: Start Time: End Time: Has subject consumed meal completely?: Details of meal left (Approximate Quantity): Remarks: HOUSING DETAILS(Period O.00 HRS PRE DOSE VITAL SIGNS AND WELL-BEING RECORD Position: Date of vital measurement: Start Time of vital measurement: Systolic Blood Pressure: | 25-Nov-2017 20:24 24 hrs. clock 20:40 24 hrs. clock • Yes • No od - 1) Period: Sitting 26-Nov-2017 07:04 24 hrs. clock 116 mmHg 76 mmHg 84 beats/min |
| Date of meal distribution: Start Time: End Time: Has subject consumed meal completely?: Details of meal left (Approximate Quantity): Remarks: HOUSING DETAILS(Period O.00 HRS PRE DOSE VITAL SIGNS AND WELL-BEING RECORD Position: Date of vital measurement: Start Time of vital measurement: Systolic Blood Pressure: Diastolic Blood Pressure: | 25-Nov-2017 20:24 24 hrs. clock 20:40 24 hrs. clock • Yes • No od - 1) Period: 1 Sitting 26-Nov-2017 07:04 24 hrs. clock 116 mmHg 76 mmHg |
| Date of meal distribution: Start Time: End Time: Has subject consumed meal completely?: Details of meal left (Approximate Quantity): Remarks: HOUSING DETAILS(Periodon On the Present of Management of Manage | 25-Nov-2017 20:24 24 hrs. clock 20:40 24 hrs. clock • Yes • No od - 1) Period: Sitting 26-Nov-2017 07:04 24 hrs. clock 116 mmHg 76 mmHg 84 beats/min |
| Date of meal distribution: Start Time: End Time: Has subject consumed meal completely?: Details of meal left (Approximate Quantity): Remarks: HOUSING DETAILS(Period O.00 HRS PRE DOSE VITAL SIGNS AND WELL-BEING RECORD Position: Date of vital measurement: Start Time of vital measurement: Systolic Blood Pressure: Diastolic Blood Pressure: Radial Pulse: Oral Body Temperature: | 25-Nov-2017 20:24 24 hrs. clock 20:40 24 hrs. clock • Yes • No od - 1) Period: 1 Sitting 26-Nov-2017 07:04 24 hrs. clock 116 mmHg 76 mmHg 84 beats/min 98.0 °F |
| Date of meal distribution: Start Time: End Time: Has subject consumed meal completely?: Details of meal left (Approximate Quantity): Remarks: HOUSING DETAILS(Period O.00 HRS PRE DOSE VITAL SIGNS AND WELL-BEING RECORD Position: Date of vital measurement: Start Time of vital measurement: Systolic Blood Pressure: Diastolic Blood Pressure: Radial Pulse: Oral Body Temperature: Well-being: | 25-Nov-2017 20:24 24 hrs. clock 20:40 24 hrs. clock • Yes • No od - 1) Period: 1 Sitting 26-Nov-2017 07:04 24 hrs. clock 116 mmHg 76 mmHg 84 beats/min 98.0 °F • Well • Unwell |
| Date of meal distribution: Start Time: End Time: Has subject consumed meal completely?: Details of meal left (Approximate Quantity): Remarks: HOUSING DETAILS(Period O.00 HRS PRE DOSE VITAL SIGNS AND WELL-BEING RECORD Position: Date of vital measurement: Start Time of vital measurement: Systolic Blood Pressure: Diastolic Blood Pressure: Radial Pulse: Oral Body Temperature: Well-being: If unwell then specify: | 25-Nov-2017 20:24 24 hrs. clock 20:40 24 hrs. clock Yes C No od - 1) Period: 1 Sitting 26-Nov-2017 07:04 24 hrs. clock 116 mmHg 76 mmHg 84 beats/min 98.0 °F • Well C Unwell - |

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

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Sponsor Name:Cipla Limited

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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 | Perio |
| Date and Time of Dosing: | 26-Nov-2017 08:24 |
| Date of sample collection: | 26-Nov-2017 |
| Scheduled date and Time of sample collection (for post dose only): | 26-Nov-2017 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 | Perio |
| 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 C Unwell |
| If unwell then specify: | - |
| Remarks: | - |
| 1.333 HRS POST DOSE PK SAMPLE COLLECTION | Perio |
| Date and Time of Dosing: | 26-Nov-2017 08:24 |
| Date of sample collection: | 26-Nov-2017 |
| Scheduled date and Time of sample collection (for post dose only): | 26-Nov-2017 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 | Perio |
| Date and Time of Dosing: | 26-Nov-2017 08:24 |
| Date of sample collection: | 26-Nov-2017 |
| Scheduled date and Time of sample collection (for post dose only): | 26-Nov-2017 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 | Perio |
| | |

