

Lambda Therapeutic Research.

Sponsor Name: Intas Pharmaceuticals Ltd.

CASE REPORT FORM

Project No: 745-15

Subject No: 1002 Subject Initials: SCK



CHECK-IN DETAILS(Period - 1)

BREATH TEST FOR ALCOHOL CONSUMPTION		Period: 1
Date::	23-Jan-2016	
Start Time:	11:45 24 hrs. clock	
Breath Alcohol Level (BAL):	.000 %	
Result:	<input type="radio"/> Positive <input checked="" type="radio"/> Negative	
Start Time of 1st Repeat:	24 hrs. clock	
Breath Alcohol Level (BAL):	%	
1st Repeat result:	<input type="radio"/> Positive <input type="radio"/> Negative	
Start Time of 2nd Repeat:	24 hrs. clock	
Breath Alcohol Level (BAL):	%	
2nd Repeat Result:	<input type="radio"/> Positive <input type="radio"/> Negative	
Final Result:	<input type="radio"/> Positive <input checked="" type="radio"/> Negative	
Remarks:	--	

URINE SCAN FOR DRUGS OF ABUSE		Period: 1
SOP reference no:CPMA-26-07		
Date:	23-Jan-2016	
1. URINE SCAN FOR DRUGS ABUSE		
1.0 Tested for:	<input checked="" type="checkbox"/> Amphetamine (AMP) <input checked="" type="checkbox"/> Barbiturates (BAR) <input checked="" type="checkbox"/> Benzodiazepines (BZD) <input checked="" type="checkbox"/> Cocaine (COC) <input checked="" type="checkbox"/> Morphine (MOR) <input checked="" type="checkbox"/> Cannabinoids (THC)	
1.1 Start time:	11:51 24 hrs. clock	
1.2 Observation of Results:	<input checked="" type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D	
Note: A=Two bands indicates negative (Control and Test),B=One band indicates Positive (Control),C=No band indicates Invalid ,D=One band indicates Invalid (Test)		
1.3 Result:	<input type="radio"/> Positive <input checked="" type="radio"/> Negative <input type="radio"/> Invalid	
1.4 Positive for:	<input type="checkbox"/> Amphetamine (AMP) <input type="checkbox"/> Barbiturates (BAR) <input type="checkbox"/> Benzodiazepines (BZD) <input type="checkbox"/> Cocaine (COC) <input type="checkbox"/> Morphine (MOR) <input type="checkbox"/> Cannabinoids (THC)	
1.5 Any additional test performed-1:	<input type="radio"/> Yes <input type="radio"/> No <input checked="" type="radio"/> NAP	
1.5a. Please Specify:		
1.5b. Start time:	24 hrs. clock	
1.5c. Observation of result:	<input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D	

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Note: A=Two bands indicates negative (Control and Test), B=One band indicates Positive (Control), C=No band indicates Invalid, D=One band indicates Invalid (Test)

1.5d. Result:	<input type="radio"/> Positive <input type="radio"/> Negative <input type="radio"/> Invalid
1.6 Any additional test performed-2:	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NAP
1.6a. Please Specify:	
1.6b. Start time:	24 hrs. clock
1.6c. Observation of result:	<input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D

Note: A=Two bands indicates negative (Control and Test), B=One band indicates Positive (Control), C=No band indicates Invalid, D=One band indicates Invalid (Test)

1.6d. Result:	<input type="radio"/> Positive <input type="radio"/> Negative <input type="radio"/> Invalid
2. URINE SCAN FOR DRUGS ABUSE (1st REPEAT)	
2.0 Start time:	24 hrs. clock
2.1 Observation of result:	<input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D

Note: A=Two bands indicates negative (Control and Test), B=One band indicates Positive (Control), C=No band indicates Invalid, D=One band indicates Invalid (Test)

2.2 Result:	<input type="radio"/> Positive <input type="radio"/> Negative <input type="radio"/> Invalid												
2.3 Positive for:	<table><tr><td><input type="checkbox"/></td><td><input type="checkbox"/></td><td><input type="checkbox"/></td></tr><tr><td>Amphetamine (AMP)</td><td>Barbiturates (BAR)</td><td>Benzodiazepines (BZD)</td></tr><tr><td><input type="checkbox"/></td><td><input type="checkbox"/></td><td><input type="checkbox"/></td></tr><tr><td>Cocaine (COC)</td><td>Morphine (MOR)</td><td>Cannabinoids (THC)</td></tr></table>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Amphetamine (AMP)	Barbiturates (BAR)	Benzodiazepines (BZD)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Cocaine (COC)	Morphine (MOR)	Cannabinoids (THC)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>											
Amphetamine (AMP)	Barbiturates (BAR)	Benzodiazepines (BZD)											
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>											
Cocaine (COC)	Morphine (MOR)	Cannabinoids (THC)											
2.4 Any additional test performed-1:	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NAP												
2.4a. Please Specify:													
2.4b. Start time:	24 hrs. clock												
2.4c. Observation of result:	<input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D												

Note: A=Two bands indicates negative (Control and Test), B=One band indicates Positive (Control), C=No band indicates Invalid, D=One band indicates Invalid (Test)

2.4d. Result:	<input type="radio"/> Positive <input type="radio"/> Negative <input type="radio"/> Invalid
2.5 Any additional test performed-2:	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NAP
2.5a. Please Specify:	
2.5b. Start time:	24 hrs. clock
2.5c. Observation of result:	<input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D

Note: A=Two bands indicates negative (Control and Test), B=One band indicates Positive (Control), C=No band indicates Invalid, D=One band indicates Invalid (Test)

2.5d. Result:	<input type="radio"/> Positive <input type="radio"/> Negative <input type="radio"/> Invalid
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3. URINE SCAN FOR DRUGS ABUSE (2nd REPEAT)	
3.0 Start time:	24 hrs. clock
3.1 Observation of result:	<input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D
Note: A=Two bands indicates negative (Control and Test),B=One band indicates Positive (Control),C=No band indicates Invalid ,D=One band indicates Invalid (Test)	
3.2 Result:	<input type="radio"/> Positive <input type="radio"/> Negative <input type="radio"/> Invalid
3.3 Positive for:	<input type="checkbox"/> Amphetamine (AMP) <input type="checkbox"/> Barbiturates (BAR) <input type="checkbox"/> Benzodiazepines (BZD) <input type="checkbox"/> Cocaine (COC) <input type="checkbox"/> Morphine (MOR) <input type="checkbox"/> Cannabinoids (THC)
3.4 Any additional test performed-1:	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NAP
3.4a. Please Specify:	
3.4b. Start time:	24 hrs. clock
3.4c. Observation of result:	<input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D
Note: A=Two bands indicates negative (Control and Test),B=One band indicates Positive (Control),C=No band indicates Invalid ,D=One band indicates Invalid (Test)	
3.4d. Result:	<input type="radio"/> Positive <input type="radio"/> Negative <input type="radio"/> Invalid
3.5 Any additional test performed-2:	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NAP
3.5a. Please Specify:	
3.5b. Start time:	24 hrs. clock
3.5c. Observation of result:	<input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D
Note: A=Two bands indicates negative (Control and Test),B=One band indicates Positive (Control),C=No band indicates Invalid ,D=One band indicates Invalid (Test)	
3.5d. Result:	<input type="radio"/> Positive <input type="radio"/> Negative <input type="radio"/> Invalid
Final result:	<input type="radio"/> Positive <input checked="" type="radio"/> Negative
Positive for:	<input type="checkbox"/> Amphetamine (AMP) <input type="checkbox"/> Barbiturates (BAR) <input type="checkbox"/> Benzodiazepines (BZD) <input type="checkbox"/> Cocaine (COC) <input type="checkbox"/> Morphine (MOR) <input type="checkbox"/> Cannabinoids (THC)
Final result (For additional test-1):	<input type="radio"/> Positive <input type="radio"/> Negative
Positive for (For additional test-1):	
Final result (For additional test-2):	<input type="radio"/> Positive <input type="radio"/> Negative
Positive for (For additional test-2):	
Remarks (for repeats or any other information):	-

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CRITERIA FOR SELECTION OF SUBJECTS Period: 1

Inclusion Criteria

Non smokers, normal, Healthy, adult, human, subjects between 18 and 45 years of age (both inclusive) living in and around Ahmedabad city or western part of India:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Having a Body Mass Index (BMI) between 18.5 and 30 (both inclusive), calculated as weight in kg/height in m ² :	<input checked="" type="radio"/> Yes <input type="radio"/> No
Not having significant diseases or clinically significant abnormal findings during screening, medical history, clinical examination, laboratory evaluations, 12 lead ECG, and chest X-ray recordings (postero-anterior view):	<input checked="" type="radio"/> Yes <input type="radio"/> No
Able to understand and comply with the study procedures, in the opinion of the Principal investigator:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Able to give voluntary written informed consent for participation in the trial:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Creatinine Clearance (CrCl) should be more than 50 mL/min for each subject before dosing:	<input checked="" type="radio"/> Yes <input type="radio"/> No

Inclusion Criteria in case of Female subjects

Surgically sterilized at least 6 months prior to study participation. or:	<input type="radio"/> Yes <input type="radio"/> No <input checked="" type="radio"/> NAP
If of child bearing potential is willing to use a suitable and effective double barrier contraceptive method or intra uterine device during the study. And:	<input type="radio"/> Yes <input type="radio"/> No <input checked="" type="radio"/> NAP
Serum pregnancy test must be negative:	<input type="radio"/> Yes <input type="radio"/> No <input checked="" type="radio"/> NAP

Exclusion criteria

Known hypersensitivity or idiosyncratic reaction to Dabigatran or any of the excipients or any related drug:	<input type="radio"/> Yes <input checked="" type="radio"/> No
History or presence of any disease or condition which might compromise the haemopoietic, renal, hepatic, endocrine, pulmonary, central nervous, cardiovascular, immunological, dermatological, gastrointestinal or any other body system:	<input type="radio"/> Yes <input checked="" type="radio"/> No
Any history or presence of asthma (including aspirin induced asthma) or nasal polyp or NSAID induced urticaria:	<input type="radio"/> Yes <input checked="" type="radio"/> No
A recent history of harmful use of alcohol (less than 2 years), i.e. alcohol consumption of more than 14 standard drinks per week for men and more than 7 standard drinks per week for women (A standard drink is defined as 360 ml of beer or 150 ml of wine or 45 ml of 40% distilled spirits, such as rum, whisky, brandy etc):	<input type="radio"/> Yes <input checked="" type="radio"/> No
Smokers, or who have smoked within last six months prior to start of the study:	<input type="radio"/> Yes <input checked="" type="radio"/> No
The presence of clinically significant abnormal laboratory values during screening [including prothrombin time (PT) and activated partial thromboplastin time (APTT):	<input type="radio"/> Yes <input checked="" type="radio"/> No
Use of any recreational drugs or history of drug addiction:	<input type="radio"/> Yes <input checked="" type="radio"/> No
History or presence of psychiatric disorders:	<input type="radio"/> Yes <input checked="" type="radio"/> No
A history of difficulty with donating blood:	<input type="radio"/> Yes <input checked="" type="radio"/> No

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Donation of blood (1 unit or 350 mL) or receipt of an investigational medicinal product 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. Note: If subject had participated in a study in which blood loss was ≤ 200 mL, subject may be dosed 60 days after the last sample of previous study:	<input type="radio"/> Yes <input checked="" type="radio"/> No
A positive hepatitis screen including hepatitis B surface antigen and/or HCV antibodies:	<input type="radio"/> Yes <input checked="" type="radio"/> No
A positive test result for HIV (I and/or II) antibody:	<input type="radio"/> Yes <input checked="" type="radio"/> No
Nursing mothers (females):	<input type="radio"/> Yes <input type="radio"/> No <input checked="" type="radio"/> NAP
Subject taking oral or parenteral anticoagulants:	<input type="radio"/> Yes <input checked="" type="radio"/> No
suitability	
Based on above criterias, Subject is:	<input checked="" type="radio"/> Suitable <input type="radio"/> Not-suitable
Criteria to be checked at the time of compliance check	
Ingestion of a medicine [including herbal remedies, non-steroidal anti-inflammatory drugs (NSAIDs), platelet inhibitors and any other anticoagulants, P-gp inhibitors (e.g., rifampin)] at any time within 14 days before dosing in Period I and an unusual diet, for whatever reason (e.g. low-sodium), for four weeks prior to receiving the study drug in period-I. In any such case subject selection will be at the discretion of the Principal Investigator.	
Consumption of Grapefruits or its products within a period of 72 hours prior to receiving the study drug.	
Consumption of alcohol or alcoholic products within 48 hours prior to receiving study medicine.	
Testing positive in pre-study drug scans.	
Remarks:	-
COMPLIANCE CHECK-PI Period: 1	
Demographic Details	
Age in Years (Completed as of Screening Date):	24
Subject Reporting And Consent Procedure Record	
Date of reporting to the clinical facility:	23-Jan-2016
Presentation of ICF & obtained the consent on ICF:	<input checked="" type="radio"/> Yes <input type="radio"/> No
If 'Yes', mention pagination number of ICF:	02
Protocol Compliance Assessment	
Criteria Check Complete:	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NAP
Urine scan for drugs of abuse tested negative:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Breath test for alcohol consumption tested negative:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Date of last menstruation period (for female subject):	-
Result of serum pregnancy test:	<input type="radio"/> Positive <input type="radio"/> Negative <input checked="" type="radio"/> NAP (For Male subject)
Prohibitions	
Are you suffering from any illness since the last visit (Including allergic reaction, itching, rash on your skin):	<input type="radio"/> Yes <input checked="" type="radio"/> No
Have you consumed any xanthine containing food or beverages (tea, coffee, chocolates or cola drinks) within 24 hours prior to IMP administration?:	<input type="radio"/> Yes <input checked="" type="radio"/> No

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Have you consumed tobacco, tobacco containing products (Gutkha, Pan/Pan Masala) within 24 hours prior to IMP administration?:	<input type="radio"/> Yes <input checked="" type="radio"/> No
Have you consumed alcohol, alcoholic products, recreational drugs within 48 hours prior to IMP administration?:	<input type="radio"/> Yes <input checked="" type="radio"/> No
Have you consumed grapefruit and grapefruit products within 72 hours prior to IMP administration?:	<input type="radio"/> Yes <input checked="" type="radio"/> No
Any history of smoking within 06 months prior to start of the study?:	<input type="radio"/> Yes <input checked="" type="radio"/> No
Ingestion of a medicine [including herbal remedies, non-steroidal anti-inflammatory drugs (NSAIDs), platelet inhibitors and any other anticoagulants, P-gp inhibitors (e.g., rifampin)] at any time within 14 days before dosing?:	<input type="radio"/> Yes <input checked="" type="radio"/> No
Have you consumed an unusual diet for whatever reason (e.g. low-sodium) within four weeks prior to receiving the study medication?:	<input type="radio"/> Yes <input checked="" type="radio"/> No
Has the subject been instructed not to participate in other clinical trial or donate blood anywhere else during the study?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Is subject compliant to all above restrictions/requirement?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Remark If any:	-

CHECK-IN B&B Period: 1

Baggage and Body Search done:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Date of Check In:	23-Jan-2016
Time of Check-in:	17:29 24 hrs. clock
Remarks:	--

