

Lambda Therapeutic Research.

Sponsor Name: Intas Pharmaceuticals Ltd.

### CASE REPORT FORM

Project No: 489-14-G-II

Subject No: 1020

Subject Initials: SNG



### CHECK-IN DETAILS( Period - 1)

BREATH TEST FOR ALCOHOL CONSUMPTION		Period: 1
Date::	12-Apr-2016	
Start Time:	11:54 <b>24 hrs. clock</b>	
Breath Alcohol Level (BAL):	.000 %	
Result:	<input type="radio"/> Positive <input checked="" type="radio"/> Negative	
Start Time of 1st Repeat:	<b>24 hrs. clock</b>	
Breath Alcohol Level (BAL):	%	
1st Repeat result:	<input type="radio"/> Positive <input type="radio"/> Negative	
Start Time of 2nd Repeat:	<b>24 hrs. clock</b>	
Breath Alcohol Level (BAL):	%	
2nd Repeat Result:	<input type="radio"/> Positive <input type="radio"/> Negative	
Final Result:	<input type="radio"/> Positive <input checked="" type="radio"/> Negative	
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:	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NAP	
1. URINE SCAN FOR DRUGS ABUSE		
1.0 Tested for:	<input checked="" type="checkbox"/> Amphetamine (AMP) <input checked="" type="checkbox"/> Barbiturates (BAR) <input checked="" type="checkbox"/> Benzodiazepines (BZD) <input checked="" type="checkbox"/> Cocaine (COC) <input checked="" type="checkbox"/> Morphine (MOR) <input checked="" type="checkbox"/> Cannabinoids (THC)	
1.1 Start time:	12:27 <b>24 hrs. clock</b>	
1.2 Observation of Results:	<input checked="" type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D	
Note: A=Two bands indicates negative (Control and Test),B=One band indicates Positive (Control),C=No band indicates Invalid ,D=One band indicates Invalid (Test)		
1.3 Result:	<input type="radio"/> Positive <input checked="" type="radio"/> Negative <input type="radio"/> Invalid	
1.4 Positive for:	<input type="checkbox"/> Amphetamine (AMP) <input type="checkbox"/> Barbiturates (BAR) <input type="checkbox"/> Benzodiazepines (BZD) <input type="checkbox"/> Cocaine (COC) <input type="checkbox"/> Morphine (MOR) <input type="checkbox"/> Cannabinoids (THC)	
1.5 Any additional test performed-1:	<input type="radio"/> Yes <input type="radio"/> No <input checked="" type="radio"/> NAP	
1.5a. Please Specify:		
1.5b. Start time:	<b>24 hrs. clock</b>	

\*This is an electronically authenticated report.

Page 1 of 67

[Authenticated By:Dr. Ketul Modi]

[Authenticated On:04-Jun-2016 16:23 IST (+5:30 GMT)]

Lambda Therapeutic Research.

Sponsor Name: Intas Pharmaceuticals Ltd.

**CASE REPORT FORM**

Project No: 489-14-G-II

Subject No: 1020

Subject Initials: SNG



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

\*This is an electronically authenticated report.

Page 2 of 67

[Authenticated By:Dr. Ketul Modi]

[Authenticated On:04-Jun-2016 16:23 IST (+5:30 GMT)]

Lambda Therapeutic Research.

Sponsor Name: Intas Pharmaceuticals Ltd.

### CASE REPORT FORM

Project No: 489-14-G-II

Subject No: 1020

Subject Initials: SNG



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

\*This is an electronically authenticated report.

Page 3 of 67

[Authenticated By:Dr. Ketul Modi]

[Authenticated On:04-Jun-2016 16:23 IST (+5:30 GMT)]

Lambda Therapeutic Research.

Sponsor Name: Intas Pharmaceuticals Ltd.

### CASE REPORT FORM

Project No: 489-14-G-II

Subject No: 1020

Subject Initials: SNG



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

#### 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.:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Having a Body Mass Index (BMI) between 18.5 to 30 (both inclusive), calculated as weight in kg / height in m2.:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Not having any significant diseases or clinically significant abnormal findings during screening, medical history, clinical examination, laboratory evaluations, 12-lead ECG and X-ray chest (postero-anterior view) recordings:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Able to understand and comply with the study procedures, in the opinion of the investigator:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Able to give voluntary written informed consent for participation in the trial:	<input checked="" type="radio"/> Yes <input type="radio"/> No

##### Inclusion Criteria in case of Female subjects

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

##### Exclusion criteria

Known hypersensitivity or idiosyncratic reaction to fampridine to any of its excipients or any related drug or any substance:	<input type="radio"/> Yes <input checked="" type="radio"/> 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:	<input type="radio"/> Yes <input checked="" type="radio"/> No
Difficulty in swallowing oral solid dosage form like tablet.:	<input type="radio"/> Yes <input checked="" type="radio"/> No
Any history or presence of asthma (including aspirin induced asthma) or nasal polyp or NSAIDs induced urticaria:	<input type="radio"/> Yes <input checked="" type="radio"/> No
A recent history of harmful use of alcohol (less than 2 years), i.e. alcohol consumption of more than 14 standard drinks per week for men and more than 7 standard drinks per week for women (A standard drink is defined as 360 ml of beer or 150 ml of wine or 45 ml of 40% distilled spirits, such as rum, whisky, brandy etc):	<input type="radio"/> Yes <input checked="" type="radio"/> No
Smokers, or who have smoked within last six months prior to start of the study:	<input type="radio"/> Yes <input checked="" type="radio"/> No
The presence of clinically significant abnormal laboratory values during screening:	<input type="radio"/> Yes <input checked="" type="radio"/> No
Use of any recreational drugs or history of drug addiction:	<input type="radio"/> Yes <input checked="" type="radio"/> No
History or presence of psychiatric disorders:	<input type="radio"/> Yes <input checked="" type="radio"/> No
A history of difficulty with donating blood:	<input type="radio"/> Yes <input checked="" type="radio"/> No

\*This is an electronically authenticated report.

Page 4 of 67

[Authenticated By: Dr. Ketul Modi]

[Authenticated On: 04-Jun-2016 16:23 IST (+5:30 GMT)]

Lambda Therapeutic Research.

Sponsor Name: Intas Pharmaceuticals Ltd.

### CASE REPORT FORM

Project No: 489-14-G-II

Subject No: 1020

Subject Initials: SNG



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:	<input type="radio"/> Yes <input checked="" type="radio"/> No
A positive hepatitis screen including hepatitis B surface antigen and/or HCV antibodies:	<input type="radio"/> Yes <input checked="" type="radio"/> No
A positive test result for anti HIV AB (I & II):	<input type="radio"/> Yes <input checked="" type="radio"/> No
Nursing mothers (females):	<input type="radio"/> Yes <input type="radio"/> No <input checked="" type="radio"/> NAP
<b>suitability</b>	
Based on above criterias, Subject is:	<input checked="" type="radio"/> Suitable <input type="radio"/> Not-suitable
<b>Criteria to be checked at the time of compliance check</b>	
Ingestion of medicine (including herbal remedies) at any time within 14 days prior to dosing of period-I and an unusual diet, for whatever reason (e.g. low-sodium), for four weeks prior to dosing of Period I. In any such case subject selection will be at the discretion of the Principal Investigator.	
Consumption of grape fruit or grape fruit products within 72 hours prior to first dosing in period-I.	
Consumption of alcohol or alcoholic products within 48 hours prior to first dosing of period-I.	
Testing positive in pre-study drug scans.	
Remarks:	-
<b>COMPLIANCE CHECK-PI</b> <span style="float: right;">Period: 1</span>	
<b>Demographic Details</b>	
Age in Years (Completed as of Screening Date):	34
<b>Subject Reporting And Consent Procedure Record</b>	
Date of reporting to the clinical facility:	12-Apr-2016
Presentation of ICF & obtained the consent on ICF:	<input checked="" type="radio"/> Yes <input type="radio"/> No
If 'Yes', mention pagination number of ICF:	34
<b>Protocol Compliance Assessment</b>	
Criteria Check Complete:	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NAP
Urine scan for drugs of abuse tested negative:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Breath test for alcohol consumption tested negative:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Date of last menstruation period (for female subject):	-
Result of serum pregnancy test:	<input type="radio"/> Positive <input type="radio"/> Negative <input checked="" type="radio"/> NAP (For Male subject)
<b>Prohibitions</b>	
Are you suffering from any illness since the last visit (Including allergic reaction, itching, rash on your skin):	<input type="radio"/> Yes <input checked="" type="radio"/> No
Have you consumed any xanthine containing food or beverages (like tea, coffee, chocolates or cola drinks or any other) within 24 hours prior to first dose administration?:	<input type="radio"/> Yes <input checked="" type="radio"/> No
Have you consumed tobacco, tobacco containing products (Like Gutkha, Pan / Pan Masala) within 24 hours prior to first dose administration?:	<input type="radio"/> Yes <input checked="" type="radio"/> No

\*This is an electronically authenticated report.

Page 5 of 67

[Authenticated By: Dr. Ketul Modi]

[Authenticated On: 04-Jun-2016 16:23 IST (+5:30 GMT)]

Lambda Therapeutic Research.

Sponsor Name: Intas Pharmaceuticals Ltd.

### CASE REPORT FORM

Project No: 489-14-G-II

Subject No: 1020

Subject Initials: SNG



Have you consumed alcohol or alcoholic products and recreational drugs within 48 hours prior to first dose administration?:	<input type="radio"/> Yes <input checked="" type="radio"/> No
Have you consumed grapefruit or grapefruit products within 72 hours prior to first dose administration?:	<input type="radio"/> Yes <input checked="" type="radio"/> No
Any history of smoking within 06 months prior to start of the study?:	<input type="radio"/> Yes <input checked="" type="radio"/> No
Ingestion of medicine (including herbal remedies) at any time within 14 days prior to dosing.:	<input type="radio"/> Yes <input checked="" type="radio"/> No
Have you consumed an unusual diet, for whatever reason (e.g. low-sodium), within four weeks prior to receiving the study drug?:	<input type="radio"/> Yes <input checked="" type="radio"/> No
Has the subject been instructed not to participate in other clinical trial or donate blood anywhere else during the study?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Is subject compliant to all above restrictions/requirement?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Remark If any:	-

CHECK-IN B&B		Period: 1
Baggage and Body Search done:	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Date of Check In:	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:	<input checked="" type="radio"/> No <input type="radio"/> Yes	
If YES, provide details:	-	
General Physical examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal	
Oral Body Temperature:	97.8 °F	
Blood Pressure (Systolic):	120 mmHg	
Blood Pressure (Diastolic):	76 mmHg	
Radial Pulse Rate:	80 beats/min	
Cardiovascular System Examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal	
Respiratory System Examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal	
Central Nervous System Examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal	
Per Abdomen Examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal	
Any other Significant finding:	-	
Any investigations recommended:	-	
Vein puncture site:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal	
Subject well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell	
If 'Abnormal' in any of the above-mentioned sections, please enter details.:	-	
Remark if Any:	-	
Subject is fit:	<input checked="" type="radio"/> Yes <input type="radio"/> No	

\*This is an electronically authenticated report.

Page 6 of 67

[Authenticated By: Dr. Ketul Modi]

[Authenticated On: 04-Jun-2016 16:23 IST (+5:30 GMT)]

Lambda Therapeutic Research.

Sponsor Name: Intas Pharmaceuticals Ltd.

### CASE REPORT FORM

Project No: 489-14-G-II

Subject No: 1020

Subject Initials: SNG



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

### IMP ADMINISTRATION-MORNING (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?:	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NA	
TIME:	08:06 24 hrs. clock	
MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA:	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NA	
ML OF WATER ADMINISTERED WITH IP:	240	
LABEL:	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-MORNING (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:	<input checked="" type="radio"/> Well <input type="radio"/> 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:		
Date of sample collection:	13-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:	PK16210290	
Remarks if any other reason:		

STUDY DRUG ADMINISTRATION-COMPLIANCE [MORNING (DAY 1)]		Period: 1
Has the subject resumed in supine positions immediately after dose administration?:	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Has the subject compliant to 01 hour post dose water restriction?:	<input checked="" type="radio"/> Yes <input type="radio"/> No	

\*This is an electronically authenticated report.

Page 7 of 67

[Authenticated By: Dr. Ketul Modi]

[Authenticated On: 04-Jun-2016 16:23 IST (+5:30 GMT)]

Lambda Therapeutic Research.

Sponsor Name: Intas Pharmaceuticals Ltd.