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| 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: |
| 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: | 10000000 |
| 2.667 HRS POST DOSE PK SAMPLE COLLECTION | Period: |
| Date and Time of Dosing: | 26-Nov-2017 08:24 |
| Date of sample collection: | 26-Nov-2017 08.24 26-Nov-2017 |
| Scheduled date and Time of sample collection (for post dose only): | 26-Nov-2017 26-Nov-2017 11:04 |
| Actual Time of sample collection: | 11:04 24 hrs. clock |
| Remarks: | 11:04 24 Hrs. Clock |
| | PK17863423 |
| PK Sample ID: Remarks if any other reason: | FK1/803423 |
| * | |
| 3.000 HRS POST DOSE PK SAMPLE COLLECTION | Period: |
| Date and Time of Dosing: | 26-Nov-2017 08:24 |
| Date of sample collection: | 26-Nov-2017 |
| Scheduled date and Time of sample collection (for post dose only): | 26-Nov-2017 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: |
| 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: |
| 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 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 | |
| End Time. | *** * * * * | |
| Has subject consumed meal completely?: | © Yes C No | |
| | • Yes C No | |
| Has subject consumed meal completely?: | | |
| Has subject consumed meal completely?: Details of meal left (Approximate Quantity): | - | Period: 1 |
| Has subject consumed meal completely?: Details of meal left (Approximate Quantity): Remarks: | - | Period: 1 |
| Has subject consumed meal completely?: Details of meal left (Approximate Quantity): Remarks: 4.500 HRS POST DOSE PK SAMPLE COLLECTION | - | Period: 1 |
| Has subject consumed meal completely?: Details of meal left (Approximate Quantity): Remarks: 4.500 HRS POST DOSE PK SAMPLE COLLECTION Date and Time of Dosing: | - - 26-Nov-2017 08:24 | Period: 1 |
| Has subject consumed meal completely?: Details of meal left (Approximate Quantity): Remarks: 4.500 HRS POST DOSE PK SAMPLE COLLECTION Date and Time of Dosing: Date of sample collection: | - - 26-Nov-2017 08:24 26-Nov-2017 | Period: 1 |
| Has subject consumed meal completely?: Details of meal left (Approximate Quantity): Remarks: 4.500 HRS POST DOSE PK SAMPLE COLLECTION Date and Time of Dosing: Date of sample collection: Scheduled date and Time of sample collection (for post dose only): | - 26-Nov-2017 08:24 26-Nov-2017 26-Nov-2017 12:54 | Period: 1 |
| Has subject consumed meal completely?: Details of meal left (Approximate Quantity): Remarks: 4.500 HRS POST DOSE PK SAMPLE COLLECTION Date and Time of Dosing: Date of sample collection: Scheduled date and Time of sample collection (for post dose only): Actual Time of sample collection: | - 26-Nov-2017 08:24 26-Nov-2017 26-Nov-2017 12:54 | Period: 1 |
| Has subject consumed meal completely?: Details of meal left (Approximate Quantity): Remarks: 4.500 HRS POST DOSE PK SAMPLE COLLECTION Date and Time of Dosing: Date of sample collection: Scheduled date and Time of sample collection (for post dose only): Actual Time of sample collection: Remarks: | - 26-Nov-2017 08:24 26-Nov-2017 26-Nov-2017 12:54 12:54 24 hrs. clock | Period: 1 |
| Has subject consumed meal completely?: Details of meal left (Approximate Quantity): Remarks: 4.500 HRS POST DOSE PK SAMPLE COLLECTION Date and Time of Dosing: Date of sample collection: Scheduled date and Time of sample collection (for post dose only): Actual Time of sample collection: Remarks: PK Sample ID: Remarks if any other reason: | - 26-Nov-2017 08:24 26-Nov-2017 26-Nov-2017 12:54 12:54 24 hrs. clock | |
| Has subject consumed meal completely?: Details of meal left (Approximate Quantity): Remarks: 4.500 HRS POST DOSE PK SAMPLE COLLECTION Date and Time of Dosing: Date of sample collection: Scheduled date and Time of sample collection (for post dose only): Actual Time of sample collection: Remarks: PK Sample ID: Remarks if any other reason: 5.000 HRS POST DOSE PK SAMPLE COLLECTION | - 26-Nov-2017 08:24 26-Nov-2017 26-Nov-2017 12:54 12:54 24 hrs. clock | Period: 1 |
| Has subject consumed meal completely?: Details of meal left (Approximate Quantity): Remarks: 4.500 HRS POST DOSE PK SAMPLE COLLECTION Date and Time of Dosing: Date of sample collection: Scheduled date and Time of sample collection (for post dose only): Actual Time of sample collection: Remarks: PK Sample ID: Remarks if any other reason: 5.000 HRS POST DOSE PK SAMPLE COLLECTION Date and Time of Dosing: | - 26-Nov-2017 08:24 26-Nov-2017 26-Nov-2017 12:54 12:54 24 hrs. clock PK17863782 | |
| Has subject consumed meal completely?: Details of meal left (Approximate Quantity): Remarks: 4.500 HRS POST DOSE PK SAMPLE COLLECTION Date and Time of Dosing: Date of sample collection: Scheduled date and Time of sample collection (for post dose only): Actual Time of sample collection: Remarks: PK Sample ID: Remarks if any other reason: 5.000 HRS POST DOSE PK SAMPLE COLLECTION Date and Time of Dosing: Date of sample collection: | - 26-Nov-2017 08:24 26-Nov-2017 26-Nov-2017 12:54 12:54 24 hrs. clock PK17863782 26-Nov-2017 08:24 | |
| Has subject consumed meal completely?: Details of meal left (Approximate Quantity): Remarks: 4.500 HRS POST DOSE PK SAMPLE COLLECTION Date and Time of Dosing: Date of sample collection: Scheduled date and Time of sample collection (for post dose only): Actual Time of sample collection: Remarks: PK Sample ID: Remarks if any other reason: 5.000 HRS POST DOSE PK SAMPLE COLLECTION Date and Time of Dosing: | | |
| Has subject consumed meal completely?: Details of meal left (Approximate Quantity): Remarks: 4.500 HRS POST DOSE PK SAMPLE COLLECTION Date and Time of Dosing: Date of sample collection: Scheduled date and Time of sample collection (for post dose only): Actual Time of sample collection: Remarks: PK Sample ID: Remarks if any other reason: 5.000 HRS POST DOSE PK SAMPLE COLLECTION Date and Time of Dosing: Date of sample collection: Scheduled date and Time of sample collection (for post dose only): | - 26-Nov-2017 08:24 26-Nov-2017 26-Nov-2017 12:54 12:54 24 hrs. clock PK17863782 26-Nov-2017 08:24 26-Nov-2017 26-Nov-2017 13:24 | |
| Has subject consumed meal completely?: Details of meal left (Approximate Quantity): Remarks: 4.500 HRS POST DOSE PK SAMPLE COLLECTION Date and Time of Dosing: Date of sample collection: Scheduled date and Time of sample collection (for post dose only): Actual Time of sample collection: Remarks: PK Sample ID: Remarks if any other reason: 5.000 HRS POST DOSE PK SAMPLE COLLECTION Date and Time of Dosing: Date of sample collection: Scheduled date and Time of sample collection (for post dose only): Actual Time of sample collection: | - 26-Nov-2017 08:24 26-Nov-2017 26-Nov-2017 12:54 12:54 24 hrs. clock PK17863782 26-Nov-2017 08:24 26-Nov-2017 26-Nov-2017 13:24 | |