CLINICAL EXAMINATION - CHECK IN Period: 1

Date of clinical examination:	23-Jan-2016
Start Time of Clinical Examination:	19:28 24 hrs. clock
Complaints of any illness:	<input checked="" type="radio"/> No <input type="radio"/> Yes
If YES, provide details:	-
General Physical examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Oral Body Temperature:	98.0 °F
Blood Pressure (Systolic):	118 mmHg
Blood Pressure (Diastolic):	70 mmHg
Radial Pulse Rate:	80 beats/min
Cardiovascular System Examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Respiratory System Examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Central Nervous System Examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Per Abdomen Examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Any other Significant finding:	-
Any investigations recommended:	-
Vein puncture site:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Subject well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If 'Abnormal' in any of the above-mentioned sections, please enter details.:	-

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Remark if Any:	-
Subject is fit:	<input checked="" type="radio"/> Yes <input type="radio"/> No
DINNER CHECK-IN (DAY-2) Period: 1	
Date of meal distribution:	23-Jan-2016
Start Time:	20:00 24 hrs. clock
End Time:	20:12 24 hrs. clock
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-
HOUSING DETAILS(Period - 1)	
BREAKFAST (DAY-1) Period: 1	
Date of meal distribution:	24-Jan-2016
Start Time:	08:07 24 hrs. clock
End Time:	08:15 24 hrs. clock
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-
LUNCH (DAY-1) Period: 1	
Date of meal distribution:	24-Jan-2016
Start Time:	12:02 24 hrs. clock
End Time:	12:17 24 hrs. clock
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-
SNACKS (DAY-1) Period: 1	
Date of meal distribution:	24-Jan-2016
Start Time:	16:00 24 hrs. clock
End Time:	16:11 24 hrs. clock
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-
DINNER (DAY-1) Period: 1	
Date of meal distribution:	24-Jan-2016
Start Time:	20:00 24 hrs. clock
End Time:	20:13 24 hrs. clock
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-
0.00 HRS PRE DOSE VITAL SIGNS AND WELL-BEING RECORD Period: 1	
Position:	Sitting

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Date of vital measurement:	25-Jan-2016
Start Time of vital measurement:	06:07 24 hrs. clock
Systolic Blood Pressure:	116 mmHg
Diastolic Blood Pressure:	72 mmHg
Radial Pulse:	72 beats/min
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-

0.000 HRS PRE DOSE PK SAMPLE COLLECTION Period: 1

Date and Time of Dosing:	
Date of sample collection:	25-Jan-2016
Scheduled date and Time of sample collection (for post dose only):	
Actual Time of sample collection:	07:15 24 hrs. clock
Remarks:	
PK Sample ID:	PK16032651
Remarks if any other reason:	

IMP ADMINISTRATION Period: 1

DATE:	25-Jan-2016
IS SUBJECT COMPLIANT TO ALL PREDOSE REQUIREMENTS AS PER PROTOCOL?:	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NA
TIME:	08:00 24 hrs. clock
MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA:	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NA
ML OF WATER ADMINISTERED WITH IP:	240
LABEL:	0000175572
PRODUCT CODE/ TYPE:	Test
DOSING SUPERVISION DONE BY:	jayvyas (Dosing)
REMARKS:	

STUDY DRUG ADMINISTRATION-COMPLIANCE Period: 1

Has the subject compliant to 01 hour post dose water restriction?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Has the subject compliant to postural restriction for the first 03 hours after dosing in sitting or ambulatory posture? (unless medically necessary due to adverse event or procedurally required):	<input checked="" type="radio"/> Yes <input type="radio"/> No
Has the subject compliant to 05 hours post dose fasting condition?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Remark if any:	-

0.250 HRS POST DOSE PK SAMPLE COLLECTION Period: 1

Date and Time of Dosing:	25-Jan-2016 08:00
Date of sample collection:	25-Jan-2016
Scheduled date and Time of sample collection (for post dose only):	25-Jan-2016 08:15
Actual Time of sample collection:	08:15 24 hrs. clock
Remarks:	
PK Sample ID:	PK16032741
Remarks if any other reason:	

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0.500 HRS POST DOSE PK SAMPLE COLLECTION		Period: 1
Date and Time of Dosing:	25-Jan-2016 08:00	
Date of sample collection:	25-Jan-2016	
Scheduled date and Time of sample collection (for post dose only):	25-Jan-2016 08:30	
Actual Time of sample collection:	08:30 24 hrs. clock	
Remarks:		
PK Sample ID:	PK16032831	
Remarks if any other reason:		

0.750 HRS POST DOSE PK SAMPLE COLLECTION		Period: 1
Date and Time of Dosing:	25-Jan-2016 08:00	
Date of sample collection:	25-Jan-2016	
Scheduled date and Time of sample collection (for post dose only):	25-Jan-2016 08:45	
Actual Time of sample collection:	08:45 24 hrs. clock	
Remarks:		
PK Sample ID:	PK16032921	
Remarks if any other reason:		

1.000 HRS POST DOSE PK SAMPLE COLLECTION		Period: 1
Date and Time of Dosing:	25-Jan-2016 08:00	
Date of sample collection:	25-Jan-2016	
Scheduled date and Time of sample collection (for post dose only):	25-Jan-2016 09:00	
Actual Time of sample collection:	09:00 24 hrs. clock	
Remarks:		
PK Sample ID:	PK16033011	
Remarks if any other reason:		

1.250 HRS POST DOSE PK SAMPLE COLLECTION		Period: 1
Date and Time of Dosing:	25-Jan-2016 08:00	
Date of sample collection:	25-Jan-2016	
Scheduled date and Time of sample collection (for post dose only):	25-Jan-2016 09:15	
Actual Time of sample collection:	09:15 24 hrs. clock	
Remarks:		
PK Sample ID:	PK16033101	
Remarks if any other reason:		

1.500 HRS POST DOSE PK SAMPLE COLLECTION		Period: 1
Date and Time of Dosing:	25-Jan-2016 08:00	
Date of sample collection:	25-Jan-2016	
Scheduled date and Time of sample collection (for post dose only):	25-Jan-2016 09:30	
Actual Time of sample collection:	09:30 24 hrs. clock	
Remarks:		
PK Sample ID:	PK16033191	
Remarks if any other reason:	Data has been transcribed from blood sample collection sheet no. DMS-12-00002773.	

1.750 HRS POST DOSE PK SAMPLE COLLECTION		Period: 1
Date and Time of Dosing:	25-Jan-2016 08:00	

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Date of sample collection:	25-Jan-2016
Scheduled date and Time of sample collection (for post dose only):	25-Jan-2016 09:45
Actual Time of sample collection:	09:45 24 hrs. clock
Remarks:	
PK Sample ID:	PK16033281
Remarks if any other reason:	

2.000 HRS POST DOSE PK SAMPLE COLLECTION Period: 1

Date and Time of Dosing:	25-Jan-2016 08:00
Date of sample collection:	25-Jan-2016
Scheduled date and Time of sample collection (for post dose only):	25-Jan-2016 10:00
Actual Time of sample collection:	10:00 24 hrs. clock
Remarks:	
PK Sample ID:	PK16033371
Remarks if any other reason:	

2.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD Period: 1

Position:	Sitting
Date of vital measurement:	25-Jan-2016
Start Time of vital measurement:	09:23 24 hrs. clock
Systolic Blood Pressure:	112 mmHg
Diastolic Blood Pressure:	72 mmHg
Radial Pulse:	68 beats/min
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-

2.250 HRS POST DOSE PK SAMPLE COLLECTION Period: 1

Date and Time of Dosing:	25-Jan-2016 08:00
Date of sample collection:	25-Jan-2016
Scheduled date and Time of sample collection (for post dose only):	25-Jan-2016 10:15
Actual Time of sample collection:	10:16 24 hrs. clock
Remarks:	
PK Sample ID:	PK16033461
Remarks if any other reason:	

2.500 HRS POST DOSE PK SAMPLE COLLECTION Period: 1

Date and Time of Dosing:	25-Jan-2016 08:00
Date of sample collection:	25-Jan-2016
Scheduled date and Time of sample collection (for post dose only):	25-Jan-2016 10:30
Actual Time of sample collection:	10:30 24 hrs. clock
Remarks:	
PK Sample ID:	PK16033551
Remarks if any other reason:	

2.750 HRS POST DOSE PK SAMPLE COLLECTION Period: 1

Date and Time of Dosing:	25-Jan-2016 08:00
Date of sample collection:	25-Jan-2016

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Sponsor Name: Intas Pharmaceuticals Ltd.

CASE REPORT FORM

Project No: 745-15

Subject No: 1002 Subject Initials: SCK



Scheduled date and Time of sample collection (for post dose only):	25-Jan-2016 10:45
Actual Time of sample collection:	10:45 24 hrs. clock
Remarks:	
PK Sample ID:	PK16033641
Remarks if any other reason:	
3.000 HRS POST DOSE PK SAMPLE COLLECTION Period: 1	
Date and Time of Dosing:	25-Jan-2016 08:00
Date of sample collection:	25-Jan-2016
Scheduled date and Time of sample collection (for post dose only):	25-Jan-2016 11:00
Actual Time of sample collection:	11:00 24 hrs. clock
Remarks:	
PK Sample ID:	PK16033731
Remarks if any other reason:	
3.333 HRS POST DOSE PK SAMPLE COLLECTION Period: 1	
Date and Time of Dosing:	25-Jan-2016 08:00
Date of sample collection:	25-Jan-2016
Scheduled date and Time of sample collection (for post dose only):	25-Jan-2016 11:20
Actual Time of sample collection:	11:20 24 hrs. clock
Remarks:	
PK Sample ID:	PK16033821
Remarks if any other reason:	
3.667 HRS POST DOSE PK SAMPLE COLLECTION Period: 1	
Date and Time of Dosing:	25-Jan-2016 08:00
Date of sample collection:	25-Jan-2016
Scheduled date and Time of sample collection (for post dose only):	25-Jan-2016 11:40
Actual Time of sample collection:	11:40 24 hrs. clock
Remarks:	
PK Sample ID:	PK16033911
Remarks if any other reason:	
4.000 HRS POST DOSE PK SAMPLE COLLECTION Period: 1	
Date and Time of Dosing:	25-Jan-2016 08:00
Date of sample collection:	25-Jan-2016
Scheduled date and Time of sample collection (for post dose only):	25-Jan-2016 12:00
Actual Time of sample collection:	12:00 24 hrs. clock
Remarks:	
PK Sample ID:	PK16034001
Remarks if any other reason:	
4.500 HRS POST DOSE PK SAMPLE COLLECTION Period: 1	
Date and Time of Dosing:	25-Jan-2016 08:00
Date of sample collection:	25-Jan-2016
Scheduled date and Time of sample collection (for post dose only):	25-Jan-2016 12:30
Actual Time of sample collection:	12:30 24 hrs. clock
Remarks:	

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CASE REPORT FORM

Project No: 745-15

Subject No: 1002 Subject Initials: SCK



PK Sample ID:	PK16034091
Remarks if any other reason:	
5.000 HRS POST DOSE PK SAMPLE COLLECTION Period: 1	
Date and Time of Dosing:	25-Jan-2016 08:00
Date of sample collection:	25-Jan-2016
Scheduled date and Time of sample collection (for post dose only):	25-Jan-2016 13:00
Actual Time of sample collection:	13:00 24 hrs. clock
Remarks:	
PK Sample ID:	PK16034181
Remarks if any other reason:	
LUNCH (5.00 HRS POST DOSE) (DAY 1) Period: 1	
Date of meal distribution:	25-Jan-2016
Start Time:	13:02 24 hrs. clock
End Time:	13:18 24 hrs. clock
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-
6.000 HRS POST DOSE PK SAMPLE COLLECTION Period: 1	
Date and Time of Dosing:	25-Jan-2016 08:00
Date of sample collection:	25-Jan-2016
Scheduled date and Time of sample collection (for post dose only):	25-Jan-2016 14:00
Actual Time of sample collection:	14:01 24 hrs. clock
Remarks:	
PK Sample ID:	PK16034271
Remarks if any other reason:	
8.000 HRS POST DOSE PK SAMPLE COLLECTION Period: 1	
Date and Time of Dosing:	25-Jan-2016 08:00
Date of sample collection:	25-Jan-2016
Scheduled date and Time of sample collection (for post dose only):	25-Jan-2016 16:00
Actual Time of sample collection:	16:00 24 hrs. clock
Remarks:	
PK Sample ID:	PK16034361
Remarks if any other reason:	
SNACKS (DAY 1) Period: 1	
Date of meal distribution:	25-Jan-2016
Start Time:	16:01 24 hrs. clock
End Time:	16:14 24 hrs. clock
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-
8.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD Period: 1	
Position:	Sitting

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CASE REPORT FORM

Project No: 745-15

Subject No: 1002 Subject Initials: SCK



Date of vital measurement:	25-Jan-2016
Start Time of vital measurement:	15:56 24 hrs. clock
Systolic Blood Pressure:	114 mmHg
Diastolic Blood Pressure:	72 mmHg
Radial Pulse:	68 beats/min
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-

12.000 HRS POST DOSE PK SAMPLE COLLECTION Period: 1

Date and Time of Dosing:	25-Jan-2016 08:00
Date of sample collection:	25-Jan-2016
Scheduled date and Time of sample collection (for post dose only):	25-Jan-2016 20:00
Actual Time of sample collection:	20:00 24 hrs. clock
Remarks:	
PK Sample ID:	PK16034451
Remarks if any other reason:	

DINNER (DAY 1) Period: 1

Date of meal distribution:	25-Jan-2016
Start Time:	20:01 24 hrs. clock
End Time:	20:19 24 hrs. clock
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-

12.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD Period: 1

Position:	Sitting
Date of vital measurement:	25-Jan-2016
Start Time of vital measurement:	19:37 24 hrs. clock
Systolic Blood Pressure:	120 mmHg
Diastolic Blood Pressure:	78 mmHg
Radial Pulse:	76 beats/min
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-

16.000 HRS POST DOSE PK SAMPLE COLLECTION Period: 1

Date and Time of Dosing:	25-Jan-2016 08:00
Date of sample collection:	26-Jan-2016
Scheduled date and Time of sample collection (for post dose only):	26-Jan-2016 00:00
Actual Time of sample collection:	00:00 24 hrs. clock
Remarks:	
PK Sample ID:	PK16034541
Remarks if any other reason:	

24.000 HRS POST DOSE PK SAMPLE COLLECTION Period: 1

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Project No: 745-15

Subject No: 1002 Subject Initials: SCK



Date and Time of Dosing:	25-Jan-2016 08:00
Date of sample collection:	26-Jan-2016
Scheduled date and Time of sample collection (for post dose only):	26-Jan-2016 08:00
Actual Time of sample collection:	08:00 24 hrs. clock
Remarks:	
PK Sample ID:	PK16034631
Remarks if any other reason:	

BREAKFAST (DAY 2) Period: 1

Date of meal distribution:	26-Jan-2016
Start Time:	08:08 24 hrs. clock
End Time:	08:16 24 hrs. clock
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-

