CASE REPORT FORM

Solifenacin Succinate Tablets 10 mg BE Fasting Study

QPS Bioserve India Pvt. Limited

Study No: 765/15

Principal Investigator: Dr. A. Srinivas

Sponsor: PHARMA Private Limited., India

CRF Number:765/15/F001 V00, 02/11/2016

Volunteer ID:	01	Subject ID:	01

Study No: 765/15 **Volunteer ID:** 01

SCREENING

DEMOGRPHIC DETAILS

Gender

☑ Male

☐ Female

Age (Years) 20

Ethnicity

☑ Asian
☐ Other
If Other, specify_____

☐

Height 175

Height Units CM

Weight 59

Weight Units KG

BMI 19.3.

BMI Units KG/M2

Study No: 765/15 **Volunteer ID:** 01

ELIGIBILITY CRITERIA

Check-in Vital Signs

Blood Pressure (mm of Hg) Systolic/Diastolic	Oral Temperature (°F)	Pulse Rate (per min)	Recording Time	Recorded By (Sign & Date)
110/80	98	82	21-10-2018 15:00	

COMMENTS	

INCLUSION CRITERIA

(A response of "No" to any of the Inclusion Criteria below means the participant DOES NOT meet criteria)

S. No	Activity	Yes	No
1.	The volunteer is able to understand and willingness to sign statements of informed consent.	✓	
2.	The volunteer is healthy, adult, human **being between 18 and 45 years of age** (both inclusive) and weighing at least 50 kg.	✓	
3.	The volunteer has a body mass index between **18.5and 29.9 (both inclusive),** calculated as weight in Kg/height in m^2.	✓	

Study No: 765/15 **Volunteer ID:** 01

EXCLUSION CRITERIA

(A response of "Yes" to any of the Exclusion criteria below means the participant DOES NOT meet criteria)

S. No	Activity	Yes	No
1.	The volunteer's systolic blood pressure is less than 90 mm of Hg or more than 140 mm of Hg.		✓
2.	The volunteer's diastolic blood pressure is less than 60 mm of Hg or more than 90 mm of Hg.		✓
3.	The volunteer's oral temperature is below 95.0°F or above 98.6°F.		✓
4.	The volunteer's pulse rate is below 60 /min or above 100 /min.		✓
5.	**The volunteer is confirmed positive in alcohol screening (breath alcohol test).**		✓
6.	**The volunteer is confirmed positive in selected drug of abuse (for benzodiazepines, cannabinoids, amphetamine, cocaine, barbiturates, morphine).**		✓
7.	The volunteer is confirmed positive in hepatitis screening (HbsAg/HCV) or for HIV antibody.		✓

COMMENTS

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ELIGIBILITYSTATEMENT

Tick the appropriate:

☑ The subject is complying all the inclusion and exclusion criteria as per the study protocol and is eligible to participate in the study.

Enrollment Date: 21-10-2018

EnrollmentTime: 18:00 Subject ID: 01

Study No:	765/15		Subject ID:	~~01~~ S1

INVESTIGATIONAL PRODUCT ADMINISTRATION (P – I)

DRUG ADMINISTRATION PROCEDURE

Subject will receive single dose of Test (T) or Reference (R) products while in sitting posture with about 240 ± 2ml of drinking water according to a randomization schedule.

Dosing Date:	22-10-2018	Dosing Time:	09:00

DRUG TYPE: TABLET
DOSAGE: **10 mg**
Solifenacin Succinate

REF DRUG

Study No: 765/15 **Subject ID:** S1

PK SAMPLING LOG (P – I)

Dosing Date: 22-10-2018 Dosing Time: 09:00.

PK SAMPLING PROCEDURE

Collect 4ml of blood sample in sample tubes containing K_2EDTA as anticoagulant.Thesample tube will be inverted gently to and fro for each sample point. Any deviation will be recorded in the comments.

S. No	Sample Point (hour)	Schedule Time	Actual Time	Deviation		Done By (Sign & Date)
				Time (min)	Reason #	
1.	Pre-dose (0.00)	within 1 hour prior to dosing	08:00	–	–	
2.	1.00	10:00	10:00	–	–	
3.	1.50	10:30	10:30	–	–	
4.	2.00	11:00	11:00	–	–	
5.	2.50	11:30	11:30	–	–	
6.	3.00	12:00	12:00	–	–	
7.	3.50	12:30	12:30	–	–	
8.	4.00	13:00	13:00	–	–	
9.	4.50	13:30	13:30	–	–	
10.	5.00	14:00	14:00	–	–	
11.	5.50	14:30	14:30	–	–	
12.	6.00	15:00	15:00	–	–	
13.	6.50	15:30	15:30	–	–	

Study No: 765/15 **Subject ID:** S1

S. No	Sample Point (hour)	Schedule Time	Actual Time	Deviation		Done By (Sign & Date)
				Time (min)	Reason #	
14.	7.00	16:00	16:00	–	–	
15.	7.50	16:30	16:30	–	–	
16.	8.00	17:00	17:00	–	–	
17.	8.50	17:30	17:30	–	–	
18.	9.00	18:00	18:00	–	–	
19.	10.00	19:00	19:00	–	–	
20.	12.00	21:00	21:00	–	–	
21.	24.00	09:00	09:00	–	–	

1. Late arrival of the Subject 2. Cannula Blockage 3. Vein Collapse 4. Others (Specify)

Note: The post dose samples will be collected within 2 minutes of the schedule time. Any blood samples drawn beyond the specified window period will be recorded in the deviation column.

