Sponsor Name:Intas Pharmaceuticals Ltd.

CASE REPORT FORM

Project No: 489-14-G-II



CHECK-IN DETAILS(Period - 1)			
BREATH TEST FOR ALCOHOL CONSUMPTION			Period: 1
Date::	12-Apr-2016		
Start Time:	11:54 24 hrs.	clock	
Breath Alcohol Level (BAL):	.000 %		
Result:	C Positive © 1	Negative	
Start Time of 1st Repeat:	24 hrs. clock		
Breath Alcohol Level (BAL):	%		
1st Repeat result:	C Positive C	Negative	
Start Time of 2nd Repeat:	24 hrs. clock		
Breath Alcohol Level (BAL):	%		
2nd Repeat Result:	C Positive C1	Negative	
Final Result:	C Positive C	Negative	
Remarks:	-		
URINE SCAN FOR DRUGS OF ABUSE			Period: 1
SOP reference no:CPMA-26-07			
Date:	12-Apr-2016		
Refer/Read leaflet before start activity:	C Yes C No C	NAP	
1. URINE SCAN FOR DRUGS ABUSE			
1.0 Tested for:	Amphetamine (AMP)	Barbiturates (BAR)	Benzodiazepines (BZD)
	Cocaine (COC)	✓ Morphine (MOR)	▼ Cannabinoids (THC)
1.1 Start time:	12:27 24 hrs.		(1110)
1.1 Start time.	MA DB DO		
1.2 Observation of Results:		J	
	□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:	C Positive C1	Negative C Inva	ılid
1.4 Positive for:	Amphetamine (AMP)	Barbiturates (BAR)	Benzodiazepines (BZD)
	Cocaine (COC)	☐ Morphine (MOR)	Cannabinoids (THC)
1.5 Any additional test performed-1:	C Yes C No G	NAP	
1.5a. Please Specify:			
1.5b. Start time:	24 hrs. clock		

Lambda Therapeutic Research.	
Sponsor Name:Intas Pharmaceuticals Ltd.	
CASE REPORT FORM	
Project No: 489-14-G-II	LAMBDA
Subject No: 1020 Subject Initials: SNG	Lambda Therapeutic Research

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

Lambda Therapeutic Research. Sponsor Name:Intas Pharmaceuticals Ltd.	
CASE REPORT FORM	
Project No: 489-14-G-II Subject No: 1020 Subject Initials: SNG	LAMBDA Lambda Therapeutic Research

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:	C Positive C	Negative C Inva	alid
3. URINE SCAN FOR DRUGS ABUSE (2nd REPEAT)			
3.0 Start time:	24 hrs. clock	K	
3.1 Observation of result:		С	
Note: A=Two bands indicates negative (Control and Test),B=One band indicates,D=One band indicates Invalid (Test)	es Positive (Contr	rol),C=No band	indicates Invalid
3.2 Result:	C Positive C	Negative C Inva	alid
3.3 Positive for:	Amphetamine (AMP) Cocaine (COC)	Barbiturates (BAR) Morphine (MOR)	Benzodiazepines (BZD) Cannabinoids (THC)
3.4 Any additional test performed-1:	C Yes C No	O NAP	
3.4a. Please Specify:			
3.4b. Start time:	24 hrs. clock	ζ	
3.4c. Observation of result:		С	
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:	C Positive C	Negative C Inva	alid
3.5 Any additional test performed-2:	C Yes C No C	○NAP	
3.5a. Please Specify:			
3.5b. Start time:	24 hrs. clock	(
3.5c. Observation of result:		С	
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:	C Positive C	Negative C Inva	alid
Final result:	C Positive C	Negative	
Positive for:	Amphetamine (AMP) Cocaine (COC)	Barbiturates (BAR) Morphine (MOR)	Benzodiazepines (BZD) Cannabinoids (THC)
Final result (For additional test-1):	C Positive C 1	Negative	
Positive for (For additional test-1):			

Sponsor Name:Intas Pharmaceuticals Ltd.

CASE REPORT FORM

Project No: 489-14-G-II



Final result (For additional test-2):	C Positive C Negative
Positive for (For additional test-2):	
Remarks (for repeats or any other information)::	
CRITERIA FOR SELECTION OF SUBJECTS	Period: 1
Inclusion Criteria	
Non smokers, healthy adult human volunteers between 18 to 45 years of age (both inclusive) living in and around Ahmedabad city or western part of India.:	€ Yes C No
Having a Body Mass Index (BMI) between 18.5 to 30 (both inclusive), calculated as weight in kg / height in m2.:	€ Yes C No
Not having any significant diseases or clinically significant abnormal findings during screening, medical history, clinical examination, laboratory evaluations, 12-lead ECG and X-ray chest (postero-anterior view) recordings:	© Yes C No
Able to understand and comply with the study procedures, in the opinion of the investigator:	G Yes C No
Able to give voluntary written informed consent for participation in the trial:	G Yes C No
Inclusion Criteria in case of Female subjects	
Surgically sterilized at least 6 months prior to study participation or:	C Yes C No © NAP
If of child bearing potential is willing to use a suitable and effective double barrier contraceptive method or intra uterine device during the study:	C Yes C No © NAP
Serum pregnancy test must be negative (for females).:	C Yes C No © NAP
Exclusion criteria	
Known hypersensitivity or idiosyncratic reaction to fampridine to any of its excipients or any related drug or any substance:	C Yes • No
History or presence of any disease or disorder known to influence bone metabolism, compromise the haemopoietic, renal, hepatic, endocrine, pulmonary, central nervous, cardiovascular, immunological, dermatological, gastrointestinal or any other body system:	C Yes © No
Difficulty in swallowing oral solid dosage form like tablet.:	C Yes • No
Any history or presence of asthma (including aspirin induced asthma) or nasal polyp or NSAIDs induced urticaria:	C Yes • No
A recent history of harmful use of alcohol (less than 2 years), i.e. alcohol consumption of more than 14 standard drinks per week for men and 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):	C Yes • No
Smokers, or who have smoked within last six months prior to start of the study:	C Yes • No
The presence of clinically significant abnormal laboratory values during screening:	C Yes • No
Use of any recreational drugs or history of drug addiction:	C Yes © No
History or presence of psychiatric disorders:	C Yes • No
A history of difficulty with donating blood:	C Yes • No

Sponsor Name:Intas Pharmaceuticals Ltd.

CASE REPORT FORM

Project No: 489-14-G-II



Donation of blood (1 unit or 350 mL) or receipt of an investigational medicinal product or participation in a drug research study within 90 days prior to receiving the first dose of study medicine. Elimination half-life of the study drug should be taken into consideration for inclusion of the subject in the study. Note: In case the blood loss was less than or equal to 200 mL; subject may be dosed 60 days after blood donation or after the last sample of previous study:	C Yes No
A positive hepatitis screen including hepatitis B surface antigen and/or HCV antibodies:	C Yes € No
A positive test result for anti HIV AB (I & II).:	C Yes 6 No
Nursing mothers (females):	C Yes C No G NAP
suitability	
Based on above criterias, Subject is:	G Suitable C Not-suitable
Criteria to be checked at the time of compliance check	
Ingestion of medicine (including herbal remedies) at any time within 14 days pr whatever reason (e.g. low-sodium), for four weeks prior to dosing of Period I. I. discretion of the Principal Investigator.	- ·
Consumption of grape fruit or grape fruit products within 72 hours prior to firs	t dosing in period-I.
Consumption of alcohol or alcoholic products within 48 hours prior to first dos	ing of period-I.
Testing positive in pre-study drug scans.	
Remarks:	-
COMPLIANCE CHECK-PI	Period: 1
Demographic Details	
Age in Years (Completed as of Screening Date):	34
Subject Reporting And Consent Procedure Record	
Date of reporting to the clinical facility:	12-Apr-2016
Presentation of ICF & obtained the consent on ICF:	G Yes C No
If 'Yes', mention pagination number of ICF:	34
Protocol Compliance Assessment	
Criteria Check Complete:	• Yes C No C NAP
Urine scan for drugs of abuse tested negative:	• Yes C No
Breath test for alcohol consumption tested negative:	• Yes C No
Date of last menstruation period (for female subject):	-
Result of serum pregnancy test:	C C NAP (For Male Positive Negative subject)
Prohibitions	
Are you suffering from any illness since the last visit (Including allergic reaction, itching, rash on your skin):	C Yes © No
Have you consumed any xanthine containing food or beverages (like tea, coffee, chocolates or cola drinks or any other) within 24 hours prior to first dose administration?:	C Yes • No
Have you consumed tobacco, tobacco containing products (Like Gutkha, Pan / Pan Masala) within 24 hours prior to first dose administration?:	C Yes • No

Sponsor Name:Intas Pharmaceuticals Ltd.

CASE REPORT FORM

Project No: 489-14-G-II



Have you consumed alcohol or alcoholic products and recreational drugs within 48 hours prior to first dose administration?:	C Yes 6 No
Have you consumed grapefruit or grapefruit products within 72 hours prior to first dose administration?:	C Yes • No
Any history of smoking within 06 months prior to start of the study?:	C Yes 6 No
Ingestion of medicine (including herbal remedies) at any time within 14 days prior to dosing.:	C Yes © No
Have you consumed an unusual diet, for whatever reason (e.g. low-sodium), within four weeks prior to receiving the study drug?:	C Yes • No
Has the subject been instructed not to participate in other clinical trial or donate blood anywhere else during the study?:	€ Yes C No
Is subject compliant to all above restrictions/requirement?:	• Yes C No
Remark If any:	-
CHECK-IN B&B	Period: 1
Baggage and Body Search done:	€ Yes C No
Date of Check In:	12-Apr-2016
Time of Check-in:	16:51 24 hrs. clock
Remarks:	-
CLINICAL EXAMINATION - CHECK IN	Period: 1
Date of clinical examination:	12-Apr-2016
Start Time of Clinical Examination:	17:53 24 hrs. clock
Complaints of any illness:	€ No C Yes
If YES, provide details:	-
General Physical examination:	☞ Normal ○ Abnormal
Oral Body Temperature:	97.8 °F
Blood Pressure (Systolic):	120 mmHg
Blood Pressure (Diastolic):	76 mmHg
Radial Pulse Rate:	80 beats/min
Cardiovascular System Examination:	• Normal C Abnormal
Respiratory System Examination:	© Normal C Abnormal
Central Nervous System Examination:	• Normal C Abnormal
Per Abdomen Examination:	• Normal C Abnormal
Any other Significant finding:	-
Any investigations recommended:	-
Vein puncture site:	• Normal C Abnormal
Subject well-being:	€ Well € Unwell
If 'Abnormal' in any of the above-mentioned sections, please enter details.:	-
Remark if Any:	-
Subject is fit:	€ Yes C No

^{*}This is an electronically authenticated report.

Sponsor Name:Intas Pharmaceuticals Ltd.

CASE REPORT FORM

Project No: 489-14-G-II



DINNER CHECK-IN (DAY-1)	Period: 1
Date of meal distribution:	12-Apr-2016
Start Time:	20:05 24 hrs. clock
End Time:	20:19 24 hrs. clock
Has subject consumed meal completely?:	€ Yes C No
Details of meal left (Approximate Quantity):	-
Remarks:	-
IMP ADMINISTRATION-MORNII	NG (PI-DAY 1)
IMP ADMINISTRATION-MORNING (PI-DAY 1)	Period: 1
DATE:	13-Apr-2016
IS SUBJECT COMPLIANT TO ALL PREDOSE REQUIREMENTS AS PER PROTOCOL?:	G Yes C No C NA
TIME:	08:06 24 hrs. clock
MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA:	€ Yes C No C NA
ML OF WATER ADMINISTERED WITH IP:	240
LABEL:	0000183243
PRODUCT CODE/ TYPE:	Reference
DOSING DONE BY:	Noel (Dosing)
DOSING SUPERVISION DONE BY:	PradipPatel (Dosing)
REMARKS:	
0.00 HRS PRE DOSE VITAL SIGNS AND WELL-BEING RECORD-MOR	NING (DAY 1) Period: 1
Position:	Sitting
Date of vital measurement:	13-Apr-2016
Start Time of vital measurement:	06:22 24 hrs. clock
Systolic Blood Pressure:	118 mmHg
Diastolic Blood Pressure:	78 mmHg
Radial Pulse:	80 beats/min
Well-being:	• Well • Unwell
If unwell then specify:	-
Remarks:	-
0.000 HRS PRE DOSE PK SAMPLE COLLECTION MORNING (DAY 1)	-MD1 Period: 1
Date and Time of Dosing:	10.1.0016
Date of sample collection:	13-Apr-2016
Scheduled date and Time of sample collection (for post dose only):	00.02.241
Actual Time of sample collection:	08:02 24 hrs. clock
Remarks:	PK 1 (210200
PK Sample ID: Remarks if any other reason:	PK16210290
·	1)]
STUDY DRUG ADMINISTRATION-COMPLIANCE [MORNING (DAY	1)] Period:
Has the subject resumed in supine positions immediately after dose administration?:	© Yes C No
Has the subject compliant to 01 hour post dose water restriction?:	€ Yes C No

Sponsor Name:Intas Pharmaceuticals Ltd.

CASE REPORT FORM

Project No: 489-14-G-II



Has the subject compliant to 04 hours post dose fasting condition?:	€ Yes C No
Has the subject compliant to postural restriction till 06 hours post dose in supine position? (except receiving of meals):	€ Yes C No
Has all the planned activities (including sampling and Vitals) including the allowed time window performed at bed side till 06 hours post dose in supine position?:	€ Yes C No
Remark if any:	-
ECG EXAMINATION (3.00 HRS POST DOSE)-MORNING (DAY 1)	Period:
ECG EXAMINATION	
Date Of ECG:	13-Apr-2016
Time of ECG:	10:47 24 hrs. clock
Was ECG Repeated:	C Yes 6 No
If Yes, Date of Repeat ECG:	
ECG Impression:	SINUS BRADYCARDIA,NCS
Overall Assessment:	C Not Clinically C Clinically Normal Significant Significant
Remark, If any:	-
3.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-MOR	NING (DAY 1) Period:
Position:	Supine
Date of vital measurement:	13-Apr-2016
Start Time of vital measurement:	10:28 24 hrs. clock
Systolic Blood Pressure:	112 mmHg
Diastolic Blood Pressure:	74 mmHg
Radial Pulse:	68 beats/min
Well-being:	€ Well C Unwell
If unwell then specify:	-
Remarks:	-
LUNCH (4.00 HRS POST DOSE) (DAY 1)	Period:
Date of meal distribution:	13-Apr-2016
Start Time:	12:09 24 hrs. clock
End Time:	12:29 24 hrs. clock
Has subject consumed meal completely?:	• Yes C No
Details of meal left (Approximate Quantity):	-
Remarks:	-
6.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-MOR	NING (DAY 1) Period:
Position:	Supine
Date of vital measurement:	13-Apr-2016
Start Time of vital measurement:	13:29 24 hrs. clock
Systolic Blood Pressure:	116 mmHg
Diastolic Blood Pressure:	76 mmHg
Radial Pulse:	80 beats/min

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CASE REPORT FORM

Project No: 489-14-G-II



Well-being:	€ Well € Unwell
If unwell then specify:	-
Remarks:	-
SNACKS (DAY 1)	Period:
Date of meal distribution:	13-Apr-2016
Start Time:	17:08 24 hrs. clock
End Time:	17:22 24 hrs. clock
Has subject consumed meal completely?:	G Yes C No
Details of meal left (Approximate Quantity):	-
Remarks:	-
9.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-MOR	RNING (DAY 1) Period: 1
Position:	Sitting
Date of vital measurement:	13-Apr-2016
Start Time of vital measurement:	16:36 24 hrs. clock
Systolic Blood Pressure:	112 mmHg
Diastolic Blood Pressure:	80 mmHg
Radial Pulse:	72 beats/min
Well-being:	• Well • Unwell
If unwell then specify:	1 -
Remarks:	-
IMP ADMINISTRATION-EVENING	G (PI-DAY 1)
IMP ADMINISTRATION-EVENING (PI-DAY 1)	Period: 1
DATE:	13-Apr-2016
IS SUBJECT COMPLIANT TO ALL PREDOSE REQUIREMENTS AS	-
PER PROTOCOL?:	© Yes C No C NA
	© Yes C No C NA 20:06 24 hrs. clock
PER PROTOCOL?:	
PER PROTOCOL?: TIME:	20:06 24 hrs. clock
PER PROTOCOL?: TIME: MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA:	20:06 24 hrs. clock • Yes C No C NA
PER PROTOCOL?: TIME: MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA: ML OF WATER ADMINISTERED WITH IP:	20:06 24 hrs. clock • Yes C No C NA 240
PER PROTOCOL?: TIME: MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA: ML OF WATER ADMINISTERED WITH IP: LABEL:	20:06 24 hrs. clock • Yes • No • NA 240 0000183244
PER PROTOCOL?: TIME: MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA: ML OF WATER ADMINISTERED WITH IP: LABEL: PRODUCT CODE/ TYPE:	20:06 24 hrs. clock • Yes • No • NA 240 0000183244 Reference
PER PROTOCOL?: TIME: MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA: ML OF WATER ADMINISTERED WITH IP: LABEL: PRODUCT CODE/ TYPE: DOSING DONE BY:	20:06 24 hrs. clock • Yes • No • NA 240 0000183244 Reference kanarampatel (Dosing)
PER PROTOCOL?: TIME: MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA: ML OF WATER ADMINISTERED WITH IP: LABEL: PRODUCT CODE/ TYPE: DOSING DONE BY: DOSING SUPERVISION DONE BY:	20:06 24 hrs. clock • Yes • No • NA 240 0000183244 Reference kanarampatel (Dosing) vishalhpatel (Dosing)
PER PROTOCOL?: TIME: MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA: ML OF WATER ADMINISTERED WITH IP: LABEL: PRODUCT CODE/ TYPE: DOSING DONE BY: DOSING SUPERVISION DONE BY: REMARKS:	20:06 24 hrs. clock • Yes • No • NA 240 0000183244 Reference kanarampatel (Dosing) vishalhpatel (Dosing)
PER PROTOCOL?: TIME: MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA: ML OF WATER ADMINISTERED WITH IP: LABEL: PRODUCT CODE/ TYPE: DOSING DONE BY: DOSING SUPERVISION DONE BY: REMARKS: 0.00 HRS PRE DOSE VITAL SIGNS AND WELL-BEING RECORD-EVEN	20:06 24 hrs. clock • Yes • No • NA 240 0000183244 Reference kanarampatel (Dosing) vishalhpatel (Dosing)
PER PROTOCOL?: TIME: MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA: ML OF WATER ADMINISTERED WITH IP: LABEL: PRODUCT CODE/ TYPE: DOSING DONE BY: DOSING SUPERVISION DONE BY: REMARKS: 0.00 HRS PRE DOSE VITAL SIGNS AND WELL-BEING RECORD-EVENT Position:	20:06 24 hrs. clock Yes C No C NA 240 0000183244 Reference kanarampatel (Dosing) vishalhpatel (Dosing) NG (DAY 1) Sitting
PER PROTOCOL?: TIME: MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA: ML OF WATER ADMINISTERED WITH IP: LABEL: PRODUCT CODE/ TYPE: DOSING DONE BY: DOSING SUPERVISION DONE BY: REMARKS: 0.00 HRS PRE DOSE VITAL SIGNS AND WELL-BEING RECORD-EVENT Position: Date of vital measurement:	20:06 24 hrs. clock Yes C No C NA 240 0000183244 Reference kanarampatel (Dosing) vishalhpatel (Dosing) NG (DAY 1) Sitting 13-Apr-2016
PER PROTOCOL?: TIME: MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA: ML OF WATER ADMINISTERED WITH IP: LABEL: PRODUCT CODE/ TYPE: DOSING DONE BY: DOSING SUPERVISION DONE BY: REMARKS: 0.00 HRS PRE DOSE VITAL SIGNS AND WELL-BEING RECORD-EVENT Position: Date of vital measurement: Start Time of vital measurement:	20:06 24 hrs. clock • Yes • No • NA 240 0000183244 Reference kanarampatel (Dosing) vishalhpatel (Dosing) Vishalhpatel (Dosing) Sitting 13-Apr-2016 19:11 24 hrs. clock
PER PROTOCOL?: TIME: MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA: ML OF WATER ADMINISTERED WITH IP: LABEL: PRODUCT CODE/ TYPE: DOSING DONE BY: DOSING SUPERVISION DONE BY: REMARKS: 0.00 HRS PRE DOSE VITAL SIGNS AND WELL-BEING RECORD-EVENT Position: Date of vital measurement: Start Time of vital measurement: Systolic Blood Pressure:	20:06 24 hrs. clock Yes C No C NA 240 0000183244 Reference kanarampatel (Dosing) vishalhpatel (Dosing) NG (DAY 1) Sitting 13-Apr-2016 19:11 24 hrs. clock 124 mmHg

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Sponsor Name:Intas Pharmaceuticals Ltd.

