

**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

**SUBJID SUBJID**

**VID**

Volunteer ID: Subject ID:

SCREENING **VISIT**

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| **Demogrphic DetailsDemo\_raw SDTM.DM** |

Gender **GEN SEX**

Male

Female

Age (Years)\_**AGEU**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Ethnicity**ETH**

Asian

Other

If Other, specify\_\_**ETHOT**\_\_\_\_\_

Height \_**\_HT**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Height Units\_\_\_\_\_\_cm\_\_\_\_\_\_\_\_\_\_\_ **HTU**

Weight \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**WT**

Weight Units \_\_\_\_\_\_\_\_\_\_Kg\_\_\_\_\_\_\_\_\_\_\_**WTU**

BMI \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**BMI**

BMI Units\_\_\_\_\_\_kg/m2\_\_\_\_\_\_**BMIU**

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| **ELIGIBILITY CRITERIA** |

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| **Check-in Vital Signs** | | | | |
| **Blood Pressure (mm of Hg)**  **Systolic/Diastolic** | **Oral Temperature (°F)** | **Pulse Rate**  **(per min)** | **Recording Time** | **Recorded By**  **( Sign & Date)** |
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| **COMMENTS** |  |

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| **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** |
|  | The volunteer is able to understand and willingness to sign statements of informed consent. |  |  |
|  | The volunteer is healthy, adult, human **being between 18 and 45 years of age** (both inclusive) and weighing at least 50 kg. |  |  |
|  | The volunteer has a body mass index between **18.5and 29.9 (both inclusive),** calculated as weight in Kg/height in m2. |  |  |

| **EXCLUSION CRITERIA**  (A response of “Yes” to any of the Exclusion criteria below means the participant DOES NOT meet criteria) | | | |
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| **S. No** | **Activity** | **Yes** | **No** |
|  | The volunteer’s systolic blood pressure is less than 90 mm of Hg or more than 140 mm of Hg. |  |  |
|  | The volunteer’s diastolic blood pressure is less than 60 mm of Hg or more than 90 mm of Hg. |  |  |
|  | The volunteer’s oral temperature is below 95.0°F or above 98.6°F. |  |  |
|  | The volunteer’s pulse rate is below 60 /min or above 100 /min. |  |  |
|  | **The volunteer is confirmed positive in alcohol screening (breath alcohol test).** |  |  |
|  | **The volunteer is confirmed positive in selected drug of abuse (for benzodiazepines, cannabinoids, amphetamine, cocaine, barbiturates, morphine).** |  |  |
|  | The volunteer is confirmed positive in hepatitis screening (HbsAg/HCV) or for HIV antibody. |  |  |

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| **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.  The subject is not complying the inclusion and exclusion criteria as per the study protocol and is  not eligible to participate in the study. |

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| Enrollment Date: | **ENRDT** |

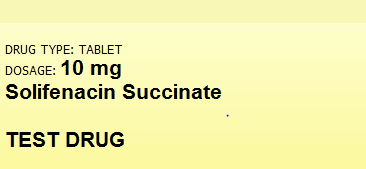
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| EnrollmentTime: | **ENRTM** |

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| Subject ID:**SUBJID** |  |

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| **investigational product administration (P – I)VISIT** |

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| **DRUG ADMINISTRATION PROCEDUREEXPOSURE\_RAW** |
| 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. |

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| Dosing Date:**DSDT** |  | Dosing Time:**DSDTM** |  |



Please affix the Investigational Product

Label and sign across

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| **PK SAMPLING LOG (P – I)** |

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| Dosing Date: |  | Dosing Time: |  |

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| **PK SAMPLING PROCEDURE** |
| Collect 4ml of blood sample in sample tubes containing K2EDTA 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 #** |
|  | Pre-dose (0.00) | **within 1 hour prior to dosing** |  |  |  |  |
|  | 1.00 |  |  |  |  |  |
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|  | 9.00 |  |  |  |  |  |
|  | 10.00 |  |  |  |  |  |
|  | 12.00 |  |  |  |  |  |
|  | 24.00 |  |  |  |  |  |
| **# 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.

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| **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** |
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| **vital signs and wellbeing log (P – I)** |

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| **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)** | ---- |  |  |  |  |  |  |  |
| **2.00** |  |  | ---- |  |  |  |  |  |
| **8.00** |  |  | ---- |  |  |  |  |  |
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| **Check-Out** | ---- |  |  |  |  |  |  |  |

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

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| **DEVIATIONS** |
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| **COMMENTS** |
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| **Reviewed By** | **Signature** | **Date** |
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| **ELIGIBILITY CRITERIAfor period – ii** |

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| **Check-in Vital Signs** | | | | |
| **Blood Pressure (mm of Hg)**  **Systolic/Diastolic** | **Oral Temperature (°F)** | **Pulse Rate**  **(per min)** | **Recording Time** | **Recorded By**  **( Sign & Date)** |
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| **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** |
|  | The subject is confirmed positive in alcohol screening (breath alcohol test). |  |  |
|  | The subject is confirmed positive in selected drug of abuse(for benzodiazepines, cannabinoids, amphetamine, cocaine, barbiturates, morphine). |  |  |
|  | The subject’s systolic blood pressure is less than 90 mm of Hg or more than 140 mm of Hg. |  |  |
|  | The subject’s diastolic blood pressure is less than 60 mm of Hg or more than 90 mm of Hg. |  |  |
|  | The subject’s oral temperature is below 95.0°F or above 98.6°F. |  |  |
|  | The subject’s pulse rate is below 60 /min or above 100 /min. |  |  |

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| **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. |

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| Check-in Date: |  |

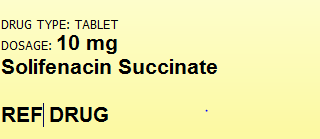
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| Check-in Time: |  |

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|  | **Signature** | **Date** |
| **Done By** |  |  |
| **Reviewed By** |  |  |

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| **investigational product administration (P – II)** |

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| **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. |

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| Dosing Date: |  | Dosing Time: |  |



Please affix the Investigational Product

Label and sign across

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| **PK SAMPLING LOG (P – II)** |

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| Dosing Date: |  | Dosing Time: |  |

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| **PK SAMPLING PROCEDURE** |
| Collect 4ml of blood sample in sample tubes containing K2EDTA 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 #** |
|  | Pre-dose (0.00) | **within 1 hour prior to dosing** |  |  |  |  |
|  | 1.00 |  |  |  |  |  |
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|  | 12.00 |  |  |  |  |  |
|  | 24.00 |  |  |  |  |  |
| **# 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.

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| **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** |
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| **vital signs and wellbeing log (P – II)** |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **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)** | ---- |  |  |  |  |  |  |  |
| **2.00** |  |  | ---- |  |  |  |  |  |
| **8.00** |  |  | ---- |  |  |  |  |  |
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| **Check-Out** | ---- |  |  |  |  |  |  |  |

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

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

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| **Remarks** |  |

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| 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. | | |
| **Principal Investigator** | **Signature** | **Date** |
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| [**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** |
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| **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 | | |

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| **Any concomitant medication will interact with the study drug pharmacokinetics** | **Yes**🗖**NO**🗖**Not Applicable**🗖 |

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| **Remarks** |  |

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| **END OF THE STUDY** |

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| Did the Subject complete the study? Yes No  (Complete the below mentioned details for Early withdrawal). |

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| **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 tmax 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)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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| **Date of withdrawal** |  | | **Time of Withdrawal** |  |
| Follow Up required: Yes No | | | | |
| If Yes : Follow Up Remark \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | |
| **Done By**  **Signature and Date** | |  | | |

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| **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** |  |