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| Date of Time of Dosing: 26-Nov-2017 08:24 | Remarks if any other reason: | | |
|--|--|----------------------------|-----------|
| Date of sample collection: Scheduled date and Time of sample collection (for post dose only): Scheduled date and Time of sample collection: Remarks: | 5.500 HRS POST DOSE PK SAMPLE COLLECTION | | Period: 1 |
| Scheduled date and Time of sample collection: 26-Nov-2017 13:54 Actual Time of sample collection: 13:54 24 hrs. clock Remarks: PK Sample ID: PK Sample ID: PK17863926 Remarks if any other reason: PK17863926 6000 HRS POST DOSE PK SAMPLE COLLECTION Period: Date of ample collection: 26-Nov-2017 08:24 Date of Sample collection: 26-Nov-2017 14:24 Actual Time of sample collection: 14:24 24 hrs. clock Remarks: PK Sample ID: PK17863998 Remarks: Position: Sitting Date of vital measurement: 26-Nov-2017 Start Time of vital measurement: 26-Nov-2017 Start Time of vital measurement: 13:50 24 hrs. clock Systolic Blood Pressure: 110 mmHg Disatolic Blood Pressure: 70 mmHg Radial Pulse: 68 beats/min Well-being: G Well C Unwell If unwell then specify: - Remarks: - 8000 HRS POST DOSE PK SAMPLE COLLECTION Period: < | Date and Time of Dosing: | 26-Nov-2017 08:24 | |
| Actual Time of sample collection: Remarks: PK Sample ID: Remarks if any other reason: | Date of sample collection: | 26-Nov-2017 | |
| Remarks: PK Sample ID: PK17863926 PK Sample ID: PK17863926 Remarks if any other reason: Period. 6000 HRS POST DOSE PK SAMPLE COLLECTION Period. Date of sample collection: 26-Nov-2017 08:24 Scheduled date and Time of sample collection (for post dose only): 26-Nov-2017 14:24 Actual Time of sample collection: 14:24 24 1hrs. clock Remarks: PK Sample ID: PK17863998 Remarks if any other reason: Period. 600 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD Period. Position: Sitting Date of vital measurement: 26-Nov-2017 Start Time of vital measurement: 13:50 24 hrs. clock Systolic Blood Pressure: 110 mmHg Diastolic Blood Pressure: 101 mmHg Diastolic Blood Pressure: 68 beats/min Well-being: 6 Well C Unwell If unwell then specify: - Remarks: - 8000 HRS POST DOSE PK SAMPLE COLLECTION Period: Date of sample collection: 26-Nov-2017 86:24 Actual Time of Sample collection: | Scheduled date and Time of sample collection (for post dose only): | 26-Nov-2017 13:54 | |
| PK Sample ID: Remarks if any other reason: | Actual Time of sample collection: | 13:54 24 hrs. clock | |
| Remarks if any other reason: | Remarks: | | |
| Date and Time of Dosing: 26-Nov-2017 08:24 Date of Sample collection: 26-Nov-2017 08:24 Date of Sample collection: 26-Nov-2017 Actual Time of sample collection: 14:24 | PK Sample ID: | PK17863926 | |
| 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: | Remarks if any other reason: | | |
| 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: | 6.000 HRS POST DOSE PK SAMPLE COLLECTION | | Period: |
| 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 17863998 PK Sample ID: PK17863998 Remarks if any other reason: Period: 6.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD Period: Position: Sitting Date of vital measurement: 26-Nov-2017 Start Time of vital measurement: 13:50 24 hrs. clock Systolic Blood Pressure: 110 mmHg Diastolic Blood Pressure: 70 mmHg Radial Pulse: 68 beats/min Well-being: G Well C Unwell If unwell then specify: - Remarks: - 8000 HRS POST DOSE PK SAMPLE COLLECTION Period: Date and Time of Dosing: 26-Nov-2017 08:24 Date of sample collection: 26-Nov-2017 16:24 Actual Time of Sample collection: 16:24 24 hrs. clock Remarks: PK 17864070 Remarks: PK 26-Nov-2017 Start Time: 16:25 24 hrs. clock End Time: 16:25 24 hrs. clock End Tim | Date and Time of Dosing: | 26-Nov-2017 08:24 | |
| Actual Time of sample collection: Remarks: PK Sample ID: Remarks if any other reason: 600 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD 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: 6 Well C Unwell If unwell then specify: Remarks: - 8.000 HRS POST DOSE PK SAMPLE COLLECTION Period: 26-Nov-2017 08:24 Date of sample collection: Scheduled date and Time of sample collection (for post dose only): 26-Nov-2017 16:24 Actual Time of sample collection: Remarks: PK Sample ID: Remarks if any other reason: SNACKS (DAY 1) Period: Date of meal distribution: \$26-Nov-2017 Start Time: 16:25 24 hrs. clock Has subject consumed meal completely?: 6 Yes C No Details of meal left (Approximate Quantity): Remarks: - - - - - - - - - - - - - | Date of sample collection: | 26-Nov-2017 | |
| Remarks: PK Sample ID: PK17863998 Remarks if any other reason: Period: 6.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD Period: Position: Sitting Date of vital measurement: 26-Nov-2017 Start Time of vital measurement: 13:50 24 hrs. clock Systolic Blood Pressure: 110 mmHg Diastolic Blood Pressure: 70 mmHg Radial Pulse: 68 beats/min Well-being: 6 Well C Unwell If unwell then specify: | Scheduled date and Time of sample collection (for post dose only): | 26-Nov-2017 14:24 | |
| PK Sample ID: PK17863998 Remarks if any other reason: 6.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD Period: Position: Sitting Date of vital measurement: 26-Nov-2017 Start Time of vital measurement: 13:50 24 hrs. clock Systolic Blood Pressure: 110 mmHg Diastolic Blood Pressure: 7 mmHg Radial Pulse: 68 beats/min Well-being: Ge Well C Unwell If unwell then specify: - Remarks: - Body In unwell then specify: - - Remarks: - Body In unwell then specify: - - Remarks: - - Date and Time of Dosing: 26-Nov-2017 08:24 - Date of Sample collection: 16:24 24 hrs. clock - Remarks: <td>Actual Time of sample collection:</td> <td>14:24 24 hrs. clock</td> <td></td> | Actual Time of sample collection: | 14:24 24 hrs. clock | |
| Remarks if any other reason: Period: Objection: 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: 6 Well C Unwell If unwell then specify: - Remarks: - 8000 HRS POST DOSE PK SAMPLE COLLECTION Period: 8004 HRS POST DOSE PK SAMPLE COLLECTION 26-Nov-2017 08:24 Date and Time of Dosing: 26-Nov-2017 Scheduled date and Time of sample collection (for post dose only): 26-Nov-2017 Scheduled date and Time of sample collection: 16:24 24 hrs. clock Remarks: PK Sample ID: Remarks if any other reason: PK17864070 SNACKS (DAY I) Period: 26-Nov-2017 Start Time: 16:25 24 hrs. clock End Time: 16:33 24 hrs. clock Has subject consumed meal completely?: 6 Yes C No | Remarks: | | |
| Period: Position: Sitting | PK Sample ID: | PK17863998 | |
| 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: 6 Well C Unwell If unwell then specify: - | Remarks if any other reason: | | |
| 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 C Unwell If unwell then specify: - Remarks: - 8.000 HRS POST DOSE PK SAMPLE COLLECTION Period: 8.000 HRS POST DOSE PK SAMPLE COLLECTION Period: 9 Actual Time of Dosing: 26-Nov-2017 08:24 9 Date and Time of sample collection: 26-Nov-2017 9 Scheduled date and Time of sample collection (for post dose only): 26-Nov-2017 9 Scheduled date and Time of sample collection: 16:24 24 hrs. clock 1 Remarks: PK Sample ID: 9 PK 17864070 Period: 28 NOCKS (DAY 1) Period: 29 Nov-2017 Period: 20 Actual Time: 16:25 24 hrs. clock End Time: 16:25 24 hrs. clock End Time: 16:33 24 hrs. clock Has subject consumed meal completely?: Fys. C No Details of meal left (Appro | 6.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD | | Period: 1 |
| 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: 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: PK17864070 Remarks if any other reason: PK17864070 Snacks (DAY I) Period: Date of meal distribution: 26-Nov-2017 Start Time: 16:25 24 hrs. clock End Time: 16:25 24 hrs. clock Has subject consumed meal completely?: © Yes C No Details of meal left (Approximate Quantity): - Remarks: - | Position: | Sitting | |
| Systolic Blood Pressure: Diastolic Blood Pressure: 70 mmHg Radial Pulse: 68 beats/min Well-being: G Well C Unwell If unwell then specify: Remarks: | Date of vital measurement: | 26-Nov-2017 | |
| Diastolic Blood Pressure: Radial Pulse: 68 beats/min Well-being: G Well C Unwell If unwell then specify: Remarks: | Start Time of vital measurement: | 13:50 24 hrs. clock | |
| Radial Pulse: 68 beats/min Well-being: (F Well C Unwell If unwell then specify: Remarks: - 8000 HRS POST DOSE PK SAMPLE COLLECTION 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 Scheduled fare and Time of sample collection: 16:24 24 hrs. clock Remarks: PK Sample ID: PK17864070 Remarks if any other reason: SNACKS (DAY 1) Period: SNACKS (DAY 1) Period: Start Time: 16:25 24 hrs. clock End Time: 16:33 24 hrs. clock Has subject consumed meal completely?: GYes C No Details of meal left (Approximate Quantity): Remarks: - - - - - - - - - - - - - | Systolic Blood Pressure: | 110 mmHg | |
| Well-being: If unwell then specify: Remarks: - 8.000 HRS POST DOSE PK SAMPLE COLLECTION 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: Remarks if any other reason: SNACKS (DAY 1) Date of meal distribution: 26-Nov-2017 Start Time: 16:25 24 hrs. clock Has subject consumed meal completely?: CYES CNO Details of meal left (Approximate Quantity): Remarks: - Converted: Conve | Diastolic Blood Pressure: | 70 mmHg | |
| If unwell then specify: Remarks: - 8.000 HRS POST DOSE PK SAMPLE COLLECTION Date and Time of Dosing: 26-Nov-2017 Scheduled date and Time of sample collection: 26-Nov-2017 Scheduled date and Time of sample collection (for post dose only): 26-Nov-2017 Scheduled date and Time of sample collection: 16:24 24 hrs. clock Remarks: PK Sample ID: Remarks if any other reason: SNACKS (DAY 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?: Green Yes C No Details of meal left (Approximate Quantity): Remarks: - | Radial Pulse: | 68 beats/min | |
| Remarks: 8.000 HRS POST DOSE PK SAMPLE COLLECTION 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: Remarks if any other reason: SNACKS (DAY 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?: GYES C No Details of meal left (Approximate Quantity): Remarks: | Well-being: | € Well C Unwell | |
| 8.000 HRS POST DOSE PK SAMPLE COLLECTION 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: Remarks if any other reason: SNACKS (DAY 1) Date of meal distribution: 26-Nov-2017 Start Time: 16:25 24 hrs. clock Has subject consumed meal completely?: 6 Yes C No Details of meal left (Approximate Quantity): Remarks: | If unwell then specify: | - | |
| Date and Time of Dosing: Date of sample collection: Scheduled date and Time of sample collection (for post dose only): Actual Time of sample collection: 16:24 24 hrs. clock Remarks: PK Sample ID: Remarks if any other reason: SNACKS (DAY 1) Date of meal distribution: Start Time: 16:25 24 hrs. clock End Time: 16:25 24 hrs. clock End Time: 16:25 24 hrs. clock CYes C No Details of meal left (Approximate Quantity): Remarks: | Remarks: | - | |
| Date of sample collection: 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) 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 C No Details of meal left (Approximate Quantity): Remarks: | 8.000 HRS POST DOSE PK SAMPLE COLLECTION | | Period: 1 |
| Scheduled date and Time of sample collection (for post dose only): Actual Time of sample collection: 16:24 24 hrs. clock Remarks: PK Sample ID: Remarks if any other reason: SNACKS (DAY 1) Date of meal distribution: Start Time: 16:25 24 hrs. clock End Time: 16:33 24 hrs. clock Has subject consumed meal completely?: Period: Fyes C No Details of meal left (Approximate Quantity): Remarks: - | Date and Time of Dosing: | 26-Nov-2017 08:24 | |
| Actual Time of sample collection: Remarks: PK Sample ID: Remarks if any other reason: SNACKS (DAY 1) Date of meal distribution: Start Time: 16:25 24 hrs. clock End Time: 16:33 24 hrs. clock Has subject consumed meal completely?: Period: The collection of the collection | Date of sample collection: | 26-Nov-2017 | |
| Remarks: PK Sample ID: Remarks if any other reason: SNACKS (DAY 1) Date of meal distribution: Start Time: 16:25 24 hrs. clock End Time: 16:33 24 hrs. clock Has subject consumed meal completely?: Period: Fyes © No Details of meal left (Approximate Quantity): Remarks: - | Scheduled date and Time of sample collection (for post dose only): | 26-Nov-2017 16:24 | |
| PK Sample ID: Remarks if any other reason: SNACKS (DAY 1) Date of meal distribution: Start Time: End Time: 16:25 24 hrs. clock End Time: 16:33 24 hrs. clock Has subject consumed meal completely?: Period: 6 Yes 6 No Details of meal left (Approximate Quantity): Remarks: - | Actual Time of sample collection: | 16:24 24 hrs. clock | |
| Remarks if any other reason: SNACKS (DAY 1) Date of meal distribution: Start Time: 16:25 24 hrs. clock End Time: 16:33 24 hrs. clock Has subject consumed meal completely?: For Yes O No Details of meal left (Approximate Quantity): Remarks: - | Remarks: | | |
| SNACKS (DAY 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: - | PK Sample ID: | PK17864070 | |
| Date of meal distribution: Start Time: 16:25 24 hrs. clock End Time: 16:33 24 hrs. clock Has subject consumed meal completely?: Petails of meal left (Approximate Quantity): Remarks: - | Remarks if any other reason: | | |
| Start Time: 16:25 24 hrs. clock End Time: 16:33 24 hrs. clock Has subject consumed meal completely?: | SNACKS (DAY 1) | | Period: |
| End Time: 16:33 24 hrs. clock Has subject consumed meal completely?: | Date of meal distribution: | 26-Nov-2017 | |
| Has subject consumed meal completely?: Details of meal left (Approximate Quantity): Remarks: - | Start Time: | 16:25 24 hrs. clock | |
| Details of meal left (Approximate Quantity): Remarks: - | End Time: | 16:33 24 hrs. clock | |
| Remarks: - | Has subject consumed meal completely?: | © Yes C No | |
| · · | Details of meal left (Approximate Quantity): | - | |
| 10.000 HRS POST DOSE PK SAMPLE COLLECTION Period: | Remarks: | - | |
| | 10.000 HRS POST DOSE PK SAMPLE COLLECTION | | Period: 1 |