CASE REPORT FORM

Project No: 489-14-G-II



If unwell then specify:	-
Remarks:	-
STUDY DRUG ADMINISTRATION-COMPLIANCE [EVENING (DAY 1)]	Period: 1
Has the subject resumed in supine positions immediately after dose	
administration?:	G Yes C No
Has the subject compliant to 01 hour post dose water restriction?:	G Yes C No
Has the subject compliant to 02 hours post dose fasting condition?:	G Yes C No
Has the subject compliant to postural restriction till 06 hours post dose in supine position? (except receiving of meals):	€ Yes C No
Has all the planned activities (including sampling and Vitals) including the allowed time window performed at bed side till 06 hours post dose in supine position?:	€ Yes C No
Remark if any:	-
1.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-EVEN	IING (DAY 1) Period: 1
Position:	Supine
Date of vital measurement:	13-Apr-2016
Start Time of vital measurement:	20:42 24 hrs. clock
Systolic Blood Pressure:	110 mmHg
Diastolic Blood Pressure:	76 mmHg
Radial Pulse:	78 beats/min
Well-being:	• Well • Unwell
If unwell then specify:	-
Remarks:	-
DINNER (2.00 HRS POST DOSE) (DAY 1)	Period: 1
Date of meal distribution:	13-Apr-2016
Start Time:	22:08 24 hrs. clock
End Time:	22:25 24 hrs. clock
Has subject consumed meal completely?:	• Yes C No
Details of meal left (Approximate Quantity):	-
Remarks:	-
IMP ADMINISTRATION-MORNING	G (PI-DAY 2)
IMP ADMINISTRATION-MORNING (PI-DAY 2)	Period: 1
DATE:	14-Apr-2016
IS SUBJECT COMPLIANT TO ALL PREDOSE REQUIREMENTS AS PER PROTOCOL?:	G Y⊗ C No C NA
TIME:	08:06 24 hrs. clock
MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA:	G Yes C No C NA
ML OF WATER ADMINISTERED WITH IP:	240
LABEL:	0000183259
PRODUCT CODE/ TYPE:	Reference
DOSING DONE BY:	Noel (Dosing)
DOSING SUPERVISION DONE BY:	PradipPatel (Dosing)

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Sponsor Name:Intas Pharmaceuticals Ltd.

CASE REPORT FORM

Project No: 489-14-G-II



REMARKS:	
0.00 HRS PRE DOSE VITAL SIGNS AND WELL-BEING RECORD-MORN	VING (DAY 2) Period:
Position:	Sitting
Date of vital measurement:	14-Apr-2016
Start Time of vital measurement:	07:04 24 hrs. clock
Systolic Blood Pressure:	118 mmHg
Diastolic Blood Pressure:	72 mmHg
Radial Pulse:	68 beats/min
Well-being:	€ Well € Unwell
If unwell then specify:	-
Remarks:	-
STUDY DRUG ADMINISTRATION-COMPLIANCE [MORNING (DAY 2)] Period:
Has the subject resumed in supine positions immediately after dose administration?:	€ Yes C No
Has the subject compliant to 01 hour post dose water restriction?:	€ Yes C No
Has the subject compliant to 04 hours post dose fasting condition?:	€ Yes C No
Has the subject compliant to postural restriction till 06 hours post dose in supine position? (except receiving of meals):	€ Yes C No
Has all the planned activities (including sampling and Vitals) including the allowed time window performed at bed side till 06 hours post dose in supine position?:	← Yes ← No
Remark if any:	-
ECG EXAMINATION (3.00 HRS POST DOSE)-MORNING (DAY 2)	Period:
ECG EXAMINATION	
Date Of ECG:	14-Apr-2016
Time of ECG:	10:42 24 hrs. clock
Was ECG Repeated:	C Yes • No
If Yes, Date of Repeat ECG:	
ECG Impression:	WNL
Overall Assessment:	Normal Significant C Not Clinically C Clinically Significant
Remark, If any:	-
3.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-MOR	NING (DAY 2) Period:
Position:	Supine
Date of vital measurement:	14-Apr-2016
Start Time of vital measurement:	10:44 24 hrs. clock
Systolic Blood Pressure:	110 mmHg
Diastolic Blood Pressure:	76 mmHg
Radial Pulse:	72 beats/min
Well-being:	• Well • Unwell

Sponsor Name:Intas Pharmaceuticals Ltd.

CASE REPORT FORM

Project No: 489-14-G-II



Remarks:	-
LUNCH (4.00 HRS POST DOSE) (DAY 2)	Period: 1
Date of meal distribution:	14-Apr-2016
Start Time:	12:11 24 hrs. clock
End Time:	12:33 24 hrs. clock
Has subject consumed meal completely?:	€ Yes C No
Details of meal left (Approximate Quantity):	-
Remarks:	-
6.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-MOR	RNING (DAY 2) Period: 1
Position:	Supine
Date of vital measurement:	14-Apr-2016
Start Time of vital measurement:	13:51 24 hrs. clock
Systolic Blood Pressure:	112 mmHg
Diastolic Blood Pressure:	74 mmHg
Radial Pulse:	72 beats/min
Well-being:	• Well C Unwell
If unwell then specify:	-
Remarks:	-
SNACKS (DAY 2)	Period: 1
Date of meal distribution:	14-Apr-2016
Start Time:	17:08 24 hrs. clock
End Time:	17:16 24 hrs. clock
Has subject consumed meal completely?:	G Yes C No
Details of meal left (Approximate Quantity):	-
Remarks:	-
9.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-MOF	RNING (DAY 2) Period: 1
Position:	Sitting
Date of vital measurement:	14-Apr-2016
Start Time of vital measurement:	16:28 24 hrs. clock
Systolic Blood Pressure:	118 mmHg
Diastolic Blood Pressure:	72 mmHg
Radial Pulse:	68 beats/min
Well-being:	• Well C Unwell
If unwell then specify:	-
Remarks:	-
IMP ADMINISTRATION-EVENING	G (PI-DAY 2)
IMP ADMINISTRATION-EVENING (PI-DAY 2)	Period: 1
DATE:	14-Apr-2016
IS SUBJECT COMPLIANT TO ALL PREDOSE REQUIREMENTS AS PER PROTOCOL?:	© Yes C No C NA
TIME:	20:06 24 hrs. clock

^{*}This is an electronically authenticated report.

Sponsor Name:Intas Pharmaceuticals Ltd.

CASE REPORT FORM

Project No: 489-14-G-II



MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA:	• Yes C No C NA
ML OF WATER ADMINISTERED WITH IP:	240
LABEL:	0000183260
PRODUCT CODE/ TYPE:	Reference
DOSING DONE BY:	rajendra (Dosing)
DOSING SUPERVISION DONE BY:	vishalhpatel (Dosing)
REMARKS:	
0.00 HRS PRE DOSE VITAL SIGNS AND WELL-BEING RECORD-EVENI	NG (DAY 2) Period: 1
Position:	Sitting
Date of vital measurement:	14-Apr-2016
Start Time of vital measurement:	19:16 24 hrs. clock
Systolic Blood Pressure:	114 mmHg
Diastolic Blood Pressure:	78 mmHg
Radial Pulse:	76 beats/min
Well-being:	• Well C Unwell
If unwell then specify:	-
Remarks:	-
STUDY DRUG ADMINISTRATION-COMPLIANCE [EVENING (DAY 2)]	Period:
Has the subject resumed in supine positions immediately after dose administration?:	• Yes C No
Has the subject compliant to 01 hour post dose water restriction?:	€ Yes € No
Has the subject compliant to 02 hours post dose fasting condition?:	€ Yes € No
Has the subject compliant to postural restriction till 06 hours post dose in supine position? (except receiving of meals):	€ Yes € No
Has all the planned activities (including sampling and Vitals) including the allowed time window performed at bed side till 06 hours post dose in supine position?:	© Yes C No
Remark if any:	-
1.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-EVEN	NING (DAY 2) Period:
Position:	Supine
Date of vital measurement:	14-Apr-2016
Start Time of vital measurement:	20:40 24 hrs. clock
Systolic Blood Pressure:	120 mmHg
Diastolic Blood Pressure:	72 mmHg
Radial Pulse:	68 beats/min
Well-being:	⊙ Well ○ Unwell
If unwell then specify:	-
Remarks:	-
DINNER (2.00 HRS POST DOSE) (DAY 2)	Period:
Date of meal distribution:	14-Apr-2016
Start Time:	22:08 24 hrs. clock
End Time:	22:20 24 hrs. clock

^{*}This is an electronically authenticated report.

Sponsor Name:Intas Pharmaceuticals Ltd.

CASE REPORT FORM

Project No: 489-14-G-II



Has subject consumed meal completely?:	G Yes C No
Details of meal left (Approximate Quantity):	-
Remarks:	-
IMP ADMINISTRATION-MORNIN	NG (PI-DAY 3)
IMP ADMINISTRATION-MORNING (PI-DAY 3)	Period: 1
DATE:	15-Apr-2016
IS SUBJECT COMPLIANT TO ALL PREDOSE REQUIREMENTS AS PER PROTOCOL?:	© Yes O No O NA
TIME:	08:06 24 hrs. clock
MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA:	G Yes C No C NA
ML OF WATER ADMINISTERED WITH IP:	240
LABEL:	0000183275
PRODUCT CODE/ TYPE:	Reference
DOSING DONE BY:	AmitKhatri (Dosing)
DOSING SUPERVISION DONE BY:	jileshpatel (Dosing)
REMARKS:	
0.00 HRS PRE DOSE VITAL SIGNS AND WELL-BEING RECORD-MOR	NING (DAY 3) Period: 1
Position:	Sitting
Date of vital measurement:	15-Apr-2016
Start Time of vital measurement:	06:38 24 hrs. clock
Systolic Blood Pressure:	112 mmHg
Diastolic Blood Pressure:	72 mmHg
Radial Pulse:	68 beats/min
Well-being:	€ Well € Unwell
If unwell then specify:	-
Remarks:	-
0.000 HRS PRE DOSE PK SAMPLE COLLECTION MORNING (DAY 3)-	-MD3 Period: 1
Date and Time of Dosing:	
Date of sample collection:	15-Apr-2016
Scheduled date and Time of sample collection (for post dose only):	
Actual Time of sample collection:	08:02 24 hrs. clock
Remarks:	
PK Sample ID:	PK16210338
Remarks if any other reason:	
STUDY DRUG ADMINISTRATION-COMPLIANCE [MORNING (DAY :	3)] Period: 1
Has the subject resumed in supine positions immediately after dose administration?:	€ Yes C No
Has the subject compliant to 01 hour post dose water restriction?:	€ Yes C No
Has the subject compliant to 04 hours post dose fasting condition?:	© Yes C No
Has the subject compliant to postural restriction till 06 hours post dose in supine position? (except receiving of meals):	© Yes C No

Sponsor Name:Intas Pharmaceuticals Ltd.

CASE REPORT FORM

Project No: 489-14-G-II



Has all the planned activities (including sampling and Vitals) including the allowed time window performed at bed side till 06 hours post dose in supine position?:	€ Yes € No
Remark if any:	-
ECG EXAMINATION (3.00 HRS POST DOSE)-MORNING (DAY 3)	Period: 1
ECG EXAMINATION	
Date Of ECG:	15-Apr-2016
Time of ECG:	11:06 24 hrs. clock
Was ECG Repeated:	C Yes 6 No
If Yes, Date of Repeat ECG:	
ECG Impression:	WNL
Overall Assessment:	O Not Clinically C Clinically Normal Significant Significant
Remark, If any:	-
3.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-MOR	RNING (DAY 3) Period: 1
Position:	Supine
Date of vital measurement:	15-Apr-2016
Start Time of vital measurement:	10:45 24 hrs. clock
Systolic Blood Pressure:	116 mmHg
Diastolic Blood Pressure:	78 mmHg
Radial Pulse:	68 beats/min
Well-being:	• Well • Unwell
If unwell then specify:	-
Remarks:	-
LUNCH (4.00 HRS POST DOSE) (DAY 3)	Period: 1
Date of meal distribution:	15-Apr-2016
Start Time:	12:08 24 hrs. clock
End Time:	12:28 24 hrs. clock
Has subject consumed meal completely?:	• Yes C No
Details of meal left (Approximate Quantity):	-
Remarks:	-
6.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-MOR	RNING (DAY 3) Period: 1
Position:	Supine
Date of vital measurement:	15-Apr-2016
Start Time of vital measurement:	13:54 24 hrs. clock
Systolic Blood Pressure:	118 mmHg
Diastolic Blood Pressure:	72 mmHg
Radial Pulse:	60 beats/min
Well-being:	• Well C Unwell
If unwell then specify:	-
Remarks:	-

Sponsor Name:Intas Pharmaceuticals Ltd.

CASE REPORT FORM

Project No: 489-14-G-II



SNACKS (DAY 3)	Period: 1
Date of meal distribution:	15-Apr-2016
Start Time:	17:08 24 hrs. clock
End Time:	17:15 24 hrs. clock
Has subject consumed meal completely?:	© Yes C No
Details of meal left (Approximate Quantity):	-
Remarks:	-
9.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-MOF	RNING (DAY 3) Period: 1
Position:	Sitting
Date of vital measurement:	15-Apr-2016
Start Time of vital measurement:	16:33 24 hrs. clock
Systolic Blood Pressure:	110 mmHg
Diastolic Blood Pressure:	80 mmHg
Radial Pulse:	72 beats/min
Well-being:	• Well C Unwell
If unwell then specify:	-
Remarks:	-
IMP ADMINISTRATION-EVENING	G (PI-DAY 3)
IMP ADMINISTRATION-EVENING (PI-DAY 3)	Period: 1
DATE:	15-Apr-2016
IS SUBJECT COMPLIANT TO ALL PREDOSE REQUIREMENTS AS PER PROTOCOL?:	© Yes C No C NA
TIME:	20:06 24 hrs. clock
MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA:	© Yes C No C NA
ML OF WATER ADMINISTERED WITH IP:	240
LABEL:	0000183276
PRODUCT CODE/ TYPE:	Reference
DOSING DONE BY:	Noel (Dosing)
DOSING SUPERVISION DONE BY:	pratiktrivedi (Dosing)
REMARKS:	
0.00 HRS PRE DOSE VITAL SIGNS AND WELL-BEING RECORD-EVEN	ING (DAY 3) Period:
Position:	Sitting
Date of vital measurement:	15-Apr-2016
Start Time of vital measurement:	19:07 24 hrs. clock
Systolic Blood Pressure:	118 mmHg
Diastolic Blood Pressure:	82 mmHg
Radial Pulse:	72 beats/min
Well-being:	€ Well C Unwell
If unwell then specify:	-
Remarks:	-
0.000 HRS PRE DOSE PK SAMPLE COLLECTION EVENING (DAY 3)-EI	D3 Period: 1
Date and Time of Dosing:	

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CASE REPORT FORM

Project No: 489-14-G-II



Date of sample collection:	15-Apr-2016	
Scheduled date and Time of sample collection (for post dose only):		
Actual Time of sample collection:	20:01 24 hrs. clock	
Remarks:		
PK Sample ID:	PK16210306	
Remarks if any other reason:		
STUDY DRUG ADMINISTRATION-COMPLIANCE [EVENING (DAY 3)]	Period:	
Has the subject resumed in supine positions immediately after dose administration?:	← Yes C No	
Has the subject compliant to 01 hour post dose water restriction?:	€ Yes C No	
Has the subject compliant to 02 hours post dose fasting condition?:	€ Yes C No	
Has the subject compliant to postural restriction till 06 hours post dose in supine position? (except receiving of meals):	← Yes C No	
Has all the planned activities (including sampling and Vitals) including the allowed time window performed at bed side till 06 hours post dose in supine position?:	• Yes C No	
Remark if any:	-	
1.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-EVEN	VING (DAY 3) Period:	
Position:	Supine	
Date of vital measurement:	15-Apr-2016	
Start Time of vital measurement:	20:32 24 hrs. clock	
Systolic Blood Pressure:	116 mmHg	
Diastolic Blood Pressure:	78 mmHg	
Radial Pulse:	76 beats/min	
Well-being:	€ Well € Unwell	
If unwell then specify:	-	
Remarks:	-	
DINNER (2.00 HRS POST DOSE) (DAY 3)	Period:	
Date of meal distribution:	15-Apr-2016	
Start Time:	22:08 24 hrs. clock	
End Time:	22:21 24 hrs. clock	
Has subject consumed meal completely?:	€ Yes C No	
Details of meal left (Approximate Quantity):	-	
Remarks:	-	
IMP ADMINISTRATION-MORNING (PI-DAY 4)		
IMP ADMINISTRATION-MORNING (PI-DAY 4)	Period:	
DATE:	16-Apr-2016	
IS SUBJECT COMPLIANT TO ALL PREDOSE REQUIREMENTS AS PER PROTOCOL?:	€ Yes C No C NA	
TIME:	08:06 24 hrs. clock	
MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA:	G Yes C No C NA	

Sponsor Name:Intas Pharmaceuticals Ltd.

CASE REPORT FORM

Project No: 489-14-G-II



LABEL:	0000183291
PRODUCT CODE/ TYPE:	Reference
DOSING DONE BY:	Noel (Dosing)
DOSING SUPERVISION DONE BY:	PradipPatel (Dosing)
REMARKS:	
0.00 HRS PRE DOSE VITAL SIGNS AND WELL-BEING RECORD-MORN	ING (DAY 4) Period: 1
Position:	Sitting
Date of vital measurement:	16-Apr-2016
Start Time of vital measurement:	06:51 24 hrs. clock
Systolic Blood Pressure:	116 mmHg
Diastolic Blood Pressure:	78 mmHg
Radial Pulse:	72 beats/min
Well-being:	• Well C Unwell
If unwell then specify:	-
Remarks:	-
0.000 HRS PRE DOSE PK SAMPLE COLLECTION MORNING (DAY 4)-N	MD4 Period: 1
Date and Time of Dosing:	
Date of sample collection:	16-Apr-2016
Scheduled date and Time of sample collection (for post dose only):	
Actual Time of sample collection:	08:01 24 hrs. clock
Remarks:	
PK Sample ID:	PK16210354
Remarks if any other reason:	
STUDY DRUG ADMINISTRATION-COMPLIANCE [MORNING (DAY 4)] Period: 1
Has the subject resumed in supine positions immediately after dose administration?:	G Yes C No
Has the subject compliant to 01 hour post dose water restriction?:	€ Yes C No
Has the subject compliant to 04 hours post dose fasting condition?:	€ Yes C No
Has the subject compliant to postural restriction till 06 hours post dose in supine position? (except receiving of meals):	• Yes C No
Has all the planned activities (including sampling and Vitals) including the allowed time window performed at bed side till 06 hours post dose in supine position?:	• Yes C No
Remark if any:	-
ECG EXAMINATION (3.00 HRS POST DOSE)-MORNING (DAY 4)	Period: 1
ECG EXAMINATION	
Date Of ECG:	16-Apr-2016
Time of ECG:	10:52 24 hrs. clock
Was ECG Repeated:	C Yes © No
If Yes, Date of Repeat ECG:	
ECG Impression:	SINUS BRADYCARDIA,NCS

Sponsor Name:Intas Pharmaceuticals Ltd.