### CASE REPORT FORM

Project No: 489-14-G-II

Subject No: 1020

Subject Initials: SNG



Has the subject compliant to 04 hours post dose fasting condition?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Has the subject compliant to postural restriction till 06 hours post dose in supine position? (except receiving of meals):	<input checked="" type="radio"/> Yes <input type="radio"/> 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?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Remark if any:	-

#### ECG EXAMINATION (3.00 HRS POST DOSE)-MORNING (DAY 1) Period: 1

<b>ECG EXAMINATION</b>	
Date Of ECG:	13-Apr-2016
Time of ECG:	10:47 <b>24 hrs. clock</b>
Was ECG Repeated:	<input type="radio"/> Yes <input checked="" type="radio"/> No
If Yes, Date of Repeat ECG:	
ECG Impression:	SINUS BRADYCARDIA,NCS
Overall Assessment:	<input type="radio"/> Normal <input checked="" type="radio"/> Not Clinically Significant <input type="radio"/> Clinically Significant
Remark, If any:	-

#### 3.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-MORNING (DAY 1) Period: 1

Position:	Supine
Date of vital measurement:	13-Apr-2016
Start Time of vital measurement:	10:28 <b>24 hrs. clock</b>
Systolic Blood Pressure:	112 <b>mmHg</b>
Diastolic Blood Pressure:	74 <b>mmHg</b>
Radial Pulse:	68 <b>beats/min</b>
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-

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

Date of meal distribution:	13-Apr-2016
Start Time:	12:09 <b>24 hrs. clock</b>
End Time:	12:29 <b>24 hrs. clock</b>
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-

#### 6.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-MORNING (DAY 1) Period: 1

Position:	Supine
Date of vital measurement:	13-Apr-2016
Start Time of vital measurement:	13:29 <b>24 hrs. clock</b>
Systolic Blood Pressure:	116 <b>mmHg</b>
Diastolic Blood Pressure:	76 <b>mmHg</b>
Radial Pulse:	80 <b>beats/min</b>

\*This is an electronically authenticated report.

Page 8 of 67

[Authenticated By:Dr. Ketul Modi]

[Authenticated On:04-Jun-2016 16:23 IST (+5:30 GMT)]



Lambda Therapeutic Research.

Sponsor Name: Intas Pharmaceuticals Ltd.

### CASE REPORT FORM

Project No: 489-14-G-II

Subject No: 1020

Subject Initials: SNG



Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-

#### SNACKS (DAY 1) Period: 1

Date of meal distribution:	13-Apr-2016
Start Time:	17:08 <b>24 hrs. clock</b>
End Time:	17:22 <b>24 hrs. clock</b>
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-

#### 9.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-MORNING (DAY 1) Period: 1

Position:	Sitting
Date of vital measurement:	13-Apr-2016
Start Time of vital measurement:	16:36 <b>24 hrs. clock</b>
Systolic Blood Pressure:	112 <b>mmHg</b>
Diastolic Blood Pressure:	80 <b>mmHg</b>
Radial Pulse:	72 <b>beats/min</b>
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-

#### IMP ADMINISTRATION-EVENING (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?:	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NA
TIME:	20:06 <b>24 hrs. clock</b>
MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA:	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NA
ML OF WATER ADMINISTERED WITH IP:	240
LABEL:	0000183244
PRODUCT CODE/ TYPE:	Reference
DOSING DONE BY:	kanarampatel (Dosing)
DOSING SUPERVISION DONE BY:	vishalhpate (Dosing)
REMARKS:	

#### 0.00 HRS PRE DOSE VITAL SIGNS AND WELL-BEING RECORD-EVENING (DAY 1) Period: 1

Position:	Sitting
Date of vital measurement:	13-Apr-2016
Start Time of vital measurement:	19:11 <b>24 hrs. clock</b>
Systolic Blood Pressure:	124 <b>mmHg</b>
Diastolic Blood Pressure:	80 <b>mmHg</b>
Radial Pulse:	84 <b>beats/min</b>
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell

\*This is an electronically authenticated report.

Page 9 of 67

[Authenticated By: Dr. Ketul Modi]

[Authenticated On: 04-Jun-2016 16:23 IST (+5:30 GMT)]

Lambda Therapeutic Research.

Sponsor Name: Intas Pharmaceuticals Ltd.

### CASE REPORT FORM

Project No: 489-14-G-II

Subject No: 1020

Subject Initials: SNG



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?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Has the subject compliant to 01 hour post dose water restriction?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Has the subject compliant to 02 hours post dose fasting condition?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Has the subject compliant to postural restriction till 06 hours post dose in supine position? (except receiving of meals):	<input checked="" type="radio"/> Yes <input type="radio"/> 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?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Remark if any:	-

#### 1.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-EVENING (DAY 1) Period: 1

Position:	Supine
Date of vital measurement:	13-Apr-2016
Start Time of vital measurement:	20:42 <b>24 hrs. clock</b>
Systolic Blood Pressure:	110 <b>mmHg</b>
Diastolic Blood Pressure:	76 <b>mmHg</b>
Radial Pulse:	78 <b>beats/min</b>
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> 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 <b>24 hrs. clock</b>
End Time:	22:25 <b>24 hrs. clock</b>
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-

#### IMP ADMINISTRATION-MORNING (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?:	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NA
TIME:	08:06 <b>24 hrs. clock</b>
MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA:	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NA
ML OF WATER ADMINISTERED WITH IP:	240
LABEL:	0000183259
PRODUCT CODE/ TYPE:	Reference
DOSING DONE BY:	Noel (Dosing)
DOSING SUPERVISION DONE BY:	PradipPatel (Dosing)

\*This is an electronically authenticated report.

Page 10 of 67

[Authenticated By: Dr. Ketul Modi]

[Authenticated On: 04-Jun-2016 16:23 IST (+5:30 GMT)]

Lambda Therapeutic Research.

Sponsor Name: Intas Pharmaceuticals Ltd.

# CASE REPORT FORM

Project No: 489-14-G-II

Subject No: 1020

Subject Initials: SNG



REMARKS:	
<b>0.00 HRS PRE DOSE VITAL SIGNS AND WELL-BEING RECORD-MORNING (DAY 2)</b> Period: 1	
Position:	Sitting
Date of vital measurement:	14-Apr-2016
Start Time of vital measurement:	07:04 <b>24 hrs. clock</b>
Systolic Blood Pressure:	118 <b>mmHg</b>
Diastolic Blood Pressure:	72 <b>mmHg</b>
Radial Pulse:	68 <b>beats/min</b>
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-
<b>STUDY DRUG ADMINISTRATION-COMPLIANCE [MORNING (DAY 2)]</b> Period: 1	
Has the subject resumed in supine positions immediately after dose administration?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Has the subject compliant to 01 hour post dose water restriction?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Has the subject compliant to 04 hours post dose fasting condition?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Has the subject compliant to postural restriction till 06 hours post dose in supine position? (except receiving of meals):	<input checked="" type="radio"/> Yes <input type="radio"/> 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?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Remark if any:	-
<b>ECG EXAMINATION (3.00 HRS POST DOSE)-MORNING (DAY 2)</b> Period: 1	
<b>ECG EXAMINATION</b>	
Date Of ECG:	14-Apr-2016
Time of ECG:	10:42 <b>24 hrs. clock</b>
Was ECG Repeated:	<input type="radio"/> Yes <input checked="" type="radio"/> No
If Yes, Date of Repeat ECG:	
ECG Impression:	WNL
Overall Assessment:	<input checked="" type="radio"/> Normal <input type="radio"/> Not Clinically Significant <input type="radio"/> Clinically Significant
Remark, If any:	-
<b>3.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-MORNING (DAY 2)</b> Period: 1	
Position:	Supine
Date of vital measurement:	14-Apr-2016
Start Time of vital measurement:	10:44 <b>24 hrs. clock</b>
Systolic Blood Pressure:	110 <b>mmHg</b>
Diastolic Blood Pressure:	76 <b>mmHg</b>
Radial Pulse:	72 <b>beats/min</b>
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-

\*This is an electronically authenticated report.

Page 11 of 67

[Authenticated By: Dr. Ketul Modi]

[Authenticated On: 04-Jun-2016 16:23 IST (+5:30 GMT)]

Lambda Therapeutic Research.

Sponsor Name: Intas Pharmaceuticals Ltd.

### CASE REPORT FORM

Project No: 489-14-G-II

Subject No: 1020

Subject Initials: SNG



Remarks:	-
----------	---

#### LUNCH (4.00 HRS POST DOSE) (DAY 2) Period: 1

Date of meal distribution:	14-Apr-2016
Start Time:	12:11 <b>24 hrs. clock</b>
End Time:	12:33 <b>24 hrs. clock</b>
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-

#### 6.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-MORNING (DAY 2) Period: 1

Position:	Supine
Date of vital measurement:	14-Apr-2016
Start Time of vital measurement:	13:51 <b>24 hrs. clock</b>
Systolic Blood Pressure:	112 <b>mmHg</b>
Diastolic Blood Pressure:	74 <b>mmHg</b>
Radial Pulse:	72 <b>beats/min</b>
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-

#### SNACKS (DAY 2) Period: 1

Date of meal distribution:	14-Apr-2016
Start Time:	17:08 <b>24 hrs. clock</b>
End Time:	17:16 <b>24 hrs. clock</b>
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-

#### 9.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-MORNING (DAY 2) Period: 1

Position:	Sitting
Date of vital measurement:	14-Apr-2016
Start Time of vital measurement:	16:28 <b>24 hrs. clock</b>
Systolic Blood Pressure:	118 <b>mmHg</b>
Diastolic Blood Pressure:	72 <b>mmHg</b>
Radial Pulse:	68 <b>beats/min</b>
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-

#### IMP ADMINISTRATION-EVENING (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?:	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NA
TIME:	20:06 <b>24 hrs. clock</b>

\*This is an electronically authenticated report.

Page 12 of 67

[Authenticated By: Dr. Ketul Modi]

[Authenticated On: 04-Jun-2016 16:23 IST (+5:30 GMT)]

Lambda Therapeutic Research.

Sponsor Name: Intas Pharmaceuticals Ltd.

### CASE REPORT FORM

Project No: 489-14-G-II

Subject No: 1020

Subject Initials: SNG



MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA:	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NA
ML OF WATER ADMINISTERED WITH IP:	240
LABEL:	0000183260
PRODUCT CODE/ TYPE:	Reference
DOSING DONE BY:	rajendra (Dosing)
DOSING SUPERVISION DONE BY:	vishalhpate (Dosing)
REMARKS:	

#### 0.00 HRS PRE DOSE VITAL SIGNS AND WELL-BEING RECORD-EVENING (DAY 2) Period: 1

Position:	Sitting
Date of vital measurement:	14-Apr-2016
Start Time of vital measurement:	19:16 <b>24 hrs. clock</b>
Systolic Blood Pressure:	114 <b>mmHg</b>
Diastolic Blood Pressure:	78 <b>mmHg</b>
Radial Pulse:	76 <b>beats/min</b>
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-

#### STUDY DRUG ADMINISTRATION-COMPLIANCE [EVENING (DAY 2)] Period: 1

Has the subject resumed in supine positions immediately after dose administration?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Has the subject compliant to 01 hour post dose water restriction?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Has the subject compliant to 02 hours post dose fasting condition?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Has the subject compliant to postural restriction till 06 hours post dose in supine position? (except receiving of meals):	<input checked="" type="radio"/> Yes <input type="radio"/> 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?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Remark if any:	-

#### 1.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-EVENING (DAY 2) Period: 1

Position:	Supine
Date of vital measurement:	14-Apr-2016
Start Time of vital measurement:	20:40 <b>24 hrs. clock</b>
Systolic Blood Pressure:	120 <b>mmHg</b>
Diastolic Blood Pressure:	72 <b>mmHg</b>
Radial Pulse:	68 <b>beats/min</b>
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-

#### DINNER (2.00 HRS POST DOSE) (DAY 2) Period: 1

Date of meal distribution:	14-Apr-2016
Start Time:	22:08 <b>24 hrs. clock</b>
End Time:	22:20 <b>24 hrs. clock</b>

\*This is an electronically authenticated report.

Page 13 of 67

[Authenticated By: Dr. Ketul Modi]

[Authenticated On: 04-Jun-2016 16:23 IST (+5:30 GMT)]

Lambda Therapeutic Research.

Sponsor Name: Intas Pharmaceuticals Ltd.

### CASE REPORT FORM

Project No: 489-14-G-II

Subject No: 1020

Subject Initials: SNG



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

#### IMP ADMINISTRATION-MORNING (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?:	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NA	
TIME:	08:06 <b>24 hrs. clock</b>	
MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA:	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NA	
ML OF WATER ADMINISTERED WITH IP:	240	
LABEL:	0000183275	
PRODUCT CODE/ TYPE:	Reference	
DOSING DONE BY:	AmitKhatra (Dosing)	
DOSING SUPERVISION DONE BY:	jileshpatel (Dosing)	
REMARKS:		

#### 0.00 HRS PRE DOSE VITAL SIGNS AND WELL-BEING RECORD-MORNING (DAY 3)

0.00 HRS PRE DOSE VITAL SIGNS AND WELL-BEING RECORD-MORNING (DAY 3)		Period: 1
Position:	Sitting	
Date of vital measurement:	15-Apr-2016	
Start Time of vital measurement:	06:38 <b>24 hrs. clock</b>	
Systolic Blood Pressure:	112 <b>mmHg</b>	
Diastolic Blood Pressure:	72 <b>mmHg</b>	
Radial Pulse:	68 <b>beats/min</b>	
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell	
If unwell then specify:	-	
Remarks:	-	

#### 0.000 HRS PRE DOSE PK SAMPLE COLLECTION MORNING (DAY 3)-MD3

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 <b>24 hrs. clock</b>	
Remarks:		
PK Sample ID:	PK16210338	
Remarks if any other reason:		

#### STUDY DRUG ADMINISTRATION-COMPLIANCE [MORNING (DAY 3)]

STUDY DRUG ADMINISTRATION-COMPLIANCE [MORNING (DAY 3)]		Period: 1
Has the subject resumed in supine positions immediately after dose administration?:	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Has the subject compliant to 01 hour post dose water restriction?:	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Has the subject compliant to 04 hours post dose fasting condition?:	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Has the subject compliant to postural restriction till 06 hours post dose in supine position? (except receiving of meals):	<input checked="" type="radio"/> Yes <input type="radio"/> No	

\*This is an electronically authenticated report.