^{*}This is an electronically authenticated report.

Sponsor Name:Cipla Limited

CASE REPORT FORM

Project No: 0326-17



| Date and Time of Dosing: | 26-Nov-2017 08:24 |
|--|---|
| Date of sample collection: | 26-Nov-2017 06.24 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: | 10.24 24 Hrs. clock |
| PK Sample ID: | PK17864142 |
| Remarks if any other reason: | 1 K1/004142 |
| 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: | 20120 21 111 30 010011 |
| 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 C No |
| Details of meal left (Approximate Quantity): | - |
| | |
| Remarks: | - |
| Remarks: 12.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD | - Period: 1 |
| | |
| 12.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD | Period: 1 |
| 12.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD Position: | Period: 1 |
| 12.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD Position: Date of vital measurement: | Period: 1 Sitting 26-Nov-2017 |
| 12.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD Position: Date of vital measurement: Start Time of vital measurement: | Period: 1 Sitting 26-Nov-2017 19:45 24 hrs. clock |
| 12.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD Position: Date of vital measurement: Start Time of vital measurement: Systolic Blood Pressure: | Period: 1 Sitting 26-Nov-2017 19:45 24 hrs. clock 108 mmHg |
| 12.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD Position: Date of vital measurement: Start Time of vital measurement: Systolic Blood Pressure: Diastolic Blood Pressure: | Period: 1 Sitting 26-Nov-2017 19:45 24 hrs. clock 108 mmHg 68 mmHg |
| 12.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD Position: Date of vital measurement: Start Time of vital measurement: Systolic Blood Pressure: Diastolic Blood Pressure: Radial Pulse: | Period: 1 Sitting 26-Nov-2017 19:45 24 hrs. clock 108 mmHg 68 mmHg 72 beats/min |
| 12.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD Position: Date of vital measurement: Start Time of vital measurement: Systolic Blood Pressure: Diastolic Blood Pressure: Radial Pulse: Well-being: | Period: 1 Sitting 26-Nov-2017 19:45 24 hrs. clock 108 mmHg 68 mmHg 72 beats/min |
| 12.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD Position: Date of vital measurement: Start Time of vital measurement: Systolic Blood Pressure: Diastolic Blood Pressure: Radial Pulse: Well-being: If unwell then specify: | Period: 1 Sitting 26-Nov-2017 19:45 24 hrs. clock 108 mmHg 68 mmHg 72 beats/min |
| 12.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD Position: Date of vital measurement: Start Time of vital measurement: Systolic Blood Pressure: Diastolic Blood Pressure: Radial Pulse: Well-being: If unwell then specify: Remarks: | Period: 1 Sitting 26-Nov-2017 19:45 24 hrs. clock 108 mmHg 68 mmHg 72 beats/min • Well • Unwell - |
| 12.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD Position: Date of vital measurement: Start Time of vital measurement: Systolic Blood Pressure: Diastolic Blood Pressure: Radial Pulse: Well-being: If unwell then specify: Remarks: 16.000 HRS POST DOSE PK SAMPLE COLLECTION | Period: 1 Sitting 26-Nov-2017 19:45 24 hrs. clock 108 mmHg 68 mmHg 72 beats/min © Well © Unwell Period: 1 |
| 12.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD Position: Date of vital measurement: Start Time of vital measurement: Systolic Blood Pressure: Diastolic Blood Pressure: Radial Pulse: Well-being: If unwell then specify: Remarks: 16.000 HRS POST DOSE PK SAMPLE COLLECTION Date and Time of Dosing: | Period: 1 Sitting 26-Nov-2017 19:45 24 hrs. clock 108 mmHg 68 mmHg 72 beats/min © Well © Unwell Period: 1 26-Nov-2017 08:24 |
| 12.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD Position: Date of vital measurement: Start Time of vital measurement: Systolic Blood Pressure: Diastolic Blood Pressure: Radial Pulse: Well-being: If unwell then specify: Remarks: 16.000 HRS POST DOSE PK SAMPLE COLLECTION Date and Time of Dosing: Date of sample collection: | Period: 1 Sitting 26-Nov-2017 19:45 24 hrs. clock 108 mmHg 68 mmHg 72 beats/min • Well • Unwell Period: 1 26-Nov-2017 08:24 27-Nov-2017 |
| 12.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD Position: Date of vital measurement: Start Time of vital measurement: Systolic Blood Pressure: Diastolic Blood Pressure: Radial Pulse: Well-being: If unwell then specify: Remarks: 16.000 HRS POST DOSE PK SAMPLE COLLECTION Date and Time of Dosing: Date of sample collection: Scheduled date and Time of sample collection (for post dose only): | Period: 1 Sitting 26-Nov-2017 19:45 24 hrs. clock 108 mmHg 68 mmHg 72 beats/min © Well © Unwell - - Period: 1 26-Nov-2017 08:24 27-Nov-2017 27-Nov-2017 00:24 |
| 12.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD Position: Date of vital measurement: Start Time of vital measurement: Systolic Blood Pressure: Diastolic Blood Pressure: Radial Pulse: Well-being: If unwell then specify: Remarks: 16.000 HRS POST DOSE PK SAMPLE COLLECTION Date and Time of Dosing: Date of sample collection: Scheduled date and Time of sample collection (for post dose only): Actual Time of sample collection: | Period: 1 Sitting 26-Nov-2017 19:45 24 hrs. clock 108 mmHg 68 mmHg 72 beats/min © Well © Unwell - - Period: 1 26-Nov-2017 08:24 27-Nov-2017 27-Nov-2017 00:24 |
| 12.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD Position: Date of vital measurement: Start Time of vital measurement: Systolic Blood Pressure: Diastolic Blood Pressure: Radial Pulse: Well-being: If unwell then specify: Remarks: 16.000 HRS POST DOSE PK SAMPLE COLLECTION Date and Time of Dosing: Date of sample collection: Scheduled date and Time of sample collection (for post dose only): Actual Time of sample collection: Remarks: | Period: 1 Sitting 26-Nov-2017 19:45 24 hrs. clock 108 mmHg 68 mmHg 72 beats/min • Well • Unwell Period: 1 26-Nov-2017 08:24 27-Nov-2017 00:24 00:24 24 hrs. clock |
| 12.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD Position: Date of vital measurement: Start Time of vital measurement: Systolic Blood Pressure: Diastolic Blood Pressure: Radial Pulse: Well-being: If unwell then specify: Remarks: 16.000 HRS POST DOSE PK SAMPLE COLLECTION Date and Time of Dosing: Date of sample collection: Scheduled date and Time of sample collection (for post dose only): Actual Time of sample collection: Remarks: PK Sample ID: | Period: 1 Sitting 26-Nov-2017 19:45 24 hrs. clock 108 mmHg 68 mmHg 72 beats/min • Well • Unwell Period: 1 26-Nov-2017 08:24 27-Nov-2017 00:24 00:24 24 hrs. clock |
| 12.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD Position: Date of vital measurement: Start Time of vital measurement: Systolic Blood Pressure: Diastolic Blood Pressure: Radial Pulse: Well-being: If unwell then specify: Remarks: 16.000 HRS POST DOSE PK SAMPLE COLLECTION Date and Time of Dosing: Date of sample collection: Scheduled date and Time of sample collection (for post dose only): Actual Time of sample collection: Remarks: PK Sample ID: Remarks if any other reason: | Period: 1 Sitting 26-Nov-2017 19:45 24 hrs. clock 108 mmHg 68 mmHg 72 beats/min • Well • Unwell - - Period: 1 26-Nov-2017 08:24 27-Nov-2017 27-Nov-2017 00:24 00:24 24 hrs. clock |