CASE REPORT FORM

Project No: 489-14-G-II



Overall Assessment:	C Not Clinically C Clinically
	Normal Significant Significant
Remark, If any:	-
3.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING	RECORD-MORNING (DAY 4) Period
Position:	Supine
Date of vital measurement:	16-Apr-2016
Start Time of vital measurement:	10:31 24 hrs. clock
Systolic Blood Pressure:	114 mmHg
Diastolic Blood Pressure:	76 mmHg
Radial Pulse:	68 beats/min
Well-being:	€ Well € Unwell
If unwell then specify:	-
Remarks:	-
LUNCH (4.00 HRS POST DOSE) (DAY 4)	Period
Date of meal distribution:	16-Apr-2016
Start Time:	12:10 24 hrs. clock
End Time:	12:28 24 hrs. clock
Has subject consumed meal completely?:	€ Yes C No
Details of meal left (Approximate Quantity):	-
Remarks:	-
6.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING	RECORD-MORNING (DAY 4) Period
Position:	Supine
Date of vital measurement:	16-Apr-2016
Start Time of vital measurement:	13:36 24 hrs. clock
Systolic Blood Pressure:	108 mmHg
Diastolic Blood Pressure:	64 mmHg
Radial Pulse:	68 beats/min
Well-being:	• Well C Unwell
If unwell then specify:	-
Remarks:	-
SNACKS (DAY 4)	Perioc
Date of meal distribution:	16-Apr-2016
Start Time:	17:08 24 hrs. clock
End Time:	17:17 24 hrs. clock
Has subject consumed meal completely?:	G Yes C No
Details of meal left (Approximate Quantity):	-
Remarks:	-
9.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING	RECORD-MORNING (DAY 4) Period
	Sitting
Position: Date of vital measurement:	Sitting 16-Apr-2016

Sponsor Name:Intas Pharmaceuticals Ltd.

CASE REPORT FORM

Project No: 489-14-G-II



Subject No: 1020 Subject Initials: SNG	Lambda Therapeutic Research
Systolic Blood Pressure:	114 mmHg
Diastolic Blood Pressure:	72 mmHg
Radial Pulse:	68 beats/min
Well-being:	€ Well € Unwell
If unwell then specify:	-
Remarks:	-
IMP ADMINISTRATION-EVENING	G (PI-DAY 4)
IMP ADMINISTRATION-EVENING (PI-DAY 4)	Period: 1
DATE:	16-Apr-2016
IS SUBJECT COMPLIANT TO ALL PREDOSE REQUIREMENTS AS PER PROTOCOL?:	G Yes C No C NA
TIME:	20:06 24 hrs. clock
MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA:	G Yes C No C NA
ML OF WATER ADMINISTERED WITH IP:	240
LABEL:	0000183292
PRODUCT CODE/ TYPE:	Reference
DOSING DONE BY:	hiralseju (Dosing)
DOSING SUPERVISION DONE BY:	avdheshpandey (Dosing)
REMARKS:	
0.00 HRS PRE DOSE VITAL SIGNS AND WELL-BEING RECORD-EVENI	NG (DAY 4) Period: 1
0.00 HRS PRE DOSE VITAL SIGNS AND WELL-BEING RECORD-EVENII Position:	Sitting
Position: Date of vital measurement:	Sitting 16-Apr-2016
Position: Date of vital measurement: Start Time of vital measurement:	Sitting 16-Apr-2016 19:03 24 hrs. clock
Position: Date of vital measurement: Start Time of vital measurement: Systolic Blood Pressure:	Sitting 16-Apr-2016 19:03 24 hrs. clock 112 mmHg
Position: Date of vital measurement: Start Time of vital measurement: Systolic Blood Pressure: Diastolic Blood Pressure:	Sitting 16-Apr-2016 19:03 24 hrs. clock 112 mmHg 78 mmHg
Position: Date of vital measurement: Start Time of vital measurement: Systolic Blood Pressure:	Sitting 16-Apr-2016 19:03 24 hrs. clock 112 mmHg 78 mmHg 76 beats/min
Position: Date of vital measurement: Start Time of vital measurement: Systolic Blood Pressure: Diastolic Blood Pressure:	Sitting 16-Apr-2016 19:03 24 hrs. clock 112 mmHg 78 mmHg
Position: Date of vital measurement: Start Time of vital measurement: Systolic Blood Pressure: Diastolic Blood Pressure: Radial Pulse:	Sitting 16-Apr-2016 19:03 24 hrs. clock 112 mmHg 78 mmHg 76 beats/min
Position: Date of vital measurement: Start Time of vital measurement: Systolic Blood Pressure: Diastolic Blood Pressure: Radial Pulse: Well-being:	Sitting 16-Apr-2016 19:03 24 hrs. clock 112 mmHg 78 mmHg 76 beats/min
Position: Date of vital measurement: Start Time of vital measurement: Systolic Blood Pressure: Diastolic Blood Pressure: Radial Pulse: Well-being: If unwell then specify: Remarks: 0.000 HRS PRE DOSE PK SAMPLE COLLECTION EVENING (DAY 4)-ED	Sitting 16-Apr-2016 19:03 24 hrs. clock 112 mmHg 78 mmHg 76 beats/min
Position: Date of vital measurement: Start Time of vital measurement: Systolic Blood Pressure: Diastolic Blood Pressure: Radial Pulse: Well-being: If unwell then specify: Remarks: 0.000 HRS PRE DOSE PK SAMPLE COLLECTION EVENING (DAY 4)-ED Date and Time of Dosing:	Sitting 16-Apr-2016 19:03 24 hrs. clock 112 mmHg 78 mmHg 76 beats/min © Well © Unwell Period: 1
Position: Date of vital measurement: Start Time of vital measurement: Systolic Blood Pressure: Diastolic Blood Pressure: Radial Pulse: Well-being: If unwell then specify: Remarks: 0.000 HRS PRE DOSE PK SAMPLE COLLECTION EVENING (DAY 4)-EDD Date and Time of Dosing: Date of sample collection:	Sitting 16-Apr-2016 19:03 24 hrs. clock 112 mmHg 78 mmHg 76 beats/min
Position: Date of vital measurement: Start Time of vital measurement: Systolic Blood Pressure: Diastolic Blood Pressure: Radial Pulse: Well-being: If unwell then specify: Remarks: 0.000 HRS PRE DOSE PK SAMPLE COLLECTION EVENING (DAY 4)-ED Date and Time of Dosing: Date of sample collection: Scheduled date and Time of sample collection (for post dose only):	Sitting 16-Apr-2016 19:03 24 hrs. clock 112 mmHg 78 mmHg 76 beats/min © Well © Unwell 16-Apr-2016
Position: Date of vital measurement: Start Time of vital measurement: Systolic Blood Pressure: Diastolic Blood Pressure: Radial Pulse: Well-being: If unwell then specify: Remarks: 0.000 HRS PRE DOSE PK SAMPLE COLLECTION EVENING (DAY 4)-ED Date and Time of Dosing: Date of sample collection: Scheduled date and Time of sample collection (for post dose only): Actual Time of sample collection:	Sitting 16-Apr-2016 19:03 24 hrs. clock 112 mmHg 78 mmHg 76 beats/min © Well © Unwell Period: 1
Position: Date of vital measurement: Start Time of vital measurement: Systolic Blood Pressure: Diastolic Blood Pressure: Radial Pulse: Well-being: If unwell then specify: Remarks: 0.000 HRS PRE DOSE PK SAMPLE COLLECTION EVENING (DAY 4)-ED Date and Time of Dosing: Date of sample collection: Scheduled date and Time of sample collection (for post dose only): Actual Time of sample collection: Remarks:	Sitting 16-Apr-2016 19:03 24 hrs. clock 112 mmHg 78 mmHg 76 beats/min • Well • Unwell 16-Apr-2016 20:01 24 hrs. clock
Position: Date of vital measurement: Start Time of vital measurement: Systolic Blood Pressure: Diastolic Blood Pressure: Radial Pulse: Well-being: If unwell then specify: Remarks: 0.000 HRS PRE DOSE PK SAMPLE COLLECTION EVENING (DAY 4)-ED Date and Time of Dosing: Date of sample collection: Scheduled date and Time of sample collection (for post dose only): Actual Time of sample collection: Remarks: PK Sample ID:	Sitting 16-Apr-2016 19:03 24 hrs. clock 112 mmHg 78 mmHg 76 beats/min © Well © Unwell 16-Apr-2016
Position: Date of vital measurement: Start Time of vital measurement: Systolic Blood Pressure: Diastolic Blood Pressure: Radial Pulse: Well-being: If unwell then specify: Remarks: 0.000 HRS PRE DOSE PK SAMPLE COLLECTION EVENING (DAY 4)-ED Date and Time of Dosing: Date of sample collection: Scheduled date and Time of sample collection (for post dose only): Actual Time of sample collection: Remarks: PK Sample ID: Remarks if any other reason:	Sitting 16-Apr-2016 19:03 24 hrs. clock 112 mmHg 78 mmHg 76 beats/min • Well • Unwell 16-Apr-2016 20:01 24 hrs. clock
Position: Date of vital measurement: Start Time of vital measurement: Systolic Blood Pressure: Diastolic Blood Pressure: Radial Pulse: Well-being: If unwell then specify: Remarks: 0.000 HRS PRE DOSE PK SAMPLE COLLECTION EVENING (DAY 4)-ED Date and Time of Dosing: Date of sample collection: Scheduled date and Time of sample collection (for post dose only): Actual Time of sample collection: Remarks: PK Sample ID: Remarks if any other reason: STUDY DRUG ADMINISTRATION-COMPLIANCE [EVENING (DAY 4)]	Sitting 16-Apr-2016 19:03 24 hrs. clock 112 mmHg 78 mmHg 76 beats/min • Well • Unwell 16-Apr-2016 20:01 24 hrs. clock
Position: Date of vital measurement: Start Time of vital measurement: Systolic Blood Pressure: Diastolic Blood Pressure: Radial Pulse: Well-being: If unwell then specify: Remarks: 0.000 HRS PRE DOSE PK SAMPLE COLLECTION EVENING (DAY 4)-ED Date and Time of Dosing: Date of sample collection: Scheduled date and Time of sample collection (for post dose only): Actual Time of sample collection: Remarks: PK Sample ID: Remarks if any other reason:	Sitting 16-Apr-2016 19:03 24 hrs. clock 112 mmHg 78 mmHg 76 beats/min • Well • Unwell Period: 1 16-Apr-2016 20:01 24 hrs. clock

Sponsor Name:Intas Pharmaceuticals Ltd.

CASE REPORT FORM

Project No: 489-14-G-II



Has the subject compliant to 02 hours post dose fasting condition?:	⊙ Yes ○ No
Has the subject compliant to postural restriction till 06 hours post dose in supine position? (except receiving of meals):	€ Yes € No
Has all the planned activities (including sampling and Vitals) including the allowed time window performed at bed side till 06 hours post dose in supine position?:	€ Yes C No
Remark if any:	-
1.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-EVEN	NING (DAY 4) Period: 1
Position:	Supine
Date of vital measurement:	16-Apr-2016
Start Time of vital measurement:	20:41 24 hrs. clock
Systolic Blood Pressure:	108 mmHg
Diastolic Blood Pressure:	74 mmHg
Radial Pulse:	76 beats/min
Well-being:	• Well • Unwell
If unwell then specify:	-
Remarks:	-
DINNER (2.00 HRS POST DOSE) (DAY 4)	Period: 1
Date of meal distribution:	16-Apr-2016
Start Time:	22:08 24 hrs. clock
End Time:	22:22 24 hrs. clock
Has subject consumed meal completely?:	€ Yes C No
Details of meal left (Approximate Quantity):	-
Remarks:	-
IMP ADMINISTRATION-MORNIN	G (PI-DAY 5)
IMP ADMINISTRATION-MORNING (PI-DAY 5)	Period: 1
DATE:	17-Apr-2016
IS SUBJECT COMPLIANT TO ALL PREDOSE REQUIREMENTS AS PER PROTOCOL?:	G Yes C No C NA
TIME:	08:06 24 hrs. clock
MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA:	© Yes C No C NA
ML OF WATER ADMINISTERED WITH IP:	240
LABEL:	0000183307
PRODUCT CODE/ TYPE:	Reference
DOSING DONE BY:	pratiktrivedi (Dosing)
DOSING SUPERVISION DONE BY:	vishalhpatel (Dosing)
REMARKS:	
0.00 HRS PRE DOSE VITAL SIGNS AND WELL-BEING RECORD-MORN	VING (DAY 5) Period: 1
Position:	Sitting
Date of vital measurement:	17-Apr-2016
Start Time of vital measurement:	06:28 24 hrs. clock
Systolic Blood Pressure:	114 mmHg

^{*}This is an electronically authenticated report.

Sponsor Name:Intas Pharmaceuticals Ltd.

CASE REPORT FORM

Project No: 489-14-G-II



Diastolic Blood Pressure:	78 mmHg
Radial Pulse:	72 beats/min
Well-being:	€ Well C Unwell
If unwell then specify:	-
Remarks:	-
0.000 HRS PRE DOSE PK SAMPLE COLLECTION MORNING (DAY 5)-1	MD5 Period: 1
Date and Time of Dosing:	
Date of sample collection:	17-Apr-2016
Scheduled date and Time of sample collection (for post dose only):	-
Actual Time of sample collection:	08:02 24 hrs. clock
Remarks:	
PK Sample ID:	PK16210370
Remarks if any other reason:	
STUDY DRUG ADMINISTRATION-COMPLIANCE [MORNING (DAY 5)] Period: 1
Has the subject resumed in supine positions immediately after dose administration?:	G Yes C No
Has the subject compliant to 01 hour post dose water restriction?:	• Yes C No
Has the subject compliant to 04 hours post dose fasting condition?:	G Yes C No
Has the subject compliant to postural restriction till 06 hours post dose in supine position? (except receiving of meals):	G Yes C No
Has all the planned activities (including sampling and Vitals) including the allowed time window performed at bed side till 06 hours post dose in supine position?:	G Yes C No
Remark if any:	-
0.333 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DAY 5)	-MD5 Period: 1
Date and Time of Dosing:	17-Apr-2016 08:06
Date of sample collection:	17-Apr-2016
Scheduled date and Time of sample collection (for post dose only):	17-Apr-2016 08:26
Actual Time of sample collection:	08:26 24 hrs. clock
Remarks:	
PK Sample ID:	PK16210386
Remarks if any other reason:	
0.667 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DAY 5)	-MD5 Period: 1
Date and Time of Dosing:	17-Apr-2016 08:06
Date of sample collection:	17-Apr-2016
Scheduled date and Time of sample collection (for post dose only):	17-Apr-2016 08:46
Actual Time of sample collection:	08:46 24 hrs. clock
Remarks:	
PK Sample ID:	PK16210402
Remarks if any other reason:	
1.000 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DAY 5)	-MD5 Period: 1
Date and Time of Dosing:	17-Apr-2016 08:06

Sponsor Name:Intas Pharmaceuticals Ltd.

CASE REPORT FORM

Project No: 489-14-G-II

Subject No: 1020 Subject Initials: SNG



Date of sample collection:	17-Apr-2016	
Scheduled date and Time of sample collection (for post dose only):	17-Apr-2016 09:06	
Actual Time of sample collection:	09:06 24 hrs. clock	
Remarks:		
PK Sample ID:	PK16210418	
Remarks if any other reason:		
1.333 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DA	Y 5)-MD5	Period:
Date and Time of Dosing:	17-Apr-2016 08:06	
Date of sample collection:	17-Apr-2016	
Scheduled date and Time of sample collection (for post dose only):	17-Apr-2016 09:26	
Actual Time of sample collection:	09:26 24 hrs. clock	
Remarks:	03.20 21 m 3. clock	
PK Sample ID:	PK16210434	
Remarks if any other reason:		
1.667 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DA	Y 5)-MD5	Period:
Date and Time of Dosing:	17-Apr-2016 08:06	T CITO C.
Date of sample collection:	17-Apr-2016	
Scheduled date and Time of sample collection (for post dose only):	17-Apr-2016 09:46	
Actual Time of sample collection:	09:46 24 hrs. clock	
Remarks:	03.10 21 m 31 clock	
PK Sample ID:	PK16210450	
Remarks if any other reason:	11110210.00	
2.000 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DA	V 5)-MD5	Period:
Date and Time of Dosing:	17-Apr-2016 08:06	i criod.
Date of sample collection:	17-Apr-2016	
Scheduled date and Time of sample collection (for post dose only):	17-Apr-2016 10:06	
Actual Time of sample collection:	10:06 24 hrs. clock	
Remarks:	10.00 21 m 3, clock	
PK Sample ID:	PK16210466	
Remarks if any other reason:		
2.333 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DA	Y 5)-MD5	Period:
Date and Time of Dosing:	17-Apr-2016 08:06	
Date of sample collection:	17-Apr-2016	
Scheduled date and Time of sample collection (for post dose only):	17-Apr-2016 10:26	
Actual Time of sample collection:	10:26 24 hrs. clock	
Remarks:	10.20 21 11.50 010011	
	PK16210482	
PK Sample ID:	11110210102	
-		
PK Sample ID: Remarks if any other reason: 2.667 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DA	Y 5)-MD5	Period
Remarks if any other reason: 2.667 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DA		Period:
Remarks if any other reason:	Y 5)-MD5 17-Apr-2016 08:06 17-Apr-2016	Period:

^{*}This is an electronically authenticated report.

Actual Time of sample collection:

10:46 **24 hrs. clock**

Sponsor Name:Intas Pharmaceuticals Ltd.