COMMENTS

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PK SAMPLING STATEMENT

All samples were collected, processed and stored as per study protocol and applicable procedures.

Reviewed By	Signature	Date
		23-10-2015.

Study No: 765/15 QPS Subject ID: S1

VITAL SIGNS AND WELLBEING LOG (P – I)

Time Point (hr)	Schedule Time	Pulse Rate (per min)	Oral Temperature (°F)	Blood Pressure (mm of Hg) Systolic/Diastolic	Well Being	Recording Time	Recorded By (Sign & Date)	Remarks
Pre-dose (0.00)	----	82	98	110/80	OK	08:00		
2.00	11:00	78	----	114/78	OK	11:00		
8.00	19.00	74	----	110/76	OK	19:00		

Check-Out	05:00 ----	78	97.2	108/70	OK	05:00		

Note: The vitals and wellbeing will be examinedwithin ± 40 minutes from the scheduled time

DEVIATIONS
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COMMENTS
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Reviewed By	Signature	Date
		23-4-2016

Study No: 765/15 QPS Subject ID: S1

ELIGIBILITY CRITERIAFOR PERIOD – II

Check-in Vital Signs

Blood Pressure (mm of Hg) Systolic/Diastolic	Oral Temperature (°F)	Pulse Rate (per min)	Recording Time	Recorded By (Sign & Date)
100 / 70	98	70	09-NOV-18. 09:00.	

COMMENTS	

EXCLUSION CRITERIA

(A response of "Yes" to any of the Exclusion criteria below means the participant DOES NOT meet criteria)

S. No	Activity	Yes	No
1.	The subject is confirmed positive in alcohol screening (breath alcohol test).	✗	✓
2.	The subject is confirmed positive in selected drug of abuse(for benzodiazepines, cannabinoids, amphetamine, cocaine, barbiturates, morphine).	✗	✓
3.	The subject's systolic blood pressure is less than 90 mm of Hg or more than 140 mm of Hg.		✓
4.	The subject's diastolic blood pressure is less than 60 mm of Hg or more than 90 mm of Hg.		✓
5.	The subject's oral temperature is below 95.0°F or above 98.6°F.		✓
6.	The subject's pulse rate is below 60 /min or above 100 /min.		✓

COMMENTS

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ELIGIBILITY STATEMENT

Tick the appropriate:

☑ The subject is complying all the exclusion criteria as per the study protocol and is eligible to continue in the study.

☒ The subject is not complying exclusion criteria as per the study protocol and is not eligible to continue in the study.

Check-in Date: 09-11-2018

Study No: 765/15 **Subject ID:**

Check-in Time: 18:05

	Signature	Date
Done By		05-Nov-16
Reviewed By		05-Nov-16

Study No:	765/15	QPS	Subject ID:	S1

INVESTIGATIONAL PRODUCT ADMINISTRATION (P – II)

DRUG ADMINISTRATION PROCEDURE

Subject will receive single dose of Test (T) or Reference (R) products while in sitting posture with about 240 ± 2ml of drinking water according to a randomization schedule.

Dosing Date:	10-NOV-18	Dosing Time:	09:00

DRUG TYPE: TABLET
DOSAGE: **10 mg**
Solifenacin Succinate

TEST DRUG

Study No: 765/15 **Subject ID:** S1

PK SAMPLING LOG (P – II)

Dosing Date: 09-Nov-18 Dosing Time: 09:00.

PK SAMPLING PROCEDURE

Collect 4ml of blood sample in sample tubes containing K_2EDTA as anticoagulant.Thesample tube will be inverted gently to and fro for each sample point. Any deviation will be recorded in the comments.

S. No	Sample Point (hour)	Schedule Time	Actual Time	Deviation		Done By (Sign & Date)
				Time (min)	Reason #	
1.	Pre-dose (0.00)	within 1 hour prior to dosing	08.00.	-	-	
2.	1.00	10:00	10:00	-	-	
3.	1.50	10:30	10:30	-	-	
4.	2.00	11:00	11:00	-	-	
5.	2.50	11:30	11:30	-	-	
6.	3.00	12:00	12:00	-	-	
7.	3.50	12:30	12:30	-	-	
8.	4.00	13:00	13:00	-	-	
9.	4.50	13:30	13:30	-	-	
10.	5.00	14:00	14:0	-	-	
11.	5.50	14:30	14:30	-	-	
12.	6.00	15:00	15:00	-	-	
13.	6.50	15:30	15:3	-	-	

Study No: 765/15 **Subject ID:** 51

S. No	Sample Point (hour)	Schedule Time	Actual Time	Deviation		Done By (Sign & Date)
				Time (min)	Reason #	
14.	7.00	16:00	16:00			
15.	7.50	16:30	16:30			
16.	8.00	17:00	17:00			
17.	8.50	17:30	17:20			
18.	9.00	18:00	18:00			
19.	10.00	19:00	19:00			
20.	12.00	21:00	21:00			
21.	24.00	05:00	05:00			

1. Late arrival of the Subject 2. Cannula Blockage 3. Vein Collapse 4. Others (Specify)

Note: The post dose samples will be collected within 2 minutes of the schedule time. Any blood samples drawn beyond the specified window period will be recorded in the deviation column.