^{*}This is an electronically authenticated report.

CASE REPORT FORM

Project No: 0326-17



| 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 AMBULA | ATORY VISIT) Period: 1 |
| Date: | 27-Nov-2017 |
| Start Time: | 20:05 24 hrs. clock |
| Breath Alcohol Level (BAL): | .000 % |
| Result: | C Positive © Negative |
| Start Time of 1st Repeat: | 24 hrs. clock |
| Breath Alcohol Level (BAL): | 0% |
| 1st Repeat result: | C Positive C Negative |
| Start Time of 2nd Repeat: | 24 hrs. clock |
| Breath Alcohol Level (BAL): | % |
| 2nd Repeat Result: | C Positive C Negative |
| Final Result: | C Positive • Negative |
| For Positive results (if any) Informed to Principal Investigator/Co- | C Yes C No 6 NAP |
| Investigator/designate: | O IS ONO WNAP |
| 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 AMB | BULATORY SAMPLE Period: 1 |
| (DAY 2) | |
| Compliance at the Time of Ambulatory | 25.37 2015 |
| Date of compliance at the time of ambulatory sample: | 27-Nov-2017 |
| Have you consumed any medication (Prescribed or Over the counter medicine 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 appropriate for whetever resear (e.g., lawy so divers) or smoked gives lost visits. | C Yes • No |
| unusual diet, for whatever reason (e.g. low-sodium) or smoked since last visit? Have you donated blood anywhere else or participated in other clinical trial | |
| since last visit?: | C Yes © No |
| If Yes, Remarks: | - |
| Well Being at the Time of Ambulatory | |
| Date of well being: | 27-Nov-2017 |
| | |

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CASE REPORT FORM

Project No: 0326-17



| Start Time of well being: | 20:36 24 hrs. clock |
|---|----------------------------|
| Well-Being at the time of ambulatory sample: | • Well • Unwell |
| Remarks if Unwell: | - |
| Remark if any: | - |
| BREATH TEST FOR ALCOHOL CONSUMPTION (48.000 HRS AMBULA' | TORY VISIT) Period: 1 |
| Date: | 28-Nov-2017 |
| Start Time: | 09:57 24 hrs. clock |
| Breath Alcohol Level (BAL): | .000 % |
| Result: | C Positive © Negative |
| Start Time of 1st Repeat: | 24 hrs. clock |
| Breath Alcohol Level (BAL): | % |
| 1st Repeat result: | C Positive C Negative |
| Start Time of 2nd Repeat: | 24 hrs. clock |
| Breath Alcohol Level (BAL): | % |
| 2nd Repeat Result: | C Positive C Negative |
| Final Result: | C Positive • Negative |
| For Positive results (if any) Informed to Principal Investigator/Co-Investigator/designate: | C Yes C No © 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: | |
| $48.000\mathrm{HRS}$ COMPLIANCE AND WELL BEING AT THE TIME OF AMBU (DAY 3) | JLATORY SAMPLE 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 | C Yes © No |
| containing products (Gutkha, Pan/Pan masala or any other), recreational products, alcohol or alcoholic products, grapefruit or grapefruit products, an unusual diet, for whatever reason (e.g. low-sodium) or smoked since last visit?: | |
| Have you donated blood anywhere else or participated in other clinical trial since last visit?: | C Yes © No |
| If Yes, Remarks: | - |
| Well Being at the Time of Ambulatory | |
| Date of well being: | 28-Nov-2017 |
| | 201.01 2017 |

CASE REPORT FORM

Project No: 0326-17



| 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(Per | iod - 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 C Yes |
| If YES, provide details: | - |
| General Physical examination: | ☞ Normal C Abnormal |
| Oral Body Temperature: | 97.8 °F |
| Radial Pulse Rate: | 76 beats/min |
| Blood Pressure(Systolic): | 112 mmHg |
| Blood Pressure(Diastolic): | 78 mmHg |
| Cardiovascular System Examination: | Normal C Abnormal |
| Respiratory System Examination: | • Normal • Abnormal |
| Central Nervous System Examination: | • Normal C Abnormal |
| Per Abdomen Examination: | ☞ Normal C Abnormal |
| Any other Significant finding: | - |
| Any investigations recommended: | - |
| If 'Abnormal' in any of the above-mentioned sections, please enter details: | - |
| To be performed at the time of check-out | |
| Vein puncture site: | Normal C Abnormal |
| Subject well-being: | • Well C Unwell |
| Comments: | - |
| Subject is fit for Check-out: | • Yes C No |
| Remark If any: | - |
| CHECK-OUT B&B | Period: 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 |
| | C Medical Event C Adverse Event Discontinuation |
| Purpose: | C Safety Assessment C Subject Not reported for scheduled visit C others |
| If Others, Specify: | - |
| | i e e e e e e e e e e e e e e e e e e e |

^{*}This is an electronically authenticated report.