Page 14 of 67

[Authenticated By: Dr. Ketul Modi]

[Authenticated On: 04-Jun-2016 16:23 IST (+5:30 GMT)]

Lambda Therapeutic Research.

Sponsor Name: Intas Pharmaceuticals Ltd.

### CASE REPORT FORM

Project No: 489-14-G-II

Subject No: 1020

Subject Initials: SNG



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

#### ECG EXAMINATION (3.00 HRS POST DOSE)-MORNING (DAY 3) Period: 1

<b>ECG EXAMINATION</b>	
Date Of ECG:	15-Apr-2016
Time of ECG:	11:06 <b>24 hrs. clock</b>
Was ECG Repeated:	<input type="radio"/> Yes <input checked="" type="radio"/> No
If Yes, Date of Repeat ECG:	
ECG Impression:	WNL
Overall Assessment:	<input checked="" type="radio"/> Normal <input type="radio"/> Not Clinically Significant <input type="radio"/> Clinically Significant
Remark, If any:	-

#### 3.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-MORNING (DAY 3) Period: 1

Position:	Supine
Date of vital measurement:	15-Apr-2016
Start Time of vital measurement:	10:45 <b>24 hrs. clock</b>
Systolic Blood Pressure:	116 <b>mmHg</b>
Diastolic Blood Pressure:	78 <b>mmHg</b>
Radial Pulse:	68 <b>beats/min</b>
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-

#### LUNCH (4.00 HRS POST DOSE) (DAY 3) Period: 1

Date of meal distribution:	15-Apr-2016
Start Time:	12:08 <b>24 hrs. clock</b>
End Time:	12:28 <b>24 hrs. clock</b>
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-

#### 6.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-MORNING (DAY 3) Period: 1

Position:	Supine
Date of vital measurement:	15-Apr-2016
Start Time of vital measurement:	13:54 <b>24 hrs. clock</b>
Systolic Blood Pressure:	118 <b>mmHg</b>
Diastolic Blood Pressure:	72 <b>mmHg</b>
Radial Pulse:	60 <b>beats/min</b>
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-

\*This is an electronically authenticated report.

Page 15 of 67

[Authenticated By: Dr. Ketul Modi]

[Authenticated On: 04-Jun-2016 16:23 IST (+5:30 GMT)]

Lambda Therapeutic Research.

Sponsor Name: Intas Pharmaceuticals Ltd.

# CASE REPORT FORM

Project No: 489-14-G-II

Subject No: 1020

Subject Initials: SNG



## SNACKS (DAY 3) Period: 1

Date of meal distribution:	15-Apr-2016
Start Time:	17:08 <b>24 hrs. clock</b>
End Time:	17:15 <b>24 hrs. clock</b>
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-

## 9.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-MORNING (DAY 3) Period: 1

Position:	Sitting
Date of vital measurement:	15-Apr-2016
Start Time of vital measurement:	16:33 <b>24 hrs. clock</b>
Systolic Blood Pressure:	110 <b>mmHg</b>
Diastolic Blood Pressure:	80 <b>mmHg</b>
Radial Pulse:	72 <b>beats/min</b>
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-

## IMP ADMINISTRATION-EVENING (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?:	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NA
TIME:	20:06 <b>24 hrs. clock</b>
MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA:	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NA
ML OF WATER ADMINISTERED WITH IP:	240
LABEL:	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-EVENING (DAY 3) Period: 1

Position:	Sitting
Date of vital measurement:	15-Apr-2016
Start Time of vital measurement:	19:07 <b>24 hrs. clock</b>
Systolic Blood Pressure:	118 <b>mmHg</b>
Diastolic Blood Pressure:	82 <b>mmHg</b>
Radial Pulse:	72 <b>beats/min</b>
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-

## 0.000 HRS PRE DOSE PK SAMPLE COLLECTION EVENING (DAY 3)-ED3 Period: 1

Date and Time of Dosing:	
--------------------------	--

\*This is an electronically authenticated report.

Page 16 of 67

[Authenticated By: Dr. Ketul Modi]

[Authenticated On: 04-Jun-2016 16:23 IST (+5:30 GMT)]



Lambda Therapeutic Research.

Sponsor Name: Intas Pharmaceuticals Ltd.

### CASE REPORT FORM

Project No: 489-14-G-II

Subject No: 1020

Subject Initials: SNG



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 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK16210306
Remarks if any other reason:	

#### STUDY DRUG ADMINISTRATION-COMPLIANCE [EVENING (DAY 3)] Period: 1

Has the subject resumed in supine positions immediately after dose administration?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Has the subject compliant to 01 hour post dose water restriction?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Has the subject compliant to 02 hours post dose fasting condition?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Has the subject compliant to postural restriction till 06 hours post dose in supine position? (except receiving of meals):	<input checked="" type="radio"/> Yes <input type="radio"/> 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?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Remark if any:	-

#### 1.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-EVENING (DAY 3) Period: 1

Position:	Supine
Date of vital measurement:	15-Apr-2016
Start Time of vital measurement:	20:32 <b>24 hrs. clock</b>
Systolic Blood Pressure:	116 <b>mmHg</b>
Diastolic Blood Pressure:	78 <b>mmHg</b>
Radial Pulse:	76 <b>beats/min</b>
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-

#### DINNER (2.00 HRS POST DOSE) (DAY 3) Period: 1

Date of meal distribution:	15-Apr-2016
Start Time:	22:08 <b>24 hrs. clock</b>
End Time:	22:21 <b>24 hrs. clock</b>
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-

#### IMP ADMINISTRATION-MORNING (PI-DAY 4)

#### IMP ADMINISTRATION-MORNING (PI-DAY 4) Period: 1

DATE:	16-Apr-2016
IS SUBJECT COMPLIANT TO ALL PREDOSE REQUIREMENTS AS PER PROTOCOL?:	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NA
TIME:	08:06 <b>24 hrs. clock</b>
MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA:	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NA
ML OF WATER ADMINISTERED WITH IP:	240

\*This is an electronically authenticated report.

Page 17 of 67

[Authenticated By: Dr. Ketul Modi]

[Authenticated On: 04-Jun-2016 16:23 IST (+5:30 GMT)]

Lambda Therapeutic Research.

Sponsor Name: Intas Pharmaceuticals Ltd.

### CASE REPORT FORM

Project No: 489-14-G-II

Subject No: 1020

Subject Initials: SNG



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-MORNING (DAY 4) Period: 1

Position:	Sitting
Date of vital measurement:	16-Apr-2016
Start Time of vital measurement:	06:51 <b>24 hrs. clock</b>
Systolic Blood Pressure:	116 <b>mmHg</b>
Diastolic Blood Pressure:	78 <b>mmHg</b>
Radial Pulse:	72 <b>beats/min</b>
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-

#### 0.000 HRS PRE DOSE PK SAMPLE COLLECTION MORNING (DAY 4)-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 <b>24 hrs. clock</b>
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?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Has the subject compliant to 01 hour post dose water restriction?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Has the subject compliant to 04 hours post dose fasting condition?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Has the subject compliant to postural restriction till 06 hours post dose in supine position? (except receiving of meals):	<input checked="" type="radio"/> Yes <input type="radio"/> 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?:	<input checked="" type="radio"/> Yes <input type="radio"/> 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 <b>24 hrs. clock</b>
Was ECG Repeated:	<input type="radio"/> Yes <input checked="" type="radio"/> No
If Yes, Date of Repeat ECG:	
ECG Impression:	SINUS BRADYCARDIA,NCS

\*This is an electronically authenticated report.

Page 18 of 67

[Authenticated By:Dr. Ketul Modi]

[Authenticated On:04-Jun-2016 16:23 IST (+5:30 GMT)]

Lambda Therapeutic Research.

Sponsor Name: Intas Pharmaceuticals Ltd.

### CASE REPORT FORM

Project No: 489-14-G-II

Subject No: 1020

Subject Initials: SNG



Overall Assessment:	<input type="radio"/> Normal <input checked="" type="radio"/> Not Clinically Significant <input type="radio"/> Clinically Significant
Remark, If any:	-

#### 3.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-MORNING (DAY 4) Period: 1

Position:	Supine
Date of vital measurement:	16-Apr-2016
Start Time of vital measurement:	10:31 <b>24 hrs. clock</b>
Systolic Blood Pressure:	114 <b>mmHg</b>
Diastolic Blood Pressure:	76 <b>mmHg</b>
Radial Pulse:	68 <b>beats/min</b>
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-

#### LUNCH (4.00 HRS POST DOSE) (DAY 4) Period: 1

Date of meal distribution:	16-Apr-2016
Start Time:	12:10 <b>24 hrs. clock</b>
End Time:	12:28 <b>24 hrs. clock</b>
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-

#### 6.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-MORNING (DAY 4) Period: 1

Position:	Supine
Date of vital measurement:	16-Apr-2016
Start Time of vital measurement:	13:36 <b>24 hrs. clock</b>
Systolic Blood Pressure:	108 <b>mmHg</b>
Diastolic Blood Pressure:	64 <b>mmHg</b>
Radial Pulse:	68 <b>beats/min</b>
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-

#### SNACKS (DAY 4) Period: 1

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

#### 9.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-MORNING (DAY 4) Period: 1

Position:	Sitting
Date of vital measurement:	16-Apr-2016
Start Time of vital measurement:	17:27 <b>24 hrs. clock</b>

\*This is an electronically authenticated report.

Page 19 of 67

[Authenticated By: Dr. Ketul Modi]

[Authenticated On: 04-Jun-2016 16:23 IST (+5:30 GMT)]

Lambda Therapeutic Research.

Sponsor Name: Intas Pharmaceuticals Ltd.

### CASE REPORT FORM

Project No: 489-14-G-II

Subject No: 1020

Subject Initials: SNG



Systolic Blood Pressure:	114 mmHg
Diastolic Blood Pressure:	72 mmHg
Radial Pulse:	68 beats/min
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-

#### IMP ADMINISTRATION-EVENING (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?:	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NA	
TIME:	20:06 24 hrs. clock	
MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA:	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NA	
ML OF WATER ADMINISTERED WITH IP:	240	
LABEL:	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-EVENING (DAY 4)		Period: 1
Position:	Sitting	
Date of vital measurement:	16-Apr-2016	
Start Time of vital measurement:	19:03 24 hrs. clock	
Systolic Blood Pressure:	112 mmHg	
Diastolic Blood Pressure:	78 mmHg	
Radial Pulse:	76 beats/min	
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell	
If unwell then specify:	-	
Remarks:	-	

0.000 HRS PRE DOSE PK SAMPLE COLLECTION EVENING (DAY 4)-ED4		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:	20:01 24 hrs. clock	
Remarks:		
PK Sample ID:	PK16210322	
Remarks if any other reason:		

STUDY DRUG ADMINISTRATION-COMPLIANCE [EVENING (DAY 4)]		Period: 1
Has the subject resumed in supine positions immediately after dose administration?:	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Has the subject compliant to 01 hour post dose water restriction?:	<input checked="" type="radio"/> Yes <input type="radio"/> No	

\*This is an electronically authenticated report.

Page 20 of 67

[Authenticated By: Dr. Ketul Modi]

[Authenticated On: 04-Jun-2016 16:23 IST (+5:30 GMT)]

Lambda Therapeutic Research.

Sponsor Name: Intas Pharmaceuticals Ltd.

### CASE REPORT FORM

Project No: 489-14-G-II

Subject No: 1020

Subject Initials: SNG



Has the subject compliant to 02 hours post dose fasting condition?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Has the subject compliant to postural restriction till 06 hours post dose in supine position? (except receiving of meals):	<input checked="" type="radio"/> Yes <input type="radio"/> 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?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Remark if any:	-

#### 1.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-EVENING (DAY 4) Period: 1

Position:	Supine
Date of vital measurement:	16-Apr-2016
Start Time of vital measurement:	20:41 <b>24 hrs. clock</b>
Systolic Blood Pressure:	108 <b>mmHg</b>
Diastolic Blood Pressure:	74 <b>mmHg</b>
Radial Pulse:	76 <b>beats/min</b>
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-

#### DINNER (2.00 HRS POST DOSE) (DAY 4) Period: 1

Date of meal distribution:	16-Apr-2016
Start Time:	22:08 <b>24 hrs. clock</b>
End Time:	22:22 <b>24 hrs. clock</b>
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-

#### IMP ADMINISTRATION-MORNING (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?:	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NA
TIME:	08:06 <b>24 hrs. clock</b>
MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA:	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NA
ML OF WATER ADMINISTERED WITH IP:	240
LABEL:	0000183307
PRODUCT CODE/ TYPE:	Reference
DOSING DONE BY:	pratiktrivedi (Dosing)
DOSING SUPERVISION DONE BY:	vishalhpate (Dosing)
REMARKS:	

#### 0.00 HRS PRE DOSE VITAL SIGNS AND WELL-BEING RECORD-MORNING (DAY 5) Period: 1

Position:	Sitting
Date of vital measurement:	17-Apr-2016
Start Time of vital measurement:	06:28 <b>24 hrs. clock</b>
Systolic Blood Pressure:	114 <b>mmHg</b>

\*This is an electronically authenticated report.

Page 21 of 67

[Authenticated By: Dr. Ketul Modi]

[Authenticated On: 04-Jun-2016 16:23 IST (+5:30 GMT)]

Lambda Therapeutic Research.