CASE REPORT FORM

Project No: 489-14-G-II



Remarks:		
PK Sample ID:	PK16210498	
Remarks if any other reason:		
3.000 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DA	Y 5)-MD5	Period: 1
Date and Time of Dosing:	17-Apr-2016 08:06	T Office.
Date of sample collection:	17-Apr-2016	
Scheduled date and Time of sample collection (for post dose only):	17-Apr-2016 11:06	
Actual Time of sample collection:	11:06 24 hrs. clock	
Remarks:		
PK Sample ID:	PK16210514	
Remarks if any other reason:		
ECG EXAMINATION (3.00 HRS POST DOSE)-MORNING (DAY 5)		Period: 1
ECG EXAMINATION		
Date Of ECG:	17-Apr-2016	
Time of ECG:	10:44 24 hrs. clock	
Was ECG Repeated:	C Yes 6 No	
If Yes, Date of Repeat ECG:		
ECG Impression:	SINUS BRADYCARDIA,N	CS
Overall Assessment:	○ • Not Clinically	C Clinically
	Normal Significant	Significant
Remark, If any:	Normal Significant	Significant
	-	Significant Period: 1
Remark, If any: 3.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-Position:	-	-
3.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-	MORNING (DAY 5)	-
3.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-Position:	MORNING (DAY 5) Supine	-
3.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-Position: Date of vital measurement:	- MORNING (DAY 5) Supine 17-Apr-2016	-
3.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-Position: Date of vital measurement: Start Time of vital measurement:	- MORNING (DAY 5) Supine 17-Apr-2016 10:30 24 hrs. clock	-
3.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-Position: Date of vital measurement: Start Time of vital measurement: Systolic Blood Pressure:	- MORNING (DAY 5) Supine 17-Apr-2016 10:30 24 hrs. clock 116 mmHg	-
3.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-Position: Date of vital measurement: Start Time of vital measurement: Systolic Blood Pressure: Diastolic Blood Pressure:	- MORNING (DAY 5) Supine 17-Apr-2016 10:30 24 hrs. clock 116 mmHg 70 mmHg	-
3.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-Position: Date of vital measurement: Start Time of vital measurement: Systolic Blood Pressure: Diastolic Blood Pressure: Radial Pulse:	- MORNING (DAY 5) Supine 17-Apr-2016 10:30 24 hrs. clock 116 mmHg 70 mmHg 64 beats/min	-
3.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-Position: Date of vital measurement: Start Time of vital measurement: Systolic Blood Pressure: Diastolic Blood Pressure: Radial Pulse: Well-being:	Supine 17-Apr-2016 10:30 24 hrs. clock 116 mmHg 70 mmHg 64 beats/min © Well © Unwell	-
3.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-Position: Date of vital measurement: Start Time of vital measurement: Systolic Blood Pressure: Diastolic Blood Pressure: Radial Pulse: Well-being: If unwell then specify: Remarks:	- MORNING (DAY 5) Supine 17-Apr-2016 10:30 24 hrs. clock 116 mmHg 70 mmHg 64 beats/min • Well • Unwell	-
3.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-Position: Date of vital measurement: Start Time of vital measurement: Systolic Blood Pressure: Diastolic Blood Pressure: Radial Pulse: Well-being: If unwell then specify:	- MORNING (DAY 5) Supine 17-Apr-2016 10:30 24 hrs. clock 116 mmHg 70 mmHg 64 beats/min • Well • Unwell	Period: 1
3.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-Position: Date of vital measurement: Start Time of vital measurement: Systolic Blood Pressure: Diastolic Blood Pressure: Radial Pulse: Well-being: If unwell then specify: Remarks: 3.333 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DA	- MORNING (DAY 5) Supine 17-Apr-2016 10:30 24 hrs. clock 116 mmHg 70 mmHg 64 beats/min • Well • Unwell	Period: 1
3.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-Position: Date of vital measurement: Start Time of vital measurement: Systolic Blood Pressure: Diastolic Blood Pressure: Radial Pulse: Well-being: If unwell then specify: Remarks: 3.333 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DAD Date and Time of Dosing:	- MORNING (DAY 5) Supine 17-Apr-2016 10:30 24 hrs. clock 116 mmHg 70 mmHg 64 beats/min • Well • Unwell	Period: 1
3.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-Position: Date of vital measurement: Start Time of vital measurement: Systolic Blood Pressure: Diastolic Blood Pressure: Radial Pulse: Well-being: If unwell then specify: Remarks: 3.333 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DAD Date and Time of Dosing: Date of sample collection:	- MORNING (DAY 5) Supine 17-Apr-2016 10:30 24 hrs. clock 116 mmHg 70 mmHg 64 beats/min • Well • Unwell Y 5)-MD5 17-Apr-2016 08:06 17-Apr-2016	Period: 1
3.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-Position: Date of vital measurement: Start Time of vital measurement: Systolic Blood Pressure: Diastolic Blood Pressure: Radial Pulse: Well-being: If unwell then specify: Remarks: 3.333 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DAD) Date and Time of Dosing: Date of sample collection: Scheduled date and Time of sample collection (for post dose only):	- MORNING (DAY 5) Supine 17-Apr-2016 10:30 24 hrs. clock 116 mmHg 70 mmHg 64 beats/min • Well • Unwell	Period: 1
3.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-Position: Date of vital measurement: Start Time of vital measurement: Systolic Blood Pressure: Diastolic Blood Pressure: Radial Pulse: Well-being: If unwell then specify: Remarks: 3.333 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DADate and Time of Dosing: Date of sample collection: Scheduled date and Time of sample collection (for post dose only): Actual Time of sample collection:	- MORNING (DAY 5) Supine 17-Apr-2016 10:30 24 hrs. clock 116 mmHg 70 mmHg 64 beats/min • Well • Unwell	Period:
3.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-Position: Date of vital measurement: Start Time of vital measurement: Systolic Blood Pressure: Diastolic Blood Pressure: Radial Pulse: Well-being: If unwell then specify: Remarks: 3.333 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DADate and Time of Dosing: Date of sample collection: Scheduled date and Time of sample collection (for post dose only): Actual Time of sample collection: Remarks:	- MORNING (DAY 5) Supine 17-Apr-2016 10:30 24 hrs. clock 116 mmHg 70 mmHg 64 beats/min • Well • Unwell	Period: 1
3.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-Position: Date of vital measurement: Start Time of vital measurement: Systolic Blood Pressure: Diastolic Blood Pressure: Radial Pulse: Well-being: If unwell then specify: Remarks: 3.333 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DAD Date and Time of Dosing: Date of sample collection: Scheduled date and Time of sample collection (for post dose only): Actual Time of sample collection: Remarks: PK Sample ID:	- MORNING (DAY 5) Supine 17-Apr-2016 10:30 24 hrs. clock 116 mmHg 70 mmHg 64 beats/min Well © Unwell	Period: 1
3.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-Position: Date of vital measurement: Start Time of vital measurement: Systolic Blood Pressure: Diastolic Blood Pressure: Radial Pulse: Well-being: If unwell then specify: Remarks: 3.333 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DAD Date and Time of Dosing: Date of sample collection: Scheduled date and Time of sample collection (for post dose only): Actual Time of sample collection: Remarks: PK Sample ID: Remarks if any other reason:	- MORNING (DAY 5) Supine 17-Apr-2016 10:30 24 hrs. clock 116 mmHg 70 mmHg 64 beats/min Well © Unwell	Period: 1

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Sponsor Name:Intas Pharmaceuticals Ltd.

CASE REPORT FORM

Project No: 489-14-G-II



Scheduled date and Time of sample collection (for post dose only):	17-Apr-2016 11:46
Actual Time of sample collection:	11:46 24 hrs. clock
Remarks:	
PK Sample ID:	PK16210546
Remarks if any other reason:	
4.000 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DA	Y 5)-MD5 Period:
Date and Time of Dosing:	17-Apr-2016 08:06
Date of sample collection:	17-Apr-2016
Scheduled date and Time of sample collection (for post dose only):	17-Apr-2016 12:06
Actual Time of sample collection:	12:06 24 hrs. clock
Remarks:	
PK Sample ID:	PK16210562
Remarks if any other reason:	
LUNCH (4.00 HRS POST DOSE) (DAY 5)	Period
Date of meal distribution:	17-Apr-2016
Start Time:	12:09 24 hrs. clock
End Time:	12:33 24 hrs. clock
Has subject consumed meal completely?:	• Yes C No
Details of meal left (Approximate Quantity):	-
Remarks:	-
4.500 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DA	Y 5)-MD5 Period:
Date and Time of Dosing:	17-Apr-2016 08:06
Date of sample collection:	17-Apr-2016
Scheduled date and Time of sample collection (for post dose only):	17-Apr-2016 12:36
Actual Time of sample collection:	12:36 24 hrs. clock
Remarks:	
PK Sample ID:	PK16210578
Remarks if any other reason:	
5.000 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DA	Y 5)-MD5 Period:
Date and Time of Dosing:	17-Apr-2016 08:06
Date of sample collection:	17-Apr-2016
Scheduled date and Time of sample collection (for post dose only):	17-Apr-2016 13:06
Actual Time of sample collection:	13:06 24 hrs. clock
Remarks:	
PK Sample ID:	PK16210594
Remarks if any other reason:	
6.000 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DA	Y 5)-MD5 Period:
Date and Time of Dosing:	17-Apr-2016 08:06
Date of sample collection:	17-Apr-2016
Scheduled date and Time of sample collection (for post dose only):	17-Apr-2016 14:06
Actual Time of sample collection:	14:06 24 hrs. clock
Treatment of Sample Concession.	
Remarks:	

Sponsor Name:Intas Pharmaceuticals Ltd.

CASE REPORT FORM

Project No: 489-14-G-II



Remarks if any other reason:		
6.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-	MORNING (DAY 5)	Period
Position:	Supine	
Date of vital measurement:	17-Apr-2016	
Start Time of vital measurement:	13:37 24 hrs. clock	
Systolic Blood Pressure:	116 mmHg	
Diastolic Blood Pressure:	76 mmHg	
Radial Pulse:	68 beats/min	
Well-being:	• Well • Unwell	
If unwell then specify:	-	
Remarks:	-	
8.000 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DA	AY 5)-MD5	Period
Date and Time of Dosing:	17-Apr-2016 08:06	
Date of sample collection:	17-Apr-2016	
Scheduled date and Time of sample collection (for post dose only):	17-Apr-2016 16:06	
Actual Time of sample collection:	16:06 24 hrs. clock	
Remarks:		
PK Sample ID:	PK16210626	
Remarks if any other reason:		
SNACKS (DAY 5)		Perioc
Date of meal distribution:	17-Apr-2016	
Start Time:	17:08 24 hrs. clock	
End Time:	17:17 24 hrs. clock	
Has subject consumed meal completely?:	• Yes C No	
Details of meal left (Approximate Quantity):	-	
Remarks:	-	
9.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-1	MORNING (DAY 5)	Perioc
Position:	Sitting	
Date of vital measurement:	17-Apr-2016	
Start Time of vital measurement:	16:30 24 hrs. clock	
Systolic Blood Pressure:	110 mmHg	
Diastolic Blood Pressure:	72 mmHg	
Radial Pulse:	72 beats/min	
Well-being:		
If unwell then specify:	-	
Remarks:	-	
10.000 HRS POST DOSE PK SAMPLE COLLECTION MORNING (D.	AY 5)-MD5	Period
Date and Time of Dosing:	17-Apr-2016 08:06	
Date of sample collection:	17-Apr-2016	
Scheduled date and Time of sample collection (for post dose only):	17-Apr-2016 18:06	
Actual Time of sample collection:	18:06 24 hrs. clock	
Remarks:		

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Sponsor Name:Intas Pharmaceuticals Ltd.

CASE REPORT FORM

Project No: 489-14-G-II



PK Sample ID:	PK16210642
Remarks if any other reason:	
12.000 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DAY	5)-MD5 Period:
Date and Time of Dosing:	17-Apr-2016 08:06
Date of sample collection:	17-Apr-2016
Scheduled date and Time of sample collection (for post dose only):	17-Apr-2016 20:06
Actual Time of sample collection:	20:01 24 hrs. clock
Remarks:	
PK Sample ID:	PK16210658
Remarks if any other reason:	
IMP ADMINISTRATION-EVENIN	G (PI-DAY 5)
IMP ADMINISTRATION-EVENING (PI-DAY 5)	Period:
DATE:	17-Apr-2016
IS SUBJECT COMPLIANT TO ALL PREDOSE REQUIREMENTS AS PER PROTOCOL?:	€ Yes C No C NA
TIME:	20:06 24 hrs. clock
MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA:	€ Yes C No C NA
ML OF WATER ADMINISTERED WITH IP:	240
LABEL:	0000183308
PRODUCT CODE/ TYPE:	Reference
DOSING DONE BY:	Noel (Dosing)
DOSING SUPERVISION DONE BY:	kanarampatel (Dosing)
REMARKS:	
0.00 HRS PRE DOSE VITAL SIGNS AND WELL-BEING RECORD-EVEN	ING (DAY 5) Period:
Position:	Sitting
Date of vital measurement:	17-Apr-2016
Start Time of vital measurement:	19:07 24 hrs. clock
Systolic Blood Pressure:	114 mmHg
Diastolic Blood Pressure:	74 mmHg
Radial Pulse:	80 beats/min
Well-being:	© Well C Unwell
If unwell then specify:	-
Remarks:	-
STUDY DRUG ADMINISTRATION-COMPLIANCE [EVENING (DAY 5)	Period:
Has the subject resumed in supine positions immediately after dose administration?:	• Yes C No
Has the subject compliant to 01 hour post dose water restriction?:	€ Yes C No
Has the subject compliant to 02 hours post dose fasting condition?:	© Yes C No
Has the subject compliant to postural restriction till 06 hours post dose in supine position? (except receiving of meals):	€ Yes C No

Sponsor Name:Intas Pharmaceuticals Ltd.

CASE REPORT FORM

Project No: 489-14-G-II



Has all the planned activities (including sampling and Vitals) including the allowed time window performed at bed side till 06 hours post dose in supine position?:	€ Yes C No
Remark if any:	-
1.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-EVEN	NING (DAY 5) Period:
Position:	Supine
Date of vital measurement:	17-Apr-2016
Start Time of vital measurement:	20:41 24 hrs. clock
Systolic Blood Pressure:	114 mmHg
Diastolic Blood Pressure:	74 mmHg
Radial Pulse:	64 beats/min
Well-being:	• Well C Unwell
If unwell then specify:	-
Remarks:	-
DINNER (2.00 HRS POST DOSE) (DAY 5)	Period:
Date of meal distribution:	17-Apr-2016
Start Time:	22:08 24 hrs. clock
End Time:	22:20 24 hrs. clock
Has subject consumed meal completely?:	© Yes C No
Details of meal left (Approximate Quantity):	-
Remarks:	-
IMP ADMINISTRATION-MORNIN	G (PI-DAY 6)
IMP ADMINISTRATION-MORNING (PI-DAY 6)	Period:
DATE:	18-Apr-2016
IS SUBJECT COMPLIANT TO ALL PREDOSE REQUIREMENTS AS PER PROTOCOL?:	© Yes C No C NA
TIME:	08:06 24 hrs. clock
MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA:	© Yes C No C NA
ML OF WATER ADMINISTERED WITH IP:	240
LABEL:	0000183322
PRODUCT CODE/ TYPE:	Reference
DOSING DONE BY:	Noel (Dosing)
DOSING SUPERVISION DONE BY:	vishalhpatel (Dosing)
REMARKS:	
0.00 HRS PRE DOSE VITAL SIGNS AND WELL-BEING RECORD-MORN	NING (DAY 6) Period:
Position:	Sitting
Date of vital measurement:	18-Apr-2016
Start Time of vital measurement:	06:49 24 hrs. clock
Systolic Blood Pressure:	122 mmHg
	82 mmHg
Diastolic Blood Pressure:	
Diastolic Blood Pressure: Radial Pulse:	80 beats/min

Sponsor Name:Intas Pharmaceuticals Ltd.

CASE REPORT FORM

Project No: 489-14-G-II



16	T
If unwell then specify: Remarks:	-
0.000 HRS PRE DOSE PK SAMPLE COLLECTION MORNING (DAY 6)-N	MD6 Period: 1
Date and Time of Dosing:	10.4. 2016
Date of sample collection:	18-Apr-2016
Scheduled date and Time of sample collection (for post dose only):	00.02.241
Actual Time of sample collection: Remarks:	08:02 24 hrs. clock
	PK16210674
PK Sample ID: Remarks if any other reason:	FK10210074
-	
STUDY DRUG ADMINISTRATION-COMPLIANCE [MORNING (DAY 6))] Period: 1
Has the subject resumed in supine positions immediately after dose administration?:	G Yes C No
Has the subject compliant to 01 hour post dose water restriction?:	G Yes C No
Has the subject compliant to 04 hours post dose fasting condition?:	• Yes C No
Has the subject compliant to postural restriction till 06 hours post dose in supine position? (except receiving of meals):	• Yes C No
Has all the planned activities (including sampling and Vitals) including the allowed time window performed at bed side till 06 hours post dose in supine position?:	← Yes C No
Remark if any:	-
0.333 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DAY 6)	-MD6 Period: 1
Date and Time of Dosing:	18-Apr-2016 08:06
Date of sample collection:	18-Apr-2016
Scheduled date and Time of sample collection (for post dose only):	18-Apr-2016 08:26
Actual Time of sample collection:	08:26 24 hrs. clock
Remarks:	
PK Sample ID:	PK16210690
Remarks if any other reason:	
0.667 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DAY 6)	-MD6 Period: 1
	10. 4 2016 00:06
Date and Time of Dosing:	18-Apr-2016 08:06
Date and Time of Dosing: Date of sample collection:	18-Apr-2016 08:06
-	-
Date of sample collection:	18-Apr-2016
Date of sample collection: Scheduled date and Time of sample collection (for post dose only):	18-Apr-2016 18-Apr-2016 08:46
Date of sample collection: Scheduled date and Time of sample collection (for post dose only): Actual Time of sample collection:	18-Apr-2016 18-Apr-2016 08:46
Date of sample collection: Scheduled date and Time of sample collection (for post dose only): Actual Time of sample collection: Remarks:	18-Apr-2016 18-Apr-2016 08:46 08:46 24 hrs. clock
Date of sample collection: Scheduled date and Time of sample collection (for post dose only): Actual Time of sample collection: Remarks: PK Sample ID:	18-Apr-2016 18-Apr-2016 08:46 08:46 24 hrs. clock PK16210706
Date of sample collection: Scheduled date and Time of sample collection (for post dose only): Actual Time of sample collection: Remarks: PK Sample ID: Remarks if any other reason:	18-Apr-2016 18-Apr-2016 08:46 08:46 24 hrs. clock PK16210706
Date of sample collection: Scheduled date and Time of sample collection (for post dose only): Actual Time of sample collection: Remarks: PK Sample ID: Remarks if any other reason: 1.000 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DAY 6):	18-Apr-2016 18-Apr-2016 08:46 08:46 24 hrs. clock PK16210706 -MD6 Period: 1
Date of sample collection: Scheduled date and Time of sample collection (for post dose only): Actual Time of sample collection: Remarks: PK Sample ID: Remarks if any other reason: 1.000 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DAY 6): Date and Time of Dosing:	18-Apr-2016 18-Apr-2016 08:46 08:46 24 hrs. clock PK16210706 -MD6 Period: 1 18-Apr-2016 08:06
Date of sample collection: Scheduled date and Time of sample collection (for post dose only): Actual Time of sample collection: Remarks: PK Sample ID: Remarks if any other reason: 1.000 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DAY 6): Date and Time of Dosing: Date of sample collection:	18-Apr-2016 18-Apr-2016 08:46 08:46

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CASE REPORT FORM

Project No: 489-14-G-II



PK Sample ID:	PK16210722	
Remarks if any other reason:		
1.333 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DA	Y 6)-MD6	Period:
Date and Time of Dosing:	18-Apr-2016 08:06	
Date of sample collection:	18-Apr-2016	
Scheduled date and Time of sample collection (for post dose only):	18-Apr-2016 09:26	
Actual Time of sample collection:	09:26 24 hrs. clock	
Remarks:		
PK Sample ID:	PK16210738	
Remarks if any other reason:		
1.667 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DA	Y 6)-MD6	Period:
Date and Time of Dosing:	18-Apr-2016 08:06	
Date of sample collection:	18-Apr-2016	
Scheduled date and Time of sample collection (for post dose only):	18-Apr-2016 09:46	
Actual Time of sample collection:	09:46 24 hrs. clock	
Remarks:		
PK Sample ID:	PK16210754	
Remarks if any other reason:		
2.000 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DA	Y 6)-MD6	Period:
Date and Time of Dosing:	18-Apr-2016 08:06	
Date of sample collection:	18-Apr-2016	
Scheduled date and Time of sample collection (for post dose only):	18-Apr-2016 10:06	
Actual Time of sample collection:	10:06 24 hrs. clock	
Remarks:		
PK Sample ID:	PK16210770	
Remarks if any other reason:		
2.333 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DA	Y 6)-MD6	Period:
Date and Time of Dosing:	18-Apr-2016 08:06	
Date of sample collection:	18-Apr-2016	
Scheduled date and Time of sample collection (for post dose only):	18-Apr-2016 10:26	
Actual Time of sample collection:	10:27 24 hrs. clock	
Remarks:		
PK Sample ID:	PK16210786	
Remarks if any other reason:		
2.667 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DA	Y 6)-MD6	Period:
Date and Time of Dosing:	18-Apr-2016 08:06	
Date of sample collection:	18-Apr-2016	
Scheduled date and Time of sample collection (for post dose only):	18-Apr-2016 10:46	
Actual Time of sample collection:	10:46 24 hrs. clock	
Remarks:		
PK Sample ID:	PK16210802	
Remarks if any other reason:		
3.000 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DA	V 6)-MD6	Period: 1

Sponsor Name:Intas Pharmaceuticals Ltd.