24.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD Period: 1

Position:	Sitting
Date of vital measurement:	26-Jan-2016
Start Time of vital measurement:	07:31 24 hrs. clock
Systolic Blood Pressure:	112 mmHg
Diastolic Blood Pressure:	70 mmHg
Radial Pulse:	76 beats/min
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-

LUNCH (DAY 2) Period: 1

Date of meal distribution:	26-Jan-2016
Start Time:	12:00 24 hrs. clock
End Time:	12:18 24 hrs. clock
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-

SNACKS (DAY 2) Period: 1

Date of meal distribution:	26-Jan-2016
Start Time:	16:00 24 hrs. clock
End Time:	16:10 24 hrs. clock
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-

36.000 HRS POST DOSE PK SAMPLE COLLECTION Period: 1

Date and Time of Dosing:	25-Jan-2016 08:00
Date of sample collection:	26-Jan-2016

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CASE REPORT FORM

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Subject No: 1002 Subject Initials: SCK



Scheduled date and Time of sample collection (for post dose only):	26-Jan-2016 20:00
Actual Time of sample collection:	20:00 24 hrs. clock
Remarks:	
PK Sample ID:	PK16034721
Remarks if any other reason:	

DINNER (DAY 2) Period: 1

Date of meal distribution:	26-Jan-2016
Start Time:	20:01 24 hrs. clock
End Time:	20:20 24 hrs. clock
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-

48.000 HRS POST DOSE PK SAMPLE COLLECTION Period: 1

Date and Time of Dosing:	25-Jan-2016 08:00
Date of sample collection:	27-Jan-2016
Scheduled date and Time of sample collection (for post dose only):	27-Jan-2016 08:00
Actual Time of sample collection:	08:00 24 hrs. clock
Remarks:	
PK Sample ID:	PK16034811
Remarks if any other reason:	

72.000 HRS AMBULATORY PK SAMPLE COLLECTION (DAY 4) Period: 1

Date and Time of Dosing:	25-Jan-2016 08:00
Date of sample collection:	28-Jan-2016
Scheduled date and Time of sample collection (for post dose only):	28-Jan-2016 08:00
Actual Time of sample collection:	08:00 24 hrs. clock
Remarks:	
PK Sample ID:	PK16034901
Remarks if any other reason:	

72.000 HRS COMPLIANCE AND WELL BEING AT THE TIME OF AMBULATORY SAMPLE (DAY 4) Period: 1

Compliance at the Time of Ambulatory

Date of compliance at the time of ambulatory sample:	28-Jan-2016
Have you consumed any medicine [including herbal remedies, non-steroidal anti-inflammatory drugs (NSAIDs), platelet inhibitors and any other anticoagulants, P-gp inhibitors (e.g., rifampin)] alcohol, alcoholic products, recreational drugs, grapefruit and grapefruit products, an unusual diet for whatever reason (e.g. low-sodium) or smoked since last visit?:	<input type="radio"/> Yes <input checked="" type="radio"/> No
Have you donated blood anywhere else or participated in other clinical trial since last visit?:	<input type="radio"/> Yes <input checked="" type="radio"/> No
If Yes, Remarks:	-

Well Being at the Time of Ambulatory

Date of well being:	28-Jan-2016
Start Time of well being:	08:04 24 hrs. clock

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CASE REPORT FORM

Project No: 745-15

Subject No: 1002 Subject Initials: SCK



Well-Being at the time of ambulatory sample:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
Remarks if Unwell:	-
Remark if any:	-

CHECK-OUT DETAILS(Period - 1)

CLINICAL EXAMINATION-CHECKOUT		Period: 1
Date of Clinical Examination:	27-Jan-2016	
Start Time of Clinical Examination:	06:14 24 hrs. clock	
Complaint of any illness:	<input checked="" type="radio"/> No <input type="radio"/> Yes	
If YES, provide details:	-	
General Physical examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal	
Oral Body Temperature:	98.2 °F	
Radial Pulse Rate:	72 beats/min	
Blood Pressure(Systolic):	114 mmHg	
Blood Pressure(Diastolic):	76 mmHg	
Cardiovascular System Examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal	
Respiratory System Examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal	
Central Nervous System Examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal	
Per Abdomen Examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal	
Any other Significant finding:	-	
Any investigations recommended:	-	
If 'Abnormal' in any of the above-mentioned sections, please enter details:	-	
To be performed at the time of check-out		
Vein puncture site:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal	
Subject well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell	
Comments:	-	
Subject is fit for Check-out:	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Remark If any:	-	

CHECK-OUT B&B		Period: 1
Date of check out:	27-Jan-2016	
Time of Check-out:	08:33 24 hrs. clock	
Remarks:	-	

LABORATORY ASSESSMENT-WITHIN THREE WORKING DAYS PRIOR TO DOSING OF (PERIOD-II)		Period: 1
Note: For Estimation of coagulation tests (APTT, PT) and Creatinine Clearance (CrCl).		
Period:	II	
Has the blood sample been collected as per protocol?:	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Date of blood sample collection:	31-Jan-2016	
Lab report clinically acceptable:	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NAP	

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CASE REPORT FORM

Project No: 745-15

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Comments (if any): -

Note: CrCl should be more than 50 mL/min before dosing.

CHECK-IN DETAILS(Period - 2)

BREATH TEST FOR ALCOHOL CONSUMPTION Period: 2

Date::	31-Jan-2016
Start Time:	16:31 24 hrs. clock
Breath Alcohol Level (BAL):	.000 %
Result:	<input type="radio"/> Positive <input checked="" type="radio"/> Negative
Start Time of 1st Repeat:	24 hrs. clock
Breath Alcohol Level (BAL):	%
1st Repeat result:	<input type="radio"/> Positive <input type="radio"/> Negative
Start Time of 2nd Repeat:	24 hrs. clock
Breath Alcohol Level (BAL):	%
2nd Repeat Result:	<input type="radio"/> Positive <input type="radio"/> Negative
Final Result:	<input type="radio"/> Positive <input checked="" type="radio"/> Negative
Remarks:	--

URINE SCAN FOR DRUGS OF ABUSE Period: 2

SOP reference no:CPMA-26-07

Date: 31-Jan-2016

1. URINE SCAN FOR DRUGS ABUSE

1.0 Tested for:	<input checked="" type="checkbox"/> Amphetamine (AMP) <input checked="" type="checkbox"/> Barbiturates (BAR) <input checked="" type="checkbox"/> Benzodiazepines (BZD) <input checked="" type="checkbox"/> Cocaine (COC) <input checked="" type="checkbox"/> Morphine (MOR) <input checked="" type="checkbox"/> Cannabinoids (THC)
-----------------	---

1.1 Start time: 16:46 **24 hrs. clock**

1.2 Observation of Results: ☒ A ☐ B ☐ C
☐ D

Note: A=Two bands indicates negative (Control and Test),B=One band indicates Positive (Control),C=No band indicates Invalid ,D=One band indicates Invalid (Test)

1.3 Result: ☐ Positive ☒ Negative ☐ Invalid

1.4 Positive for:	<input type="checkbox"/> Amphetamine (AMP) <input type="checkbox"/> Barbiturates (BAR) <input type="checkbox"/> Benzodiazepines (BZD) <input type="checkbox"/> Cocaine (COC) <input type="checkbox"/> Morphine (MOR) <input type="checkbox"/> Cannabinoids (THC)
-------------------	---

1.5 Any additional test performed-1: ☐ Yes ☐ No ☒ NAP

1.5a. Please Specify:

1.5b. Start time: **24 hrs. clock**

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1.5c. Observation of result:	<input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D
Note: A=Two bands indicates negative (Control and Test),B=One band indicates Positive (Control),C=No band indicates Invalid ,D=One band indicates Invalid (Test)	
1.5d. Result:	<input type="radio"/> Positive <input type="radio"/> Negative <input type="radio"/> Invalid
1.6 Any additional test performed-2:	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NAP
1.6a. Please Specify:	
1.6b. Start time:	24 hrs. clock
1.6c. Observation of result:	<input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D
Note: A=Two bands indicates negative (Control and Test),B=One band indicates Positive (Control),C=No band indicates Invalid ,D=One band indicates Invalid (Test)	
1.6d. Result:	<input type="radio"/> Positive <input type="radio"/> Negative <input type="radio"/> Invalid
2. URINE SCAN FOR DRUGS ABUSE (1st REPEAT)	
2.0 Start time:	24 hrs. clock
2.1 Observation of result:	<input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D
Note: A=Two bands indicates negative (Control and Test),B=One band indicates Positive (Control),C=No band indicates Invalid ,D=One band indicates Invalid (Test)	
2.2 Result:	<input type="radio"/> Positive <input type="radio"/> Negative <input type="radio"/> Invalid
2.3 Positive for:	<input type="checkbox"/> Amphetamine (AMP) <input type="checkbox"/> Barbiturates (BAR) <input type="checkbox"/> Benzodiazepines (BZD) <input type="checkbox"/> Cocaine (COC) <input type="checkbox"/> Morphine (MOR) <input type="checkbox"/> Cannabinoids (THC)
2.4 Any additional test performed-1:	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NAP
2.4a. Please Specify:	
2.4b. Start time:	24 hrs. clock
2.4c. Observation of result:	<input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D
Note: A=Two bands indicates negative (Control and Test),B=One band indicates Positive (Control),C=No band indicates Invalid ,D=One band indicates Invalid (Test)	
2.4d. Result:	<input type="radio"/> Positive <input type="radio"/> Negative <input type="radio"/> Invalid
2.5 Any additional test performed-2:	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NAP
2.5a. Please Specify:	
2.5b. Start time:	24 hrs. clock
2.5c. Observation of result:	<input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D

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Sponsor Name: Intas Pharmaceuticals Ltd.

CASE REPORT FORM

Project No: 745-15

Subject No: 1002 Subject Initials: SCK



Note: A=Two bands indicates negative (Control and Test),B=One band indicates Positive (Control),C=No band indicates Invalid ,D=One band indicates Invalid (Test)	
2.5d. Result:	<input type="radio"/> Positive <input type="radio"/> Negative <input type="radio"/> Invalid
3. URINE SCAN FOR DRUGS ABUSE (2nd REPEAT)	
3.0 Start time:	24 hrs. clock
3.1 Observation of result:	<input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D
Note: A=Two bands indicates negative (Control and Test),B=One band indicates Positive (Control),C=No band indicates Invalid ,D=One band indicates Invalid (Test)	
3.2 Result:	<input type="radio"/> Positive <input type="radio"/> Negative <input type="radio"/> Invalid
3.3 Positive for:	<input type="checkbox"/> Amphetamine (AMP) <input type="checkbox"/> Barbiturates (BAR) <input type="checkbox"/> Benzodiazepines (BZD) <input type="checkbox"/> Cocaine (COC) <input type="checkbox"/> Morphine (MOR) <input type="checkbox"/> Cannabinoids (THC)
3.4 Any additional test performed-1:	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NAP
3.4a. Please Specify:	
3.4b. Start time:	24 hrs. clock
3.4c. Observation of result:	<input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D
Note: A=Two bands indicates negative (Control and Test),B=One band indicates Positive (Control),C=No band indicates Invalid ,D=One band indicates Invalid (Test)	
3.4d. Result:	<input type="radio"/> Positive <input type="radio"/> Negative <input type="radio"/> Invalid
3.5 Any additional test performed-2:	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NAP
3.5a. Please Specify:	
3.5b. Start time:	24 hrs. clock
3.5c. Observation of result:	<input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D
Note: A=Two bands indicates negative (Control and Test),B=One band indicates Positive (Control),C=No band indicates Invalid ,D=One band indicates Invalid (Test)	
3.5d. Result:	<input type="radio"/> Positive <input type="radio"/> Negative <input type="radio"/> Invalid
Final result:	<input type="radio"/> Positive <input checked="" type="radio"/> Negative
Positive for:	<input type="checkbox"/> Amphetamine (AMP) <input type="checkbox"/> Barbiturates (BAR) <input type="checkbox"/> Benzodiazepines (BZD) <input type="checkbox"/> Cocaine (COC) <input type="checkbox"/> Morphine (MOR) <input type="checkbox"/> Cannabinoids (THC)
Final result (For additional test-1):	<input type="radio"/> Positive <input type="radio"/> Negative
Positive for (For additional test-1):	

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CASE REPORT FORM

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Final result (For additional test-2):	<input type="radio"/> Positive <input type="radio"/> Negative
Positive for (For additional test-2):	
Remarks (for repeats or any other information):	-

COMPLIANCE CHECK-PII Period: 2

Demographic Details

Age in Years (Completed as of Screening Date): 24

Subject Reporting Record

Date of reporting to the clinical facility: 31-Jan-2016

Protocol Compliance Assessment

Urine scans for drugs of abuse tested negative: ☒ Yes ☐ No

Breath test for alcohol consumption tested negative: ☒ Yes ☐ No

Date of last menstruation period (For Female subject): --

Result of serum pregnancy test: ☐ Positive ☐ Negative ☒ NAP (For Male subject)

Prohibitions

Are you suffering from any illness since the last visit (Including allergic reaction, itching, rash on your skin): ☐ Yes ☒ No

Have you consumed any xanthine containing food or beverages (tea, coffee, chocolates or cola drinks) within 24 hours prior to IMP administration?: ☐ Yes ☒ No

Have you consumed tobacco, tobacco containing products (Gutkha, Pan/Pan Masala) within 24 hours prior to IMP administration?: ☐ Yes ☒ No

Have you consumed alcohol, alcoholic products, recreational drugs since last PK sample collection of Period I?: ☐ Yes ☒ No

Have you consumed grapefruit and grapefruit products since last PK sample collection of Period I?: ☐ Yes ☒ No

Have you smoked since last PK sample collection of Period I?: ☐ Yes ☒ No

Ingestion of a medicine [including herbal remedies, non-steroidal anti-inflammatory drugs (NSAIDs), platelet inhibitors and any other anticoagulants, P-gp inhibitors (e.g., rifampin)] at any time since last PK sample collection of Period I?: ☐ Yes ☒ No

Have you consumed an unusual diet for whatever reason (e.g. low-sodium) since last PK sample collection of Period I?: ☐ Yes ☒ No

Have you donated blood anywhere else or participated in other clinical trial since last PK sample collection of Period I?: ☐ Yes ☒ No

Is subject compliant to all above restrictions/requirement?: ☒ Yes ☐ No

Remark If any: --

CHECK-IN B&B Period: 2

Baggage and Body Search done: ☒ Yes ☐ No

Date of Check In: 31-Jan-2016

Time of Check-in: 18:14 **24 hrs. clock**

Remarks: -

CLINICAL EXAMINATION - CHECK IN Period: 2

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CASE REPORT FORM

Project No: 745-15

Subject No: 1002 Subject Initials: SCK



Date of clinical examination:	31-Jan-2016
Start Time of Clinical Examination:	18:23 24 hrs. clock
Complaints of any illness:	<input checked="" type="radio"/> No <input type="radio"/> Yes
If YES, provide details:	-
General Physical examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Oral Body Temperature:	98.2 °F
Blood Pressure (Systolic):	116 mmHg
Blood Pressure (Diastolic):	80 mmHg
Radial Pulse Rate:	80 beats/min
Cardiovascular System Examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Respiratory System Examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Central Nervous System Examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Per Abdomen Examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Any other Significant finding:	-
Any investigations recommended:	-
Vein puncture site:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Subject well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If 'Abnormal' in any of the above-mentioned sections, please enter details.:	-
Remark if Any:	-
Subject is fit:	<input checked="" type="radio"/> Yes <input type="radio"/> No

DINNER CHECK-IN (DAY-2) Period: 2

Date of meal distribution:	31-Jan-2016
Start Time:	20:10 24 hrs. clock
End Time:	20:26 24 hrs. clock
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-

HOUSING DETAILS(Period - 2)

BREAKFAST (DAY-1) Period: 2

Date of meal distribution:	01-Feb-2016
Start Time:	08:09 24 hrs. clock
End Time:	08:16 24 hrs. clock
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-

LUNCH (DAY-1) Period: 2

Date of meal distribution:	01-Feb-2016
Start Time:	12:00 24 hrs. clock
End Time:	12:20 24 hrs. clock

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Sponsor Name: Intas Pharmaceuticals Ltd.