Sponsor Name: Intas Pharmaceuticals Ltd.

### CASE REPORT FORM

Project No: 489-14-G-II

Subject No: 1020

Subject Initials: SNG



Diastolic Blood Pressure:	78 mmHg
Radial Pulse:	72 beats/min
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-

#### 0.000 HRS PRE DOSE PK SAMPLE COLLECTION MORNING (DAY 5)-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?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Has the subject compliant to 01 hour post dose water restriction?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Has the subject compliant to 04 hours post dose fasting condition?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Has the subject compliant to postural restriction till 06 hours post dose in supine position? (except receiving of meals):	<input checked="" type="radio"/> Yes <input type="radio"/> 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?:	<input checked="" type="radio"/> Yes <input type="radio"/> 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
--------------------------	-------------------

\*This is an electronically authenticated report.

Page 22 of 67

[Authenticated By: Dr. Ketul Modi]

[Authenticated On: 04-Jun-2016 16:23 IST (+5:30 GMT)]

Lambda Therapeutic Research.

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 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK16210418
Remarks if any other reason:	

**1.333 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 09:26
Actual Time of sample collection:	09:26 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK16210434
Remarks if any other reason:	

**1.667 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 09:46
Actual Time of sample collection:	09:46 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK16210450
Remarks if any other reason:	

**2.000 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 10:06
Actual Time of sample collection:	10:06 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK16210466
Remarks if any other reason:	

**2.333 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 10:26
Actual Time of sample collection:	10:26 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK16210482
Remarks if any other reason:	

**2.667 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 10:46
Actual Time of sample collection:	10:46 <b>24 hrs. clock</b>

\*This is an electronically authenticated report.

Page 23 of 67

[Authenticated By: Dr. Ketul Modi]

[Authenticated On: 04-Jun-2016 16:23 IST (+5:30 GMT)]

Lambda Therapeutic Research.

Sponsor Name: Intas Pharmaceuticals Ltd.

# CASE REPORT FORM

Project No: 489-14-G-II

Subject No: 1020

Subject Initials: SNG



Remarks:	
PK Sample ID:	PK16210498
Remarks if any other reason:	

## 3.000 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 11:06
Actual Time of sample collection:	11:06 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK16210514
Remarks if any other reason:	

## ECG EXAMINATION (3.00 HRS POST DOSE)-MORNING (DAY 5) Period: 1

<b>ECG EXAMINATION</b>	
Date Of ECG:	17-Apr-2016
Time of ECG:	10:44 <b>24 hrs. clock</b>
Was ECG Repeated:	<input type="radio"/> Yes <input checked="" type="radio"/> No
If Yes, Date of Repeat ECG:	
ECG Impression:	SINUS BRADYCARDIA,NCS
Overall Assessment:	<input type="radio"/> Normal <input checked="" type="radio"/> Not Clinically Significant <input type="radio"/> Clinically Significant
Remark, If any:	-

## 3.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-MORNING (DAY 5) Period: 1

Position:	Supine
Date of vital measurement:	17-Apr-2016
Start Time of vital measurement:	10:30 <b>24 hrs. clock</b>
Systolic Blood Pressure:	116 <b>mmHg</b>
Diastolic Blood Pressure:	70 <b>mmHg</b>
Radial Pulse:	64 <b>beats/min</b>
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-

## 3.333 HRS POST DOSE PK SAMPLE COLLECTION 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 11:26
Actual Time of sample collection:	11:26 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK16210530
Remarks if any other reason:	

## 3.667 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

\*This is an electronically authenticated report.

Page 24 of 67

[Authenticated By:Dr. Ketul Modi]

[Authenticated On:04-Jun-2016 16:23 IST (+5:30 GMT)]



Lambda Therapeutic Research.

Sponsor Name: Intas Pharmaceuticals Ltd.

### CASE REPORT FORM

Project No: 489-14-G-II

Subject No: 1020

Subject Initials: SNG



Scheduled date and Time of sample collection (for post dose only):	17-Apr-2016 11:46
Actual Time of sample collection:	11:46 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK16210546
Remarks if any other reason:	
<b>4.000 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DAY 5)-MD5</b> 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 12:06
Actual Time of sample collection:	12:06 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK16210562
Remarks if any other reason:	
<b>LUNCH (4.00 HRS POST DOSE) (DAY 5)</b> Period: 1	
Date of meal distribution:	17-Apr-2016
Start Time:	12:09 <b>24 hrs. clock</b>
End Time:	12:33 <b>24 hrs. clock</b>
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-
<b>4.500 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DAY 5)-MD5</b> 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 12:36
Actual Time of sample collection:	12:36 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK16210578
Remarks if any other reason:	
<b>5.000 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DAY 5)-MD5</b> 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 13:06
Actual Time of sample collection:	13:06 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK16210594
Remarks if any other reason:	
<b>6.000 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DAY 5)-MD5</b> 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 14:06
Actual Time of sample collection:	14:06 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK16210610

\*This is an electronically authenticated report.

Page 25 of 67

[Authenticated By: Dr. Ketul Modi]

[Authenticated On: 04-Jun-2016 16:23 IST (+5:30 GMT)]

Lambda Therapeutic Research.

Sponsor Name: Intas Pharmaceuticals Ltd.

# CASE REPORT FORM

Project No: 489-14-G-II

Subject No: 1020

Subject Initials: SNG



Remarks if any other reason:

## 6.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-MORNING (DAY 5) Period: 1

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:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-

## 8.000 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 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) Period: 1

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

## 9.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-MORNING (DAY 5) Period: 1

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:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-

## 10.000 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 18:06
Actual Time of sample collection:	18:06 24 hrs. clock
Remarks:	

\*This is an electronically authenticated report.

Page 26 of 67

[Authenticated By: Dr. Ketul Modi]

[Authenticated On: 04-Jun-2016 16:23 IST (+5:30 GMT)]

Lambda Therapeutic Research.

Sponsor Name: Intas Pharmaceuticals Ltd.

### CASE REPORT FORM

Project No: 489-14-G-II

Subject No: 1020

Subject Initials: SNG



PK Sample ID:	PK16210642
Remarks if any other reason:	

#### 12.000 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 20:06
Actual Time of sample collection:	20:01 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK16210658
Remarks if any other reason:	

#### IMP ADMINISTRATION-EVENING (PI-DAY 5)

#### IMP ADMINISTRATION-EVENING (PI-DAY 5) Period: 1

DATE:	17-Apr-2016
IS SUBJECT COMPLIANT TO ALL PREDOSE REQUIREMENTS AS PER PROTOCOL?:	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NA
TIME:	20:06 <b>24 hrs. clock</b>
MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA:	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NA
ML OF WATER ADMINISTERED WITH IP:	240
LABEL:	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-EVENING (DAY 5) Period: 1

Position:	Sitting
Date of vital measurement:	17-Apr-2016
Start Time of vital measurement:	19:07 <b>24 hrs. clock</b>
Systolic Blood Pressure:	114 <b>mmHg</b>
Diastolic Blood Pressure:	74 <b>mmHg</b>
Radial Pulse:	80 <b>beats/min</b>
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-

#### STUDY DRUG ADMINISTRATION-COMPLIANCE [EVENING (DAY 5)] Period: 1

Has the subject resumed in supine positions immediately after dose administration?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Has the subject compliant to 01 hour post dose water restriction?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Has the subject compliant to 02 hours post dose fasting condition?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Has the subject compliant to postural restriction till 06 hours post dose in supine position? (except receiving of meals):	<input checked="" type="radio"/> Yes <input type="radio"/> No

\*This is an electronically authenticated report.

Page 27 of 67

[Authenticated By: Dr. Ketul Modi]

[Authenticated On: 04-Jun-2016 16:23 IST (+5:30 GMT)]

Lambda Therapeutic Research.

Sponsor Name: Intas Pharmaceuticals Ltd.

### CASE REPORT FORM

Project No: 489-14-G-II

Subject No: 1020

Subject Initials: SNG



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

#### 1.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-EVENING (DAY 5) Period: 1

Position:	Supine
Date of vital measurement:	17-Apr-2016
Start Time of vital measurement:	20:41 <b>24 hrs. clock</b>
Systolic Blood Pressure:	114 <b>mmHg</b>
Diastolic Blood Pressure:	74 <b>mmHg</b>
Radial Pulse:	64 <b>beats/min</b>
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-

#### DINNER (2.00 HRS POST DOSE) (DAY 5) Period: 1

Date of meal distribution:	17-Apr-2016
Start Time:	22:08 <b>24 hrs. clock</b>
End Time:	22:20 <b>24 hrs. clock</b>
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-

#### IMP ADMINISTRATION-MORNING (PI-DAY 6)

#### IMP ADMINISTRATION-MORNING (PI-DAY 6) Period: 1

DATE:	18-Apr-2016
IS SUBJECT COMPLIANT TO ALL PREDOSE REQUIREMENTS AS PER PROTOCOL?:	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NA
TIME:	08:06 <b>24 hrs. clock</b>
MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA:	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NA
ML OF WATER ADMINISTERED WITH IP:	240
LABEL:	0000183322
PRODUCT CODE/ TYPE:	Reference
DOSING DONE BY:	Noel (Dosing)
DOSING SUPERVISION DONE BY:	vishalpatel (Dosing)
REMARKS:	

#### 0.00 HRS PRE DOSE VITAL SIGNS AND WELL-BEING RECORD-MORNING (DAY 6) Period: 1

Position:	Sitting
Date of vital measurement:	18-Apr-2016
Start Time of vital measurement:	06:49 <b>24 hrs. clock</b>
Systolic Blood Pressure:	122 <b>mmHg</b>
Diastolic Blood Pressure:	82 <b>mmHg</b>
Radial Pulse:	80 <b>beats/min</b>
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell

\*This is an electronically authenticated report.

Page 28 of 67

[Authenticated By: Dr. Ketul Modi]

[Authenticated On: 04-Jun-2016 16:23 IST (+5:30 GMT)]

Lambda Therapeutic Research.

Sponsor Name: Intas Pharmaceuticals Ltd.

### CASE REPORT FORM

Project No: 489-14-G-II

Subject No: 1020

Subject Initials: SNG



If unwell then specify:	-
Remarks:	-
<b>0.000 HRS PRE DOSE PK SAMPLE COLLECTION MORNING (DAY 6)-MD6</b> Period: 1	
Date and Time of Dosing:	
Date of sample collection:	18-Apr-2016
Scheduled date and Time of sample collection (for post dose only):	
Actual Time of sample collection:	08:02 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK16210674
Remarks if any other reason:	
<b>STUDY DRUG ADMINISTRATION-COMPLIANCE [MORNING (DAY 6)]</b> Period: 1	
Has the subject resumed in supine positions immediately after dose administration?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Has the subject compliant to 01 hour post dose water restriction?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Has the subject compliant to 04 hours post dose fasting condition?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Has the subject compliant to postural restriction till 06 hours post dose in supine position? (except receiving of meals):	<input checked="" type="radio"/> Yes <input type="radio"/> 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?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Remark if any:	-
<b>0.333 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DAY 6)-MD6</b> 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 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK16210690
Remarks if any other reason:	
<b>0.667 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DAY 6)-MD6</b> 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 08:46
Actual Time of sample collection:	08:46 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK16210706
Remarks if any other reason:	
<b>1.000 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DAY 6)-MD6</b> 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 09:06
Actual Time of sample collection:	09:06 <b>24 hrs. clock</b>
Remarks:	

\*This is an electronically authenticated report.

Page 29 of 67

[Authenticated By: Dr. Ketul Modi]

[Authenticated On: 04-Jun-2016 16:23 IST (+5:30 GMT)]

Lambda Therapeutic Research.

Sponsor Name: Intas Pharmaceuticals Ltd.

**CASE REPORT FORM**

Project No: 489-14-G-II

Subject No: 1020

Subject Initials: SNG



PK Sample ID:	PK16210722
Remarks if any other reason:	
<b>1.333 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DAY 6)-MD6</b> 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 09:26
Actual Time of sample collection:	09:26 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK16210738
Remarks if any other reason:	
<b>1.667 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DAY 6)-MD6</b> 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 09:46
Actual Time of sample collection:	09:46 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK16210754
Remarks if any other reason:	
<b>2.000 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DAY 6)-MD6</b> 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 10:06
Actual Time of sample collection:	10:06 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK16210770
Remarks if any other reason:	
<b>2.333 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DAY 6)-MD6</b> 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 10:26
Actual Time of sample collection:	10:27 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK16210786
Remarks if any other reason:	
<b>2.667 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DAY 6)-MD6</b> 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 10:46
Actual Time of sample collection:	10:46 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK16210802
Remarks if any other reason:	
<b>3.000 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DAY 6)-MD6</b> Period: 1	

\*This is an electronically authenticated report.

Page 30 of 67

[Authenticated By: Dr. Ketul Modi]

[Authenticated On: 04-Jun-2016 16:23 IST (+5:30 GMT)]

Lambda Therapeutic Research.

Sponsor Name: Intas Pharmaceuticals Ltd.