CASE REPORT FORM

Project No: 0326-17



| Date: | | 01-Dec-201 | 7 | |
|---|-------------|---|------------------------------------|---|
| Mode of communication: | | Telephone | | |
| Detail of Discussion: | | | contacted telephone check in day o | onically and info rmed of period II. |
| Remark if any: | | - | | |
| CHECK-IN DETAILS(| Perio | d - 2) | | |
| BREATH TEST FOR ALCOHOL CONSUMPTION | | | | Period: 2 |
| Date: | | 01-Dec-201 | 7 | |
| Start Time: | | 16:39 24 h | rs. clock | |
| Breath Alcohol Level (BAL): | | .000 % | | |
| Result: | | C Positive | Negative | |
| Start Time of 1st Repeat: | | 24 hrs. clo | ock | |
| Breath Alcohol Level (BAL): | | % | | |
| 1st Repeat result: | | C Positive | O Negative | |
| Start Time of 2nd Repeat: | | 24 hrs. clo | ock | |
| Breath Alcohol Level (BAL): | | % | | |
| 2nd Repeat Result: | | C Positive | O Negative | |
| Final Result: | | C Positive | Negative | |
| For Positive results (if any) Informed to Principal Investigator/Co- Investigator/designate: | | O Yes O No | o (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: | ⊙ 7 | Tes C No C | NAP | |
| 1. URINE SCAN FOR DRUGS ABUSE | | | | |
| 1.1 Urine drug scan tested for: | (AM | • | Barbiturates (BAR) | Benzodiazepines (BZD) |
| | (CO | Cocaine (C) | Morphine (MOR) | Cannabinoids (THC) |
| 1.2 Start time: | 16:4 | 45 24 hrs. cl | ock | |
| 1.3 Observation of Results: | one (Con | Positive with band ntrol) nvalid with band (Test) | © Negative wit band (Control a | with No |
| 1.4 Positive for: | (AM | Л Р) | Barbiturates (BAR) | Benzodiazepines (BZD) |
| | (CO | Cocaine (C) | ☐ Morphine (MOR) | Cannabinoids (THC) |

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

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| Lambda Therapeutic Research. | ^ |
|--|--------|
| Sponsor Name:Cipla Limited | |
| CASE REPORT FORM | arjen |
| Project No: 0326-17 | Votomo |
| Subject No: 1026 Subject Initials: KSM | ystems |

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

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

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

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

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CASE REPORT FORM

Project No: 0326-17



| Date of sample collection: | 02-Dec-2017 | |
|---|--|----------------------|
| Scheduled date and Time of sample collection (for post dose only): | 02-Dec-2017 08:39 | |
| Actual Time of sample collection: | 08:39 24 hrs. clock | |
| Remarks: | ooley 21 may elden | |
| PK Sample ID: | PK17879870 | |
| Remarks if any other reason: | 1121,61,50,0 | |
| 0.500 HRS POST DOSE PK SAMPLE COLLECTION | | Period: 2 |
| Date and Time of Dosing: | 02-Dec-2017 08:24 | renou. 2 |
| Date of sample collection: | 02-Dec-2017 02-Dec-2017 | |
| Scheduled date and Time of sample collection (for post dose only): | 02-Dec-2017 02-Dec-2017 08:54 | |
| Actual Time of sample collection: | 08:54 24 hrs. clock | |
| Remarks: | 06.34 24 HTS. CIOCK | |
| PK Sample ID: | PK17879906 | |
| | PK1/8/9900 | |
| Remarks if any other reason: | | |
| 0.750 HRS POST DOSE PK SAMPLE COLLECTION | | Period: 2 |
| Date and Time of Dosing: | 02-Dec-2017 08:24 | |
| Date of sample collection: | 02-Dec-2017 | |
| Scheduled date and Time of sample collection (for post dose only): | 02-Dec-2017 09:09 | |
| Actual Time of sample collection: | 09:09 24 hrs. clock | |
| Remarks: | | |
| PK Sample ID: | PK17879942 | |
| Remarks if any other reason: | | |
| | | |
| 1.000 HRS POST DOSE PK SAMPLE COLLECTION | | Period: 2 |
| • | 02-Dec-2017 08:24 | Period: 2 |
| 1.000 HRS POST DOSE PK SAMPLE COLLECTION | 02-Dec-2017 08:24 02-Dec-2017 | Period: 2 |
| 1.000 HRS POST DOSE PK SAMPLE COLLECTION Date and Time of Dosing: | | Period: 2 |
| 1.000 HRS POST DOSE PK SAMPLE COLLECTION Date and Time of Dosing: Date of sample collection: | 02-Dec-2017 | Period: 2 |
| 1.000 HRS POST DOSE PK SAMPLE COLLECTION Date and Time of Dosing: Date of sample collection: Scheduled date and Time of sample collection (for post dose only): | 02-Dec-2017 02-Dec-2017 09:24 | Period: 2 |
| 1.000 HRS POST DOSE PK SAMPLE COLLECTION Date and Time of Dosing: Date of sample collection: Scheduled date and Time of sample collection (for post dose only): Actual Time of sample collection: | 02-Dec-2017 02-Dec-2017 09:24 | Period: 2 |
| 1.000 HRS POST DOSE PK SAMPLE COLLECTION Date and Time of Dosing: Date of sample collection: Scheduled date and Time of sample collection (for post dose only): Actual Time of sample collection: Remarks: | 02-Dec-2017 02-Dec-2017 09:24 09:24 24 hrs. clock | Period: 2 |
| 1.000 HRS POST DOSE PK SAMPLE COLLECTION Date and Time of Dosing: Date of sample collection: Scheduled date and Time of sample collection (for post dose only): Actual Time of sample collection: Remarks: PK Sample ID: | 02-Dec-2017 02-Dec-2017 09:24 09:24 24 hrs. clock | |
| 1.000 HRS POST DOSE PK SAMPLE COLLECTION Date and Time of Dosing: Date of sample collection: Scheduled date and Time of sample collection (for post dose only): Actual Time of sample collection: Remarks: PK Sample ID: Remarks if any other reason: | 02-Dec-2017 02-Dec-2017 09:24 09:24 24 hrs. clock | |
| 1.000 HRS POST DOSE PK SAMPLE COLLECTION Date and Time of Dosing: Date of sample collection: Scheduled date and Time of sample collection (for post dose only): Actual Time of sample collection: Remarks: PK Sample ID: Remarks if any other reason: 1.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD | 02-Dec-2017 02-Dec-2017 09:24 09:24 24 hrs. clock PK17879978 | |
| 1.000 HRS POST DOSE PK SAMPLE COLLECTION Date and Time of Dosing: Date of sample collection: Scheduled date and Time of sample collection (for post dose only): Actual Time of sample collection: Remarks: PK Sample ID: Remarks if any other reason: 1.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD Position: | 02-Dec-2017 02-Dec-2017 09:24 09:24 24 hrs. clock PK17879978 | |
| 1.000 HRS POST DOSE PK SAMPLE COLLECTION Date and Time of Dosing: Date of sample collection: Scheduled date and Time of sample collection (for post dose only): Actual Time of sample collection: Remarks: PK Sample ID: Remarks if any other reason: 1.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD Position: Date of vital measurement: | 02-Dec-2017 02-Dec-2017 09:24 09:24 24 hrs. clock PK17879978 Sitting 02-Dec-2017 | |
| 1.000 HRS POST DOSE PK SAMPLE COLLECTION Date and Time of Dosing: Date of sample collection: Scheduled date and Time of sample collection (for post dose only): Actual Time of sample collection: Remarks: PK Sample ID: Remarks if any other reason: 1.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD Position: Date of vital measurement: Start Time of vital measurement: | 02-Dec-2017 02-Dec-2017 09:24 09:24 24 hrs. clock PK17879978 Sitting 02-Dec-2017 09:15 24 hrs. clock | |
| 1.000 HRS POST DOSE PK SAMPLE COLLECTION Date and Time of Dosing: Date of sample collection: Scheduled date and Time of sample collection (for post dose only): Actual Time of sample collection: Remarks: PK Sample ID: Remarks if any other reason: 1.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD Position: Date of vital measurement: Start Time of vital measurement: Systolic Blood Pressure: | 02-Dec-2017 02-Dec-2017 09:24 09:24 24 hrs. clock PK17879978 Sitting 02-Dec-2017 09:15 24 hrs. clock 116 mmHg | |
| 1.000 HRS POST DOSE PK SAMPLE COLLECTION Date and Time of Dosing: Date of sample collection: Scheduled date and Time of sample collection (for post dose only): Actual Time of sample collection: Remarks: PK Sample ID: Remarks if any other reason: 1.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD Position: Date of vital measurement: Start Time of vital measurement: Systolic Blood Pressure: Diastolic Blood Pressure: | 02-Dec-2017 02-Dec-2017 09:24 09:24 24 hrs. clock PK17879978 Sitting 02-Dec-2017 09:15 24 hrs. clock 116 mmHg 72 mmHg | |
| 1.000 HRS POST DOSE PK SAMPLE COLLECTION Date and Time of Dosing: Date of sample collection: Scheduled date and Time of sample collection (for post dose only): Actual Time of sample collection: Remarks: PK Sample ID: Remarks if any other reason: 1.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD Position: Date of vital measurement: Start Time of vital measurement: Systolic Blood Pressure: Diastolic Blood Pressure: Radial Pulse: Well-being: | 02-Dec-2017 02-Dec-2017 09:24 09:24 24 hrs. clock PK17879978 Sitting 02-Dec-2017 09:15 24 hrs. clock 116 mmHg 72 mmHg 68 beats/min | |
| 1.000 HRS POST DOSE PK SAMPLE COLLECTION Date and Time of Dosing: Date of sample collection: Scheduled date and Time of sample collection (for post dose only): Actual Time of sample collection: Remarks: PK Sample ID: Remarks if any other reason: 1.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD Position: Date of vital measurement: Start Time of vital measurement: Systolic Blood Pressure: Diastolic Blood Pressure: Radial Pulse: Well-being: If unwell then specify: | 02-Dec-2017 02-Dec-2017 09:24 09:24 24 hrs. clock PK17879978 Sitting 02-Dec-2017 09:15 24 hrs. clock 116 mmHg 72 mmHg 68 beats/min € Well € Unwell | |
| 1.000 HRS POST DOSE PK SAMPLE COLLECTION Date and Time of Dosing: Date of sample collection: Scheduled date and Time of sample collection (for post dose only): Actual Time of sample collection: Remarks: PK Sample ID: Remarks if any other reason: 1.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD Position: Date of vital measurement: Start Time of vital measurement: Systolic Blood Pressure: Diastolic Blood Pressure: Radial Pulse: Well-being: If unwell then specify: Remarks: | 02-Dec-2017 02-Dec-2017 09:24 09:24 24 hrs. clock PK17879978 Sitting 02-Dec-2017 09:15 24 hrs. clock 116 mmHg 72 mmHg 68 beats/min © Well © Unwell | Period: 2 |
| 1.000 HRS POST DOSE PK SAMPLE COLLECTION Date and Time of Dosing: Date of sample collection: Scheduled date and Time of sample collection (for post dose only): Actual Time of sample collection: Remarks: PK Sample ID: Remarks if any other reason: 1.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD Position: Date of vital measurement: Start Time of vital measurement: Systolic Blood Pressure: Diastolic Blood Pressure: Radial Pulse: Well-being: If unwell then specify: Remarks: 1.333 HRS POST DOSE PK SAMPLE COLLECTION | 02-Dec-2017 02-Dec-2017 09:24 09:24 24 hrs. clock PK17879978 Sitting 02-Dec-2017 09:15 24 hrs. clock 116 mmHg 72 mmHg 68 beats/min © Well © Unwell - | Period: 2 |
| 1.000 HRS POST DOSE PK SAMPLE COLLECTION Date and Time of Dosing: Date of sample collection: Scheduled date and Time of sample collection (for post dose only): Actual Time of sample collection: Remarks: PK Sample ID: Remarks if any other reason: 1.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD Position: Date of vital measurement: Start Time of vital measurement: Systolic Blood Pressure: Diastolic Blood Pressure: Radial Pulse: Well-being: If unwell then specify: Remarks: | 02-Dec-2017 02-Dec-2017 09:24 09:24 24 hrs. clock PK17879978 Sitting 02-Dec-2017 09:15 24 hrs. clock 116 mmHg 72 mmHg 68 beats/min © Well © Unwell | Period: 2 Period: 2 |