CASE REPORT FORM

Project No: 745-15

Subject No: 1002 Subject Initials: SCK



Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-

SNACKS (DAY-1) Period: 2

Date of meal distribution:	01-Feb-2016
Start Time:	16:00 24 hrs. clock
End Time:	16:10 24 hrs. clock
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-

DINNER (DAY-1) Period: 2

Date of meal distribution:	01-Feb-2016
Start Time:	20:00 24 hrs. clock
End Time:	20:18 24 hrs. clock
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-

0.00 HRS PRE DOSE VITAL SIGNS AND WELL-BEING RECORD Period: 2

Position:	Sitting
Date of vital measurement:	02-Feb-2016
Start Time of vital measurement:	06:37 24 hrs. clock
Systolic Blood Pressure:	116 mmHg
Diastolic Blood Pressure:	74 mmHg
Radial Pulse:	64 beats/min
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-

0.000 HRS PRE DOSE PK SAMPLE COLLECTION Period: 2

Date and Time of Dosing:	
Date of sample collection:	02-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	
Actual Time of sample collection:	07:24 24 hrs. clock
Remarks:	
PK Sample ID:	PK16044923
Remarks if any other reason:	

IMP ADMINISTRATION Period: 2

DATE:	02-Feb-2016
IS SUBJECT COMPLIANT TO ALL PREDOSE REQUIREMENTS AS PER PROTOCOL?:	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NA
TIME:	08:00 24 hrs. clock
MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA:	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NA

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CASE REPORT FORM

Project No: 745-15

Subject No: 1002 Subject Initials: SCK



ML OF WATER ADMINISTERED WITH IP:	240
LABEL:	0000176618
PRODUCT CODE/ TYPE:	Reference
DOSING SUPERVISION DONE BY:	jayvyas (Dosing)
REMARKS:	

STUDY DRUG ADMINISTRATION-COMPLIANCE Period: 2

Has the subject compliant to 01 hour post dose water restriction?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Has the subject compliant to postural restriction for the first 03 hours after dosing in sitting or ambulatory posture? (unless medically necessary due to adverse event or procedurally required):	<input checked="" type="radio"/> Yes <input type="radio"/> No
Has the subject compliant to 05 hours post dose fasting condition?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Remark if any:	-

0.250 HRS POST DOSE PK SAMPLE COLLECTION Period: 2

Date and Time of Dosing:	02-Feb-2016 08:00
Date of sample collection:	02-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	02-Feb-2016 08:15
Actual Time of sample collection:	08:15 24 hrs. clock
Remarks:	
PK Sample ID:	PK16045013
Remarks if any other reason:	

0.500 HRS POST DOSE PK SAMPLE COLLECTION Period: 2

Date and Time of Dosing:	02-Feb-2016 08:00
Date of sample collection:	02-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	02-Feb-2016 08:30
Actual Time of sample collection:	08:31 24 hrs. clock
Remarks:	
PK Sample ID:	PK16045103
Remarks if any other reason:	

0.750 HRS POST DOSE PK SAMPLE COLLECTION Period: 2

Date and Time of Dosing:	02-Feb-2016 08:00
Date of sample collection:	02-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	02-Feb-2016 08:45
Actual Time of sample collection:	08:46 24 hrs. clock
Remarks:	
PK Sample ID:	PK16045193
Remarks if any other reason:	

1.000 HRS POST DOSE PK SAMPLE COLLECTION Period: 2

Date and Time of Dosing:	02-Feb-2016 08:00
Date of sample collection:	02-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	02-Feb-2016 09:00
Actual Time of sample collection:	09:00 24 hrs. clock
Remarks:	

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CASE REPORT FORM

Project No: 745-15

Subject No: 1002 Subject Initials: SCK



PK Sample ID:	PK16045283
Remarks if any other reason:	
1.250 HRS POST DOSE PK SAMPLE COLLECTION Period: 2	
Date and Time of Dosing:	02-Feb-2016 08:00
Date of sample collection:	02-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	02-Feb-2016 09:15
Actual Time of sample collection:	09:15 24 hrs. clock
Remarks:	
PK Sample ID:	PK16045373
Remarks if any other reason:	
1.500 HRS POST DOSE PK SAMPLE COLLECTION Period: 2	
Date and Time of Dosing:	02-Feb-2016 08:00
Date of sample collection:	02-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	02-Feb-2016 09:30
Actual Time of sample collection:	09:30 24 hrs. clock
Remarks:	
PK Sample ID:	PK16045463
Remarks if any other reason:	
1.750 HRS POST DOSE PK SAMPLE COLLECTION Period: 2	
Date and Time of Dosing:	02-Feb-2016 08:00
Date of sample collection:	02-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	02-Feb-2016 09:45
Actual Time of sample collection:	09:45 24 hrs. clock
Remarks:	
PK Sample ID:	PK16045553
Remarks if any other reason:	
2.000 HRS POST DOSE PK SAMPLE COLLECTION Period: 2	
Date and Time of Dosing:	02-Feb-2016 08:00
Date of sample collection:	02-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	02-Feb-2016 10:00
Actual Time of sample collection:	10:01 24 hrs. clock
Remarks:	
PK Sample ID:	PK16045643
Remarks if any other reason:	
2.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD Period: 2	
Position:	Sitting
Date of vital measurement:	02-Feb-2016
Start Time of vital measurement:	09:33 24 hrs. clock
Systolic Blood Pressure:	112 mmHg
Diastolic Blood Pressure:	72 mmHg
Radial Pulse:	68 beats/min
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-

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CASE REPORT FORM

Project No: 745-15

Subject No: 1002 Subject Initials: SCK



Remarks:	-
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2.250 HRS POST DOSE PK SAMPLE COLLECTION Period: 2

Date and Time of Dosing:	02-Feb-2016 08:00
Date of sample collection:	02-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	02-Feb-2016 10:15
Actual Time of sample collection:	10:16 24 hrs. clock
Remarks:	
PK Sample ID:	PK16045733
Remarks if any other reason:	

2.500 HRS POST DOSE PK SAMPLE COLLECTION Period: 2

Date and Time of Dosing:	02-Feb-2016 08:00
Date of sample collection:	02-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	02-Feb-2016 10:30
Actual Time of sample collection:	10:30 24 hrs. clock
Remarks:	
PK Sample ID:	PK16045823
Remarks if any other reason:	

2.750 HRS POST DOSE PK SAMPLE COLLECTION Period: 2

Date and Time of Dosing:	02-Feb-2016 08:00
Date of sample collection:	02-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	02-Feb-2016 10:45
Actual Time of sample collection:	10:45 24 hrs. clock
Remarks:	
PK Sample ID:	PK16045913
Remarks if any other reason:	

3.000 HRS POST DOSE PK SAMPLE COLLECTION Period: 2

Date and Time of Dosing:	02-Feb-2016 08:00
Date of sample collection:	02-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	02-Feb-2016 11:00
Actual Time of sample collection:	11:00 24 hrs. clock
Remarks:	
PK Sample ID:	PK16046003
Remarks if any other reason:	

3.333 HRS POST DOSE PK SAMPLE COLLECTION Period: 2

Date and Time of Dosing:	02-Feb-2016 08:00
Date of sample collection:	02-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	02-Feb-2016 11:20
Actual Time of sample collection:	11:20 24 hrs. clock
Remarks:	
PK Sample ID:	PK16046093
Remarks if any other reason:	

3.667 HRS POST DOSE PK SAMPLE COLLECTION Period: 2

Date and Time of Dosing:	02-Feb-2016 08:00
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CASE REPORT FORM

Project No: 745-15

Subject No: 1002 Subject Initials: SCK



Date of sample collection:	02-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	02-Feb-2016 11:40
Actual Time of sample collection:	11:40 24 hrs. clock
Remarks:	
PK Sample ID:	PK16046183
Remarks if any other reason:	

4.000 HRS POST DOSE PK SAMPLE COLLECTION Period: 2

Date and Time of Dosing:	02-Feb-2016 08:00
Date of sample collection:	02-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	02-Feb-2016 12:00
Actual Time of sample collection:	12:00 24 hrs. clock
Remarks:	
PK Sample ID:	PK16046273
Remarks if any other reason:	

4.500 HRS POST DOSE PK SAMPLE COLLECTION Period: 2

Date and Time of Dosing:	02-Feb-2016 08:00
Date of sample collection:	02-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	02-Feb-2016 12:30
Actual Time of sample collection:	12:30 24 hrs. clock
Remarks:	
PK Sample ID:	PK16046363
Remarks if any other reason:	

5.000 HRS POST DOSE PK SAMPLE COLLECTION Period: 2

Date and Time of Dosing:	02-Feb-2016 08:00
Date of sample collection:	02-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	02-Feb-2016 13:00
Actual Time of sample collection:	13:00 24 hrs. clock
Remarks:	
PK Sample ID:	PK16046453
Remarks if any other reason:	

LUNCH (5.00 HRS POST DOSE) (DAY 1) Period: 2

Date of meal distribution:	02-Feb-2016
Start Time:	13:03 24 hrs. clock
End Time:	13:19 24 hrs. clock
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-

6.000 HRS POST DOSE PK SAMPLE COLLECTION Period: 2

Date and Time of Dosing:	02-Feb-2016 08:00
Date of sample collection:	02-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	02-Feb-2016 14:00
Actual Time of sample collection:	14:00 24 hrs. clock
Remarks:	

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CASE REPORT FORM

Project No: 745-15

Subject No: 1002 Subject Initials: SCK



PK Sample ID:	PK16046543
Remarks if any other reason:	
8.000 HRS POST DOSE PK SAMPLE COLLECTION Period: 2	
Date and Time of Dosing:	02-Feb-2016 08:00
Date of sample collection:	02-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	02-Feb-2016 16:00
Actual Time of sample collection:	16:00 24 hrs. clock
Remarks:	
PK Sample ID:	PK16046633
Remarks if any other reason:	
SNACKS (DAY 1) Period: 2	
Date of meal distribution:	02-Feb-2016
Start Time:	16:02 24 hrs. clock
End Time:	16:12 24 hrs. clock
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-
8.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD Period: 2	
Position:	Sitting
Date of vital measurement:	02-Feb-2016
Start Time of vital measurement:	15:42 24 hrs. clock
Systolic Blood Pressure:	110 mmHg
Diastolic Blood Pressure:	70 mmHg
Radial Pulse:	78 beats/min
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-
12.000 HRS POST DOSE PK SAMPLE COLLECTION Period: 2	
Date and Time of Dosing:	02-Feb-2016 08:00
Date of sample collection:	02-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	02-Feb-2016 20:00
Actual Time of sample collection:	20:00 24 hrs. clock
Remarks:	
PK Sample ID:	PK16046723
Remarks if any other reason:	
DINNER (DAY 1) Period: 2	
Date of meal distribution:	02-Feb-2016
Start Time:	20:02 24 hrs. clock
End Time:	20:20 24 hrs. clock
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-

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Subject No: 1002 Subject Initials: SCK



12.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD Period: 2

Position:	Sitting
Date of vital measurement:	02-Feb-2016
Start Time of vital measurement:	19:31 24 hrs. clock
Systolic Blood Pressure:	114 mmHg
Diastolic Blood Pressure:	76 mmHg
Radial Pulse:	64 beats/min
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-

16.000 HRS POST DOSE PK SAMPLE COLLECTION Period: 2

Date and Time of Dosing:	02-Feb-2016 08:00
Date of sample collection:	03-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	03-Feb-2016 00:00
Actual Time of sample collection:	00:00 24 hrs. clock
Remarks:	
PK Sample ID:	PK16046813
Remarks if any other reason:	

24.000 HRS POST DOSE PK SAMPLE COLLECTION Period: 2

Date and Time of Dosing:	02-Feb-2016 08:00
Date of sample collection:	03-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	03-Feb-2016 08:00
Actual Time of sample collection:	08:00 24 hrs. clock
Remarks:	
PK Sample ID:	PK16046903
Remarks if any other reason:	

BREAKFAST (DAY 2) Period: 2

Date of meal distribution:	03-Feb-2016
Start Time:	08:10 24 hrs. clock
End Time:	08:16 24 hrs. clock
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-

24.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD Period: 2

Position:	Sitting
Date of vital measurement:	03-Feb-2016
Start Time of vital measurement:	07:36 24 hrs. clock
Systolic Blood Pressure:	120 mmHg
Diastolic Blood Pressure:	80 mmHg
Radial Pulse:	76 beats/min
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-

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CASE REPORT FORM

Project No: 745-15

Subject No: 1002 Subject Initials: SCK



Remarks:	-
LUNCH (DAY 2) Period: 2	
Date of meal distribution:	03-Feb-2016
Start Time:	12:00 24 hrs. clock
End Time:	12:17 24 hrs. clock
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-
SNACKS (DAY 2) Period: 2	
Date of meal distribution:	03-Feb-2016
Start Time:	16:01 24 hrs. clock
End Time:	16:10 24 hrs. clock
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-
36.000 HRS POST DOSE PK SAMPLE COLLECTION Period: 2	
Date and Time of Dosing:	02-Feb-2016 08:00
Date of sample collection:	03-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	03-Feb-2016 20:00
Actual Time of sample collection:	20:00 24 hrs. clock
Remarks:	
PK Sample ID:	PK16046993
Remarks if any other reason:	
DINNER (DAY 2) Period: 2	
Date of meal distribution:	03-Feb-2016
Start Time:	20:02 24 hrs. clock
End Time:	20:19 24 hrs. clock
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-
48.000 HRS POST DOSE PK SAMPLE COLLECTION Period: 2	
Date and Time of Dosing:	02-Feb-2016 08:00
Date of sample collection:	04-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	04-Feb-2016 08:00
Actual Time of sample collection:	08:00 24 hrs. clock
Remarks:	
PK Sample ID:	PK16047083
Remarks if any other reason:	
72.000 HRS AMBULATORY PK SAMPLE COLLECTION (DAY 4) Period: 2	
Date and Time of Dosing:	02-Feb-2016 08:00
Date of sample collection:	05-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	05-Feb-2016 08:00

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CASE REPORT FORM

Project No: 745-15

Subject No: 1002 Subject Initials: SCK



Actual Time of sample collection:	08:00 24 hrs. clock
Remarks:	
PK Sample ID:	PK16047173
Remarks if any other reason:	

72.000 HRS COMPLIANCE AND WELL BEING AT THE TIME OF AMBULATORY SAMPLE (DAY 4) Period: 2

Compliance at the Time of Ambulatory

Date of compliance at the time of ambulatory sample:	05-Feb-2016
Have you consumed any medicine [including herbal remedies, non-steroidal anti-inflammatory drugs (NSAIDs), platelet inhibitors and any other anticoagulants, P-gp inhibitors (e.g., rifampin)] alcohol, alcoholic products, recreational drugs, grapefruit and grapefruit products, an unusual diet for whatever reason (e.g. low-sodium) or smoked since last visit?:	<input type="radio"/> Yes <input checked="" type="radio"/> No
Have you donated blood anywhere else or participated in other clinical trial since last visit?:	<input type="radio"/> Yes <input checked="" type="radio"/> No
If Yes, Remarks:	-

Well Being at the Time of Ambulatory

Date of well being:	05-Feb-2016
Start Time of well being:	08:03 24 hrs. clock
Well-Being at the time of ambulatory sample:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
Remarks if Unwell:	-
Remark if any:	-

CHECK-OUT DETAILS(Period - 2)

CLINICAL EXAMINATION-CHECKOUT Period: 2

Date of Clinical Examination:	04-Feb-2016
Start Time of Clinical Examination:	06:46 24 hrs. clock
Complaint of any illness:	<input checked="" type="radio"/> No <input type="radio"/> Yes
If YES, provide details:	-
General Physical examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Oral Body Temperature:	98.0 °F
Radial Pulse Rate:	80 beats/min
Blood Pressure(Systolic):	122 mmHg
Blood Pressure(Diastolic):	76 mmHg
Cardiovascular System Examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Respiratory System Examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Central Nervous System Examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Per Abdomen Examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Any other Significant finding:	-
Any investigations recommended:	-
If 'Abnormal' in any of the above-mentioned sections, please enter details:	-
To be performed at the time of check-out	

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Sponsor Name: Intas Pharmaceuticals Ltd.