### CASE REPORT FORM

Project No: 489-14-G-II

Subject No: 1020

Subject Initials: SNG



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 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK16210818
Remarks if any other reason:	

#### ECG EXAMINATION (3.00 HRS POST DOSE)-MORNING (DAY 6) Period: 1

<b>ECG EXAMINATION</b>	
Date Of ECG:	18-Apr-2016
Time of ECG:	10:39 <b>24 hrs. clock</b>
Was ECG Repeated:	<input type="radio"/> Yes <input checked="" type="radio"/> No
If Yes, Date of Repeat ECG:	
ECG Impression:	WNL
Overall Assessment:	<input checked="" type="radio"/> Normal <input type="radio"/> Not Clinically Significant <input type="radio"/> Clinically Significant
Remark, If any:	-

#### 3.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-MORNING (DAY 6) Period: 1

Position:	Supine
Date of vital measurement:	18-Apr-2016
Start Time of vital measurement:	10:38 <b>24 hrs. clock</b>
Systolic Blood Pressure:	116 <b>mmHg</b>
Diastolic Blood Pressure:	74 <b>mmHg</b>
Radial Pulse:	64 <b>beats/min</b>
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-

#### 3.333 HRS POST DOSE PK SAMPLE COLLECTION 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 11:26
Actual Time of sample collection:	11:26 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK16210834
Remarks if any other reason:	

#### 3.667 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 11:46
Actual Time of sample collection:	11:46 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK16210850

\*This is an electronically authenticated report.

Page 31 of 67

[Authenticated By: Dr. Ketul Modi]

[Authenticated On: 04-Jun-2016 16:23 IST (+5:30 GMT)]

Lambda Therapeutic Research.

Sponsor Name: Intas Pharmaceuticals Ltd.

# CASE REPORT FORM

Project No: 489-14-G-II

Subject No: 1020

Subject Initials: SNG



Remarks if any other reason:	
<b>4.000 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DAY 6)-MD6</b> 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 12:06
Actual Time of sample collection:	12:07 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK16210866
Remarks if any other reason:	
<b>LUNCH (4.00 HRS POST DOSE) (DAY 6)</b> Period: 1	
Date of meal distribution:	18-Apr-2016
Start Time:	12:10 <b>24 hrs. clock</b>
End Time:	12:31 <b>24 hrs. clock</b>
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-
<b>4.500 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DAY 6)-MD6</b> 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 12:36
Actual Time of sample collection:	12:36 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK16210882
Remarks if any other reason:	
<b>5.000 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DAY 6)-MD6</b> 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 13:06
Actual Time of sample collection:	13:06 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK16210898
Remarks if any other reason:	
<b>6.000 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DAY 6)-MD6</b> 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 14:06
Actual Time of sample collection:	14:06 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK16210914
Remarks if any other reason:	
<b>6.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-MORNING (DAY 6)</b> Period: 1	
Position:	Supine

\*This is an electronically authenticated report.

Page 32 of 67

[Authenticated By: Dr. Ketul Modi]

[Authenticated On: 04-Jun-2016 16:23 IST (+5:30 GMT)]



Lambda Therapeutic Research.

Sponsor Name: Intas Pharmaceuticals Ltd.

# 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:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-

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

## 9.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-MORNING (DAY 6) Period: 1

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:	<input checked="" type="radio"/> Well <input type="radio"/> 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 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DAY 6)-MD6 Period: 1

\*This is an electronically authenticated report.

Page 33 of 67

[Authenticated By: Dr. Ketul Modi]

[Authenticated On: 04-Jun-2016 16:23 IST (+5:30 GMT)]

Lambda Therapeutic Research.

Sponsor Name: Intas Pharmaceuticals Ltd.

### CASE REPORT FORM

Project No: 489-14-G-II

Subject No: 1020

Subject Initials: SNG



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

#### CHECK-OUT DETAILS( Period - 1)

#### CLINICAL EXAMINATION-CHECKOUT/ END OF STUDY Period: 1

Date of Clinical Examination:	18-Apr-2016
Start Time of Clinical Examination:	18:48 <b>24 hrs. clock</b>
Complaint of any illness:	<input checked="" type="radio"/> No <input type="radio"/> Yes
If YES, provide details:	-
General Physical examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Oral Body Temperature:	98.0 <b>°F</b>
Radial Pulse Rate:	76 <b>beats/min</b>
Blood Pressure(Systolic):	116 <b>mmHg</b>
Blood Pressure(Diastolic):	72 <b>mmHg</b>
Cardiovascular System Examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Respiratory System Examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Central Nervous System Examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Per Abdomen Examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Any other Significant finding:	-
Any investigations recommended:	-
If 'Abnormal' in any of the above-mentioned sections, please enter details:	-
To be performed at the time of check-out	
Vein puncture site:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Subject well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
Comments:	-
Subject is fit for Check-out:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Remark If any:	-

#### CHECK-OUT B&B Period: 1

\*This is an electronically authenticated report.

Page 34 of 67

[Authenticated By: Dr. Ketul Modi]

[Authenticated On: 04-Jun-2016 16:23 IST (+5:30 GMT)]

Lambda Therapeutic Research.

Sponsor Name: Intas Pharmaceuticals Ltd.

### CASE REPORT FORM

Project No: 489-14-G-II

Subject No: 1020

Subject Initials: SNG



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

#### URINE SCAN FOR DRUGS OF ABUSE Period: 2

SOP reference no:CPMA-26-07

Date:	26-Apr-2016
Refer/Read leaflet before start activity:	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NAP

#### 1. URINE SCAN FOR DRUGS ABUSE

1.0 Tested for:	<input checked="" type="checkbox"/> Amphetamine (AMP) <input checked="" type="checkbox"/> Barbiturates (BAR) <input checked="" type="checkbox"/> Benzodiazepines (BZD) <input checked="" type="checkbox"/> Cocaine (COC) <input checked="" type="checkbox"/> Morphine (MOR) <input checked="" type="checkbox"/> Cannabinoids (THC)
1.1 Start time:	18:05 24 hrs. clock
1.2 Observation of Results:	<input checked="" type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D
Note: A=Two bands indicates negative (Control and Test),B=One band indicates Positive (Control),C=No band indicates Invalid ,D=One band indicates Invalid (Test)	
1.3 Result:	<input type="radio"/> Positive <input checked="" type="radio"/> Negative <input type="radio"/> Invalid
1.4 Positive for:	<input type="checkbox"/> Amphetamine (AMP) <input type="checkbox"/> Barbiturates (BAR) <input type="checkbox"/> Benzodiazepines (BZD) <input type="checkbox"/> Cocaine (COC) <input type="checkbox"/> Morphine (MOR) <input type="checkbox"/> Cannabinoids (THC)
1.5 Any additional test performed-1:	<input type="radio"/> Yes <input type="radio"/> No <input checked="" type="radio"/> NAP
1.5a. Please Specify:	

\*This is an electronically authenticated report.

Page 35 of 67

[Authenticated By:Dr. Ketul Modi]

[Authenticated On:04-Jun-2016 16:23 IST (+5:30 GMT)]

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

Lambda Therapeutic Research.

Sponsor Name: Intas Pharmaceuticals Ltd.

### CASE REPORT FORM

Project No: 489-14-G-II

Subject No: 1020

Subject Initials: SNG



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

\*This is an electronically authenticated report.

Page 37 of 67

[Authenticated By:Dr. Ketul Modi]

[Authenticated On:04-Jun-2016 16:23 IST (+5:30 GMT)]

Lambda Therapeutic Research.

Sponsor Name: Intas Pharmaceuticals Ltd.

### CASE REPORT FORM

Project No: 489-14-G-II

Subject No: 1020

Subject Initials: SNG



Final result (For additional test-1):	<input type="radio"/> Positive <input type="radio"/> Negative
Positive for (For additional test-1):	
Final result (For additional test-2):	<input type="radio"/> Positive <input type="radio"/> Negative
Positive for (For additional test-2):	
Remarks (for repeats or any other information):	-

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

##### Prohibitions

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

#### CHECK-IN B&B

Period: 2

Baggage and Body Search done:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Date of Check In:	26-Apr-2016
Time of Check-in:	18:51 24 hrs. clock
Remarks:	-

\*This is an electronically authenticated report.

Page 38 of 67

[Authenticated By: Dr. Ketul Modi]

[Authenticated On: 04-Jun-2016 16:23 IST (+5:30 GMT)]

Lambda Therapeutic Research.

Sponsor Name: Intas Pharmaceuticals Ltd.

### CASE REPORT FORM

Project No: 489-14-G-II

Subject No: 1020

Subject Initials: SNG



#### CLINICAL EXAMINATION - CHECK IN Period: 2

Date of clinical examination:	26-Apr-2016
Start Time of Clinical Examination:	19:29 <b>24 hrs. clock</b>
Complaints of any illness:	<input checked="" type="radio"/> No <input type="radio"/> Yes
If YES, provide details:	-
General Physical examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Oral Body Temperature:	97.8 °F
Blood Pressure (Systolic):	114 mmHg
Blood Pressure (Diastolic):	74 mmHg
Radial Pulse Rate:	72 beats/min
Cardiovascular System Examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Respiratory System Examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Central Nervous System Examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Per Abdomen Examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Any other Significant finding:	-
Any investigations recommended:	-
Vein puncture site:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Subject well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If 'Abnormal' in any of the above-mentioned sections, please enter details.:	-
Remark if Any:	-
Subject is fit:	<input checked="" type="radio"/> Yes <input type="radio"/> No

#### DINNER CHECK-IN (DAY-1) Period: 2

Date of meal distribution:	26-Apr-2016
Start Time:	20:18 <b>24 hrs. clock</b>
End Time:	20:33 <b>24 hrs. clock</b>
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-

#### IMP ADMINISTRATION-MORNING (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?:	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NA
TIME:	08:06 <b>24 hrs. clock</b>
MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA:	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NA
ML OF WATER ADMINISTERED WITH IP:	240
LABEL:	0000184599
PRODUCT CODE/ TYPE:	Test
DOSING DONE BY:	AmitKhatri (Dosing)

\*This is an electronically authenticated report.

Page 39 of 67

[Authenticated By: Dr. Ketul Modi]

[Authenticated On: 04-Jun-2016 16:23 IST (+5:30 GMT)]

Lambda Therapeutic Research.

Sponsor Name: Intas Pharmaceuticals Ltd.

### CASE REPORT FORM

Project No: 489-14-G-II

Subject No: 1020

Subject Initials: SNG



DOSING SUPERVISION DONE BY:	Pradip Patel (Dosing)
REMARKS:	
<b>0.00 HRS PRE DOSE VITAL SIGNS AND WELL-BEING RECORD-MORNING (DAY 1)</b> Period: 2	
Position:	Sitting
Date of vital measurement:	27-Apr-2016
Start Time of vital measurement:	06:21 <b>24 hrs. clock</b>
Systolic Blood Pressure:	116 <b>mmHg</b>
Diastolic Blood Pressure:	76 <b>mmHg</b>
Radial Pulse:	76 <b>beats/min</b>
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-
<b>0.000 HRS PRE DOSE PK SAMPLE COLLECTION MORNING (DAY 1)-MD1</b> Period: 2	
Date and Time of Dosing:	
Date of sample collection:	27-Apr-2016
Scheduled date and Time of sample collection (for post dose only):	
Actual Time of sample collection:	08:02 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK16238446
Remarks if any other reason:	
<b>STUDY DRUG ADMINISTRATION-COMPLIANCE [MORNING (DAY 1)]</b> Period: 2	
Has the subject resumed in supine positions immediately after dose administration?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Has the subject compliant to 01 hour post dose water restriction?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Has the subject compliant to 04 hours post dose fasting condition?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Has the subject compliant to postural restriction till 06 hours post dose in supine position? (except receiving of meals):	<input checked="" type="radio"/> Yes <input type="radio"/> 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?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Remark if any:	-
<b>ECG EXAMINATION (3.00 HRS POST DOSE)-MORNING (DAY 1)</b> Period: 2	
<b>ECG EXAMINATION</b>	
Date Of ECG:	27-Apr-2016
Time of ECG:	10:58 <b>24 hrs. clock</b>
Was ECG Repeated:	<input type="radio"/> Yes <input checked="" type="radio"/> No
If Yes, Date of Repeat ECG:	
ECG Impression:	SINUS BRADYCARDIA, NCS
Overall Assessment:	<input type="radio"/> Normal <input checked="" type="radio"/> Not Clinically Significant <input type="radio"/> Clinically Significant
Remark, If any:	-
<b>3.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-MORNING (DAY 1)</b> Period: 2	

\*This is an electronically authenticated report.

Page 40 of 67

[Authenticated By: Dr. Ketul Modi]

[Authenticated On: 04-Jun-2016 16:23 IST (+5:30 GMT)]



Lambda Therapeutic Research.

Sponsor Name: Intas Pharmaceuticals Ltd.

### CASE REPORT FORM

Project No: 489-14-G-II

Subject No: 1020

Subject Initials: SNG



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:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-

#### LUNCH (4.00 HRS POST DOSE) (DAY 1) Period: 2

Date of meal distribution:	27-Apr-2016
Start Time:	12:08 24 hrs. clock
End Time:	12:26 24 hrs. clock
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-

#### 6.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-MORNING (DAY 1) Period: 2

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:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-

#### SNACKS (DAY 1) Period: 2

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

#### 9.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-MORNING (DAY 1) Period: 2

Position:	Sitting
Date of vital measurement:	27-Apr-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:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell

\*This is an electronically authenticated report.

Page 41 of 67

[Authenticated By: Dr. Ketul Modi]

[Authenticated On: 04-Jun-2016 16:23 IST (+5:30 GMT)]

Lambda Therapeutic Research.

Sponsor Name: Intas Pharmaceuticals Ltd.