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Sponsor Name:Cipla Limited

CASE REPORT FORM

Project No: 0326-17



| Actual Time of sample collection: PK17880014 PK17880014 | Scheduled date and Time of sample collection (for post dose only): | 02-Dec-2017 09:44 |
|--|--|---------------------|
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| | Actual Time of sample collection: | 11:24 24 hrs. clock |
| 777.0 | Remarks: | |
| PK Sample ID: PK17880194 | PK Sample ID: | PK17880194 |

^{*}This is an electronically authenticated report.

Sponsor Name:Cipla Limited

CASE REPORT FORM

Project No: 0326-17



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

^{*}This is an electronically authenticated report.

CASE REPORT FORM

Project No: 0326-17



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

^{*}This is an electronically authenticated report.

CASE REPORT FORM

Project No: 0326-17



| CLINICAL EXAMINATION - END OF STUDY | Period: 2 | |
|---|--|--|
| Date of clinical examination: | 05-Dec-2017 | |
| Start time of clinical examination: | 11:49 24 hrs. clock | |
| Complaints of any illness: | € No C Yes | |
| If YES, provide details: | - | |
| General Physical examination: | • Normal C Abnormal | |
| Oral Body Temperature: | 98.0 °F | |
| Systolic Blood Pressure: | 108 mmHg | |
| Diastolic Blood Pressure: | 68 mmHg | |
| Radial Pulse Rate: | 72 beats/min | |
| Cardiovascular System Examination: | • Normal C Abnormal | |
| Respiratory System Examination: | • Normal C Abnormal | |
| Central Nervous System Examination: | © Normal C Abnormal | |
| Per Abdomen Examination: | © Normal C Abnormal | |
| Any other Significant finding: | - | |
| Any investigations recommended: | - | |
| Vein puncture site: | € Normal C Abnormal | |
| Subject well-being: | € Well € Unwell | |
| If 'Abnormal' in any of the above-mentioned sections, please enter the details: | - | |
| Subject is fit: | G Yes C No | |
| Remark If any: | 1- | |
| ECG EXAMINATION-END OF STUDY Period: | | |
| ECG EXAMINATION | | |
| Date Of ECG: | 11-Dec-2017 | |
| Time of ECG: | 11:10 24 hrs. clock | |
| Was ECG Repeated: | C Yes 6 No | |
| If Yes, Date of Repeat ECG: | | |
| ECG Impression: | WNL | |
| | © C Not Clinically C Clinically | |
| Overall Assessment: | Normal Significant Significant | |
| Remark, If any: | - | |
| END STUDY LABORATORY ASSESSMENT AND STUDY COMPLETION | | |
| Note: For Estimation of Hematology, Biochemistry (except random glucose and | d sodium, potassium, chloride). | |
| Post study safety sample collected as per protocol?: | € Yes C No | |
| Date of safety sample collection: | 05-Dec-2017 | |
| Lab report clinically acceptable: | • Yes C No C NAP | |
| Result of serum pregnancy test: | C NAP (For Male Positive Negative subject) | |
| Remarks If Any: | - | |
| *This is an alastocking the authority of a local | Dana 27 af 22 | |

^{*}This is an electronically authenticated report.

CASE REPORT FORM

Project No: 0326-17



| STUDY COMPLETION STATUS | | |
|--|---|--|
| Has the subject completed the study?: | C Yes © No | |
| If "No", please refer: | C Pre dose G Post dose discontinued form | |
| If "Yes", then any protocol or sampling deviation reported for subject?: | C Yes C No | |
| If "Yes", then select appropriate option: | ☐ Protocol deviation ☐ Sampling Deviation | |
| Remarks: | - | |
| ADVERSE EVENT/ MEDICAL EVENT RECORDING | Period: 2 | |
| Is it Adverse Event or Medical Event?: | • Adverse Event C Medical Event | |
| Period: | 02 | |
| Subject No: | 1026 | |
| Subject Initials: | KSM | |
| Date of Birth: | 01-Jan-1980 | |
| Date of onset: | 02-Dec-2017 | |
| Time of Onset: | 11:44 24 hrs. clock | |
| Date of reporting or Obseved on: | 02-Dec-2017 | |
| Time of Reporting or observed at: | 11:45 24 hrs. clock | |
| Date of Recording the AE/ME: | 02-Dec-2017 | |
| Time of recording the AE/ME: | 11:49 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 C Gradual C Unknown | |
| 1.3 Occurrence: | C Continuous C Intermittent © Single Episode | |
| 1.4 Severity: | € Mild C Moderate C Severe | |
| 2.0 Clinical Examination | | |
| 2.1 Temperature: | 98.0 °F | |
| 2.2 Systolic Blood Pressure: | 120 mmHg | |
| 2.3 Diastolic Blood Pressure: | 82 mmHg | |
| 2.4 Pulse Rate: | 68 beats/min | |
| 2.5 General Physical Examination: | Normal | |
| 2.6 Systemic Examination: | Normal | |
| 2.7 Cardiovascular System: | Normal | |
| 2.8 Central Nervous System: | Normal | |
| 2.9 Respiratory System: | Normal | |
| 2.10 Per Abdomen: | Normal | |
| 2.11 If abnormal in any of above, please specify: | - | |
| Has the PI/ Designate been informed?: | Yes | |

^{*}This is an electronically authenticated report.