CASE REPORT FORM

Project No: 745-15

Subject No: 1002 Subject Initials: SCK



Vein puncture site:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Subject well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
Comments:	-
Subject is fit for Check-out:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Remark If any:	-

CHECK-OUT B&B Period: 2

Date of check out:	04-Feb-2016
Time of Check-out:	08:16 24 hrs. clock
Remarks:	-

LABORATORY ASSESSMENT-WITHIN THREE WORKING DAYS PRIOR TO DOSING OF (PERIOD-III) Period: 2

Note: For Estimation of coagulation tests (APTT, PT) and Creatinine Clearance (CrCl).

Period:	III
Has the blood sample been collected as per protocol?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Date of blood sample collection:	08-Feb-2016
Lab report clinically acceptable:	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NAP
Comments (if any):	-

Note: CrCl should be more than 50 mL/min before dosing.

CHECK-IN DETAILS(Period - 3)

BREATH TEST FOR ALCOHOL CONSUMPTION Period: 3

Date::	08-Feb-2016
Start Time:	16:17 24 hrs. clock
Breath Alcohol Level (BAL):	.000 %
Result:	<input type="radio"/> Positive <input checked="" type="radio"/> Negative
Start Time of 1st Repeat:	24 hrs. clock
Breath Alcohol Level (BAL):	%
1st Repeat result:	<input type="radio"/> Positive <input type="radio"/> Negative
Start Time of 2nd Repeat:	24 hrs. clock
Breath Alcohol Level (BAL):	%
2nd Repeat Result:	<input type="radio"/> Positive <input type="radio"/> Negative
Final Result:	<input type="radio"/> Positive <input checked="" type="radio"/> Negative
Remarks:	--

URINE SCAN FOR DRUGS OF ABUSE Period: 3

SOP reference no:CPMA-26-07

Date:	08-Feb-2016
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1. URINE SCAN FOR DRUGS ABUSE

Lambda Therapeutic Research.

Sponsor Name: Intas Pharmaceuticals Ltd.

CASE REPORT FORM

Project No: 745-15

Subject No: 1002 Subject Initials: SCK



1.0 Tested for:	<input checked="" type="checkbox"/> Amphetamine (AMP) <input checked="" type="checkbox"/> Cocaine (COC) <input checked="" type="checkbox"/> Barbiturates (BAR) <input checked="" type="checkbox"/> Morphine (MOR) <input checked="" type="checkbox"/> Benzodiazepines (BZD) <input checked="" type="checkbox"/> Cannabinoids (THC)
1.1 Start time:	16:31 24 hrs. clock
1.2 Observation of Results:	<input checked="" type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D
Note: A=Two bands indicates negative (Control and Test), B=One band indicates Positive (Control), C=No band indicates Invalid, D=One band indicates Invalid (Test)	
1.3 Result:	<input type="radio"/> Positive <input checked="" type="radio"/> Negative <input type="radio"/> Invalid
1.4 Positive for:	<input type="checkbox"/> Amphetamine (AMP) <input type="checkbox"/> Cocaine (COC) <input type="checkbox"/> Barbiturates (BAR) <input type="checkbox"/> Morphine (MOR) <input type="checkbox"/> Benzodiazepines (BZD) <input type="checkbox"/> Cannabinoids (THC)
1.5 Any additional test performed-1:	<input type="radio"/> Yes <input type="radio"/> No <input checked="" type="radio"/> NAP
1.5a. Please Specify:	
1.5b. Start time:	24 hrs. clock
1.5c. Observation of result:	<input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D
Note: A=Two bands indicates negative (Control and Test), B=One band indicates Positive (Control), C=No band indicates Invalid, D=One band indicates Invalid (Test)	
1.5d. Result:	<input type="radio"/> Positive <input type="radio"/> Negative <input type="radio"/> Invalid
1.6 Any additional test performed-2:	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NAP
1.6a. Please Specify:	
1.6b. Start time:	24 hrs. clock
1.6c. Observation of result:	<input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D
Note: A=Two bands indicates negative (Control and Test), B=One band indicates Positive (Control), C=No band indicates Invalid, D=One band indicates Invalid (Test)	
1.6d. Result:	<input type="radio"/> Positive <input type="radio"/> Negative <input type="radio"/> Invalid
2. URINE SCAN FOR DRUGS ABUSE (1st REPEAT)	
2.0 Start time:	24 hrs. clock
2.1 Observation of result:	<input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D
Note: A=Two bands indicates negative (Control and Test), B=One band indicates Positive (Control), C=No band indicates Invalid, D=One band indicates Invalid (Test)	
2.2 Result:	<input type="radio"/> Positive <input type="radio"/> Negative <input type="radio"/> Invalid

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Project No: 745-15

Subject No: 1002 Subject Initials: SCK



2.3 Positive for:	<input type="checkbox"/> Amphetamine (AMP) <input type="checkbox"/> Cocaine (COC)	<input type="checkbox"/> Barbiturates (BAR) <input type="checkbox"/> Morphine (MOR)	<input type="checkbox"/> Benzodiazepines (BZD) <input type="checkbox"/> Cannabinoids (THC)
2.4 Any additional test performed-1:	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NAP		
2.4a. Please Specify:			
2.4b. Start time:	24 hrs. clock		
2.4c. Observation of result:	<input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D		
Note: A=Two bands indicates negative (Control and Test),B=One band indicates Positive (Control),C=No band indicates Invalid ,D=One band indicates Invalid (Test)			
2.4d. Result:	<input type="radio"/> Positive <input type="radio"/> Negative <input type="radio"/> Invalid		
2.5 Any additional test performed-2:	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NAP		
2.5a. Please Specify:			
2.5b. Start time:	24 hrs. clock		
2.5c. Observation of result:	<input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D		
Note: A=Two bands indicates negative (Control and Test),B=One band indicates Positive (Control),C=No band indicates Invalid ,D=One band indicates Invalid (Test)			
2.5d. Result:	<input type="radio"/> Positive <input type="radio"/> Negative <input type="radio"/> Invalid		
3. URINE SCAN FOR DRUGS ABUSE (2nd REPEAT)			
3.0 Start time:	24 hrs. clock		
3.1 Observation of result:	<input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D		
Note: A=Two bands indicates negative (Control and Test),B=One band indicates Positive (Control),C=No band indicates Invalid ,D=One band indicates Invalid (Test)			
3.2 Result:	<input type="radio"/> Positive <input type="radio"/> Negative <input type="radio"/> Invalid		
3.3 Positive for:	<input type="checkbox"/> Amphetamine (AMP) <input type="checkbox"/> Cocaine (COC)	<input type="checkbox"/> Barbiturates (BAR) <input type="checkbox"/> Morphine (MOR)	<input type="checkbox"/> Benzodiazepines (BZD) <input type="checkbox"/> Cannabinoids (THC)
3.4 Any additional test performed-1:	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NAP		
3.4a. Please Specify:			
3.4b. Start time:	24 hrs. clock		
3.4c. Observation of result:	<input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D		

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Note: A=Two bands indicates negative (Control and Test), B=One band indicates Positive (Control), C=No band indicates Invalid, D=One band indicates Invalid (Test)

3.4d. Result:	<input type="radio"/> Positive <input type="radio"/> Negative <input type="radio"/> Invalid
3.5 Any additional test performed-2:	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NAP
3.5a. Please Specify:	
3.5b. Start time:	24 hrs. clock
3.5c. Observation of result:	<input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D

Note: A=Two bands indicates negative (Control and Test), B=One band indicates Positive (Control), C=No band indicates Invalid, D=One band indicates Invalid (Test)

3.5d. Result:	<input type="radio"/> Positive <input type="radio"/> Negative <input type="radio"/> Invalid
Final result:	<input type="radio"/> Positive <input checked="" type="radio"/> Negative
Positive for:	<input type="checkbox"/> Amphetamine (AMP) <input type="checkbox"/> Barbiturates (BAR) <input type="checkbox"/> Benzodiazepines (BZD) <input type="checkbox"/> Cocaine (COC) <input type="checkbox"/> Morphine (MOR) <input type="checkbox"/> Cannabinoids (THC)
Final result (For additional test-1):	<input type="radio"/> Positive <input type="radio"/> Negative
Positive for (For additional test-1):	
Final result (For additional test-2):	<input type="radio"/> Positive <input type="radio"/> Negative
Positive for (For additional test-2):	
Remarks (for repeats or any other information):	--

COMPLIANCE CHECK-PIII

Period: 3

Demographic Details

Age in Years (Completed as of Screening Date): 24

Subject Reporting Record

Date of reporting to the clinical facility: 08-Feb-2016

Protocol Compliance Assessment

Urine scans for drugs of abuse tested negative:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Breath test for alcohol consumption tested negative:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Date of last menstruation period (For Female subject):	-
Result of serum pregnancy test:	<input type="radio"/> Positive <input type="radio"/> Negative <input checked="" type="radio"/> NAP (For Male subject)

Prohibitions

Are you suffering from any illness since the last visit (Including allergic reaction, itching, rash on your skin):	<input type="radio"/> Yes <input checked="" type="radio"/> No
Have you consumed any xanthine containing food or beverages (tea, coffee, chocolates or cola drinks) within 24 hours prior to IMP administration?:	<input type="radio"/> Yes <input checked="" type="radio"/> No
Have you consumed tobacco, tobacco containing products (Gutkha, Pan/Pan Masala) within 24 hours prior to IMP administration?:	<input type="radio"/> Yes <input checked="" type="radio"/> No

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Have you consumed alcohol, alcoholic products, recreational drugs since last PK sample collection of Period II?:	<input type="radio"/> Yes <input checked="" type="radio"/> No
Have you consumed grapefruit and grapefruit products since last PK sample collection of Period II?:	<input type="radio"/> Yes <input checked="" type="radio"/> No
Have you smoked since last PK sample collection of Period II?:	<input type="radio"/> Yes <input checked="" type="radio"/> No
Ingestion of a medicine [including herbal remedies, non-steroidal anti-inflammatory drugs (NSAIDs), platelet inhibitors and any other anticoagulants, P-gp inhibitors (e.g., rifampin)] at any time since last PK sample collection of Period II?:	<input type="radio"/> Yes <input checked="" type="radio"/> No
Have you consumed an unusual diet for whatever reason (e.g. low-sodium) since last PK sample collection of Period II?:	<input type="radio"/> Yes <input checked="" type="radio"/> No
Have you donated blood anywhere else or participated in other clinical trial since last PK sample collection of Period II?:	<input type="radio"/> Yes <input checked="" type="radio"/> No
Is subject compliant to all above restrictions/requirement?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Remark If any:	-

CHECK-IN B&B Period: 3

Baggage and Body Search done:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Date of Check In:	08-Feb-2016
Time of Check-in:	17:56 24 hrs. clock
Remarks:	-

CLINICAL EXAMINATION - CHECK IN Period: 3

Date of clinical examination:	08-Feb-2016
Start Time of Clinical Examination:	18:25 24 hrs. clock
Complaints of any illness:	<input checked="" type="radio"/> No <input type="radio"/> Yes
If YES, provide details:	-
General Physical examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Oral Body Temperature:	98.2 °F
Blood Pressure (Systolic):	120 mmHg
Blood Pressure (Diastolic):	80 mmHg
Radial Pulse Rate:	76 beats/min
Cardiovascular System Examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Respiratory System Examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Central Nervous System Examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Per Abdomen Examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Any other Significant finding:	-
Any investigations recommended:	-
Vein puncture site:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Subject well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If 'Abnormal' in any of the above-mentioned sections, please enter details.:	-
Remark if Any:	-

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CASE REPORT FORM

Project No: 745-15

Subject No: 1002 Subject Initials: SCK



Subject is fit:	<input checked="" type="radio"/> Yes <input type="radio"/> No
-----------------	---

DINNER CHECK-IN (DAY-2) Period: 3

Date of meal distribution:	08-Feb-2016
Start Time:	20:38 24 hrs. clock
End Time:	20:54 24 hrs. clock
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-

HOUSING DETAILS(Period - 3)

BREAKFAST (DAY-1) Period: 3

Date of meal distribution:	09-Feb-2016
Start Time:	08:09 24 hrs. clock
End Time:	08:15 24 hrs. clock
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-

LUNCH (DAY-1) Period: 3

Date of meal distribution:	09-Feb-2016
Start Time:	12:05 24 hrs. clock
End Time:	12:22 24 hrs. clock
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-

SNACKS (DAY-1) Period: 3

Date of meal distribution:	09-Feb-2016
Start Time:	16:02 24 hrs. clock
End Time:	16:12 24 hrs. clock
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-

DINNER (DAY-1) Period: 3

Date of meal distribution:	09-Feb-2016
Start Time:	20:02 24 hrs. clock
End Time:	20:16 24 hrs. clock
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-

0.00 HRS PRE DOSE VITAL SIGNS AND WELL-BEING RECORD Period: 3

Position:	Sitting
Date of vital measurement:	10-Feb-2016

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CASE REPORT FORM

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Start Time of vital measurement:	06:33 24 hrs. clock
Systolic Blood Pressure:	122 mmHg
Diastolic Blood Pressure:	74 mmHg
Radial Pulse:	72 beats/min
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-