### CASE REPORT FORM

Project No: 489-14-G-II

Subject No: 1020

Subject Initials: SNG



If unwell then specify:	-
Remarks:	-

#### IMP ADMINISTRATION-EVENING (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?:	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NA	
TIME:	20:06 <b>24 hrs. clock</b>	
MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA:	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NA	
ML OF WATER ADMINISTERED WITH IP:	240	
LABEL:	0000184600	
PRODUCT CODE/ TYPE:	Test	
DOSING DONE BY:	Noel (Dosing)	
DOSING SUPERVISION DONE BY:	vishalhpate (Dosing)	
REMARKS:		

0.00 HRS PRE DOSE VITAL SIGNS AND WELL-BEING RECORD-EVENING (DAY 1)		Period: 2
Position:	Sitting	
Date of vital measurement:	27-Apr-2016	
Start Time of vital measurement:	18:28 <b>24 hrs. clock</b>	
Systolic Blood Pressure:	122 <b>mmHg</b>	
Diastolic Blood Pressure:	80 <b>mmHg</b>	
Radial Pulse:	76 <b>beats/min</b>	
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell	
If unwell then specify:	-	
Remarks:	-	

STUDY DRUG ADMINISTRATION-COMPLIANCE [EVENING (DAY 1)]		Period: 2
Has the subject resumed in supine positions immediately after dose administration?:	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Has the subject compliant to 01 hour post dose water restriction?:	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Has the subject compliant to 02 hours post dose fasting condition?:	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Has the subject compliant to postural restriction till 06 hours post dose in supine position? (except receiving of meals):	<input checked="" type="radio"/> Yes <input type="radio"/> 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?:	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Remark if any:	-	

1.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-EVENING (DAY 1)		Period: 2
Position:	Supine	
Date of vital measurement:	27-Apr-2016	
Start Time of vital measurement:	20:31 <b>24 hrs. clock</b>	
Systolic Blood Pressure:	110 <b>mmHg</b>	
Diastolic Blood Pressure:	70 <b>mmHg</b>	

\*This is an electronically authenticated report.

Page 42 of 67

[Authenticated By: Dr. Ketul Modi]

[Authenticated On: 04-Jun-2016 16:23 IST (+5:30 GMT)]

Lambda Therapeutic Research.

Sponsor Name: Intas Pharmaceuticals Ltd.

# CASE REPORT FORM

Project No: 489-14-G-II

Subject No: 1020

Subject Initials: SNG



Radial Pulse:	68 beats/min
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-

## DINNER (2.00 HRS POST DOSE) (DAY 1) Period: 2

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

## IMP ADMINISTRATION-MORNING (PII-DAY 2)

## IMP ADMINISTRATION-MORNING (PII-DAY 2) Period: 2

DATE:	28-Apr-2016
IS SUBJECT COMPLIANT TO ALL PREDOSE REQUIREMENTS AS PER PROTOCOL?:	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NA
TIME:	08:06 24 hrs. clock
MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA:	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NA
ML OF WATER ADMINISTERED WITH IP:	240
LABEL:	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-MORNING (DAY 2) Period: 2

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:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-

## STUDY DRUG ADMINISTRATION-COMPLIANCE [MORNING (DAY 2)] Period: 2

Has the subject resumed in supine positions immediately after dose administration?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Has the subject compliant to 01 hour post dose water restriction?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Has the subject compliant to 04 hours post dose fasting condition?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Has the subject compliant to postural restriction till 06 hours post dose in supine position? (except receiving of meals):	<input checked="" type="radio"/> Yes <input type="radio"/> No

\*This is an electronically authenticated report.

Page 43 of 67

[Authenticated By: Dr. Ketul Modi]

[Authenticated On: 04-Jun-2016 16:23 IST (+5:30 GMT)]

Lambda Therapeutic Research.

Sponsor Name: Intas Pharmaceuticals Ltd.

### CASE REPORT FORM

Project No: 489-14-G-II

Subject No: 1020

Subject Initials: SNG



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

#### ECG EXAMINATION (3.00 HRS POST DOSE)-MORNING (DAY 2) Period: 2

<b>ECG EXAMINATION</b>	
Date Of ECG:	28-Apr-2016
Time of ECG:	10:46 <b>24 hrs. clock</b>
Was ECG Repeated:	<input type="radio"/> Yes <input checked="" type="radio"/> No
If Yes, Date of Repeat ECG:	
ECG Impression:	SINUS BRADYCARDIA, NCS
Overall Assessment:	<input type="radio"/> Normal <input checked="" type="radio"/> Not Clinically Significant <input type="radio"/> Clinically Significant
Remark, If any:	-

#### 3.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-MORNING (DAY 2) Period: 2

Position:	Supine
Date of vital measurement:	28-Apr-2016
Start Time of vital measurement:	10:52 <b>24 hrs. clock</b>
Systolic Blood Pressure:	118 <b>mmHg</b>
Diastolic Blood Pressure:	72 <b>mmHg</b>
Radial Pulse:	56 <b>beats/min</b>
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> 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 <b>24 hrs. clock</b>
End Time:	12:30 <b>24 hrs. clock</b>
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-

#### 6.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-MORNING (DAY 2) Period: 2

Position:	Supine
Date of vital measurement:	28-Apr-2016
Start Time of vital measurement:	13:30 <b>24 hrs. clock</b>
Systolic Blood Pressure:	112 <b>mmHg</b>
Diastolic Blood Pressure:	70 <b>mmHg</b>
Radial Pulse:	68 <b>beats/min</b>
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-

\*This is an electronically authenticated report.

Page 44 of 67

[Authenticated By: Dr. Ketul Modi]

[Authenticated On: 04-Jun-2016 16:23 IST (+5:30 GMT)]

Lambda Therapeutic Research.

Sponsor Name: Intas Pharmaceuticals Ltd.

### CASE REPORT FORM

Project No: 489-14-G-II

Subject No: 1020

Subject Initials: SNG



SNACKS (DAY 2)		Period: 2
Date of meal distribution:	28-Apr-2016	
Start Time:	17:08 <b>24 hrs. clock</b>	
End Time:	17:15 <b>24 hrs. clock</b>	
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Details of meal left (Approximate Quantity):	-	
Remarks:	-	

9.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-MORNING (DAY 2)		Period: 2
Position:	Sitting	
Date of vital measurement:	28-Apr-2016	
Start Time of vital measurement:	16:40 <b>24 hrs. clock</b>	
Systolic Blood Pressure:	112 <b>mmHg</b>	
Diastolic Blood Pressure:	76 <b>mmHg</b>	
Radial Pulse:	68 <b>beats/min</b>	
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell	
If unwell then specify:	-	
Remarks:	-	

IMP ADMINISTRATION-EVENING (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?:	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NA
TIME:	20:06 <b>24 hrs. clock</b>
MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA:	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NA
ML OF WATER ADMINISTERED WITH IP:	240
LABEL:	0000184616
PRODUCT CODE/ TYPE:	Test
DOSING DONE BY:	pratiktrivedi (Dosing)
DOSING SUPERVISION DONE BY:	vishalhpate (Dosing)
REMARKS:	

0.00 HRS PRE DOSE VITAL SIGNS AND WELL-BEING RECORD-EVENING (DAY 2)		Period: 2
Position:	Sitting	
Date of vital measurement:	28-Apr-2016	
Start Time of vital measurement:	19:23 <b>24 hrs. clock</b>	
Systolic Blood Pressure:	118 <b>mmHg</b>	
Diastolic Blood Pressure:	78 <b>mmHg</b>	
Radial Pulse:	76 <b>beats/min</b>	
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell	
If unwell then specify:	-	
Remarks:	-	

STUDY DRUG ADMINISTRATION-COMPLIANCE [EVENING (DAY 2)]		Period: 2

\*This is an electronically authenticated report.

Page 45 of 67

[Authenticated By: Dr. Ketul Modi]

[Authenticated On: 04-Jun-2016 16:23 IST (+5:30 GMT)]

Lambda Therapeutic Research.

Sponsor Name: Intas Pharmaceuticals Ltd.

### CASE REPORT FORM

Project No: 489-14-G-II

Subject No: 1020

Subject Initials: SNG



Has the subject resumed in supine positions immediately after dose administration?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Has the subject compliant to 01 hour post dose water restriction?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Has the subject compliant to 02 hours post dose fasting condition?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Has the subject compliant to postural restriction till 06 hours post dose in supine position? (except receiving of meals):	<input checked="" type="radio"/> Yes <input type="radio"/> 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?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Remark if any:	-

#### 1.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-EVENING (DAY 2) Period: 2

Position:	Supine
Date of vital measurement:	28-Apr-2016
Start Time of vital measurement:	20:40 <b>24 hrs. clock</b>
Systolic Blood Pressure:	110 <b>mmHg</b>
Diastolic Blood Pressure:	68 <b>mmHg</b>
Radial Pulse:	64 <b>beats/min</b>
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> 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 <b>24 hrs. clock</b>
End Time:	22:20 <b>24 hrs. clock</b>
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-

#### IMP ADMINISTRATION-MORNING (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?:	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NA
TIME:	08:06 <b>24 hrs. clock</b>
MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA:	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NA
ML OF WATER ADMINISTERED WITH IP:	240
LABEL:	0000184631
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-MORNING (DAY 3) Period: 2

Position:	Sitting
-----------	---------

\*This is an electronically authenticated report.

Page 46 of 67

[Authenticated By: Dr. Ketul Modi]

[Authenticated On: 04-Jun-2016 16:23 IST (+5:30 GMT)]

Lambda Therapeutic Research.

Sponsor Name: Intas Pharmaceuticals Ltd.

### CASE REPORT FORM

Project No: 489-14-G-II

Subject No: 1020

Subject Initials: SNG



Date of vital measurement:	29-Apr-2016
Start Time of vital measurement:	06:26 <b>24 hrs. clock</b>
Systolic Blood Pressure:	110 <b>mmHg</b>
Diastolic Blood Pressure:	74 <b>mmHg</b>
Radial Pulse:	72 <b>beats/min</b>
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-

#### 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 <b>24 hrs. clock</b>
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?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Has the subject compliant to 01 hour post dose water restriction?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Has the subject compliant to 04 hours post dose fasting condition?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Has the subject compliant to postural restriction till 06 hours post dose in supine position? (except receiving of meals):	<input checked="" type="radio"/> Yes <input type="radio"/> 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?:	<input checked="" type="radio"/> Yes <input type="radio"/> 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 <b>24 hrs. clock</b>
Was ECG Repeated:	<input type="radio"/> Yes <input checked="" type="radio"/> No
If Yes, Date of Repeat ECG:	
ECG Impression:	SINUS BRADYCARDIA,NCS
Overall Assessment:	<input type="radio"/> Normal <input checked="" type="radio"/> Not Clinically Significant <input type="radio"/> Clinically Significant
Remark, If any:	-

#### 3.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-MORNING (DAY 3) Period: 2

Position:	Supine
Date of vital measurement:	29-Apr-2016
Start Time of vital measurement:	10:59 <b>24 hrs. clock</b>
Systolic Blood Pressure:	116 <b>mmHg</b>

\*This is an electronically authenticated report.

Page 47 of 67

[Authenticated By:Dr. Ketul Modi]

[Authenticated On:04-Jun-2016 16:23 IST (+5:30 GMT)]

Lambda Therapeutic Research.

Sponsor Name: Intas Pharmaceuticals Ltd.

### CASE REPORT FORM

Project No: 489-14-G-II

Subject No: 1020

Subject Initials: SNG



Diastolic Blood Pressure:	76 mmHg
Radial Pulse:	60 beats/min
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> 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?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-

#### 6.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-MORNING (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:	<input checked="" type="radio"/> Well <input type="radio"/> 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?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-

#### 9.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-MORNING (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:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-

#### IMP ADMINISTRATION-EVENING (PII-DAY 3)

#### IMP ADMINISTRATION-EVENING (PII-DAY 3) Period: 2

\*This is an electronically authenticated report.

Page 48 of 67

[Authenticated By: Dr. Ketul Modi]

[Authenticated On: 04-Jun-2016 16:23 IST (+5:30 GMT)]



Lambda Therapeutic Research.

Sponsor Name: Intas Pharmaceuticals Ltd.

### 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?:	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NA
TIME:	20:06 <b>24 hrs. clock</b>
MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA:	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NA
ML OF WATER ADMINISTERED WITH IP:	240
LABEL:	0000184632
PRODUCT CODE/ TYPE:	Test
DOSING DONE BY:	Noel (Dosing)
DOSING SUPERVISION DONE BY:	vishalhpate (Dosing)
REMARKS:	

#### 0.00 HRS PRE DOSE VITAL SIGNS AND WELL-BEING RECORD-EVENING (DAY 3) Period: 2

Position:	Sitting
Date of vital measurement:	29-Apr-2016
Start Time of vital measurement:	18:51 <b>24 hrs. clock</b>
Systolic Blood Pressure:	122 <b>mmHg</b>
Diastolic Blood Pressure:	80 <b>mmHg</b>
Radial Pulse:	84 <b>beats/min</b>
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-

#### 0.000 HRS PRE DOSE PK SAMPLE COLLECTION EVENING (DAY 3)-ED3 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:	20:01 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK16238414
Remarks if any other reason:	

#### STUDY DRUG ADMINISTRATION-COMPLIANCE [EVENING (DAY 3)] Period: 2

Has the subject resumed in supine positions immediately after dose administration?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Has the subject compliant to 01 hour post dose water restriction?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Has the subject compliant to 02 hours post dose fasting condition?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Has the subject compliant to postural restriction till 06 hours post dose in supine position? (except receiving of meals):	<input checked="" type="radio"/> Yes <input type="radio"/> 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?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Remark if any:	-

#### 1.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-EVENING (DAY 3) Period: 2

Position:	Supine
-----------	--------

\*This is an electronically authenticated report.