CASE REPORT FORM

Project No: 489-14-G-II



Date and Time of Dosing:	18-Apr-2016 08:06
Date of sample collection:	18-Apr-2016
Scheduled date and Time of sample collection (for post dose only):	18-Apr-2016 11:06
Actual Time of sample collection:	11:06 24 hrs. clock
Remarks:	
PK Sample ID:	PK16210818
Remarks if any other reason:	
ECG EXAMINATION (3.00 HRS POST DOSE)-MORNING (DAY 6)	Period:
ECG EXAMINATION	
Date Of ECG:	18-Apr-2016
Time of ECG:	10:39 24 hrs. clock
Was ECG Repeated:	C Yes • No
If Yes, Date of Repeat ECG:	
ECG Impression:	WNL
Overall Assessment:	© C Not Clinically C Clinically
Overall Assessment.	Normal Significant Significant
Remark, If any:	-
3.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-MC	DRNING (DAY 6) Period:
Position:	Supine
Date of vital measurement:	18-Apr-2016
Start Time of vital measurement:	10:38 24 hrs. clock
Systolic Blood Pressure:	116 mmHg
Diastolic Blood Pressure:	74 mmHg
Radial Pulse:	64 beats/min
Well-being:	• Well • Unwell
If unwell then specify:	-
Remarks:	-
3.333 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DAY	6)-MD6 Period:
Date and Time of Dosing:	18-Apr-2016 08:06
Date of sample collection:	18-Apr-2016
Scheduled date and Time of sample collection (for post dose only):	18-Apr-2016 11:26
Actual Time of sample collection:	11:26 24 hrs. clock
Remarks:	
PK Sample ID:	PK16210834
Remarks if any other reason:	
3.667 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DAY	6)-MD6 Period:
Date and Time of Dosing:	18-Apr-2016 08:06
Date of sample collection:	18-Apr-2016
Scheduled date and Time of sample collection (for post dose only):	18-Apr-2016 11:46
Actual Time of sample collection:	11:46 24 hrs. clock
Remarks:	
PK Sample ID:	PK16210850

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Sponsor Name:Intas Pharmaceuticals Ltd.

CASE REPORT FORM

Project No: 489-14-G-II



Remarks if any other reason:		
4.000 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DA	AY 6)-MD6	Period
Date and Time of Dosing:	18-Apr-2016 08:06	
Date of sample collection:	18-Apr-2016	
Scheduled date and Time of sample collection (for post dose only):	18-Apr-2016 12:06	
Actual Time of sample collection:	12:07 24 hrs. clock	
Remarks:		
PK Sample ID:	PK16210866	
Remarks if any other reason:		
LUNCH (4.00 HRS POST DOSE) (DAY 6)		Period
Date of meal distribution:	18-Apr-2016	
Start Time:	12:10 24 hrs. clock	
End Time:	12:31 24 hrs. clock	
Has subject consumed meal completely?:	• Yes O No	
Details of meal left (Approximate Quantity):	-	
Remarks:	-	
4.500 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DA	AY 6)-MD6	Period
Date and Time of Dosing:	18-Apr-2016 08:06	
Date of sample collection:	18-Apr-2016	
Scheduled date and Time of sample collection (for post dose only):	18-Apr-2016 12:36	
Actual Time of sample collection:	12:36 24 hrs. clock	
Remarks:		
PK Sample ID:	PK16210882	
Remarks if any other reason:		
5.000 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DA	AY 6)-MD6	Period
Date and Time of Dosing:	18-Apr-2016 08:06	
Date of sample collection:	18-Apr-2016	
Scheduled date and Time of sample collection (for post dose only):	18-Apr-2016 13:06	
Actual Time of sample collection:	13:06 24 hrs. clock	
Remarks:		
PK Sample ID:	PK16210898	
Remarks if any other reason:		
6.000 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DA	AY 6)-MD6	Period
Date and Time of Dosing:	18-Apr-2016 08:06	
Date of sample collection:	18-Apr-2016	
Scheduled date and Time of sample collection (for post dose only):	18-Apr-2016 14:06	
Actual Time of sample collection:	14:06 24 hrs. clock	
Remarks:		
PK Sample ID:	PK16210914	
Remarks if any other reason:		
6.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-	MORNING (DAY 6)	Period

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CASE REPORT FORM

Project No: 489-14-G-II

Subject No: 1020 Subject Initials: SNG



Date of vital measurement:	18-Apr-2016
Start Time of vital measurement:	14:03 24 hrs. clock
Systolic Blood Pressure:	114 mmHg
Diastolic Blood Pressure:	74 mmHg
Radial Pulse:	72 beats/min
Well-being:	€ Well € Unwell
If unwell then specify:	-
Remarks:	-
8.000 HRS POST DOSE PK SAMPLE COLLECTION M	ORNING (DAY 6)-MD6 Period:
Date and Time of Dosing:	18-Apr-2016 08:06
Data of cample collection:	10 Apr 2016

8.000 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DAY 6)-MD6		Period: 1
Date and Time of Dosing:	18-Apr-2016 08:06	
Date of sample collection:	18-Apr-2016	
Scheduled date and Time of sample collection (for post dose only):	18-Apr-2016 16:06	
Actual Time of sample collection:	16:06 24 hrs. clock	
Remarks:		
PK Sample ID:	PK16210930	
Remarks if any other reason:		

SNACKS (DAY 6)	Period: 1
Date of meal distribution:	18-Apr-2016
Start Time:	17:08 24 hrs. clock
End Time:	17:16 24 hrs. clock
Has subject consumed meal completely?:	• Yes C No
Details of meal left (Approximate Quantity):	-
Remarks:	-

9.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-MORNING (DAY 6) Period:		
Position:	Sitting	
Date of vital measurement:	18-Apr-2016	
Start Time of vital measurement:	16:52 24 hrs. clock	
Systolic Blood Pressure:	112 mmHg	
Diastolic Blood Pressure:	72 mmHg	
Radial Pulse:	68 beats/min	
Well-being:	○ Well ○ Unwell	
If unwell then specify:	-	
Remarks:	-	

10.000 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DAY 6)-MD6		Period: 1
Date and Time of Dosing:	18-Apr-2016 08:06	
Date of sample collection:	18-Apr-2016	
Scheduled date and Time of sample collection (for post dose only):	18-Apr-2016 18:06	
Actual Time of sample collection:	18:06 24 hrs. clock	
Remarks:		
PK Sample ID:	PK16210946	
Remarks if any other reason:		

 $12.000~{\rm HRS~POST~DOSE~PK~SAMPLE~COLLECTION~MORNING~(DAY~6)-MD6}$

Period: 1

Sponsor Name:Intas Pharmaceuticals Ltd.

CASE REPORT FORM

Project No: 489-14-G-II



Date and Time of Dosing:	18-Apr-2016 08:06	
Date of sample collection:	18-Apr-2016	
Scheduled date and Time of sample collection (for post dose only):	18-Apr-2016 20:06	
Actual Time of sample collection:	20:06 24 hrs. clock	
Remarks:		
PK Sample ID:	PK16210962	
Remarks if any other reason:		
DINNER (DAY 6)	Period: 1	
Date of meal distribution:	18-Apr-2016	
Start Time:	20:08 24 hrs. clock	
End Time:	20:20 24 hrs. clock	
Has subject consumed meal completely?:	€ Yes C No	
Details of meal left (Approximate Quantity):	-	
Remarks:	-	
CHECK-OUT DETAILS(Per	riod - 1)	
CLINICAL EXAMINATION-CHECKOUT/ END OF STUDY	Period: 1	
Date of Clinical Examination:	18-Apr-2016	
Start Time of Clinical Examination:	18:48 24 hrs. clock	
Complaint of any illness:	€ No C Yes	
If YES, provide details:	-	
General Physical examination:	€ Normal C Abnormal	
Oral Body Temperature:	98.0 °F	
Radial Pulse Rate:	76 beats/min	
Blood Pressure(Systolic):	116 mmHg	
Blood Pressure(Diastolic):	72 mmHg	
Cardiovascular System Examination:		
Respiratory System Examination:		
Central Nervous System Examination:		
Per Abdomen Examination:	© Normal C Abnormal	
Any other Significant finding:	-	
Any investigations recommended:	-	
If 'Abnormal' in any of the above-mentioned sections, please enter details:	-	
To be performed at the time of check-out		
Vein puncture site:	Normal C Abnormal	
Subject well-being:	€ Well € Unwell	
Comments:	-	
Subject is fit for Check-out:	€ Yes C No	
Remark If any:	-	
CHECK-OUT B&B	Period: 1	

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CASE REPORT FORM

Project No: 489-14-G-II



Date of check out:	18-Apr-2016			
Time of Check-out:	20:50 24 hrs. clock			
Remarks:	-			
CHECK-IN DETAILS(Period - 2)				
BREATH TEST FOR ALCOHOL CONSUMPTION			Period: 2	
Date::	26-Apr-2016			
Start Time:	17:56 24 hrs.	17:56 24 hrs. clock		
Breath Alcohol Level (BAL):	.000 %	.000 %		
Result:	C Positive C	C Positive © Negative		
Start Time of 1st Repeat:	24 hrs. clock	ζ		
Breath Alcohol Level (BAL):	%			
1st Repeat result:	C Positive C	C Positive C Negative		
Start Time of 2nd Repeat:	24 hrs. clock	24 hrs. clock		
Breath Alcohol Level (BAL):	%			
2nd Repeat Result:	C Positive C	C Positive C Negative		
Final Result:	C Positive C	C Positive • Negative		
Remarks:	-			
URINE SCAN FOR DRUGS OF ABUSE			Period: 2	
SOP reference no:CPMA-26-07				
Date:	26-Apr-2016			
Refer/Read leaflet before start activity:	€ Yes € No	G Yes C No C NAP		
1. URINE SCAN FOR DRUGS ABUSE				
	V	V	V	
1.0 Tested for:	Amphetamine (AMP)	Barbiturates (BAR)	Benzodiazepines (BZD)	
1.0 Tested for.	Cocaine (COC)	Morphine (MOR)	Cannabinoids (THC)	
1.1 Start time:	18:05 24 hrs.	18:05 24 hrs. clock		
	М А ПВ П			
1.2 Observation of Results:				
Note: A=Two bands indicates negative (Control and Test),B=One band indicates Positive (Control),C=No band indicates Inv,D=One band indicates Invalid (Test)		indicates Invalid		
1.3 Result:	C Positive ©	C Positive • Negative C Invalid		
1.4 Positive for:				
	Amphetamine (AMP)	Barbiturates (BAR)	Benzodiazepines (BZD)	
	Cocaine (COC)	☐ Morphine (MOR)	☐ Cannabinoids (THC)	
1.5 A 1177 14 4	C Yes C No © NAP			
1.5 Any additional test performed-1:	L 10 L NO	· 11/11		

Lambda Therapeutic Research.	
Sponsor Name:Intas Pharmaceuticals Ltd.	
CASE REPORT FORM	



Project No: 489-14-G-II Subject No: 1020 Subject Initials: SNG

1.5b. Start time:	24 hrs. clock		
1.5c. Observation of result:	Па∏в∏С		
1.3c. Observation of result.	□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:	C Positive C Negative C Invalid		
1.6 Any additional test performed-2:	C Yes C No C NAP		
1.6a. Please Specify:			
1.6b. Start time:	24 hrs. clock		
1.6c. Observation of result:	□ A □ B □ C □ D		
Note: A=Two bands indicates negative (Control and Test),B=One band indicates Positive (Control),C=No band indicates Inval,D=One band indicates Invalid (Test)			
1.6d. Result:	C Positive C Negative C Invalid		
2. URINE SCAN FOR DRUGS ABUSE (1st REPEAT)			
2.0 Start time:	24 hrs. clock		
	Па∏в□с		
2.1 Observation of result:	□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:	C Positive C Negative C Invalid		
2.3 Positive for:	Amphetamine Barbiturates Benzodiazepines (AMP) (BAR) (BZD) Cocaine Morphine Cannabinoids (COC) (MOR) (THC)		
2.4 Any additional test performed-1:	C Yes C No C NAP		
2.4a. Please Specify:			
2.4b. Start time:	24 hrs. clock		
2.4c. Observation of result:	□ A □ B □ C □ D		
Note: A=Two bands indicates negative (Control and Test),B=One band indicates,D=One band indicates Invalid (Test)	s Positive (Control),C=No band indicates Invalid		
2.4d. Result:	C Positive C Negative C Invalid		
2.5 Any additional test performed-2:	C Yes C No C NAP		
2.5a. Please Specify:			
2.5b. Start time:	24 hrs. clock		

Lambda Therapeutic Research. Sponsor Name:Intas Pharmaceuticals Ltd.	
CASE REPORT FORM	
Project No: 489-14-G-II	LAMBDA
Subject No: 1020 Subject Initials: SNG	Lambda Therapeutic Research

2.5c. Observation of result:	Га □в □С	
	□D	
Note: A=Two bands indicates negative (Control and Test),B=One band indicate	s Positive (Control),C=No band indicates Invalid	
,D=One band indicates Invalid (Test)		
2.5d. Result:	C Positive C Negative C Invalid	
3. URINE SCAN FOR DRUGS ABUSE (2nd REPEAT)		
3.0 Start time:	24 hrs. clock	
3.1 Observation of result:	□а□в□С	
5.1 Coservation of result.	□D	
Note: A=Two bands indicates negative (Control and Test),B=One band indicate ,D=One band indicates Invalid (Test)	s Positive (Control),C=No band indicates Invalid	
3.2 Result:	C Positive C Negative C Invalid	
3.3 Positive for:	Amphetamine Barbiturates Benzodiazepines (AMP) (BAR) (BZD)	
	Cocaine	
3.4 Any additional test performed-1:	C Yes C No C NAP	
3.4a. Please Specify:		
3.4b. Start time:	24 hrs. clock	
3.4c. Observation of result:	□а □в □ C □ D	
Notes AToro hands indicates accretion (Control and Took) DOne hand indicate		
Note: A=Two bands indicates negative (Control and Test),B=One band indicates,D=One band indicates Invalid (Test)	s Positive (Control),C=No band indicates invalid	
3.4d. Result:	C Positive C Negative C Invalid	
3.5 Any additional test performed-2:	C Yes C No C NAP	
3.5a. Please Specify:		
3.5b. Start time:	24 hrs. clock	
3.5c. Observation of result:	□а□в□С	
5.5c. Observation of festilt.	□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:	C Positive C Negative C Invalid	
Final result:	C Positive © Negative	
Positive for:	Amphetamine Barbiturates Benzodiazepines (AMP) (BAR) (BZD) Cocaine Morphine Cannabinoids (COC) (MOR) (THC)	
	(MOK) (IIIC)	

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CASE REPORT FORM

Project No: 489-14-G-II



Final result (For additional test-1):	C Positive C Negative
Positive for (For additional test-1):	
Final result (For additional test-2):	C Positive C 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):	34
Subject Reporting Record	
Date of reporting to the clinical facility:	26-Apr-2016
Protocol Compliance Assessment	
Urine scans for drugs of abuse tested negative:	G Yes C No
Breath test for alcohol consumption tested negative:	• Yes C No
Date of last menstruation period (For Female subject):	-
Pagult of corum programay toot	C C NAP (For Male
Result of serum pregnancy test:	Positive Negative subject)
Prohibitions	
Are you suffering from any illness since the last visit (Including allergic reaction, itching, rash on your skin):	C Yes © No
Have you consumed any xanthine containing food or beverages (like tea,	
coffee, chocolates or cola drinks or any other) within 24 hours prior to first dose administration?:	C Yes © No
Have you consumed tobacco, tobacco containing products (Like Gutkha, Pan /	
Pan Masala) within 24 hours prior to first dose administration?:	C Yes • No
Have you consumed alcohol or alcoholic products and recreational drugs since Check-out of Period I?:	C Yes • No
Have you consumed grapefruit or grapefruit products since Check-out of Period I?:	C Yes • No
Have you smoked since Check-out of period I?:	C Yes © No
Ingestion of medicine (including herbal remedies) at any time since Check-out of period I?:	C Yes • No
Have you consumed an unusual diet, for whatever reason (e.g. low-sodium) since Check-out of period I?:	C Yes • No
Have you donated blood anywhere else or participated in other clinical trial since Check-out of period I?:	C Yes • No
Is subject compliant to all above restrictions/requirement?:	€ Yes C No
Remark If any:	-
CHECK-IN B&B	Period: 2
Baggage and Body Search done:	€ Yes C No
Date of Check In:	26-Apr-2016
Time of Check-in:	18:51 24 hrs. clock
Remarks:	-

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CASE REPORT FORM

Project No: 489-14-G-II



CLINICAL EXAMINATION - CHECK IN	Period: 2
Date of clinical examination:	26-Apr-2016
Start Time of Clinical Examination:	19:29 24 hrs. clock
Complaints of any illness:	€ No € Yes
If YES, provide details:	-
General Physical examination:	♠ Normal ← Abnormal
Oral Body Temperature:	97.8 °F
Blood Pressure (Systolic):	114 mmHg
Blood Pressure (Diastolic):	74 mmHg
Radial Pulse Rate:	72 beats/min
Cardiovascular System Examination:	
Respiratory System Examination:	
Central Nervous System Examination:	
Per Abdomen Examination:	
Any other Significant finding:	-
Any investigations recommended:	-
Vein puncture site:	
Subject well-being:	• Well C Unwell
If 'Abnormal' in any of the above-mentioned sections, please enter details.:	-
Remark if Any:	-
Subject is fit:	€ Yes C No
DINNER CHECK-IN (DAY-1)	Period: 2
Date of meal distribution:	26-Apr-2016
Start Time:	20:18 24 hrs. clock
End Time:	20:33 24 hrs. clock
Has subject consumed meal completely?:	• Yes C No
Details of meal left (Approximate Quantity):	-
Remarks:	-
IMP ADMINISTRATION-MORNING	G (PII-DAY 1)
IMP ADMINISTRATION-MORNING (PII-DAY 1)	Period: 2
DATE:	27-Apr-2016
IS SUBJECT COMPLIANT TO ALL PREDOSE REQUIREMENTS AS PER PROTOCOL?:	© Yes C No C NA
TIME:	08:06 24 hrs. clock
MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA:	• Yes C No C NA
ML OF WATER ADMINISTERED WITH IP:	240
LABEL:	0000184599
PRODUCT CODE/ TYPE:	Test
DOSING DONE BY:	AmitKhatri (Dosing)
DOSING DONE DT.	AmitKiiatii (Dosiiig)