0.000 HRS PRE DOSE PK SAMPLE COLLECTION Period: 3

Date and Time of Dosing:	
Date of sample collection:	10-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	
Actual Time of sample collection:	07:19 24 hrs. clock
Remarks:	
PK Sample ID:	PK16065146
Remarks if any other reason:	

IMP ADMINISTRATION Period: 3

DATE:	10-Feb-2016
IS SUBJECT COMPLIANT TO ALL PREDOSE REQUIREMENTS AS PER PROTOCOL?:	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NA
TIME:	08:00 24 hrs. clock
MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA:	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NA
ML OF WATER ADMINISTERED WITH IP:	240
LABEL:	0000177633
PRODUCT CODE/ TYPE:	Test
DOSING SUPERVISION DONE BY:	bhargavjoshi (Dosing)
REMARKS:	

STUDY DRUG ADMINISTRATION-COMPLIANCE Period: 3

Has the subject compliant to 01 hour post dose water restriction?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Has the subject compliant to postural restriction for the first 03 hours after dosing in sitting or ambulatory posture? (unless medically necessary due to adverse event or procedurally required):	<input checked="" type="radio"/> Yes <input type="radio"/> No
Has the subject compliant to 05 hours post dose fasting condition?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Remark if any:	-

0.250 HRS POST DOSE PK SAMPLE COLLECTION Period: 3

Date and Time of Dosing:	10-Feb-2016 08:00
Date of sample collection:	10-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	10-Feb-2016 08:15
Actual Time of sample collection:	08:15 24 hrs. clock
Remarks:	
PK Sample ID:	PK16065236
Remarks if any other reason:	

0.500 HRS POST DOSE PK SAMPLE COLLECTION Period: 3

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Subject No: 1002 Subject Initials: SCK



Date and Time of Dosing:	10-Feb-2016 08:00
Date of sample collection:	10-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	10-Feb-2016 08:30
Actual Time of sample collection:	08:30 24 hrs. clock
Remarks:	
PK Sample ID:	PK16065326
Remarks if any other reason:	
0.750 HRS POST DOSE PK SAMPLE COLLECTION Period: 3	
Date and Time of Dosing:	10-Feb-2016 08:00
Date of sample collection:	10-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	10-Feb-2016 08:45
Actual Time of sample collection:	08:45 24 hrs. clock
Remarks:	
PK Sample ID:	PK16065416
Remarks if any other reason:	
1.000 HRS POST DOSE PK SAMPLE COLLECTION Period: 3	
Date and Time of Dosing:	10-Feb-2016 08:00
Date of sample collection:	10-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	10-Feb-2016 09:00
Actual Time of sample collection:	09:00 24 hrs. clock
Remarks:	
PK Sample ID:	PK16065506
Remarks if any other reason:	
1.250 HRS POST DOSE PK SAMPLE COLLECTION Period: 3	
Date and Time of Dosing:	10-Feb-2016 08:00
Date of sample collection:	10-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	10-Feb-2016 09:15
Actual Time of sample collection:	09:15 24 hrs. clock
Remarks:	
PK Sample ID:	PK16065596
Remarks if any other reason:	
1.500 HRS POST DOSE PK SAMPLE COLLECTION Period: 3	
Date and Time of Dosing:	10-Feb-2016 08:00
Date of sample collection:	10-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	10-Feb-2016 09:30
Actual Time of sample collection:	09:30 24 hrs. clock
Remarks:	
PK Sample ID:	PK16065686
Remarks if any other reason:	
1.750 HRS POST DOSE PK SAMPLE COLLECTION Period: 3	
Date and Time of Dosing:	10-Feb-2016 08:00
Date of sample collection:	10-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	10-Feb-2016 09:45

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Actual Time of sample collection:	09:46 24 hrs. clock
Remarks:	
PK Sample ID:	PK16065776
Remarks if any other reason:	

2.000 HRS POST DOSE PK SAMPLE COLLECTION Period: 3

Date and Time of Dosing:	10-Feb-2016 08:00
Date of sample collection:	10-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	10-Feb-2016 10:00
Actual Time of sample collection:	10:00 24 hrs. clock
Remarks:	
PK Sample ID:	PK16065866
Remarks if any other reason:	

2.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD Period: 3

Position:	Sitting
Date of vital measurement:	10-Feb-2016
Start Time of vital measurement:	10:05 24 hrs. clock
Systolic Blood Pressure:	118 mmHg
Diastolic Blood Pressure:	64 mmHg
Radial Pulse:	64 beats/min
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-

2.250 HRS POST DOSE PK SAMPLE COLLECTION Period: 3

Date and Time of Dosing:	10-Feb-2016 08:00
Date of sample collection:	10-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	10-Feb-2016 10:15
Actual Time of sample collection:	10:15 24 hrs. clock
Remarks:	
PK Sample ID:	PK16065956
Remarks if any other reason:	

2.500 HRS POST DOSE PK SAMPLE COLLECTION Period: 3

Date and Time of Dosing:	10-Feb-2016 08:00
Date of sample collection:	10-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	10-Feb-2016 10:30
Actual Time of sample collection:	10:30 24 hrs. clock
Remarks:	
PK Sample ID:	PK16066046
Remarks if any other reason:	

2.750 HRS POST DOSE PK SAMPLE COLLECTION Period: 3

Date and Time of Dosing:	10-Feb-2016 08:00
Date of sample collection:	10-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	10-Feb-2016 10:45
Actual Time of sample collection:	10:45 24 hrs. clock

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Remarks:	
PK Sample ID:	PK16066136
Remarks if any other reason:	
3.000 HRS POST DOSE PK SAMPLE COLLECTION Period: 3	
Date and Time of Dosing:	10-Feb-2016 08:00
Date of sample collection:	10-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	10-Feb-2016 11:00
Actual Time of sample collection:	11:00 24 hrs. clock
Remarks:	
PK Sample ID:	PK16066226
Remarks if any other reason:	
3.333 HRS POST DOSE PK SAMPLE COLLECTION Period: 3	
Date and Time of Dosing:	10-Feb-2016 08:00
Date of sample collection:	10-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	10-Feb-2016 11:20
Actual Time of sample collection:	11:20 24 hrs. clock
Remarks:	
PK Sample ID:	PK16066316
Remarks if any other reason:	
3.667 HRS POST DOSE PK SAMPLE COLLECTION Period: 3	
Date and Time of Dosing:	10-Feb-2016 08:00
Date of sample collection:	10-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	10-Feb-2016 11:40
Actual Time of sample collection:	11:40 24 hrs. clock
Remarks:	
PK Sample ID:	PK16066406
Remarks if any other reason:	
4.000 HRS POST DOSE PK SAMPLE COLLECTION Period: 3	
Date and Time of Dosing:	10-Feb-2016 08:00
Date of sample collection:	10-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	10-Feb-2016 12:00
Actual Time of sample collection:	12:00 24 hrs. clock
Remarks:	
PK Sample ID:	PK16066496
Remarks if any other reason:	
4.500 HRS POST DOSE PK SAMPLE COLLECTION Period: 3	
Date and Time of Dosing:	10-Feb-2016 08:00
Date of sample collection:	10-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	10-Feb-2016 12:30
Actual Time of sample collection:	12:30 24 hrs. clock
Remarks:	
PK Sample ID:	PK16066586
Remarks if any other reason:	

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5.000 HRS POST DOSE PK SAMPLE COLLECTION Period: 3

Date and Time of Dosing:	10-Feb-2016 08:00
Date of sample collection:	10-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	10-Feb-2016 13:00
Actual Time of sample collection:	13:00 24 hrs. clock
Remarks:	
PK Sample ID:	PK16066676
Remarks if any other reason:	

LUNCH (5.00 HRS POST DOSE) (DAY 1) Period: 3

Date of meal distribution:	10-Feb-2016
Start Time:	13:02 24 hrs. clock
End Time:	13:14 24 hrs. clock
Has subject consumed meal completely?:	<input type="radio"/> Yes <input checked="" type="radio"/> No
Details of meal left (Approximate Quantity):	1/2 qty of bhindi veg
Remarks:	-

6.000 HRS POST DOSE PK SAMPLE COLLECTION Period: 3

Date and Time of Dosing:	10-Feb-2016 08:00
Date of sample collection:	10-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	10-Feb-2016 14:00
Actual Time of sample collection:	14:00 24 hrs. clock
Remarks:	
PK Sample ID:	PK16066766
Remarks if any other reason:	

8.000 HRS POST DOSE PK SAMPLE COLLECTION Period: 3

Date and Time of Dosing:	10-Feb-2016 08:00
Date of sample collection:	10-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	10-Feb-2016 16:00
Actual Time of sample collection:	16:00 24 hrs. clock
Remarks:	
PK Sample ID:	PK16066856
Remarks if any other reason:	

SNACKS (DAY 1) Period: 3

Date of meal distribution:	10-Feb-2016
Start Time:	16:07 24 hrs. clock
End Time:	16:12 24 hrs. clock
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-

8.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD Period: 3

Position:	Sitting
Date of vital measurement:	10-Feb-2016
Start Time of vital measurement:	15:32 24 hrs. clock

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Systolic Blood Pressure:	116 mmHg
Diastolic Blood Pressure:	72 mmHg
Radial Pulse:	76 beats/min
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-

12.000 HRS POST DOSE PK SAMPLE COLLECTION Period: 3

Date and Time of Dosing:	10-Feb-2016 08:00
Date of sample collection:	10-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	10-Feb-2016 20:00
Actual Time of sample collection:	20:00 24 hrs. clock
Remarks:	
PK Sample ID:	PK16076271
Remarks if any other reason:	

DINNER (DAY 1) Period: 3

Date of meal distribution:	10-Feb-2016
Start Time:	20:04 24 hrs. clock
End Time:	20:23 24 hrs. clock
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-

12.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD Period: 3

Position:	Sitting
Date of vital measurement:	10-Feb-2016
Start Time of vital measurement:	19:21 24 hrs. clock
Systolic Blood Pressure:	118 mmHg
Diastolic Blood Pressure:	76 mmHg
Radial Pulse:	72 beats/min
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-

16.000 HRS POST DOSE PK SAMPLE COLLECTION Period: 3

Date and Time of Dosing:	10-Feb-2016 08:00
Date of sample collection:	11-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	11-Feb-2016 00:00
Actual Time of sample collection:	00:00 24 hrs. clock
Remarks:	
PK Sample ID:	PK16067036
Remarks if any other reason:	

24.000 HRS POST DOSE PK SAMPLE COLLECTION Period: 3

Date and Time of Dosing:	10-Feb-2016 08:00
Date of sample collection:	11-Feb-2016

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Sponsor Name: Intas Pharmaceuticals Ltd.

CASE REPORT FORM

Project No: 745-15

Subject No: 1002 Subject Initials: SCK



Scheduled date and Time of sample collection (for post dose only):	11-Feb-2016 08:00
Actual Time of sample collection:	08:00 24 hrs. clock
Remarks:	
PK Sample ID:	PK16067126
Remarks if any other reason:	
BREAKFAST (DAY 2) Period: 3	
Date of meal distribution:	11-Feb-2016
Start Time:	08:06 24 hrs. clock
End Time:	08:09 24 hrs. clock
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-
24.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD Period: 3	
Position:	Sitting
Date of vital measurement:	11-Feb-2016
Start Time of vital measurement:	07:32 24 hrs. clock
Systolic Blood Pressure:	118 mmHg
Diastolic Blood Pressure:	76 mmHg
Radial Pulse:	72 beats/min
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-
LUNCH (DAY 2) Period: 3	
Date of meal distribution:	11-Feb-2016
Start Time:	12:07 24 hrs. clock
End Time:	12:22 24 hrs. clock
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-
SNACKS (DAY 2) Period: 3	
Date of meal distribution:	11-Feb-2016
Start Time:	16:06 24 hrs. clock
End Time:	16:17 24 hrs. clock
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-
36.000 HRS POST DOSE PK SAMPLE COLLECTION Period: 3	
Date and Time of Dosing:	10-Feb-2016 08:00
Date of sample collection:	11-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	11-Feb-2016 20:00
Actual Time of sample collection:	20:00 24 hrs. clock

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CASE REPORT FORM

Project No: 745-15

Subject No: 1002 Subject Initials: SCK



Remarks:	
PK Sample ID:	PK16067216
Remarks if any other reason:	
DINNER (DAY 2) Period: 3	
Date of meal distribution:	11-Feb-2016
Start Time:	20:05 24 hrs. clock
End Time:	20:19 24 hrs. clock
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-
48.000 HRS POST DOSE PK SAMPLE COLLECTION Period: 3	
Date and Time of Dosing:	10-Feb-2016 08:00
Date of sample collection:	12-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	12-Feb-2016 08:00
Actual Time of sample collection:	08:00 24 hrs. clock
Remarks:	
PK Sample ID:	PK16067306
Remarks if any other reason:	
72.000 HRS AMBULATORY PK SAMPLE COLLECTION (DAY 4) Period: 3	
Date and Time of Dosing:	10-Feb-2016 08:00
Date of sample collection:	13-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	13-Feb-2016 08:00
Actual Time of sample collection:	08:00 24 hrs. clock
Remarks:	
PK Sample ID:	PK16067396
Remarks if any other reason:	
72.000 HRS COMPLIANCE AND WELL BEING AT THE TIME OF AMBULATORY SAMPLE (DAY 4) Period: 3	
Compliance at the Time of Ambulatory	
Date of compliance at the time of ambulatory sample:	13-Feb-2016
Have you consumed any medicine [including herbal remedies, non-steroidal anti-inflammatory drugs (NSAIDs), platelet inhibitors and any other anticoagulants, P-gp inhibitors (e.g., rifampin)] alcohol, alcoholic products, recreational drugs, grapefruit and grapefruit products, an unusual diet for whatever reason (e.g. low-sodium) or smoked since last visit?:	<input type="radio"/> Yes <input checked="" type="radio"/> No
Have you donated blood anywhere else or participated in other clinical trial since last visit?:	<input type="radio"/> Yes <input checked="" type="radio"/> No
If Yes, Remarks:	-
Well Being at the Time of Ambulatory	
Date of well being:	13-Feb-2016
Start Time of well being:	08:01 24 hrs. clock
Well-Being at the time of ambulatory sample:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
Remarks if Unwell:	-

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CASE REPORT FORM

Project No: 745-15

Subject No: 1002 Subject Initials: SCK



Remark if any: -

CHECK-OUT DETAILS(Period - 3)

CLINICAL EXAMINATION-CHECKOUT Period: 3

Date of Clinical Examination:	12-Feb-2016
Start Time of Clinical Examination:	06:31 24 hrs. clock
Complaint of any illness:	<input checked="" type="radio"/> No <input type="radio"/> Yes
If YES, provide details:	-
General Physical examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Oral Body Temperature:	98.2 °F
Radial Pulse Rate:	76 beats/min
Blood Pressure(Systolic):	120 mmHg
Blood Pressure(Diastolic):	80 mmHg
Cardiovascular System Examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Respiratory System Examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Central Nervous System Examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Per Abdomen Examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Any other Significant finding:	-
Any investigations recommended:	-
If 'Abnormal' in any of the above-mentioned sections, please enter details:	-
To be performed at the time of check-out	
Vein puncture site:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Subject well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
Comments:	-
Subject is fit for Check-out:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Remark If any:	-

CHECK-OUT B&B Period: 3

Date of check out:	12-Feb-2016
Time of Check-out:	08:26 24 hrs. clock
Remarks:	-

LABORATORY ASSESSMENT-WITHIN THREE WORKING DAYS PRIOR TO DOSING OF (PERIOD-IV) Period: 3

Note: For Estimation of coagulation tests (APTT, PT) and Creatinine Clearance (CrCl).	
Period:	IV
Has the blood sample been collected as per protocol?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Date of blood sample collection:	16-Feb-2016
Lab report clinically acceptable:	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NAP
Comments (if any):	-
Note: CrCl should be more than 50 mL/min before dosing.	