Page 49 of 67

[Authenticated By: Dr. Ketul Modi]

[Authenticated On: 04-Jun-2016 16:23 IST (+5:30 GMT)]

Lambda Therapeutic Research.

Sponsor Name: Intas Pharmaceuticals Ltd.

### CASE REPORT FORM

Project No: 489-14-G-II

Subject No: 1020

Subject Initials: SNG



Date of vital measurement:	29-Apr-2016
Start Time of vital measurement:	20:30 <b>24 hrs. clock</b>
Systolic Blood Pressure:	110 <b>mmHg</b>
Diastolic Blood Pressure:	70 <b>mmHg</b>
Radial Pulse:	68 <b>beats/min</b>
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-

#### DINNER (2.00 HRS POST DOSE) (DAY 3) Period: 2

Date of meal distribution:	29-Apr-2016
Start Time:	22:08 <b>24 hrs. clock</b>
End Time:	22:23 <b>24 hrs. clock</b>
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-

#### IMP ADMINISTRATION-MORNING (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?:	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NA
TIME:	08:06 <b>24 hrs. clock</b>
MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA:	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NA
ML OF WATER ADMINISTERED WITH IP:	240
LABEL:	0000184647
PRODUCT CODE/ TYPE:	Test
DOSING DONE BY:	AmitKhatra (Dosing)
DOSING SUPERVISION DONE BY:	vishalhpattel (Dosing)
REMARKS:	

#### 0.00 HRS PRE DOSE VITAL SIGNS AND WELL-BEING RECORD-MORNING (DAY 4) Period: 2

Position:	Sitting
Date of vital measurement:	30-Apr-2016
Start Time of vital measurement:	06:49 <b>24 hrs. clock</b>
Systolic Blood Pressure:	114 <b>mmHg</b>
Diastolic Blood Pressure:	76 <b>mmHg</b>
Radial Pulse:	72 <b>beats/min</b>
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-

#### 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):	

\*This is an electronically authenticated report.

Page 50 of 67

[Authenticated By: Dr. Ketul Modi]

[Authenticated On: 04-Jun-2016 16:23 IST (+5:30 GMT)]

Lambda Therapeutic Research.

Sponsor Name: Intas Pharmaceuticals Ltd.

### CASE REPORT FORM

Project No: 489-14-G-II

Subject No: 1020

Subject Initials: SNG



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?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Has the subject compliant to 01 hour post dose water restriction?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Has the subject compliant to 04 hours post dose fasting condition?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Has the subject compliant to postural restriction till 06 hours post dose in supine position? (except receiving of meals):	<input checked="" type="radio"/> Yes <input type="radio"/> 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?:	<input checked="" type="radio"/> Yes <input type="radio"/> 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:	<input type="radio"/> Yes <input checked="" type="radio"/> No
If Yes, Date of Repeat ECG:	
ECG Impression:	SINUS BRADYCARDIA,NCS
Overall Assessment:	<input type="radio"/> Normal <input checked="" type="radio"/> Not Clinically Significant <input type="radio"/> Clinically Significant
Remark, If any:	-

#### 3.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-MORNING (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:	<input checked="" type="radio"/> Well <input type="radio"/> 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?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-

\*This is an electronically authenticated report.

Page 51 of 67

[Authenticated By: Dr. Ketul Modi]

[Authenticated On: 04-Jun-2016 16:23 IST (+5:30 GMT)]

Lambda Therapeutic Research.

Sponsor Name: Intas Pharmaceuticals Ltd.

### CASE REPORT FORM

Project No: 489-14-G-II

Subject No: 1020

Subject Initials: SNG



Remarks:	-
----------	---

#### 6.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-MORNING (DAY 4) Period: 2

Position:	Supine
Date of vital measurement:	30-Apr-2016
Start Time of vital measurement:	13:42 <b>24 hrs. clock</b>
Systolic Blood Pressure:	114 <b>mmHg</b>
Diastolic Blood Pressure:	72 <b>mmHg</b>
Radial Pulse:	60 <b>beats/min</b>
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-

#### SNACKS (DAY 4) Period: 2

Date of meal distribution:	30-Apr-2016
Start Time:	17:08 <b>24 hrs. clock</b>
End Time:	17:21 <b>24 hrs. clock</b>
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-

#### 9.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-MORNING (DAY 4) Period: 2

Position:	Sitting
Date of vital measurement:	30-Apr-2016
Start Time of vital measurement:	16:30 <b>24 hrs. clock</b>
Systolic Blood Pressure:	122 <b>mmHg</b>
Diastolic Blood Pressure:	78 <b>mmHg</b>
Radial Pulse:	72 <b>beats/min</b>
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-

#### IMP ADMINISTRATION-EVENING (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?:	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NA
TIME:	20:06 <b>24 hrs. clock</b>
MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA:	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NA
ML OF WATER ADMINISTERED WITH IP:	240
LABEL:	0000184648
PRODUCT CODE/ TYPE:	Test
DOSING DONE BY:	HiteshPanchal (Dosing)
DOSING SUPERVISION DONE BY:	vipulkumarpatel (Dosing)
REMARKS:	

\*This is an electronically authenticated report.

Page 52 of 67

[Authenticated By: Dr. Ketul Modi]

[Authenticated On: 04-Jun-2016 16:23 IST (+5:30 GMT)]

Lambda Therapeutic Research.

Sponsor Name: Intas Pharmaceuticals Ltd.

### CASE REPORT FORM

Project No: 489-14-G-II

Subject No: 1020

Subject Initials: SNG



#### 0.00 HRS PRE DOSE VITAL SIGNS AND WELL-BEING RECORD-EVENING (DAY 4) Period: 2

Position:	Sitting
Date of vital measurement:	30-Apr-2016
Start Time of vital measurement:	18:42 <b>24 hrs. clock</b>
Systolic Blood Pressure:	118 <b>mmHg</b>
Diastolic Blood Pressure:	78 <b>mmHg</b>
Radial Pulse:	76 <b>beats/min</b>
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-

#### 0.000 HRS PRE DOSE PK SAMPLE COLLECTION EVENING (DAY 4)-ED4 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):	
Actual Time of sample collection:	20:02 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK16238430
Remarks if any other reason:	

#### STUDY DRUG ADMINISTRATION-COMPLIANCE [EVENING (DAY 4)] Period: 2

Has the subject resumed in supine positions immediately after dose administration?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Has the subject compliant to 01 hour post dose water restriction?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Has the subject compliant to 02 hours post dose fasting condition?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Has the subject compliant to postural restriction till 06 hours post dose in supine position? (except receiving of meals):	<input checked="" type="radio"/> Yes <input type="radio"/> 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?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Remark if any:	-

#### 1.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-EVENING (DAY 4) Period: 2

Position:	Supine
Date of vital measurement:	30-Apr-2016
Start Time of vital measurement:	21:18 <b>24 hrs. clock</b>
Systolic Blood Pressure:	118 <b>mmHg</b>
Diastolic Blood Pressure:	74 <b>mmHg</b>
Radial Pulse:	60 <b>beats/min</b>
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-

#### DINNER (2.00 HRS POST DOSE) (DAY 4) Period: 2

Date of meal distribution:	30-Apr-2016
Start Time:	22:08 <b>24 hrs. clock</b>

\*This is an electronically authenticated report.

Page 53 of 67

[Authenticated By: Dr. Ketul Modi]

[Authenticated On: 04-Jun-2016 16:23 IST (+5:30 GMT)]

Lambda Therapeutic Research.

Sponsor Name: Intas Pharmaceuticals Ltd.

### CASE REPORT FORM

Project No: 489-14-G-II

Subject No: 1020

Subject Initials: SNG



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

#### IMP ADMINISTRATION-MORNING (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?:	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NA	
TIME:	08:06 24 hrs. clock	
MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA:	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NA	
ML OF WATER ADMINISTERED WITH IP:	240	
LABEL:	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-MORNING (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:	<input checked="" type="radio"/> Well <input type="radio"/> 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?:	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Has the subject compliant to 01 hour post dose water restriction?:	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Has the subject compliant to 04 hours post dose fasting condition?:	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Has the subject compliant to postural restriction till 06 hours post dose in supine position? (except receiving of meals):	<input checked="" type="radio"/> Yes <input type="radio"/> No	

\*This is an electronically authenticated report.

Page 54 of 67

[Authenticated By: Dr. Ketul Modi]

[Authenticated On: 04-Jun-2016 16:23 IST (+5:30 GMT)]

Lambda Therapeutic Research.

Sponsor Name: Intas Pharmaceuticals Ltd.

**CASE REPORT FORM**

Project No: 489-14-G-II

Subject No: 1020

Subject Initials: SNG



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?:	<input checked="" type="radio"/> Yes <input type="radio"/> 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 <b>24 hrs. clock</b>
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 <b>24 hrs. clock</b>
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 <b>24 hrs. clock</b>
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 <b>24 hrs. clock</b>
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 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK16238590

\*This is an electronically authenticated report.

Page 55 of 67

[Authenticated By: Dr. Ketul Modi]

[Authenticated On: 04-Jun-2016 16:23 IST (+5:30 GMT)]

Lambda Therapeutic Research.

Sponsor Name: Intas Pharmaceuticals Ltd.

# CASE REPORT FORM

Project No: 489-14-G-II

Subject No: 1020

Subject Initials: SNG



Remarks if any other reason:	
<b>2.000 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DAY 5)-MD5</b> 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 10:06
Actual Time of sample collection:	10:06 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK16238606
Remarks if any other reason:	
<b>2.333 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DAY 5)-MD5</b> 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 10:26
Actual Time of sample collection:	10:26 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK16238622
Remarks if any other reason:	
<b>2.667 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DAY 5)-MD5</b> 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 10:46
Actual Time of sample collection:	10:46 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK16238638
Remarks if any other reason:	
<b>3.000 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DAY 5)-MD5</b> 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 11:06
Actual Time of sample collection:	11:06 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK16238654
Remarks if any other reason:	
<b>ECG EXAMINATION (3.00 HRS POST DOSE)-MORNING (DAY 5)</b> Period: 2	
<b>ECG EXAMINATION</b>	
Date Of ECG:	01-May-2016
Time of ECG:	11:07 <b>24 hrs. clock</b>
Was ECG Repeated:	<input type="radio"/> Yes <input checked="" type="radio"/> No
If Yes, Date of Repeat ECG:	
ECG Impression:	SINUS BRADYCARDIA,NCS
Overall Assessment:	<input type="radio"/> Normal <input checked="" type="radio"/> Not Clinically Significant <input type="radio"/> Clinically Significant

\*This is an electronically authenticated report.

Page 56 of 67

[Authenticated By:Dr. Ketul Modi]

[Authenticated On:04-Jun-2016 16:23 IST (+5:30 GMT)]



Lambda Therapeutic Research.

Sponsor Name: Intas Pharmaceuticals Ltd.

### CASE REPORT FORM

Project No: 489-14-G-II

Subject No: 1020

Subject Initials: SNG



Remark, If any:	-
<b>3.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-MORNING (DAY 5)</b> Period: 2	
Position:	Supine
Date of vital measurement:	01-May-2016
Start Time of vital measurement:	11:00 <b>24 hrs. clock</b>
Systolic Blood Pressure:	110 <b>mmHg</b>
Diastolic Blood Pressure:	70 <b>mmHg</b>
Radial Pulse:	68 <b>beats/min</b>
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-
<b>3.333 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DAY 5)-MD5</b> 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 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK16238670
Remarks if any other reason:	
<b>3.667 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DAY 5)-MD5</b> 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 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK16238686
Remarks if any other reason:	
<b>4.000 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DAY 5)-MD5</b> 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 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK16238702
Remarks if any other reason:	
<b>LUNCH (4.00 HRS POST DOSE) (DAY 5)</b> Period: 2	
Date of meal distribution:	01-May-2016
Start Time:	12:08 <b>24 hrs. clock</b>
End Time:	12:27 <b>24 hrs. clock</b>
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-

\*This is an electronically authenticated report.

Page 57 of 67

[Authenticated By: Dr. Ketul Modi]

[Authenticated On: 04-Jun-2016 16:23 IST (+5:30 GMT)]

Lambda Therapeutic Research.

Sponsor Name: Intas Pharmaceuticals Ltd.

### CASE REPORT FORM

Project No: 489-14-G-II

Subject No: 1020

Subject Initials: SNG



#### 4.500 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 12:36
Actual Time of sample collection:	12:36 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK16238718
Remarks if any other reason:	

#### 5.000 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 13:06
Actual Time of sample collection:	13:06 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK16238734
Remarks if any other reason:	

#### 6.000 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 14:06
Actual Time of sample collection:	14:06 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK16238750
Remarks if any other reason:	

#### 6.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-MORNING (DAY 5) Period: 2

Position:	Supine
Date of vital measurement:	01-May-2016
Start Time of vital measurement:	13:35 <b>24 hrs. clock</b>
Systolic Blood Pressure:	110 <b>mmHg</b>
Diastolic Blood Pressure:	74 <b>mmHg</b>
Radial Pulse:	68 <b>beats/min</b>
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-

#### 8.000 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 16:06
Actual Time of sample collection:	16:06 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK16238766
Remarks if any other reason:	

#### SNACKS (DAY 5) Period: 2

\*This is an electronically authenticated report.