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CASE REPORT FORM

Project No: 489-14-G-II



Fime of vital measurement: ic Blood Pressure: 116 blic Blood Pressure: 76 In Pulse: 77 In Pulse: 78 In Pulse: 79 In Pulse: 79 In Pulse: 70 In Pulse: 70 In Pulse: 70 In Pulse: 71 In Pulse: 72 In Pulse: 73 In Pulse: 74 In Pulse: 75 In Pulse: 76 In Pulse: 76 In Pulse: 76 In Pulse: 77 In Pulse: 78 In Pulse: 79 In Pulse: 79 In Pulse: 70 In Pulse: 70 In Pulse: 70 In Pulse: 70 In Pulse: 71 In Pulse: 72 In Pulse: 73 In Pulse: 74 In Pulse: 75 In Pulse: 76 In Pulse: 77 In Pulse	
Sitting of vital measurement: 27-A Time of vital measurement: 06:21 tic Blood Pressure: 116 Dic Blood Pressure: 76 Pulse: 76 Pu	pr-2016 24 hrs. clock mmHg nmHg peats/min
of vital measurement: Cime of vital measurement: Citic Blood Pressure: City Blood Pre	pr-2016 24 hrs. clock mmHg nmHg peats/min
Fine of vital measurement: ic Blood Pressure: 116 blic Blood Pressure: 76 In Pulse: Pu	24 hrs. clock mmHg nmHg peats/min
ic Blood Pressure: Dic Blood Pressure: Pulse: Peing: Fell then specify: rks: - HRS PRE DOSE PK SAMPLE COLLECTION MORNING (DAY 1)-MD1 and Time of Dosing: of sample collection: 1 Time of sample collection (for post dose only): 1 Time of sample collection:	mmHg nmHg beats/min
blic Blood Pressure: Pulse: Peing: Pell then specify: Per the specify:	nmHg peats/min
Pulse: 76 Leing: 6 Workell then specify:	peats/min
reing: rell then specify: rks:	
rks:	ell C Unwell
rks: HRS PRE DOSE PK SAMPLE COLLECTION MORNING (DAY 1)-MD1 and Time of Dosing: of sample collection: 27-A uled date and Time of sample collection (for post dose only): I Time of sample collection: 08:02 rks: mple ID: rks if any other reason:	
HRS PRE DOSE PK SAMPLE COLLECTION MORNING (DAY 1)-MD1 and Time of Dosing: of sample collection: 1 Time of sample collection: 2 T-A 2	
Ind Time of Dosing: of sample collection: 27-A uled date and Time of sample collection (for post dose only): I Time of sample collection: 08:02 rks: mple ID: rks if any other reason:	
of sample collection: 27-A uled date and Time of sample collection (for post dose only): 1 Time of sample collection: 08:02 rks: Imple ID: PK16 rks if any other reason:	Period: 2
uled date and Time of sample collection (for post dose only): I Time of sample collection: O8:02 rks: mple ID: PK16 rks if any other reason:	
Time of sample collection: rks: Imple ID: rks if any other reason:	pr-2016
rks: mple ID: PK16 rks if any other reason:	
rks if any other reason: PK16	2. 24 hrs. clock
rks if any other reason:	
	5238446
Y DRUG ADMINISTRATION-COMPLIANCE [MORNING (DAY 1)]	
	Period: 2
the subject resumed in supine positions immediately after dose stration?:	s C No
ne subject compliant to 01 hour post dose water restriction?:	s C No
the subject compliant to 04 hours post dose fasting condition?:	s C No
ne subject compliant to postural restriction till 06 hours post dose in position? (except receiving of meals):	s C No
I the planned activities (including sampling and Vitals) including the d time window performed at bed side till 06 hours post dose in supine in?:	s C No
rk if any:	
EXAMINATION (3.00 HRS POST DOSE)-MORNING (DAY 1)	Period: 2
EXAMINATION	
Of ECG: 27-A	pr-2016
of ECG: 10:58	3 24 hrs. clock
CCG Repeated:	s © No
, Date of Repeat ECG:	
Impression: SINU	
Il Assessment:	JS BRADYCARDIA,NCS
rk, If any:	US BRADYCARDIA,NCS Not Clinically C Clinically al Significant Significant
IRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-MORNING	

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CASE REPORT FORM

Project No: 489-14-G-II



Position:	Supine
Date of vital measurement:	27-Apr-2016
Start Time of vital measurement:	10:38 24 hrs. clock
Systolic Blood Pressure:	112 mmHg
Diastolic Blood Pressure:	72 mmHg
Radial Pulse:	76 beats/min
Well-being:	• Well • Unwell
If unwell then specify:	-
Remarks:	-
LUNCH (4.00 HRS POST DOSE) (DAY 1)	Peri
Date of meal distribution:	27-Apr-2016
Start Time:	12:08 24 hrs. clock
End Time:	12:26 24 hrs. clock
Has subject consumed meal completely?:	• Yes C No
Details of meal left (Approximate Quantity):	-
Remarks:	-
6.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING I	RECORD-MORNING (DAY 1) Peri
Position:	Supine
Date of vital measurement:	27-Apr-2016
Start Time of vital measurement:	13:40 24 hrs. clock
Systolic Blood Pressure:	116 mmHg
Diastolic Blood Pressure:	76 mmHg
Radial Pulse:	80 beats/min
Well-being:	• Well • Unwell
If unwell then specify:	-
Remarks:	-
SNACKS (DAY 1)	Peri
Date of meal distribution:	27-Apr-2016
Start Time:	17:08 24 hrs. clock
End Time:	17:18 24 hrs. clock
Has subject consumed meal completely?:	• Yes C No
Details of meal left (Approximate Quantity):	-
Remarks:	-
9.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING I	RECORD-MORNING (DAY 1) Peri
Position:	Sitting
Date of vital measurement:	27-Арг-2016
Start Time of vital measurement:	16:58 24 hrs. clock
Systolic Blood Pressure:	118 mmHg
Diastolic Blood Pressure:	76 mmHg
Radial Pulse:	66 beats/min
Well-being:	• Well C Unwell

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CASE REPORT FORM

Project No: 489-14-G-II



If unwell then specify:	-
Remarks:	-
IMP ADMINISTRATION-EVENING	G(PII-DAY 1)
IMP ADMINISTRATION-EVENING (PII-DAY 1)	Period: 2
DATE:	27-Apr-2016
IS SUBJECT COMPLIANT TO ALL PREDOSE REQUIREMENTS AS	
PER PROTOCOL?:	• Yes O No O NA
TIME:	20:06 24 hrs. clock
MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA:	€ Yes C No C NA
ML OF WATER ADMINISTERED WITH IP:	240
LABEL:	0000184600
PRODUCT CODE/ TYPE:	Test
DOSING DONE BY:	Noel (Dosing)
DOSING SUPERVISION DONE BY:	vishalhpatel (Dosing)
REMARKS:	
0.00 HRS PRE DOSE VITAL SIGNS AND WELL-BEING RECORD-EVENI	NG (DAY 1) Period: 2
Position:	Sitting
Date of vital measurement:	27-Apr-2016
Start Time of vital measurement:	18:28 24 hrs. clock
Systolic Blood Pressure:	122 mmHg
Diastolic Blood Pressure:	80 mmHg
Radial Pulse:	76 beats/min
Well-being:	• Well C Unwell
If unwell then specify:	-
Remarks:	-
STUDY DRUG ADMINISTRATION-COMPLIANCE [EVENING (DAY 1)]	Period: 2
Has the subject resumed in supine positions immediately after dose	G Yes C No
administration?:	
Has the subject compliant to 01 hour post dose water restriction?:	€ Yes C No
Has the subject compliant to 02 hours post dose fasting condition?:	← Yes C No
Has the subject compliant to postural restriction till 06 hours post dose in	© Yes C No
supine position? (except receiving of meals):	2.00
Has all the planned activities (including sampling and Vitals) including the	© Yes C No
allowed time window performed at bed side till 06 hours post dose in supine position?:	• Yes U No
Remark if any:	-
1.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-EVEN	VING (DAY 1) Period: 2
Position:	Supine Teriod. 2
Date of vital measurement:	27-Apr-2016
Start Time of vital measurement:	20:31 24 hrs. clock
Systolic Blood Pressure:	110 mmHg
Diastolic Blood Pressure:	70 mmHg
I and the state of	

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CASE REPORT FORM

Project No: 489-14-G-II



Radial Pulse:	68 beats/min
Well-being:	€ Well € Unwell
If unwell then specify:	-
Remarks:	-
DINNER (2.00 HRS POST DOSE) (DAY 1)	Period:
Date of meal distribution:	27-Apr-2016
Start Time:	22:08 24 hrs. clock
End Time:	22:22 24 hrs. clock
Has subject consumed meal completely?:	€ Yes C No
Details of meal left (Approximate Quantity):	-
Remarks:	-
IMP ADMINISTRATION-MORNIN	G (PII-DAY 2)
IMP ADMINISTRATION-MORNING (PII-DAY 2)	Period:
DATE:	28-Apr-2016
IS SUBJECT COMPLIANT TO ALL PREDOSE REQUIREMENTS AS PER PROTOCOL?:	G Yes C No C NA
TIME:	08:06 24 hrs. clock
MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA:	G Yes C No C NA
ML OF WATER ADMINISTERED WITH IP:	240
LABEL:	0000184615
PRODUCT CODE/ TYPE:	Test
DOSING DONE BY:	Noel (Dosing)
DOSING SUPERVISION DONE BY:	PradipPatel (Dosing)
REMARKS:	
0.00 HRS PRE DOSE VITAL SIGNS AND WELL-BEING RECORD-MORI	NING (DAY 2) Period:
Position:	Sitting
Date of vital measurement:	28-Apr-2016
Start Time of vital measurement:	06:31 24 hrs. clock
Systolic Blood Pressure:	118 mmHg
Diastolic Blood Pressure:	80 mmHg
Radial Pulse:	80 beats/min
Well-being:	ⓒ Well ◯ Unwell
If unwell then specify:	-
Remarks:	-
STUDY DRUG ADMINISTRATION-COMPLIANCE [MORNING (DAY 2	2)] Period:
Has the subject resumed in supine positions immediately after dose administration?:	€ Yes C No
Has the subject compliant to 01 hour post dose water restriction?:	• Yes C No
Has the subject compliant to 04 hours post dose fasting condition?:	F Yes C No
Has the subject compliant to postural restriction till 06 hours post dose in supine position? (except receiving of meals):	€ Yes C No

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CASE REPORT FORM

Project No: 489-14-G-II



Has all the planned activities (including sampling and Vitals) including the allowed time window performed at bed side till 06 hours post dose in supine position?: Remark if any:	• Yes C No
ECG EXAMINATION (3.00 HRS POST DOSE)-MORNING (DAY 2)	Period: 2
ECG EXAMINATION	r criod. 2
Date Of ECG:	28-Apr-2016
Time of ECG:	10:46 24 hrs. clock
Was ECG Repeated:	C Yes © No
If Yes, Date of Repeat ECG:	
ECG Impression:	SINUS BRADYCARDIA,NCS
Overall Assessment:	C Not Clinically C Clinically Normal Significant Significant
Remark, If any:	-
3.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-MOR	RNING (DAY 2) Period: 2
Position:	Supine
Date of vital measurement:	28-Apr-2016
Start Time of vital measurement:	10:52 24 hrs. clock
Systolic Blood Pressure:	118 mmHg
Diastolic Blood Pressure:	72 mmHg
Radial Pulse:	56 beats/min
Well-being:	• Well C Unwell
If unwell then specify:	-
Remarks:	Subject has been examined thoroughly.He is clinically asymptomatic. Pulse-56 beats/min is NCS
LUNCH (4.00 HRS POST DOSE) (DAY 2)	Period: 2
Date of meal distribution:	28-Apr-2016
Start Time:	12:12 24 hrs. clock
End Time:	12:30 24 hrs. clock
Has subject consumed meal completely?:	€ Yes C No
Details of meal left (Approximate Quantity):	-
Remarks:	-
6.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-MOR	RNING (DAY 2) Period: 2
Position:	Supine
Date of vital measurement:	28-Apr-2016
Start Time of vital measurement:	13:30 24 hrs. clock
Systolic Blood Pressure:	112 mmHg
Diastolic Blood Pressure:	70 mmHg
Radial Pulse:	68 beats/min
Well-being:	€ Well C Unwell
If unwell then specify:	-
Remarks:	-

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CASE REPORT FORM

Project No: 489-14-G-II



SNACKS (DAY 2)	Period: 2
Date of meal distribution:	28-Apr-2016
Start Time:	17:08 24 hrs. clock
End Time:	17:15 24 hrs. clock
Has subject consumed meal completely?:	• Yes C No
Details of meal left (Approximate Quantity):	-
Remarks:	-
9.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-MOR	RNING (DAY 2) Period: 2
Position:	Sitting
Date of vital measurement:	28-Apr-2016
Start Time of vital measurement:	16:40 24 hrs. clock
Systolic Blood Pressure:	112 mmHg
Diastolic Blood Pressure:	76 mmHg
Radial Pulse:	68 beats/min
Well-being:	€ Well € Unwell
If unwell then specify:	-
Remarks:	-
IMP ADMINISTRATION-EVENING	G (PII-DAY 2)
IMP ADMINISTRATION-EVENING (PII-DAY 2)	Period: 2
DATE:	28-Apr-2016
IS SUBJECT COMPLIANT TO ALL PREDOSE REQUIREMENTS AS PER PROTOCOL?:	€ Yes C No C NA
TIME:	20:06 24 hrs. clock
MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA:	• Yes C No C NA
ML OF WATER ADMINISTERED WITH IP:	240
LABEL:	0000184616
PRODUCT CODE/ TYPE:	Test
DOSING DONE BY:	pratiktrivedi (Dosing)
DOSING SUPERVISION DONE BY:	vishalhpatel (Dosing)
REMARKS:	
0.00 HRS PRE DOSE VITAL SIGNS AND WELL-BEING RECORD-EVENI	NG (DAY 2) Period: 2
Position:	Sitting
Date of vital measurement:	28-Apr-2016
Start Time of vital measurement:	19:23 24 hrs. clock
Systolic Blood Pressure:	118 mmHg
Diastolic Blood Pressure:	78 mmHg
Radial Pulse:	76 beats/min
Well-being:	€ Well C Unwell
If unwell then specify:	-
Remarks:	-
STUDY DRUG ADMINISTRATION-COMPLIANCE [EVENING (DAY 2)]	Period: 2

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CASE REPORT FORM

Project No: 489-14-G-II



Has the subject resumed in supine positions immediately after dose administration?:	← Yes ← No
Has the subject compliant to 01 hour post dose water restriction?:	← Yes ← No
Has the subject compliant to 02 hours post dose fasting condition?:	€ Yes C No
Has the subject compliant to postural restriction till 06 hours post dose in supine position? (except receiving of meals):	€ Yes C No
Has all the planned activities (including sampling and Vitals) including the allowed time window performed at bed side till 06 hours post dose in supine position?:	€ Yes C No
Remark if any:	-
1.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-EVEN	NING (DAY 2) Period: 2
Position:	Supine
Date of vital measurement:	28-Apr-2016
Start Time of vital measurement:	20:40 24 hrs. clock
Systolic Blood Pressure:	110 mmHg
Diastolic Blood Pressure:	68 mmHg
Radial Pulse:	64 beats/min
Well-being:	• Well • Unwell
If unwell then specify:	-
Remarks:	-
DINNER (2.00 HRS POST DOSE) (DAY 2)	Period: 2
Date of meal distribution:	28-Apr-2016
Start Time:	22:08 24 hrs. clock
End Time:	22:20 24 hrs. clock
Has subject consumed meal completely?:	€ Yes C No
Details of meal left (Approximate Quantity):	-
Remarks:	-
IMP ADMINISTRATION-MORNING	G (PII-DAY 3)
IMP ADMINISTRATION-MORNING (PII-DAY 3)	Period: 2
DATE:	29-Apr-2016
IS SUBJECT COMPLIANT TO ALL PREDOSE REQUIREMENTS AS PER PROTOCOL?:	© Yes C No C NA
TIME:	08:06 24 hrs. clock
MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA:	© Yes C No C NA
ML OF WATER ADMINISTERED WITH IP:	240
LABEL:	0000184631
PRODUCT CODE/ TYPE:	Test
DOSING DONE BY:	Noel (Dosing)
DOSING DONE BY: DOSING SUPERVISION DONE BY:	Noel (Dosing) PradipPatel (Dosing)
DOSING SUPERVISION DONE BY:	PradipPatel (Dosing)

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CASE REPORT FORM

Project No: 489-14-G-II



Date of vital measurement:	29-Apr-2016
Start Time of vital measurement:	06:26 24 hrs. clock
Systolic Blood Pressure:	110 mmHg
Diastolic Blood Pressure:	74 mmHg
Radial Pulse:	72 beats/min
Well-being:	• Well C Unwell
If unwell then specify:	-
Remarks:	-
0.000 HRS PRE DOSE PK SAMPLE COLLECTION MORNING (DAY 3)-	MD3 Period: 2
Date and Time of Dosing:	
Date of sample collection:	29-Apr-2016
Scheduled date and Time of sample collection (for post dose only):	
Actual Time of sample collection:	08:02 24 hrs. clock
Remarks:	
PK Sample ID:	PK16238462
Remarks if any other reason:	
STUDY DRUG ADMINISTRATION-COMPLIANCE [MORNING (DAY 3	Period: 2
Has the subject resumed in supine positions immediately after dose administration?:	€ Yes C No
Has the subject compliant to 01 hour post dose water restriction?:	€ Yes C No
Has the subject compliant to 04 hours post dose fasting condition?:	€ Yes C No
Has the subject compliant to postural restriction till 06 hours post dose in supine position? (except receiving of meals):	• Yes C No
Has all the planned activities (including sampling and Vitals) including the allowed time window performed at bed side till 06 hours post dose in supine position?:	• Yes C No
Remark if any:	-
ECG EXAMINATION (3.00 HRS POST DOSE)-MORNING (DAY 3)	Period: 2
ECG EXAMINATION	
Date Of ECG:	29-Apr-2016
Time of ECG:	10:57 24 hrs. clock
Was ECG Repeated:	C Yes © No
If Yes, Date of Repeat ECG:	
ECG Impression:	SINUS BRADYCARDIA,NCS
Overall Assessment:	C Not Clinically C Clinically Normal Significant Significant
Remark, If any:	-
3.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-MOR	RNING (DAY 3) Period: 2
Position:	Supine
Date of vital measurement:	29-Apr-2016
Start Time of vital measurement:	10:59 24 hrs. clock
Systolic Blood Pressure:	116 mmHg
*This is an electronically authenticated report	Page 47 of 67

Sponsor Name:Intas Pharmaceuticals Ltd.

CASE REPORT FORM

Project No: 489-14-G-II



Diastolic Blood Pressure:	76 mmHg	
Radial Pulse:	60 beats/min	
Well-being:	⊙ Well C Unwell	
If unwell then specify:	-	
Remarks:	-	
LUNCH (4.00 HRS POST DOSE) (DAY 3)	Period: 2	
Date of meal distribution:	29-Apr-2016	
Start Time:	12:08 24 hrs. clock	
End Time:	12:25 24 hrs. clock	
Has subject consumed meal completely?:	€ Yes C No	
Details of meal left (Approximate Quantity):	-	
Remarks:	-	
6.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-MC	PRNING (DAY 3) Period: 2	
Position:	Supine	
Date of vital measurement:	29-Apr-2016	
Start Time of vital measurement:	13:49 24 hrs. clock	
Systolic Blood Pressure:	114 mmHg	
Diastolic Blood Pressure:	78 mmHg	
Radial Pulse:	72 beats/min	
Well-being:	• Well • Unwell	
If unwell then specify:	-	
Remarks:	-	
SNACKS (DAY 3)	Period: 2	
Date of meal distribution:	29-Apr-2016	
Start Time:	17:08 24 hrs. clock	
End Time:	17:17 24 hrs. clock	
Has subject consumed meal completely?:	• Yes C No	
Details of meal left (Approximate Quantity):	-	
Remarks:	-	
9.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-MC	PRNING (DAY 3) Period: 2	
Position:	Sitting	
Date of vital measurement:	29-Apr-2016	
Start Time of vital measurement:	16:41 24 hrs. clock	
Systolic Blood Pressure:	116 mmHg	
Diastolic Blood Pressure:	74 mmHg	
Radial Pulse:	72 beats/min	
Well-being:	 € Well € Unwell	
If unwell then specify:	-	
Remarks:	-	
IMP ADMINISTRATION-EVENING (PII-DAY 3)		
IMP ADMINISTRATION-EVENING (PII-DAY 3)	Period: 2	

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CASE REPORT FORM

Project No: 489-14-G-II

Subject No: 1020 Subject Initials: SNG



DATE:	29-Apr-2016
IS SUBJECT COMPLIANT TO ALL PREDOSE REQUIREMENTS AS PER PROTOCOL?:	€ Yes C No C NA
TIME:	20:06 24 hrs. clock
MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA:	© Yes C No C NA
ML OF WATER ADMINISTERED WITH IP:	240
LABEL:	0000184632
PRODUCT CODE/ TYPE:	Test
DOSING DONE BY:	Noel (Dosing)
DOSING SUPERVISION DONE BY:	vishalhpatel (Dosing)
REMARKS:	X
0.00 HRS PRE DOSE VITAL SIGNS AND WELL-BEING RECORD-EVEN	ING (DAY 3) Period
Position:	Sitting
Date of vital measurement:	29-Apr-2016
Start Time of vital measurement:	18:51 24 hrs. clock
Systolic Blood Pressure:	122 mmHg
Diastolic Blood Pressure:	80 mmHg
Radial Pulse:	84 beats/min
Well-being:	€ Well C Unwell
If unwell then specify:	-
Remarks:	-
0.000 HRS PRE DOSE PK SAMPLE COLLECTION EVENING (DAY 3)-E	D3 Period
Date and Time of Dosing:	
Date of sample collection:	29-Apr-2016
Scheduled date and Time of sample collection (for post dose only):	
Actual Time of sample collection:	20:01 24 hrs. clock
Remarks:	
PK Sample ID:	PK16238414
Remarks if any other reason:	
STUDY DRUG ADMINISTRATION-COMPLIANCE [EVENING (DAY 3)	Period
Has the subject resumed in supine positions immediately after dose administration?:	€ Yes C No
Has the subject compliant to 01 hour post dose water restriction?:	€ Yes C No
Has the subject compliant to 02 hours post dose fasting condition?:	€ Yes C No
Has the subject compliant to postural restriction till 06 hours post dose in supine position? (except receiving of meals):	€ Yes C No
Has all the planned activities (including sampling and Vitals) including the	• Yes C No
allowed time window performed at bed side till 06 hours post dose in supine	
allowed time window performed at bed side till 06 hours post dose in supine position?: Remark if any:	-

Position:

Supine

Sponsor Name:Intas Pharmaceuticals Ltd.