CHECK-IN DETAILS(Period - 4)

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CASE REPORT FORM

Project No: 745-15

Subject No: 1002 Subject Initials: SCK



BREATH TEST FOR ALCOHOL CONSUMPTION Period: 4

Date::	16-Feb-2016
Start Time:	19:32 24 hrs. clock
Breath Alcohol Level (BAL):	.000 %
Result:	<input type="radio"/> Positive <input checked="" type="radio"/> Negative
Start Time of 1st Repeat:	24 hrs. clock
Breath Alcohol Level (BAL):	%
1st Repeat result:	<input type="radio"/> Positive <input type="radio"/> Negative
Start Time of 2nd Repeat:	24 hrs. clock
Breath Alcohol Level (BAL):	%
2nd Repeat Result:	<input type="radio"/> Positive <input type="radio"/> Negative
Final Result:	<input type="radio"/> Positive <input checked="" type="radio"/> Negative
Remarks:	-

URINE SCAN FOR DRUGS OF ABUSE Period: 4

SOP reference no:CPMA-26-07

Date:	16-Feb-2016
1. URINE SCAN FOR DRUGS ABUSE	
1.0 Tested for:	<input checked="" type="checkbox"/> Amphetamine (AMP) <input checked="" type="checkbox"/> Barbiturates (BAR) <input checked="" type="checkbox"/> Benzodiazepines (BZD) <input checked="" type="checkbox"/> Cocaine (COC) <input checked="" type="checkbox"/> Morphine (MOR) <input checked="" type="checkbox"/> Cannabinoids (THC)
1.1 Start time:	19:59 24 hrs. clock
1.2 Observation of Results:	<input checked="" type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D
Note: A=Two bands indicates negative (Control and Test),B=One band indicates Positive (Control),C=No band indicates Invalid ,D=One band indicates Invalid (Test)	
1.3 Result:	<input type="radio"/> Positive <input checked="" type="radio"/> Negative <input type="radio"/> Invalid
1.4 Positive for:	<input type="checkbox"/> Amphetamine (AMP) <input type="checkbox"/> Barbiturates (BAR) <input type="checkbox"/> Benzodiazepines (BZD) <input type="checkbox"/> Cocaine (COC) <input type="checkbox"/> Morphine (MOR) <input type="checkbox"/> Cannabinoids (THC)
1.5 Any additional test performed-1:	<input type="radio"/> Yes <input type="radio"/> No <input checked="" type="radio"/> NAP
1.5a. Please Specify:	
1.5b. Start time:	24 hrs. clock
1.5c. Observation of result:	<input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D
Note: A=Two bands indicates negative (Control and Test),B=One band indicates Positive (Control),C=No band indicates Invalid ,D=One band indicates Invalid (Test)	

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1.5d. Result:	<input type="radio"/> Positive <input type="radio"/> Negative <input type="radio"/> Invalid
1.6 Any additional test performed-2:	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NAP
1.6a. Please Specify:	
1.6b. Start time:	24 hrs. clock
1.6c. Observation of result:	<input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D
Note: A=Two bands indicates negative (Control and Test),B=One band indicates Positive (Control),C=No band indicates Invalid ,D=One band indicates Invalid (Test)	
1.6d. Result:	<input type="radio"/> Positive <input type="radio"/> Negative <input type="radio"/> Invalid
2. URINE SCAN FOR DRUGS ABUSE (1st REPEAT)	
2.0 Start time:	24 hrs. clock
2.1 Observation of result:	<input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D
Note: A=Two bands indicates negative (Control and Test),B=One band indicates Positive (Control),C=No band indicates Invalid ,D=One band indicates Invalid (Test)	
2.2 Result:	<input type="radio"/> Positive <input type="radio"/> Negative <input type="radio"/> Invalid
2.3 Positive for:	<input type="checkbox"/> Amphetamine (AMP) <input type="checkbox"/> Barbiturates (BAR) <input type="checkbox"/> Benzodiazepines (BZD) <input type="checkbox"/> Cocaine (COC) <input type="checkbox"/> Morphine (MOR) <input type="checkbox"/> Cannabinoids (THC)
2.4 Any additional test performed-1:	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NAP
2.4a. Please Specify:	
2.4b. Start time:	24 hrs. clock
2.4c. Observation of result:	<input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D
Note: A=Two bands indicates negative (Control and Test),B=One band indicates Positive (Control),C=No band indicates Invalid ,D=One band indicates Invalid (Test)	
2.4d. Result:	<input type="radio"/> Positive <input type="radio"/> Negative <input type="radio"/> Invalid
2.5 Any additional test performed-2:	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NAP
2.5a. Please Specify:	
2.5b. Start time:	24 hrs. clock
2.5c. Observation of result:	<input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D
Note: A=Two bands indicates negative (Control and Test),B=One band indicates Positive (Control),C=No band indicates Invalid ,D=One band indicates Invalid (Test)	
2.5d. Result:	<input type="radio"/> Positive <input type="radio"/> Negative <input type="radio"/> Invalid
3. URINE SCAN FOR DRUGS ABUSE (2nd REPEAT)	

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CASE REPORT FORM

Project No: 745-15

Subject No: 1002 Subject Initials: SCK



3.0 Start time:	24 hrs. clock
3.1 Observation of result:	<input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D
Note: A=Two bands indicates negative (Control and Test),B=One band indicates Positive (Control),C=No band indicates Invalid ,D=One band indicates Invalid (Test)	
3.2 Result:	<input type="radio"/> Positive <input type="radio"/> Negative <input type="radio"/> Invalid
3.3 Positive for:	<div> <input type="checkbox"/> Amphetamine (AMP) <input type="checkbox"/> Barbiturates (BAR) <input type="checkbox"/> Benzodiazepines (BZD) </div> <div> <input type="checkbox"/> Cocaine (COC) <input type="checkbox"/> Morphine (MOR) <input type="checkbox"/> Cannabinoids (THC) </div>
3.4 Any additional test performed-1:	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NAP
3.4a. Please Specify:	
3.4b. Start time:	24 hrs. clock
3.4c. Observation of result:	<input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D
Note: A=Two bands indicates negative (Control and Test),B=One band indicates Positive (Control),C=No band indicates Invalid ,D=One band indicates Invalid (Test)	
3.4d. Result:	<input type="radio"/> Positive <input type="radio"/> Negative <input type="radio"/> Invalid
3.5 Any additional test performed-2:	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NAP
3.5a. Please Specify:	
3.5b. Start time:	24 hrs. clock
3.5c. Observation of result:	<input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D
Note: A=Two bands indicates negative (Control and Test),B=One band indicates Positive (Control),C=No band indicates Invalid ,D=One band indicates Invalid (Test)	
3.5d. Result:	<input type="radio"/> Positive <input type="radio"/> Negative <input type="radio"/> Invalid
Final result:	<input type="radio"/> Positive <input checked="" type="radio"/> Negative
Positive for:	<div> <input type="checkbox"/> Amphetamine (AMP) <input type="checkbox"/> Barbiturates (BAR) <input type="checkbox"/> Benzodiazepines (BZD) </div> <div> <input type="checkbox"/> Cocaine (COC) <input type="checkbox"/> Morphine (MOR) <input type="checkbox"/> Cannabinoids (THC) </div>
Final result (For additional test-1):	<input type="radio"/> Positive <input type="radio"/> Negative
Positive for (For additional test-1):	
Final result (For additional test-2):	<input type="radio"/> Positive <input type="radio"/> Negative
Positive for (For additional test-2):	
Remarks (for repeats or any other information):	-

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CASE REPORT FORM

Project No: 745-15

Subject No: 1002 Subject Initials: SCK



COMPLIANCE CHECK-PIV Period: 4

Demographic Details

Age in Years (Completed as of Screening Date): 24

Subject Reporting Record

Date of reporting to the clinical facility: 16-Feb-2016

Protocol Compliance Assessment

Urine scans for drugs of abuse tested negative: ☒ Yes ☐ No

Breath test for alcohol consumption tested negative: ☒ Yes ☐ No

Date of last menstruation period (For Female subject): -

Result of serum pregnancy test: ☐ Positive ☐ Negative ☒ NAP (For Male subject)

Prohibitions

Are you suffering from any illness since the last visit (Including allergic reaction, itching, rash on your skin): ☐ Yes ☒ No

Have you consumed any Xanthine containing food or beverages (tea, coffee, chocolates or cola drinks) within 24 hours prior to IMP administration?: ☐ Yes ☒ No

Have you consumed tobacco, tobacco containing products (Gutkha, Pan/Pan Masala) within 24 hours prior to IMP administration?: ☐ Yes ☒ No

Have you consumed alcohol, alcoholic products, recreational drugs since last PK sample collection of Period III?: ☐ Yes ☒ No

Have you consumed grapefruit and grapefruit products since last PK sample collection of Period III?: ☐ Yes ☒ No

Have you smoked since last PK sample collection of Period III?: ☐ Yes ☒ No

Ingestion of a medicine [including herbal remedies, non-steroidal anti-inflammatory drugs (NSAIDs), platelet inhibitors and any other anticoagulants, P-gp inhibitors (e.g., rifampin)] at any time since last PK sample collection of Period III?: ☐ Yes ☒ No

Have you consumed an unusual diet for whatever reason (e.g. low-sodium) since last PK sample collection of Period III?: ☐ Yes ☒ No

Have you donated blood anywhere else or participated in other clinical trial since last PK sample collection of Period III?: ☐ Yes ☒ No

Is subject compliant to all above restrictions/requirement?: ☒ Yes ☐ No

Remark If any: -

CHECK-IN B&B Period: 4

Baggage and Body Search done: ☒ Yes ☐ No

Date of Check In: 16-Feb-2016

Time of Check-in: 21:09 24 hrs. clock

Remarks: -

CLINICAL EXAMINATION - CHECK IN Period: 4

Date of clinical examination: 16-Feb-2016

Start Time of Clinical Examination: 21:14 24 hrs. clock

Complaints of any illness: ☒ No ☐ Yes

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Subject No: 1002 Subject Initials: SCK



If YES, provide details:	-
General Physical examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Oral Body Temperature:	98.2 °F
Blood Pressure (Systolic):	116 mmHg
Blood Pressure (Diastolic):	76 mmHg
Radial Pulse Rate:	68 beats/min
Cardiovascular System Examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Respiratory System Examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Central Nervous System Examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Per Abdomen Examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Any other Significant finding:	-
Any investigations recommended:	-
Vein puncture site:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Subject well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If 'Abnormal' in any of the above-mentioned sections, please enter details.:	-
Remark if Any:	-
Subject is fit:	<input checked="" type="radio"/> Yes <input type="radio"/> No

DINNER CHECK-IN (DAY-2) Period: 4

Date of meal distribution:	16-Feb-2016
Start Time:	21:27 24 hrs. clock
End Time:	21:42 24 hrs. clock
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-

HOUSING DETAILS(Period - 4)

BREAKFAST (DAY-1) Period: 4

Date of meal distribution:	17-Feb-2016
Start Time:	08:09 24 hrs. clock
End Time:	08:16 24 hrs. clock
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-

LUNCH (DAY-1) Period: 4

Date of meal distribution:	17-Feb-2016
Start Time:	12:00 24 hrs. clock
End Time:	12:19 24 hrs. clock
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-

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CASE REPORT FORM

Project No: 745-15

Subject No: 1002 Subject Initials: SCK



SNACKS (DAY-1)		Period: 4
Date of meal distribution:	17-Feb-2016	
Start Time:	16:02 24 hrs. clock	
End Time:	16:12 24 hrs. clock	
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Details of meal left (Approximate Quantity):	-	
Remarks:	-	

DINNER (DAY-1)		Period: 4
Date of meal distribution:	17-Feb-2016	
Start Time:	20:00 24 hrs. clock	
End Time:	20:20 24 hrs. clock	
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Details of meal left (Approximate Quantity):	-	
Remarks:	-	

0.00 HRS PRE DOSE VITAL SIGNS AND WELL-BEING RECORD		Period: 4
Position:	Sitting	
Date of vital measurement:	18-Feb-2016	
Start Time of vital measurement:	06:46 24 hrs. clock	
Systolic Blood Pressure:	118 mmHg	
Diastolic Blood Pressure:	74 mmHg	
Radial Pulse:	80 beats/min	
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell	
If unwell then specify:	-	
Remarks:	-	

0.000 HRS PRE DOSE PK SAMPLE COLLECTION		Period: 4
Date and Time of Dosing:		
Date of sample collection:	18-Feb-2016	
Scheduled date and Time of sample collection (for post dose only):		
Actual Time of sample collection:	07:12 24 hrs. clock	
Remarks:		
PK Sample ID:	PK16094632	
Remarks if any other reason:		

IMP ADMINISTRATION		Period: 4
DATE:	18-Feb-2016	
IS SUBJECT COMPLIANT TO ALL PREDOSE REQUIREMENTS AS PER PROTOCOL?:	<input type="radio"/> Yes <input checked="" type="radio"/> No <input type="radio"/> NA	
TIME:	08:00 24 hrs. clock	
MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA:	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NA	
ML OF WATER ADMINISTERED WITH IP:	240	
LABEL:	0000178540	
PRODUCT CODE/ TYPE:	Reference	
DOSING SUPERVISION DONE BY:	hareshpatel (Dosing)	