Page 58 of 67

[Authenticated By: Dr. Ketul Modi]

[Authenticated On: 04-Jun-2016 16:23 IST (+5:30 GMT)]

Lambda Therapeutic Research.

Sponsor Name: Intas Pharmaceuticals Ltd.

### CASE REPORT FORM

Project No: 489-14-G-II

Subject No: 1020

Subject Initials: SNG



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

#### 9.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-MORNING (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:	<input checked="" type="radio"/> Well <input type="radio"/> 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 (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?:	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NA
TIME:	20:06 24 hrs. clock
MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA:	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NA
ML OF WATER ADMINISTERED WITH IP:	240
LABEL:	0000184664
PRODUCT CODE/ TYPE:	Test

\*This is an electronically authenticated report.

Page 59 of 67

[Authenticated By: Dr. Ketul Modi]

[Authenticated On: 04-Jun-2016 16:23 IST (+5:30 GMT)]

Lambda Therapeutic Research.

Sponsor Name: Intas Pharmaceuticals Ltd.

### CASE REPORT FORM

Project No: 489-14-G-II

Subject No: 1020

Subject Initials: SNG



DOSING DONE BY:	Pradip Patel (Dosing)
DOSING SUPERVISION DONE BY:	chintanpatel (Dosing)
REMARKS:	

#### 0.00 HRS PRE DOSE VITAL SIGNS AND WELL-BEING RECORD-EVENING (DAY 5) Period: 2

Position:	Sitting
Date of vital measurement:	01-May-2016
Start Time of vital measurement:	18:17 <b>24 hrs. clock</b>
Systolic Blood Pressure:	122 <b>mmHg</b>
Diastolic Blood Pressure:	82 <b>mmHg</b>
Radial Pulse:	68 <b>beats/min</b>
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-

#### STUDY DRUG ADMINISTRATION-COMPLIANCE [EVENING (DAY 5)] Period: 2

Has the subject resumed in supine positions immediately after dose administration?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Has the subject compliant to 01 hour post dose water restriction?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Has the subject compliant to 02 hours post dose fasting condition?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Has the subject compliant to postural restriction till 06 hours post dose in supine position? (except receiving of meals):	<input checked="" type="radio"/> Yes <input type="radio"/> 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?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Remark if any:	-

#### 1.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-EVENING (DAY 5) Period: 2

Position:	Supine
Date of vital measurement:	01-May-2016
Start Time of vital measurement:	21:12 <b>24 hrs. clock</b>
Systolic Blood Pressure:	120 <b>mmHg</b>
Diastolic Blood Pressure:	84 <b>mmHg</b>
Radial Pulse:	72 <b>beats/min</b>
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-

#### DINNER (2.00 HRS POST DOSE) (DAY 5) Period: 2

Date of meal distribution:	01-May-2016
Start Time:	22:08 <b>24 hrs. clock</b>
End Time:	22:24 <b>24 hrs. clock</b>
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-

#### IMP ADMINISTRATION-MORNING (PII-DAY 6)

\*This is an electronically authenticated report.

Page 60 of 67

[Authenticated By: Dr. Ketul Modi]

[Authenticated On: 04-Jun-2016 16:23 IST (+5:30 GMT)]

Lambda Therapeutic Research.

Sponsor Name: Intas Pharmaceuticals Ltd.

### CASE REPORT FORM

Project No: 489-14-G-II

Subject No: 1020

Subject Initials: SNG



#### IMP ADMINISTRATION-MORNING (PII-DAY 6) Period: 2

DATE:	02-May-2016
IS SUBJECT COMPLIANT TO ALL PREDOSE REQUIREMENTS AS PER PROTOCOL?:	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NA
TIME:	08:06 <b>24 hrs. clock</b>
MOUTH CHECK DONE WITH TORCH & DISPOSABLE SPATULA:	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NA
ML OF WATER ADMINISTERED WITH IP:	240
LABEL:	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-MORNING (DAY 6) Period: 2

Position:	Sitting
Date of vital measurement:	02-May-2016
Start Time of vital measurement:	06:47 <b>24 hrs. clock</b>
Systolic Blood Pressure:	122 <b>mmHg</b>
Diastolic Blood Pressure:	80 <b>mmHg</b>
Radial Pulse:	84 <b>beats/min</b>
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-

#### 0.000 HRS PRE DOSE PK SAMPLE COLLECTION MORNING (DAY 6)-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 <b>24 hrs. clock</b>
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?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Has the subject compliant to 01 hour post dose water restriction?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Has the subject compliant to 04 hours post dose fasting condition?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Has the subject compliant to postural restriction till 06 hours post dose in supine position? (except receiving of meals):	<input checked="" type="radio"/> Yes <input type="radio"/> 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?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Remark if any:	-

#### 0.333 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DAY 6)-MD6 Period: 2

\*This is an electronically authenticated report.

Page 61 of 67

[Authenticated By: Dr. Ketul Modi]

[Authenticated On: 04-Jun-2016 16:23 IST (+5:30 GMT)]

Lambda Therapeutic Research.

Sponsor Name: Intas Pharmaceuticals Ltd.

**CASE REPORT FORM**

Project No: 489-14-G-II

Subject No: 1020

Subject Initials: SNG



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 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK16241711
Remarks if any other reason:	
<b>0.667 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DAY 6)-MD6</b> 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 08:46
Actual Time of sample collection:	08:46 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK16241727
Remarks if any other reason:	
<b>1.000 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DAY 6)-MD6</b> 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 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK16241743
Remarks if any other reason:	
<b>1.333 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DAY 6)-MD6</b> 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 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK16241759
Remarks if any other reason:	
<b>1.667 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DAY 6)-MD6</b> 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 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK16241775
Remarks if any other reason:	
<b>2.000 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DAY 6)-MD6</b> 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

\*This is an electronically authenticated report.

Page 62 of 67

[Authenticated By: Dr. Ketul Modi]

[Authenticated On: 04-Jun-2016 16:23 IST (+5:30 GMT)]

Lambda Therapeutic Research.

Sponsor Name: Intas Pharmaceuticals Ltd.

### CASE REPORT FORM

Project No: 489-14-G-II

Subject No: 1020

Subject Initials: SNG



Actual Time of sample collection:	10:06 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK16241791
Remarks if any other reason:	

#### 2.333 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DAY 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 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK16241807
Remarks if any other reason:	

#### 2.667 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DAY 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 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK16241823
Remarks if any other reason:	

#### 3.000 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DAY 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 <b>24 hrs. clock</b>
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 <b>24 hrs. clock</b>
Was ECG Repeated:	<input type="radio"/> Yes <input checked="" type="radio"/> No
If Yes, Date of Repeat ECG:	
ECG Impression:	SINUS BRADYCARDIA,NCS
Overall Assessment:	<input type="radio"/> Normal <input checked="" type="radio"/> Not Clinically Significant <input type="radio"/> Clinically Significant
Remark, If any:	-

#### 3.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-MORNING (DAY 6) Period: 2

Position:	Supine
Date of vital measurement:	02-May-2016
Start Time of vital measurement:	10:44 <b>24 hrs. clock</b>

\*This is an electronically authenticated report.

Page 63 of 67

[Authenticated By: Dr. Ketul Modi]

[Authenticated On: 04-Jun-2016 16:23 IST (+5:30 GMT)]

Lambda Therapeutic Research.

Sponsor Name: Intas Pharmaceuticals Ltd.

# CASE REPORT FORM

Project No: 489-14-G-II

Subject No: 1020

Subject Initials: SNG



Systolic Blood Pressure:	114 mmHg
Diastolic Blood Pressure:	74 mmHg
Radial Pulse:	64 beats/min
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-

## 3.333 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DAY 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 11:26
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 (DAY 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 11:46
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 (DAY 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 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: 2

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

## 4.500 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DAY 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 12:36
Actual Time of sample collection:	12:36 24 hrs. clock

\*This is an electronically authenticated report.

Page 64 of 67

[Authenticated By: Dr. Ketul Modi]

[Authenticated On: 04-Jun-2016 16:23 IST (+5:30 GMT)]



Lambda Therapeutic Research.

Sponsor Name: Intas Pharmaceuticals Ltd.

### CASE REPORT FORM

Project No: 489-14-G-II

Subject No: 1020

Subject Initials: SNG



Remarks:	
PK Sample ID:	PK16241903
Remarks if any other reason:	
<b>5.000 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DAY 6)-MD6</b> 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 13:06
Actual Time of sample collection:	13:06 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK16241919
Remarks if any other reason:	
<b>6.000 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DAY 6)-MD6</b> 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 14:06
Actual Time of sample collection:	14:06 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK16241935
Remarks if any other reason:	
<b>6.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-MORNING (DAY 6)</b> Period: 2	
Position:	Supine
Date of vital measurement:	02-May-2016
Start Time of vital measurement:	13:38 <b>24 hrs. clock</b>
Systolic Blood Pressure:	116 <b>mmHg</b>
Diastolic Blood Pressure:	74 <b>mmHg</b>
Radial Pulse:	80 <b>beats/min</b>
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-
<b>8.000 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DAY 6)-MD6</b> 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 16:06
Actual Time of sample collection:	16:06 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK16241951
Remarks if any other reason:	
<b>SNACKS (DAY 6)</b> Period: 2	
Date of meal distribution:	02-May-2016
Start Time:	17:08 <b>24 hrs. clock</b>
End Time:	17:16 <b>24 hrs. clock</b>
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No

\*This is an electronically authenticated report.

Page 65 of 67

[Authenticated By: Dr. Ketul Modi]

[Authenticated On: 04-Jun-2016 16:23 IST (+5:30 GMT)]

Lambda Therapeutic Research.

Sponsor Name: Intas Pharmaceuticals Ltd.

# CASE REPORT FORM

Project No: 489-14-G-II

Subject No: 1020

Subject Initials: SNG



Details of meal left (Approximate Quantity):	-
Remarks:	-
<b>9.00 HRS POST DOSE VITAL SIGNS AND WELL-BEING RECORD-MORNING (DAY 6)</b> Period: 2	
Position:	Sitting
Date of vital measurement:	02-May-2016
Start Time of vital measurement:	16:48 <b>24 hrs. clock</b>
Systolic Blood Pressure:	110 <b>mmHg</b>
Diastolic Blood Pressure:	80 <b>mmHg</b>
Radial Pulse:	68 <b>beats/min</b>
Well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
If unwell then specify:	-
Remarks:	-
<b>10.000 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DAY 6)-MD6</b> 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 18:06
Actual Time of sample collection:	18:06 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK16241967
Remarks if any other reason:	
<b>12.000 HRS POST DOSE PK SAMPLE COLLECTION MORNING (DAY 6)-MD6</b> 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 20:06
Actual Time of sample collection:	20:06 <b>24 hrs. clock</b>
Remarks:	
PK Sample ID:	PK16241983
Remarks if any other reason:	
<b>DINNER (DAY 6)</b> Period: 2	
Date of meal distribution:	02-May-2016
Start Time:	20:08 <b>24 hrs. clock</b>
End Time:	20:20 <b>24 hrs. clock</b>
Has subject consumed meal completely?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Details of meal left (Approximate Quantity):	-
Remarks:	-
<b>CHECK-OUT DETAILS( Period - 2)</b>	
<b>CLINICAL EXAMINATION-CHECKOUT/ END OF STUDY</b> Period: 2	
Date of Clinical Examination:	02-May-2016
Start Time of Clinical Examination:	18:35 <b>24 hrs. clock</b>
Complaint of any illness:	<input checked="" type="radio"/> No <input type="radio"/> Yes
If YES, provide details:	-

\*This is an electronically authenticated report.

Page 66 of 67

[Authenticated By:Dr. Ketul Modi]

[Authenticated On:04-Jun-2016 16:23 IST (+5:30 GMT)]

Lambda Therapeutic Research.

Sponsor Name: Intas Pharmaceuticals Ltd.

### CASE REPORT FORM

Project No: 489-14-G-II

Subject No: 1020

Subject Initials: SNG



General Physical examination:	<input checked="" type="radio"/> Normal <input type="radio"/> 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:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Respiratory System Examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Central Nervous System Examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Per Abdomen Examination:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Any other Significant finding:	-
Any investigations recommended:	-
If 'Abnormal' in any of the above-mentioned sections, please enter details:	-
To be performed at the time of check-out	
Vein puncture site:	<input checked="" type="radio"/> Normal <input type="radio"/> Abnormal
Subject well-being:	<input checked="" type="radio"/> Well <input type="radio"/> Unwell
Comments:	-
Subject is fit for Check-out:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Remark If any:	-

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

Date of check out:	02-May-2016
Time of Check-out:	20:38 24 hrs. clock
Remarks:	-

#### END STUDY LABORATORY ASSESSMENT AND STUDY COMPLETION STATUS Period: 2

Post study safety sample collected as per protocol?:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Date of safety sample collection:	02-May-2016
Lab report clinically acceptable:	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NAP
Result of serum pregnancy test:	<input type="radio"/> Positive <input type="radio"/> Negative <input checked="" type="radio"/> NAP (For Male subject)
Remarks If Any:	-

#### STUDY COMPLETION STATUS

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

\*This is an electronically authenticated report.

Page 67 of 67

[Authenticated By: Dr. Ketul Modi]

[Authenticated On: 04-Jun-2016 16:23 IST (+5:30 GMT)]