CASE REPORT FORM

Project No: 489-14-G-II



Date of vital measurement:	29-Apr-2016
Start Time of vital measurement:	20:30 24 hrs. clock
Systolic Blood Pressure:	110 mmHg
Diastolic Blood Pressure:	70 mmHg
Radial Pulse:	68 beats/min
Well-being:	• Well C Unwell
If unwell then specify:	-
Remarks:	-
DINNER (2.00 HRS POST DOSE) (DAY 3)	Period: 2
Date of meal distribution:	29-Apr-2016
Start Time:	22:08 24 hrs. clock
End Time:	22:23 24 hrs. clock
Has subject consumed meal completely?:	• Yes C No
Details of meal left (Approximate Quantity):	-
Remarks:	-
IMP ADMINISTRATION-MORNING	G (PII-DAY 4)
IMP ADMINISTRATION-MORNING (PII-DAY 4)	Period: 2
DATE:	30-Apr-2016
IS SUBJECT COMPLIANT TO ALL PREDOSE REQUIREMENTS AS PER PROTOCOL?:	€ Yes C No C NA
TIME:	08:06 24 hrs. clock
MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA:	• Yes C No C NA
ML OF WATER ADMINISTERED WITH IP:	240
LABEL:	0000184647
PRODUCT CODE/ TYPE:	Test
DOSING DONE BY:	AmitKhatri (Dosing)
DOSING SUPERVISION DONE BY:	vishalhpatel (Dosing)
REMARKS:	
0.00 HRS PRE DOSE VITAL SIGNS AND WELL-BEING RECORD-MORN	NING (DAY 4) Period: 2
Position:	Sitting
Date of vital measurement:	30-Apr-2016
Start Time of vital measurement:	06:49 24 hrs. clock
Systolic Blood Pressure:	114 mmHg
Diastolic Blood Pressure:	76 mmHg
Radial Pulse:	72 beats/min
Well-being:	© Well C Unwell
If unwell then specify:	-
Remarks:	-
0.000 HRS PRE DOSE PK SAMPLE COLLECTION MORNING (DAY 4)-	MD4 Period: 2
Date and Time of Dosing:	
Date of sample collection:	30-Apr-2016
Scheduled date and Time of sample collection (for post dose only):	

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CASE REPORT FORM

Project No: 489-14-G-II



Actual Time of sample collection:	08:02 24 hrs. clock
Remarks:	
PK Sample ID:	PK16238478
Remarks if any other reason:	
STUDY DRUG ADMINISTRATION-COMPLIANCE [MORNING (DAY 4)] Period: 2
Has the subject resumed in supine positions immediately after dose administration?:	€ Yes C No
Has the subject compliant to 01 hour post dose water restriction?:	⊙ Yes C No
Has the subject compliant to 04 hours post dose fasting condition?:	€ Yes C No
Has the subject compliant to postural restriction till 06 hours post dose in supine position? (except receiving of meals):	© Yes C No
Has all the planned activities (including sampling and Vitals) including the allowed time window performed at bed side till 06 hours post dose in supine position?:	© Yes C No
Remark if any:	-
ECG EXAMINATION (3.00 HRS POST DOSE)-MORNING (DAY 4)	Period: 2
ECG EXAMINATION	
Date Of ECG:	30-Apr-2016
Time of ECG:	10:30 24 hrs. clock
Was ECG Repeated:	C Yes • No
If Yes, Date of Repeat ECG:	
ECG Impression:	SINUS BRADYCARDIA,NCS
Overall Assessment:	C Not Clinically C Clinically Normal Significant Significant
Remark, If any:	-
3.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-MOR	.NING (DAY 4) Period: 2
Position:	Supine
Date of vital measurement:	30-Apr-2016
Start Time of vital measurement:	10:50 24 hrs. clock
Systolic Blood Pressure:	120 mmHg
Diastolic Blood Pressure:	76 mmHg
Radial Pulse:	60 beats/min
Well-being:	• Well C Unwell
If unwell then specify:	-
Remarks:	-
LUNCH (4.00 HRS POST DOSE) (DAY 4)	Period: 2
Date of meal distribution:	30-Apr-2016
Start Time:	12:10 24 hrs. clock
End Time:	12:28 24 hrs. clock
Has subject consumed meal completely?:	€ Yes C No
Details of meal left (Approximate Quantity):	-

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CASE REPORT FORM

Project No: 489-14-G-II



Remarks:	_	
6.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-MO	RNING (DAV 4)	Period: 2
Position:	Supine	1 01100. 2
Date of vital measurement:	30-Apr-2016	
Start Time of vital measurement:	13:42 24 hrs. clock	
Systolic Blood Pressure:	114 mmHg	
Diastolic Blood Pressure:	72 mmHg	
Radial Pulse:	60 beats/min	
Well-being:	© Well C Unwell	
If unwell then specify:	-	
Remarks:	-	
SNACKS (DAY 4)		Period: 2
Date of meal distribution:	30-Apr-2016	1 0110 0. 2
Start Time:	17:08 24 hrs. clock	
End Time:	17:21 24 hrs. clock	
Has subject consumed meal completely?:	© Yes C No	
Details of meal left (Approximate Quantity):	_	
Remarks:	-	
9.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-MO	RNING (DAV 4)	Period: 2
Position:	Sitting	1 0110 0. 2
Date of vital measurement:	30-Apr-2016	
Start Time of vital measurement:	16:30 24 hrs. clock	
Systolic Blood Pressure:	122 mmHg	
Diastolic Blood Pressure:	78 mmHg	
Radial Pulse:	72 beats/min	
Well-being:		
If unwell then specify:	-	
Remarks:	-	
IMP ADMINISTRATION-EVENIN	G (PII-DAY 4)	
IMP ADMINISTRATION-EVENING (PII-DAY 4)		Period: 2
DATE:	30-Apr-2016	
IS SUBJECT COMPLIANT TO ALL PREDOSE REQUIREMENTS AS PER PROTOCOL?:	• Yes C No C NA	
TIME:	20:06 24 hrs. clock	
MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA:	© Yes C No C NA	
ML OF WATER ADMINISTERED WITH IP:	240	
LABEL:	0000184648	
PRODUCT CODE/ TYPE:	Test	
DOSING DONE BY:	HiteshPanchal (Dosing)	
	vipulkumarpatel (Dosing)	
DOSING SUPERVISION DONE BY:	Vipulkumarpater (Dosing)	

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CASE REPORT FORM

Project No: 489-14-G-II



0.00 HRS PRE DOSE VITAL SIGNS AND WELL-BEING RECORD-EVENI	NG (DAY 4) Period
Position:	Sitting
Date of vital measurement:	30-Apr-2016
Start Time of vital measurement:	18:42 24 hrs. clock
Systolic Blood Pressure:	118 mmHg
Diastolic Blood Pressure:	78 mmHg
Radial Pulse:	76 beats/min
Well-being:	• Well • Unwell
If unwell then specify:	-
Remarks:	-
0.000 HRS PRE DOSE PK SAMPLE COLLECTION EVENING (DAY 4)-EI	94 Period
Date and Time of Dosing:	
Date of sample collection:	30-Apr-2016
Scheduled date and Time of sample collection (for post dose only):	
Actual Time of sample collection:	20:02 24 hrs. clock
Remarks:	
PK Sample ID:	PK16238430
Remarks if any other reason:	
STUDY DRUG ADMINISTRATION-COMPLIANCE [EVENING (DAY 4)]	Period
Has the subject resumed in supine positions immediately after dose administration?:	← Yes C No
Has the subject compliant to 01 hour post dose water restriction?:	G Yes C No
Has the subject compliant to 02 hours post dose fasting condition?:	€ Yes C No
Has the subject compliant to postural restriction till 06 hours post dose in supine position? (except receiving of meals):	• Yes C No
Has all the planned activities (including sampling and Vitals) including the allowed time window performed at bed side till 06 hours post dose in supine position?:	• Yes C No
Remark if any:	-
1.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-EVEN	VING (DAY 4) Period
Position:	Supine
Date of vital measurement:	30-Apr-2016
Start Time of vital measurement:	21:18 24 hrs. clock
Systolic Blood Pressure:	118 mmHg
Diastolic Blood Pressure:	74 mmHg
Radial Pulse:	60 beats/min
Well-being:	• Well C Unwell
If unwell then specify:	-
Remarks:	-
DINNER (2.00 HRS POST DOSE) (DAY 4)	Period
Date of meal distribution:	30-Apr-2016
Start Time:	22:08 24 hrs. clock

Sponsor Name:Intas Pharmaceuticals Ltd.

CASE REPORT FORM

Project No: 489-14-G-II



End Time:	22:22 24 hrs. clock
Has subject consumed meal completely?:	€ Yes C No
Details of meal left (Approximate Quantity):	-
Remarks:	-
IMP ADMINISTRATION-MORNIN	IG (PII-DAY 5)
IMP ADMINISTRATION-MORNING (PII-DAY 5)	Period: 2
DATE:	01-May-2016
IS SUBJECT COMPLIANT TO ALL PREDOSE REQUIREMENTS AS PER PROTOCOL?:	© Yes C No C NA
TIME:	08:06 24 hrs. clock
MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA:	G Yes C No C NA
ML OF WATER ADMINISTERED WITH IP:	240
LABEL:	0000184663
PRODUCT CODE/ TYPE:	Test
DOSING DONE BY:	Noel (Dosing)
DOSING SUPERVISION DONE BY:	PradipPatel (Dosing)
REMARKS:	
0.00 HRS PRE DOSE VITAL SIGNS AND WELL-BEING RECORD-MOR	NING (DAY 5) Period: 2
Position:	Sitting
Date of vital measurement:	01-May-2016
Start Time of vital measurement:	06:44 24 hrs. clock
Systolic Blood Pressure:	124 mmHg
Diastolic Blood Pressure:	78 mmHg
Radial Pulse:	80 beats/min
Well-being:	 Well Unwell
If unwell then specify:	-
Remarks:	-
0.000 HRS PRE DOSE PK SAMPLE COLLECTION MORNING (DAY 5)-	-MD5 Period: 2
Date and Time of Dosing:	
Date of sample collection:	01-May-2016
Scheduled date and Time of sample collection (for post dose only):	
Actual Time of sample collection:	08:01 24 hrs. clock
Remarks:	
PK Sample ID:	PK16238494
Remarks if any other reason:	
STUDY DRUG ADMINISTRATION-COMPLIANCE [MORNING (DAY :	5)] Period: 2
Has the subject resumed in supine positions immediately after dose administration?:	€ Yes C No
Has the subject compliant to 01 hour post dose water restriction?:	€ Yes C No
Has the subject compliant to 04 hours post dose fasting condition?:	€ Yes C No
Has the subject compliant to postural restriction till 06 hours post dose in supine position? (except receiving of meals):	€ Yes C No
-	· · · · · · · · · · · · · · · · · · ·

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CASE REPORT FORM

Project No: 489-14-G-II



Has all the planned activities (including sampling and Vitals) including the allowed time window performed at bed side till 06 hours post dose in supine position?:	© Yes C No
Remark if any:	-
0.333 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DAY 5))-MD5 Period: 2
Date and Time of Dosing:	01-May-2016 08:06
Date of sample collection:	01-May-2016
Scheduled date and Time of sample collection (for post dose only):	01-May-2016 08:26
Actual Time of sample collection:	08:26 24 hrs. clock
Remarks:	
PK Sample ID:	PK16238526
Remarks if any other reason:	
0.667 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DAY 5))-MD5 Period: 2
Date and Time of Dosing:	01-May-2016 08:06
Date of sample collection:	01-May-2016
Scheduled date and Time of sample collection (for post dose only):	01-May-2016 08:46
Actual Time of sample collection:	08:46 24 hrs. clock
Remarks:	
PK Sample ID:	PK16238542
Remarks if any other reason:	
1.000 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DAY 5))-MD5 Period: 2
Date and Time of Dosing:	01-May-2016 08:06
Date of sample collection:	01-May-2016
Scheduled date and Time of sample collection (for post dose only):	01-May-2016 09:06
Actual Time of sample collection:	09:06 24 hrs. clock
Remarks:	
PK Sample ID:	PK16238558
Remarks if any other reason:	
1.333 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DAY 5))-MD5 Period: 2
Date and Time of Dosing:	01-May-2016 08:06
Date of sample collection:	01-May-2016
Scheduled date and Time of sample collection (for post dose only):	01-May-2016 09:26
Actual Time of sample collection:	09:26 24 hrs. clock
Remarks:	
PK Sample ID:	PK16238574
Remarks if any other reason:	
1.667 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DAY 5))-MD5 Period: 2
Date and Time of Dosing:	01-May-2016 08:06
Date of sample collection:	01-May-2016
Scheduled date and Time of sample collection (for post dose only):	01-May-2016 09:46
Actual Time of sample collection:	09:46 24 hrs. clock
Remarks:	
Remarks.	

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CASE REPORT FORM

Project No: 489-14-G-II



Remarks if any other reason:		
2.000 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DA	AY 5)-MD5	Period:
Date and Time of Dosing:	01-May-2016 08:06	
Date of sample collection:	01-May-2016	
Scheduled date and Time of sample collection (for post dose only):	01-May-2016 10:06	
Actual Time of sample collection:	10:06 24 hrs. clock	
Remarks:		
PK Sample ID:	PK16238606	
Remarks if any other reason:		
2.333 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DA	AY 5)-MD5	Period:
Date and Time of Dosing:	01-May-2016 08:06	
Date of sample collection:	01-May-2016	
Scheduled date and Time of sample collection (for post dose only):	01-May-2016 10:26	
Actual Time of sample collection:	10:26 24 hrs. clock	
Remarks:		
PK Sample ID:	PK16238622	
Remarks if any other reason:		
2.667 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DA	Y 5)-MD5	Period:
Date and Time of Dosing:	01-May-2016 08:06	
Date of sample collection:	01-May-2016	
Scheduled date and Time of sample collection (for post dose only):	01-May-2016 10:46	
Actual Time of sample collection:	10:46 24 hrs. clock	
Remarks:		
PK Sample ID:	PK16238638	
Remarks if any other reason:		
3.000 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DA	Y 5)-MD5	Period:
Date and Time of Dosing:	01-May-2016 08:06	
Date of sample collection:	01-May-2016	
Scheduled date and Time of sample collection (for post dose only):	01-May-2016 11:06	
Actual Time of sample collection:	11:06 24 hrs. clock	
Remarks:		
PK Sample ID:	PK16238654	
Remarks if any other reason:		
ECG EXAMINATION (3.00 HRS POST DOSE)-MORNING (DAY 5)		Period:
ECG EXAMINATION		
Date Of ECG:	01-May-2016	
Time of ECG:	11:07 24 hrs. clock	
Was ECG Repeated:	C Yes © No	
If Yes, Date of Repeat ECG:		
ECG Impression:	SINUS BRADYCARDIA,NO	CS
Overall Assessment:	C • Not Clinically Normal Significant	C Clinically Significant

Sponsor Name:Intas Pharmaceuticals Ltd.