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CASE REPORT FORM

Project No: 745-15

Subject No: 1002 Subject Initials: SCK



REMARKS:	REFER PROTOCOL DEVIATION
STUDY DRUG ADMINISTRATION-COMPLIANCE Period: 4	
Has the subject compliant to 01 hour post dose water restriction?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Has the subject compliant to postural restriction for the first 03 hours after dosing in sitting or ambulatory posture? (unless medically necessary due to adverse event or procedurally required):	<input checked="" type="radio"/> Yes <input type="radio"/> No
Has the subject compliant to 05 hours post dose fasting condition?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Remark if any:	-
0.250 HRS POST DOSE PK SAMPLE COLLECTION Period: 4	
Date and Time of Dosing:	18-Feb-2016 08:00
Date of sample collection:	18-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	18-Feb-2016 08:15
Actual Time of sample collection:	08:15 24 hrs. clock
Remarks:	
PK Sample ID:	PK16094722
Remarks if any other reason:	
0.500 HRS POST DOSE PK SAMPLE COLLECTION Period: 4	
Date and Time of Dosing:	18-Feb-2016 08:00
Date of sample collection:	18-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	18-Feb-2016 08:30
Actual Time of sample collection:	08:30 24 hrs. clock
Remarks:	
PK Sample ID:	PK16094812
Remarks if any other reason:	
0.750 HRS POST DOSE PK SAMPLE COLLECTION Period: 4	
Date and Time of Dosing:	18-Feb-2016 08:00
Date of sample collection:	18-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	18-Feb-2016 08:45
Actual Time of sample collection:	08:45 24 hrs. clock
Remarks:	
PK Sample ID:	PK16094902
Remarks if any other reason:	
1.000 HRS POST DOSE PK SAMPLE COLLECTION Period: 4	
Date and Time of Dosing:	18-Feb-2016 08:00
Date of sample collection:	18-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	18-Feb-2016 09:00
Actual Time of sample collection:	09:00 24 hrs. clock
Remarks:	
PK Sample ID:	PK16094992
Remarks if any other reason:	
1.250 HRS POST DOSE PK SAMPLE COLLECTION Period: 4	
Date and Time of Dosing:	18-Feb-2016 08:00

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Project No: 745-15

Subject No: 1002 Subject Initials: SCK



Date of sample collection:	18-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	18-Feb-2016 09:15
Actual Time of sample collection:	09:15 24 hrs. clock
Remarks:	
PK Sample ID:	PK16095082
Remarks if any other reason:	

1.500 HRS POST DOSE PK SAMPLE COLLECTION Period: 4

Date and Time of Dosing:	18-Feb-2016 08:00
Date of sample collection:	18-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	18-Feb-2016 09:30
Actual Time of sample collection:	09:30 24 hrs. clock
Remarks:	
PK Sample ID:	PK16095172
Remarks if any other reason:	

1.750 HRS POST DOSE PK SAMPLE COLLECTION Period: 4

Date and Time of Dosing:	18-Feb-2016 08:00
Date of sample collection:	18-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	18-Feb-2016 09:45
Actual Time of sample collection:	09:45 24 hrs. clock
Remarks:	
PK Sample ID:	PK16095262
Remarks if any other reason:	

2.000 HRS POST DOSE PK SAMPLE COLLECTION Period: 4

Date and Time of Dosing:	18-Feb-2016 08:00
Date of sample collection:	18-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	18-Feb-2016 10:00
Actual Time of sample collection:	10:00 24 hrs. clock
Remarks:	
PK Sample ID:	PK16095352
Remarks if any other reason:	

2.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD Period: 4

Position:	Sitting
Date of vital measurement:	18-Feb-2016
Start Time of vital measurement:	10:04 24 hrs. clock
Systolic Blood Pressure:	112 mmHg
Diastolic Blood Pressure:	70 mmHg
Radial Pulse:	64 beats/min
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-

2.250 HRS POST DOSE PK SAMPLE COLLECTION Period: 4

Date and Time of Dosing:	18-Feb-2016 08:00
Date of sample collection:	18-Feb-2016

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Sponsor Name: Intas Pharmaceuticals Ltd.

CASE REPORT FORM

Project No: 745-15

Subject No: 1002 Subject Initials: SCK



Scheduled date and Time of sample collection (for post dose only):	18-Feb-2016 10:15
Actual Time of sample collection:	10:15 24 hrs. clock
Remarks:	
PK Sample ID:	PK16095442
Remarks if any other reason:	
2.500 HRS POST DOSE PK SAMPLE COLLECTION Period: 4	
Date and Time of Dosing:	18-Feb-2016 08:00
Date of sample collection:	18-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	18-Feb-2016 10:30
Actual Time of sample collection:	10:30 24 hrs. clock
Remarks:	
PK Sample ID:	PK16095532
Remarks if any other reason:	
2.750 HRS POST DOSE PK SAMPLE COLLECTION Period: 4	
Date and Time of Dosing:	18-Feb-2016 08:00
Date of sample collection:	18-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	18-Feb-2016 10:45
Actual Time of sample collection:	10:45 24 hrs. clock
Remarks:	
PK Sample ID:	PK16095622
Remarks if any other reason:	
3.000 HRS POST DOSE PK SAMPLE COLLECTION Period: 4	
Date and Time of Dosing:	18-Feb-2016 08:00
Date of sample collection:	18-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	18-Feb-2016 11:00
Actual Time of sample collection:	11:00 24 hrs. clock
Remarks:	
PK Sample ID:	PK16095712
Remarks if any other reason:	
3.333 HRS POST DOSE PK SAMPLE COLLECTION Period: 4	
Date and Time of Dosing:	18-Feb-2016 08:00
Date of sample collection:	18-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	18-Feb-2016 11:20
Actual Time of sample collection:	11:20 24 hrs. clock
Remarks:	
PK Sample ID:	PK16095802
Remarks if any other reason:	
3.667 HRS POST DOSE PK SAMPLE COLLECTION Period: 4	
Date and Time of Dosing:	18-Feb-2016 08:00
Date of sample collection:	18-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	18-Feb-2016 11:40
Actual Time of sample collection:	11:40 24 hrs. clock
Remarks:	

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CASE REPORT FORM

Project No: 745-15

Subject No: 1002 Subject Initials: SCK



PK Sample ID:	PK16095892
Remarks if any other reason:	
4.000 HRS POST DOSE PK SAMPLE COLLECTION Period: 4	
Date and Time of Dosing:	18-Feb-2016 08:00
Date of sample collection:	18-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	18-Feb-2016 12:00
Actual Time of sample collection:	12:00 24 hrs. clock
Remarks:	
PK Sample ID:	PK16095982
Remarks if any other reason:	
4.500 HRS POST DOSE PK SAMPLE COLLECTION Period: 4	
Date and Time of Dosing:	18-Feb-2016 08:00
Date of sample collection:	18-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	18-Feb-2016 12:30
Actual Time of sample collection:	12:30 24 hrs. clock
Remarks:	
PK Sample ID:	PK16096072
Remarks if any other reason:	
5.000 HRS POST DOSE PK SAMPLE COLLECTION Period: 4	
Date and Time of Dosing:	18-Feb-2016 08:00
Date of sample collection:	18-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	18-Feb-2016 13:00
Actual Time of sample collection:	13:00 24 hrs. clock
Remarks:	
PK Sample ID:	PK16096162
Remarks if any other reason:	
LUNCH (5.00 HRS POST DOSE) (DAY 1) Period: 4	
Date of meal distribution:	18-Feb-2016
Start Time:	13:02 24 hrs. clock
End Time:	13:16 24 hrs. clock
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-
6.000 HRS POST DOSE PK SAMPLE COLLECTION Period: 4	
Date and Time of Dosing:	18-Feb-2016 08:00
Date of sample collection:	18-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	18-Feb-2016 14:00
Actual Time of sample collection:	14:00 24 hrs. clock
Remarks:	
PK Sample ID:	PK16096252
Remarks if any other reason:	
8.000 HRS POST DOSE PK SAMPLE COLLECTION Period: 4	

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CASE REPORT FORM

Project No: 745-15

Subject No: 1002 Subject Initials: SCK



Date and Time of Dosing:	18-Feb-2016 08:00
Date of sample collection:	18-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	18-Feb-2016 16:00
Actual Time of sample collection:	16:01 24 hrs. clock
Remarks:	
PK Sample ID:	PK16096342
Remarks if any other reason:	

SNACKS (DAY 1) Period: 4

Date of meal distribution:	18-Feb-2016
Start Time:	16:03 24 hrs. clock
End Time:	16:11 24 hrs. clock
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-

8.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD Period: 4

Position:	Sitting
Date of vital measurement:	18-Feb-2016
Start Time of vital measurement:	15:44 24 hrs. clock
Systolic Blood Pressure:	112 mmHg
Diastolic Blood Pressure:	74 mmHg
Radial Pulse:	68 beats/min
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-

12.000 HRS POST DOSE PK SAMPLE COLLECTION Period: 4

Date and Time of Dosing:	18-Feb-2016 08:00
Date of sample collection:	18-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	18-Feb-2016 20:00
Actual Time of sample collection:	20:00 24 hrs. clock
Remarks:	
PK Sample ID:	PK16096432
Remarks if any other reason:	

DINNER (DAY 1) Period: 4

Date of meal distribution:	18-Feb-2016
Start Time:	20:02 24 hrs. clock
End Time:	20:17 24 hrs. clock
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-

12.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD Period: 4

Position:	Sitting
Date of vital measurement:	18-Feb-2016

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CASE REPORT FORM

Project No: 745-15

Subject No: 1002 Subject Initials: SCK



Start Time of vital measurement:	19:46 24 hrs. clock
Systolic Blood Pressure:	114 mmHg
Diastolic Blood Pressure:	72 mmHg
Radial Pulse:	64 beats/min
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-

16.000 HRS POST DOSE PK SAMPLE COLLECTION Period: 4

Date and Time of Dosing:	18-Feb-2016 08:00
Date of sample collection:	19-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	19-Feb-2016 00:00
Actual Time of sample collection:	00:00 24 hrs. clock
Remarks:	
PK Sample ID:	PK16096522
Remarks if any other reason:	

24.000 HRS POST DOSE PK SAMPLE COLLECTION Period: 4

Date and Time of Dosing:	18-Feb-2016 08:00
Date of sample collection:	19-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	19-Feb-2016 08:00
Actual Time of sample collection:	08:01 24 hrs. clock
Remarks:	
PK Sample ID:	PK16096612
Remarks if any other reason:	

BREAKFAST (DAY 2) Period: 4

Date of meal distribution:	19-Feb-2016
Start Time:	08:13 24 hrs. clock
End Time:	08:17 24 hrs. clock
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-

24.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD Period: 4

Position:	Sitting
Date of vital measurement:	19-Feb-2016
Start Time of vital measurement:	07:43 24 hrs. clock
Systolic Blood Pressure:	116 mmHg
Diastolic Blood Pressure:	76 mmHg
Radial Pulse:	80 beats/min
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-

LUNCH (DAY 2) Period: 4

Date of meal distribution:	19-Feb-2016
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CASE REPORT FORM

Project No: 745-15

Subject No: 1002 Subject Initials: SCK



Start Time:	12:01 24 hrs. clock
End Time:	12:15 24 hrs. clock
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-

SNACKS (DAY 2) Period: 4

Date of meal distribution:	19-Feb-2016
Start Time:	16:02 24 hrs. clock
End Time:	16:08 24 hrs. clock
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-

36.000 HRS POST DOSE PK SAMPLE COLLECTION Period: 4

Date and Time of Dosing:	18-Feb-2016 08:00
Date of sample collection:	19-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	19-Feb-2016 20:00
Actual Time of sample collection:	20:00 24 hrs. clock
Remarks:	
PK Sample ID:	PK16096702
Remarks if any other reason:	

DINNER (DAY 2) Period: 4

Date of meal distribution:	19-Feb-2016
Start Time:	20:03 24 hrs. clock
End Time:	20:19 24 hrs. clock
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-

48.000 HRS POST DOSE PK SAMPLE COLLECTION Period: 4

Date and Time of Dosing:	18-Feb-2016 08:00
Date of sample collection:	20-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	20-Feb-2016 08:00
Actual Time of sample collection:	08:00 24 hrs. clock
Remarks:	
PK Sample ID:	PK16096792
Remarks if any other reason:	

72.000 HRS AMBULATORY PK SAMPLE COLLECTION (DAY 4) Period: 4

Date and Time of Dosing:	18-Feb-2016 08:00
Date of sample collection:	21-Feb-2016
Scheduled date and Time of sample collection (for post dose only):	21-Feb-2016 08:00
Actual Time of sample collection:	08:00 24 hrs. clock
Remarks:	
PK Sample ID:	PK16096882

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CASE REPORT FORM

Project No: 745-15

Subject No: 1002 Subject Initials: SCK



Remarks if any other reason:

72.000 HRS COMPLIANCE AT AMBULATORY SAMPLE (DAY 4) Period: 4

Compliance at the Time of Ambulatory

Date of compliance at the time of ambulatory sample:	21-Feb-2016
Have you consumed any medicine [including herbal remedies, non-steroidal anti-inflammatory drugs (NSAIDs), platelet inhibitors and any other anticoagulants, P-gp inhibitors (e.g., rifampin)] alcohol, alcoholic products, recreational drugs, grapefruit and grapefruit products, an unusual diet for whatever reason (e.g. low-sodium) or smoked since last visit?:	<input type="radio"/> Yes <input checked="" type="radio"/> No
Have you donated blood anywhere else or participated in other clinical trial since last visit?:	<input type="radio"/> Yes <input checked="" type="radio"/> No
If Yes, Remarks:	-
Remark If any:	-

CHECK-OUT DETAILS(Period - 4)

CLINICAL EXAMINATION-CHECKOUT Period: 4

Date of Clinical Examination:	20-Feb-2016
Start Time of Clinical Examination:	06:50 24 hrs. clock
Complaint of any illness:	<input checked="" type="radio"/> No <input type="radio"/> Yes
If YES, provide details:	-
General Physical examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Oral Body Temperature:	98.2 °F
Radial Pulse Rate:	80 beats/min
Blood Pressure(Systolic):	122 mmHg
Blood Pressure(Diastolic):	76 mmHg
Cardiovascular System Examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Respiratory System Examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Central Nervous System Examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Per Abdomen Examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Any other Significant finding:	-
Any investigations recommended:	-
If 'Abnormal' in any of the above-mentioned sections, please enter details:	-
To be performed at the time of check-out	
Vein puncture site:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Subject well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
Comments:	-
Subject is fit for Check-out:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Remark If any:	-

CHECK-OUT B&B Period: 4

Date of check out:	20-Feb-2016
Time of Check-out:	08:28 24 hrs. clock

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Sponsor Name: Intas Pharmaceuticals Ltd.

CASE REPORT FORM

Project No: 745-15

Subject No: 1002 Subject Initials: SCK



Remarks: -

CLINICAL EXAMINATION - END OF STUDY Period: 4

Date of clinical examination:	21-Feb-2016
Start time of clinical examination:	08:23 24 hrs. clock
Complaints of any illness:	<input checked="" type="radio"/> No <input type="radio"/> Yes
If YES, provide details:	-
General Physical examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Oral Body Temperature:	98.0 °F
Systolic Blood Pressure:	122 mmHg
Diastolic Blood Pressure:	82 mmHg
Radial Pulse Rate:	72 beats/min
Cardiovascular System Examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Respiratory System Examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Central Nervous System Examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Per Abdomen Examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Any other Significant finding:	-
Any investigations recommended:	-
Vein puncture site:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Subject well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If 'Abnormal' in any of the above-mentioned sections, please enter the details:	-
Subject is fit:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Remark If any:	-

END STUDY LABORATORY ASSESSMENT AND STUDY COMPLETION STATUS Period: 4

Note: For Estimation of coagulation tests (APTT, PT).

Post study safety sample collected as per protocol?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Date of safety sample collection:	21-Feb-2016
Lab report clinically acceptable:	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NAP
Result of serum pregnancy test:	<input type="radio"/> Positive <input type="radio"/> Negative <input checked="" type="radio"/> NAP (For Male subject)
Remarks If Any:	-

STUDY COMPLETION STATUS

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

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