COMMENTS
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PK SAMPLING STATEMENT		
All samples were collected, processed and stored as per study protocol and applicable procedures.		
Reviewed By	**Signature**	**Date**
		10-11-2016

Study No: 765/15 QPS Subject ID: S1

VITAL SIGNS AND WELLBEING LOG (P – II)

Time Point (hr)	Schedule Time	Pulse Rate (per min)	Oral Temperature (°F)	Blood Pressure (mm of Hg) Systolic/Diastolic	Well Being	Recording Time	Recorded By (Sign & Date)	Remarks
Pre-dose (0.00)	----	70	98	100/70		08:00		
2.00		78	----	108/74		11:00		
8.00		74	----	100/70		19:00		

	----				ok			

Check-Out	----	76	97.6	110/76		09:00		

Note: The vitals and wellbeing will be examinedwithin ± 40 minutes from the scheduled time

DEVIATIONS
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COMMENTS
-

Reviewed By	Signature	Date
		08-11-15

Study No: 765/15

Subject ID: S1

ADVERSE EVENT LOG

AE. No	Event Description	Start Date and Time	Physician's Advice	Seriousness	Severity/ Intensity	Causality	Expectedness	Concomitant medication given	Attended By	Date and Time	Action Taken	Stop Date and Time	Out Come	Done By

Seriousness	Severity/Intensity	Causality	Expectedness	Concomitant Medication	Action Taken	Out Come
1-Yes 2-No	1-Mild 2-Moderate 3-Severe	1-Certain4-Unlikely 2-Probable5-Conditional 3-Possible6-Unassessable	1-Expected 2-Unexpected	1-Yes 2-No	1-Continued 2-Discontinued 3-Not Applicable	1-Resolved4-Died 2-Resolved with sequelae5-Lost to follow-up 3-On-going

Remarks	

I have reviewed the AEs on this page and have assessed them for seriousness, severity, causality, and outcome and confirm that, to the best of my knowledge the data reflected is accurate.

	Signature	Date
Principal Investigator		

Study No: 765/15 **Subject ID:** S1

CONCOMITANT MEDICATION LOG

S. No	Drug Name (Preferably Generic Name)	Indication	Dose	Dosage Form	Scheduled Frequency	Route of Administration	Start Date and Time	End Date and Time	Done By

Dosage Form
1 – Tablet 5 – Injection
2 – Capsule 6 - Syrup
3 – Ointment 7 – Others (Specify)
4 – Suspension

Schedule Frequency
1 – QH (every hour) 5 – QD (once a day)
2 – QID (four times a day) 6 – QOD (every other day)
3 – TID (three times a day) 7 – SOS (as needed)
4 – BID (two times a day)

Route of Administration
1-Oral 5-Inhalation 8 – Intraocular
2-Topical 6-Intravenous9- Vaginal
3- Subcutaneous 7- Nasal10-Intramuscular
4 - Rectal

Any concomitant medication will interact with the study drug pharmacokinetics	Yes☐NC
Remarks	

Study No:	765/15	QPS	Subject ID:	S1

END OF THE STUDY

Did the Subject complete the study? ☑ Yes ☐ No

(Complete the below mentioned details for Early withdrawal).

EARLY WITHDRAWAL LOG

Indicate the primary reason the subject has withdrawn from the study (Select the appropriate)

☐	The subject chooses to dropout from the study with or without stating any reason.
☐	It is not in subject's best interest to continue in the study, as per the opinion of investigator.
☐	The subject is found to be violating the inclusion and exclusion criteria.
☐	The subject requires the use of an unacceptable concomitant medication.
☐	The subject suffered from significant inter-current illness or has to undergo surgery during the study.
☐	The subject experiencedemesis (vomiting) within two times median t_{max} of Solifenacin.
☐	The subject experienced adverse event and discontinued in the study,as per the opinion of investigator.
☐	The subject experienced serious adverse event, he/she will be discontinued from the study unconditionally.
☐	Others (Specify)_____

Date of withdrawal		**Time of Withdrawal**	

Follow Up required: Yes ☐ No ☑

If Yes : Follow Up Remark _____

Done By Signature and Date	

INVESTIGATOR'S STATEMENT

I certify that I have reviewed the Case Report Form for this Subject and verified to the best of my knowledge and the information contained herein is true and complete.

Signature		**Date**	14-11-18