CASE REPORT FORM

Project No: 0326-17



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

CASE REPORT FORM

Project No: 0326-17



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

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

| ADVERSE EVENT UPDATE FORM | | | 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 | 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 C MODERATE C SEVERE | | | |
| m · · · | ⊙ GRADE 1:MILD AE | C GRADE 2:MODERATE AE | C GRADE 3:SEVERE AE | |
| Toxicity grade: | C GRADE 4:LIFE-THREATENING OR DISABLING AE | C GRADE 5:DEATH RELATED TO AE | C NOT APPLICABLE | |
| Serious?: | C YES © NO | | | |

^{*}This is an electronically authenticated report.

CASE REPORT FORM

Project No: 0326-17



| Is it significant?: | C YES © NO | | | |
|---|---|--|---|------------------------------------|
| If Serious, Seriousness criteria: | CONGENITAL ANOMALY I | SIGNIFICANT DISABILITY | □ DEATH | |
| 11 Serious, Seriousness criteria: | LI HOSPITALIZATION | □ LIFE THREATENING | OTHER MED | |
| Unexpected adverse drug reaction?: | C YES ONO C NAP | | | |
| Relationship to Study Treatment: | C NOT RELATED C UNLIKELY C RELATED C NAP | Y RELATED © PO | SSIBLY RELATED |) |
| Action Taken with Study Treatment: | C DOSE INCREASED C DO C DRUG INTERRUPTED 6 DE C UNKNOWN | OSE NOT CHANG RUG WITHDRAW | | |
| Outcome: | C NOT RECOVERED/NOT G RESOLVED REC | COVERED/RESOLV | C RECOVERED WITH SEQUI | |
| | C RECOVERING/RESOLVING | UNKNOWN | C FATAL | |
| Caused study discontinuation: | € YES C NO | | | |
| Concomitant treatment/Therapy given: | • YES C NO | | | |
| Does given concomitant medication has drug-drug interaction along with study drug?: | C YES © NO C NAP | | | |
| If Yes, then Specify: | - | | | |
| Remarks if, any: | - | | | |
| POST-DOSE SUBJECT DISCONTINUA | TION RECORD | | | Period: 2 |
| SOP reference no: CPMA-17-12 | | | | |
| Status of Discontinuation | | | | |
| Date of Discontinuation: | | 02-Dec-2017 | | |
| Time of last IMP administered: | | 08:24 24 hrs. clock | | |
| Date of last IMP administered: | | 02-Dec-2017 | | |
| Reason for discontinuation | | | | |
| Reasons: | | C On his/her own accord | • On the grounds of Emesis | C On medical grounds |
| reasons. | | C For having withheld critical Information | C On grounds of protocol non-compliance | C Any other (please specify) |
| If any other: | | - | | |
| Description of Event: | | Subject had single roximately 1144 hrs for 01 minute. Von in amount and cont He had no any other | nitus was approximation ained fluid with fo | miting la sted ately 100 ml |

CASE REPORT FORM

Project No: 0326-17



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



Clinical Laboratory Test Report



Lambda Therapeutic Research Limited

05-Dec-2017 11:33

05-Dec-2017 11:47

Screening AH17-06704 Subject Initial: KSM

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

17063193 Lab ID: Sex: Female

Visit :

Sample Collected

Sample Collected At: Sample Received On:

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

0326-17

Ahmedabad

CHEMISTRY

[Performed By Reflectance Photometry]

| <u>PARAMETER</u> | RESULT | CS/NCS* | <u>REMARK</u> | UNIT | REFERENCE INTERVAL |
|--------------------------------------|--------|---------|---------------|-----------------|--------------------|
| BILIRUBIN TOTAL | 0.36 | | | mg/dL | 0.2 - 1.5 |
| Azobilirubin | | | | | |
| TOTAL PROTEIN | 7.83 | | | g/dL | 6.9 - 8.6 |
| Biuret | | | | | |
| ALBUMIN | 4.62 | | | g/dL | 3.9 - 5.2 |
| | 1102 | | | 3, - | 3.3 3.2 |
| BCG | | | | | |
| GLOBULIN | 3.2 | | | g/dL | 2.5 - 3.8 |
| Calculated | | | | | |
| A/G RATIO | 1.44 | | | | 1.2 - 2.2 |
| Calculated | | | | | |
| S.G.O.T. (AST) | 23 | | | U/L | 15.0 - 46.0 |
| | | | | | 20.0 .0.0 |
| UV WITH P-5-P | | | | | |
| S.G.P.T. (ALT) | 28 | | | U/L | 11.0 - 58.0 |
| UV WITH P-5-P | | | | | |
| CREATININE | 0.61 | | | mg/dL | 0.5 - 0.9 |
| Enzymatic (Creatine | | | | | |
| amidohydrolase, IDMS | | | | | |
| traceable) | 17.0 | | | mg/dL | 15.0 26.0 |
| UREA | 17.8 | | | mg/uL | 15.0 - 36.0 |
| Urease quinolinium dye | | | | | |
| CREATININE CLEARANCE | 163.06 | NCS | | H mL/min | 80 - 125 |
| Calculated by Cockcroft Gault method | | | | | |

clinically acceptable Final Remark :-

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

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

This is an Electronically authenticated report

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







Clinical Laboratory Test Report



Lambda Therapeutic Research Limited

Screening AH17-06704 Subject Initial: KSM

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

17063193 Lab ID: Sex: Female

Visit : PS **Sample Collected**

Sample Collected At: Sample Received On:

Report Date:

Ahmedabad 05-Dec-2017 11:47

05-Dec-2017 20:50

05-Dec-2017 11:33

Study /Project 0326-17

HEMATOLOGY

[Performed By Flowcytometry and Electrical Impedence Method]

| <u>PARAMETER</u> | RESULT | CS/NCS* | <u>REMARK</u> | | 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 |
| RDW CV | 13.2 | | | 70 | 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 |
| LIPITHOCITES 70 | LJ.3 | | | | 20 - 40 |
| Flowcytometry method | | | | | |

clinically acceptable Final Remark :-

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

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

This is an Electronically authenticated report

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







Clinical Laboratory Test Report



Lambda Therapeutic Research Limited

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

Final Remark :- clinically acceptable

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

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

This is an Electronically authenticated report

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







Clinical Laboratory Test Report



Lambda Therapeutic Research Limited

Screening AH17-06704
Subject Initial: KSM
Subject 1026

Date Of Birth: 01-Jan-1980

Referred By: Dr. Manish Patel

Lab ID: 17063193 **Sex :** Female

Visit: PS

Sample Collected
Sample Collected At:

Study /Project

Sample Collected At: Sample Received On: Report Date:

mIU/mL

05-Dec-2017 11:33

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

0326-17

IMMUNOLOGY

wnl

PARAMETER RESULT CS/NCS* REMARK UNIT REFERENCE INTERVAL

<2.39

Chemiluminescence

BETA hCG

- Pre menopausal females: <4.83

Final Remark :- clinically acceptable

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

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

This is an Electronically authenticated report

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







Clinical Laboratory Test Report



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

Referred By:

01-Jan-1980 Dr. Manish Patel

 Lab ID:
 17063193

 Sex :
 Female

 Visit :
 PS

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

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

Out of Summary Report

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

Final Remark :- clinically acceptable

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

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

This is an Electronically authenticated report

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