CASE REPORT FORM

Project No: 489-14-G-II



Remark, If any:	-	
3.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-M	MORNING (DAY 5)	Period: 2
Position:	Supine	
Date of vital measurement:	01-May-2016	
Start Time of vital measurement:	11:00 24 hrs. clock	
Systolic Blood Pressure:	110 mmHg	
Diastolic Blood Pressure:	70 mmHg	
Radial Pulse:	68 beats/min	
Well-being:	• Well C Unwell	
If unwell then specify:	-	
Remarks:	-	
3.333 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DA	Y 5)-MD5	Period: 2
Date and Time of Dosing:	01-May-2016 08:06	
Date of sample collection:	01-May-2016	
Scheduled date and Time of sample collection (for post dose only):	01-May-2016 11:26	
Actual Time of sample collection:	11:26 24 hrs. clock	
Remarks:		
PK Sample ID:	PK16238670	
Remarks if any other reason:		
3.667 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DA	Y 5)-MD5	Period: 2
Date and Time of Dosing:	01-May-2016 08:06	
Date of sample collection:	01-May-2016	
Scheduled date and Time of sample collection (for post dose only):	01-May-2016 11:46	
Actual Time of sample collection:	11:46 24 hrs. clock	
Remarks:		
PK Sample ID:	PK16238686	
Remarks if any other reason:		
4.000 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DA	Y 5)-MD5	Period: 2
Date and Time of Dosing:	01-May-2016 08:06	
Date of sample collection:	01-May-2016	
Scheduled date and Time of sample collection (for post dose only):	01-May-2016 12:06	
Actual Time of sample collection:	12:06 24 hrs. clock	
Remarks:		
PK Sample ID:	PK16238702	
Remarks if any other reason:		
LUNCH (4.00 HRS POST DOSE) (DAY 5)		Period: 2
	01-May-2016	
Date of meal distribution:		
Start Time:	12:08 24 hrs. clock	
	<u> </u>	
Start Time:	12:08 24 hrs. clock	
Start Time: End Time:	12:08 24 hrs. clock 12:27 24 hrs. clock	

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CASE REPORT FORM

Project No: 489-14-G-II



4.500 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DAY	Y 5)-MD5	Period: 2
Date and Time of Dosing:	01-May-2016 08:06	
Date of sample collection:	01-May-2016	
Scheduled date and Time of sample collection (for post dose only):	01-May-2016 12:36	
Actual Time of sample collection:	12:36 24 hrs. clock	
Remarks:		
PK Sample ID:	PK16238718	
Remarks if any other reason:		
5.000 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DAY	Y 5)-MD5	Period: 2
Date and Time of Dosing:	01-May-2016 08:06	
Date of sample collection:	01-May-2016	
Scheduled date and Time of sample collection (for post dose only):	01-May-2016 13:06	
Actual Time of sample collection:	13:06 24 hrs. clock	
Remarks:		
PK Sample ID:	PK16238734	
Remarks if any other reason:		
6.000 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DAY	Y 5)-MD5	Period: 2
Date and Time of Dosing:	01-May-2016 08:06	
Date of sample collection:	01-May-2016	
Scheduled date and Time of sample collection (for post dose only):	01-May-2016 14:06	
Actual Time of sample collection:	14:06 24 hrs. clock	
Remarks:		
PK Sample ID:	PK16238750	
Remarks if any other reason:		
6.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-M	MORNING (DAY 5)	Period: 2
Position:	Supine	
Date of vital measurement:	01-May-2016	
Start Time of vital measurement:	13:35 24 hrs. clock	
Systolic Blood Pressure:	110 mmHg	
Diastolic Blood Pressure:	74 mmHg	
Radial Pulse:	68 beats/min	
Well-being:	• Well • Unwell	
If unwell then specify:	-	
Remarks:	-	
8.000 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DAY	Y 5)-MD5	Period: 2
Date and Time of Dosing:	01-May-2016 08:06	
Date of sample collection:	01-May-2016	
Scheduled date and Time of sample collection (for post dose only):	01-May-2016 16:06	
Actual Time of sample collection:	16:06 24 hrs. clock	
Remarks:		
PK Sample ID:	PK16238766	
Remarks if any other reason:		
SNACKS (DAY 5)		Period: 2

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CASE REPORT FORM

Project No: 489-14-G-II



Date of meal distribution:	01-May-2016
Start Time:	17:08 24 hrs. clock
End Time:	17:15 24 hrs. clock
Has subject consumed meal completely?:	• Yes C No
Details of meal left (Approximate Quantity):	-
Remarks:	-
9.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-MOI	RNING (DAY 5) Period: 2
Position:	Sitting
Date of vital measurement:	01-May-2016
Start Time of vital measurement:	16:37 24 hrs. clock
Systolic Blood Pressure:	120 mmHg
Diastolic Blood Pressure:	74 mmHg
Radial Pulse:	72 beats/min
Well-being:	• Well C Unwell
If unwell then specify:	-
Remarks:	-
10.000 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DAY	5)-MD5 Period: 2
Date and Time of Dosing:	01-May-2016 08:06
Date of sample collection:	01-May-2016
Scheduled date and Time of sample collection (for post dose only):	01-May-2016 18:06
Actual Time of sample collection:	18:06 24 hrs. clock
Remarks:	
PK Sample ID:	PK16238782
Remarks if any other reason:	
12.000 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DAY	5)-MD5 Period: 2
Date and Time of Dosing:	01-May-2016 08:06
Date of sample collection:	01-May-2016
Scheduled date and Time of sample collection (for post dose only):	01-May-2016 20:06
Actual Time of sample collection:	20:01 24 hrs. clock
Remarks:	
PK Sample ID:	PK16238798
Remarks if any other reason:	
IMP ADMINISTRATION-EVENING	G (PII-DAY 5)
IMP ADMINISTRATION-EVENING (PII-DAY 5)	Period: 2
DATE:	01-May-2016
IS SUBJECT COMPLIANT TO ALL PREDOSE REQUIREMENTS AS PER PROTOCOL?:	© Yes C No C NA
TIME:	20:06 24 hrs. clock
MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA:	© Yes C No C NA
ML OF WATER ADMINISTERED WITH IP:	240
LABEL:	0000184664
PRODUCT CODE/ TYPE:	Test

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CASE REPORT FORM

Project No: 489-14-G-II



DOSING DONE BY:	PradipPatel (Dosing)
DOSING SUPERVISION DONE BY:	chintanpatel (Dosing)
REMARKS:	
0.00 HRS PRE DOSE VITAL SIGNS AND WELL-BEING RECORD-EVENIN	NG (DAY 5) Period: 2
Position:	Sitting
Date of vital measurement:	01-May-2016
Start Time of vital measurement:	18:17 24 hrs. clock
Systolic Blood Pressure:	122 mmHg
Diastolic Blood Pressure:	82 mmHg
Radial Pulse:	68 beats/min
Well-being:	• Well C Unwell
If unwell then specify:	-
Remarks:	-
STUDY DRUG ADMINISTRATION-COMPLIANCE [EVENING (DAY 5)]	Period: 2
Has the subject resumed in supine positions immediately after dose administration?:	€ Yes C No
Has the subject compliant to 01 hour post dose water restriction?:	€ Yes C No
Has the subject compliant to 02 hours post dose fasting condition?:	€ Yes C No
Has the subject compliant to postural restriction till 06 hours post dose in supine position? (except receiving of meals):	€ Yes C No
Has all the planned activities (including sampling and Vitals) including the allowed time window performed at bed side till 06 hours post dose in supine position?:	• Yes C No
Remark if any:	-
1.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-EVEN	IING (DAY 5) Period: 2
Position:	Supine
Date of vital measurement:	01-May-2016
Start Time of vital measurement:	21:12 24 hrs. clock
Systolic Blood Pressure:	120 mmHg
Diastolic Blood Pressure:	84 mmHg
Radial Pulse:	72 beats/min
Well-being:	€ Well C Unwell
If unwell then specify:	-
Remarks:	-
DINNER (2.00 HRS POST DOSE) (DAY 5)	Period: 2
Date of meal distribution:	01-May-2016
Start Time:	22:08 24 hrs. clock
End Time:	22:24 24 hrs. clock
Has subject consumed meal completely?:	• Yes C No
Details of meal left (Approximate Quantity):	-
Remarks:	-
IMP ADMINISTRATION-MORNING	G (PII-DAY 6)

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CASE REPORT FORM

Project No: 489-14-G-II



IMP ADMINISTRATION-MORNING (PII-DAY 6)	Period: 2
DATE:	02-May-2016
IS SUBJECT COMPLIANT TO ALL PREDOSE REQUIREMENTS AS PER PROTOCOL?:	G Yes C No C NA
TIME:	08:06 24 hrs. clock
MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA:	€ Yes C No C NA
ML OF WATER ADMINISTERED WITH IP:	240
LABEL:	0000184678
PRODUCT CODE/ TYPE:	Test
DOSING DONE BY:	Noel (Dosing)
DOSING SUPERVISION DONE BY:	PradipPatel (Dosing)
REMARKS:	
0.00 HRS PRE DOSE VITAL SIGNS AND WELL-BEING RECORD-MORN	IING (DAY 6) Period: 2
Position:	Sitting
Date of vital measurement:	02-May-2016
Start Time of vital measurement:	06:47 24 hrs. clock
Systolic Blood Pressure:	122 mmHg
Diastolic Blood Pressure:	80 mmHg
Radial Pulse:	84 beats/min
Well-being:	• Well • Unwell
If unwell then specify:	-
Remarks:	-
0.000 HRS PRE DOSE PK SAMPLE COLLECTION MORNING (DAY 6)-N	MD6 Period: 2
Date and Time of Dosing:	
Date of sample collection:	02-May-2016
Scheduled date and Time of sample collection (for post dose only):	
Actual Time of sample collection:	08:02 24 hrs. clock
Remarks:	
PK Sample ID:	PK16238510
Remarks if any other reason:	
STUDY DRUG ADMINISTRATION-COMPLIANCE [MORNING (DAY 6	Period: 2
Has the subject resumed in supine positions immediately after dose administration?:	G Yes C No
Has the subject compliant to 01 hour post dose water restriction?:	€ Yes C No
Has the subject compliant to 04 hours post dose fasting condition?:	G Yes C No
Has the subject compliant to postural restriction till 06 hours post dose in supine position? (except receiving of meals):	G Yes C No
Has all the planned activities (including sampling and Vitals) including the allowed time window performed at bed side till 06 hours post dose in supine position?:	G Yes C No
Remark if any:	-
0.333 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DAY 6)	-MD6 Period: 2

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CASE REPORT FORM

Project No: 489-14-G-II

Subject No: 1020 Subject Initials: SNG



Subject 110. 1020 Subject minus. S170	Lambda Therapeutic Research
Date and Time of Dosing:	02-May-2016 08:06
Date of sample collection:	02-May-2016
Scheduled date and Time of sample collection (for post dose only):	02-May-2016 08:26
Actual Time of sample collection:	08:26 24 hrs. clock
Remarks:	
PK Sample ID:	PK16241711
Remarks if any other reason:	
0.667 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DA	AY 6)-MD6 Period: 1
Date and Time of Dosing:	02-May-2016 08:06
Date of sample collection:	02-May-2016
Scheduled date and Time of sample collection (for post dose only):	02-May-2016 08:46
Actual Time of sample collection:	08:46 24 hrs. clock
Remarks:	
PK Sample ID:	PK16241727
Remarks if any other reason:	
1.000 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DA	AY 6)-MD6 Period: 2
Date and Time of Dosing:	02-May-2016 08:06
Date of sample collection:	02-May-2016
Scheduled date and Time of sample collection (for post dose only):	02-May-2016 09:06
Actual Time of sample collection:	09:06 24 hrs. clock
Remarks:	
PK Sample ID:	PK16241743
Remarks if any other reason:	
1.333 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DA	AY 6)-MD6 Period: 2
Date and Time of Dosing:	02-May-2016 08:06
Date of sample collection:	02-May-2016
Scheduled date and Time of sample collection (for post dose only):	02-May-2016 09:26
Actual Time of sample collection:	09:26 24 hrs. clock
Remarks:	
PK Sample ID:	PK16241759
Remarks if any other reason:	
1.667 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DA	AY 6)-MD6 Period: 2
Date and Time of Dosing:	02-May-2016 08:06
Date of sample collection:	02-May-2016
Scheduled date and Time of sample collection (for post dose only):	02-May-2016 09:46
Actual Time of sample collection:	09:46 24 hrs. clock
Remarks:	
PK Sample ID:	PK16241775
Remarks if any other reason:	
2.000 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DA	AY 6)-MD6 Period: 2
Date and Time of Dosing:	02-May-2016 08:06
Date of sample collection:	02-May-2016

Scheduled date and Time of sample collection (for post dose only):

02-May-2016 10:06

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CASE REPORT FORM

Project No: 489-14-G-II



Actual Time of sample collection:	10:06 24 hrs. clock
Remarks:	
PK Sample ID:	PK16241791
Remarks if any other reason:	
2.333 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DA	Y 6)-MD6 Period: 2
Date and Time of Dosing:	02-May-2016 08:06
Date of sample collection:	02-May-2016
Scheduled date and Time of sample collection (for post dose only):	02-May-2016 10:26
Actual Time of sample collection:	10:26 24 hrs. clock
Remarks:	
PK Sample ID:	PK16241807
Remarks if any other reason:	
2.667 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DA	Y 6)-MD6 Period: 2
Date and Time of Dosing:	02-May-2016 08:06
Date of sample collection:	02-May-2016
Scheduled date and Time of sample collection (for post dose only):	02-May-2016 10:46
Actual Time of sample collection:	10:46 24 hrs. clock
Remarks:	
PK Sample ID:	PK16241823
Remarks if any other reason:	
3.000 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DA	Y 6)-MD6 Period: 2
Date and Time of Dosing:	02-May-2016 08:06
Date of sample collection:	02-May-2016
Scheduled date and Time of sample collection (for post dose only):	02-May-2016 11:06
Actual Time of sample collection:	11:06 24 hrs. clock
Remarks:	
PK Sample ID:	PK16241839
Remarks if any other reason:	
ECG EXAMINATION (3.00 HRS POST DOSE)-MORNING (DAY 6)	Period: 2
ECG EXAMINATION	
Date Of ECG:	02-May-2016
Time of ECG:	10:41 24 hrs. clock
Was ECG Repeated:	C Yes • No
If Yes, Date of Repeat ECG:	
ECG Impression:	SINUS BRADYCARDIA,NCS
Overall Assessment:	C Not Clinically C Clinically Normal Significant Significant
Remark, If any:	-
3.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-M	MORNING (DAY 6) Period: 2
Position:	Supine
Date of vital measurement:	02-May-2016
Start Time of vital measurement:	10:44 24 hrs. clock

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CASE REPORT FORM

Project No: 489-14-G-II



Systolic Blood Pressure:	114 mmHg	
Diastolic Blood Pressure:	74 mmHg	
Radial Pulse:	64 beats/min	
Well-being:	€ Well € Unwell	
If unwell then specify:	-	
Remarks:	-	
$3.333~\mathrm{HRS}$ POST DOSE PK SAMPLE COLLECTION MORNING (DA	AY 6)-MD6	Period:
Date and Time of Dosing:	02-May-2016 08:06	
Date of sample collection:	02-May-2016	
Scheduled date and Time of sample collection (for post dose only):	02-May-2016 11:26	
Actual Time of sample collection:	11:26 24 hrs. clock	
Remarks:		
PK Sample ID:	PK16241855	
Remarks if any other reason:		
3.667 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DA	AY 6)-MD6	Period:
Date and Time of Dosing:	02-May-2016 08:06	
Date of sample collection:	02-May-2016	
Scheduled date and Time of sample collection (for post dose only):	02-May-2016 11:46	
Actual Time of sample collection:	11:46 24 hrs. clock	
Remarks:		
PK Sample ID:	PK16241871	
Remarks if any other reason:		
4.000 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DA	AY 6)-MD6	Period:
Date and Time of Dosing:	02-May-2016 08:06	
Date of sample collection:	02-May-2016	
Scheduled date and Time of sample collection (for post dose only):	02-May-2016 12:06	
Actual Time of sample collection:	12:06 24 hrs. clock	
Remarks:		
PK Sample ID:	PK16241887	
Remarks if any other reason:		
LUNCH (4.00 HRS POST DOSE) (DAY 6)		Period:
Date of meal distribution:	02-May-2016	
Start Time:	12:08 24 hrs. clock	
End Time:	12:26 24 hrs. clock	
Has subject consumed meal completely?:	• Yes C No	
Details of meal left (Approximate Quantity):		
Remarks:	-	
4.500 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DA		Period:
Date and Time of Dosing:	02-May-2016 08:06	
Date of sample collection:	02-May-2016	
Scheduled date and Time of sample collection (for post dose only):	02-May-2016 12:36	

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CASE REPORT FORM

Project No: 489-14-G-II



Remarks:		
PK Sample ID:	PK16241903	
Remarks if any other reason:	0.00000 1.0000	
5.000 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DA	Y 6)-MD6	Period
Date and Time of Dosing:	02-May-2016 08:06	
Date of sample collection:	02-May-2016	
Scheduled date and Time of sample collection (for post dose only):	02-May-2016 13:06	
Actual Time of sample collection:	13:06 24 hrs. clock	
Remarks:		
PK Sample ID:	PK16241919	
Remarks if any other reason:		
6.000 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DA	V 6)-MD6	Period
Date and Time of Dosing:	02-May-2016 08:06	1 CHOC
Date of sample collection:	02-May-2016	
Scheduled date and Time of sample collection (for post dose only):	02-May-2016 14:06	
Actual Time of sample collection:	14:06 24 hrs. clock	
Remarks:	11.00 24 H3. Clock	
PK Sample ID:	PK16241935	
Remarks if any other reason:	11210211930	
6.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-I	MODNING (DAV 6)	Period
Position:	Supine	1 CHOC
Date of vital measurement:	02-May-2016	
Start Time of vital measurement:	13:38 24 hrs. clock	
Systolic Blood Pressure:	116 mmHg	
Diastolic Blood Pressure:	74 mmHg	
Radial Pulse:	80 beats/min	
Well-being:	• Well • Unwell	
If unwell then specify:	-	
Remarks:	-	
8.000 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DA	V 6)-MD6	Period
Date and Time of Dosing:	02-May-2016 08:06	1 CITOG
Date of sample collection:	02-May-2016	
Scheduled date and Time of sample collection (for post dose only):	02-May-2016 16:06	
Actual Time of sample collection:	16:06 24 hrs. clock	
Remarks:	10.00 21 11131 01001	
PK Sample ID:	PK16241951	
Remarks if any other reason:		
·		Period
SNACKS (DAV 6)		renoc
	$02_{-May-2016}$	
SNACKS (DAY 6) Date of meal distribution: Start Time:	02-May-2016	
	02-May-2016 17:08 24 hrs. clock 17:16 24 hrs. clock	
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CASE REPORT FORM

Project No: 489-14-G-II



Details of meal left (Approximate Quantity):	-	
Remarks:	-	
9.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-	MORNING (DAY 6)	Period:
Position:	Sitting	
Date of vital measurement:	02-May-2016	
Start Time of vital measurement:	16:48 24 hrs. clock	
Systolic Blood Pressure:	110 mmHg	
Diastolic Blood Pressure:	80 mmHg	
Radial Pulse:	68 beats/min	
Well-being:	ⓒ Well ◯ Unwell	
If unwell then specify:	-	
Remarks:	-	
10.000 HRS POST DOSE PK SAMPLE COLLECTION MORNING (D	AY 6)-MD6	Period:
Date and Time of Dosing:	02-May-2016 08:06	
Date of sample collection:	02-May-2016	
Scheduled date and Time of sample collection (for post dose only):	02-May-2016 18:06	
Actual Time of sample collection:	18:06 24 hrs. clock	
Remarks:		
PK Sample ID:	PK16241967	
Remarks if any other reason:		
12.000 HRS POST DOSE PK SAMPLE COLLECTION MORNING (D	AY 6)-MD6	Period:
Date and Time of Dosing:	02-May-2016 08:06	
Date of sample collection:	02-May-2016	
Scheduled date and Time of sample collection (for post dose only):	02-May-2016 20:06	
Actual Time of sample collection:	20:06 24 hrs. clock	
Remarks:		
PK Sample ID:	PK16241983	
Remarks if any other reason:		
DINNER (DAY 6)		Period:
Date of meal distribution:	02-May-2016	
Start Time:	20:08 24 hrs. clock	
End Time:	20:20 24 hrs. clock	
Has subject consumed meal completely?:	♠ Yes C No	
Details of meal left (Approximate Quantity):	-	
Remarks:	-	
CHECK-OUT DETAILS	(Period - 2)	
CLINICAL EXAMINATION-CHECKOUT/ END OF STUDY	, ,	Period:
Date of Clinical Examination:	02-May-2016	
Start Time of Clinical Examination:	18:35 24 hrs. clock	
Complaint of any illness:	© No C Yes	
*		

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CASE REPORT FORM

Project No: 489-14-G-II



General Physical examination:	⊙ Normal C Abnormal
Oral Body Temperature:	97.8 °F
Radial Pulse Rate:	84 beats/min
Blood Pressure(Systolic):	120 mmHg
Blood Pressure(Diastolic):	80 mmHg
Cardiovascular System Examination:	
Respiratory System Examination:	
Central Nervous System Examination:	
Per Abdomen Examination:	♠ Normal C Abnormal
Any other Significant finding:	-
Any investigations recommended:	-
If 'Abnormal' in any of the above-mentioned sections, please enter details:	-
To be performed at the time of check-out	
Vein puncture site:	♠ Normal C Abnormal
Subject well-being:	€ Well C Unwell
Comments:	-
Subject is fit for Check-out:	• Yes C No
Remark If any:	-
CHECK-OUT B&B	Period: 2
Date of check out:	02-May-2016
Time of Check-out:	20:38 24 hrs. clock
Remarks:	-
END STUDY LABORATORY ASSESSMENT AND STUDY COMPLETIC	ON STATUS Period: 2
Post study safety sample collected as per protocol?:	• Yes C No
Date of safety sample collection:	02-May-2016
Lab report clinically acceptable:	• Yes C No C NAP
Result of serum pregnancy test:	C C NAP (For Male Positive Negative subject)
Remarks If Any:	-
STUDY COMPLETION STATUS	
Has the subject completed the study?:	€ Yes C No
If "No", please refer:	C Pre dose C Post dose discontinued form discontinued form
If "Yes", then any protocol or sampling deviation reported for subject?:	C Yes © No
If "Yes", then any protocol or sampling deviation reported for subject?: If "Yes", then select appropriate option:	C Yes ♠ No ☐ Protocol deviation ☐ Sampling Deviation