# Standard Pharmaceutical Product Information (Rx Product Only)

**Introduction Type:** New Item | 0 Final Version | **Date:**

## PRODUCT INFORMATION

**Company Name:** Sciegen Pharmaceuticals Inc. | **Application:** ANDA
**Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):** 211657
**DUNS:** 079391286
**Proprietary Name (If Applicable) and Established Name:** Solifenacin Succinate Tablets, USP 10mg -30's per Bottle
**Selling Unit NDC:** 50228-428-90 | **Individual Unit NDC:** 1 Bottle | **UPC:** 350228428903
**UDI** | **CVX Code:** | **MVX Code:**
**Description:** Light Pink,Round Shape, film coated tablets, debossed with ' SG ' on one side '428' on the other side.
**Active Ingredient(s):**
**URL for Additional Product Information:**

**Address:** 89 arkay drive | **Address 2:**
**City:** Hauppauge | **State:** NY | **Zip:** 11788
**Key Contact:** Siva Reddy.P.V | **Email:** sivareddyp@sciegenpharm.com
**Phone Number:** 631-434-2723 XT 107, 631-524-5509 | **Fax:** 631-357-3178
**Product Therapeutic Classification:** Urinary Anti Spasmodic

## ADDITIONAL PRODUCT INFORMATION

**Is the Product…**
**a legend device?** No
**reverse numbered?** No
**co-licensed?** No
**Is the Product…** Direct-Ship Only
**Is the Product…** Unit of Use

If Unit Dose, is item bar coded to unit dose for hospital scanning?
If Unit Dose NDC, indicate NDC here:
Country of Origin: USA
Is this product covered under the Trade Agreements Act (TAA)? Yes

## PRODUCT DESCRIPTION INFORMATION

**Size:** 7.54 mm
**Strength:** 10mg
**Dosage Form:** Tablet
**Product Shape:** Round
**Product Color:** Light pink
**Product Imprint:** SG' on one side & '428' on the other side

## FOR GENERIC DRUG PRODUCTS

Authorized Generic — *If Authorized Generic, other section fields are not applicable

**I. Orange Book Rating:** AB
**II. Generic Equivalent to What Brand?:** VESIcare

## DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

**Does supplier meet DSCSA definition of manufacturer?** Yes
**Is product exempt from DSCSA?** No
**If yes, select exemption:**
**Other exemption - Write in:**
**Is product repackaged?** No
**Is product sold by manufacturer's exclusive distributor?**
**Has FDA granted waiver/exception/exemption for product?** No

**GLN:** 350228000000
**If Yes, was original product purchased direct from mfr?**
**If yes, attach documentation from FDA.**

## GTIN PRODUCT INFORMATION

Serialized? Yes
If not, when?
Items aggregated? No

| Level | | Saleable Unit | | | | Quantity | GTIN-14 |
|---|---|---|---|---|---|---|---|
| X | Item | X | X | 2D | Linear | 1 | 00350228428903 |
| | Box/Carton/Bundle/Inner Pack | | | 2D | Linear | | |
| X | Case | | X | 2D | Linear | 24 | 20350228428907 |
| | Pallet | | | 2D | Linear | | |
| | | | | 2D | Linear | | |
| | | | | 2D | Linear | | |
| | | | | 2D | Linear | | |
| | | | | 2D | Linear | | |

## SPECIAL HANDLING AND STORAGE REQUIREMENTS*

**a. Temperature – Indicate the USP temperature range for this product.**
Temperature Range: Controlled Room – between 20 and 25 C (68° – 77° I
Other Temperature Range Requirement (write in):
Is this product to be shipped to customers on ice? No
Is this product to be shipped to customers on dry ice? No

**b. Contact for temperature excursion questions:**
**Name:** Siva Reddy.P.V
**Number:** 631-434-2723 XT 107, 631-524-5509
**Group E-mail:** sivareddyp@sciegenpharm.com

**c. Special regulations for product in any states?** No
Special returns requirements for this product? No

**d. Store product (unit of sale) upright?** Yes
**Protect product (unit of sale) from light?** No

**e. Shelf life:** 24 Months
**Initial shelf life at launch (if different):** Months

## ORDER INFORMATION

**Unit of Sale**

| | |
|---|---|
| Yes | Bottle |
| | Box/Carton |
| | Ampule |
| | Glass |
| | Tube |
| | Vial Liquid Sgl |
| | Vial Liquid Multi |
| | Vial Powder Sql |
| | Vial Powder Multi |
| | Other: Write In |

**What is the NDC selling unit?** 1 Bottle of 90 Tablets
(Write-in, e.g. 1 Box of 10 Vials)

**Minimum order quantity?** Yes

**If Yes, how many of which package type?**

| | |
|---|---|
| 24 Bottles | Each |
| per case | Inner/Carton/Pack |
| 3 Cases | Case |

## PHARMACY ORDER / BILL UNIT

**Rec. sell unit to customer?** Bottle
(Write-in, e.g. 1 Vial)

**Rx billing unit to pharmacy:**

| | |
|---|---|
| X | Each |
| | Gram |
| | Milliliter |

## ITEM AND PACKING INFORMATION

| | Weight Lbs. | Dimensions (US msmts.) Depth | Height | Width | Volume (Cube) | # Pieces: |
|---|---|---|---|---|---|---|
| **Item:** | 0.09 | NA | 2.7 | 1.6 | #VALUE! | 90 Tablets per Bottle |
| **Box/Carton/Bundle/ Inner Pack:** | NA | NA | NA | NA | #VALUE! | NA |
| **Case:** | 2.66 | 11.5 | 4.1 | 7.4 | 348.91 | 24 Bottles per Case |
| **Pallet:** | 665 | 48 | 48 | 40 | 92160 | 220 Cases per Pallet |

**UPC:** Case: 350228428903 | Carton:

## COST INFORMATION

**Regular Cost**
**Invoice Cost (WAC) ($)**
**Federal Excise Tax Per Unit of Sale**
As of date:

## WHOLESALER USE ONLY:

**Vendor #:**
**Whsl. Code #:**
**Fineline Code:**

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.

***Please provide any additional information on page 2.**

**See new p. 3 for Designated Drop Ship Only.**

**Signature:**

# Standard Pharmaceutical Product Information (Page 2)

For Designated Drop Ship Only Products, Please Use Page 3

## MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION

Is this product (check all that apply):

| | |
|---|---|
| a. Cytotoxic? | No |
| b. CA Prop. 65 Carcinogen or Reproductive Toxicant? | |
| Is the product a CA Prop 65 carcinogen? | No |
| Is the product a CA Prop 65 reproductive toxicant? | No |
| Does the product label bear a CA Prop 65 warning? | No |
| c. Contact Hazard? | No |
| d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.) | |
| e. Does the product contain DEHP? | No |
| Is this product regulated for shipment by DOT or IATA? | No |

(if yes, answer a-e below and provide SDS)

| | |
|---|---|
| a. UN/Identification Number | |
| b. Proper Shipping Name | |
| c. DOT Hazard Class | |
| d. Packing Group | |
| e. Inhalation Hazard? | No |

Is the product restricted for air shipment? If so, indicate restriction:

- [ ] Passenger
- [ ] Cargo
- [ ] Passenger & Cargo

Is this a reportable quantity?

RQ Threshold:

Is this a marine pollutant? No

Is this product shipped utilizing an authorized DOT exception or Special Permit?

(if yes, identify method below)

- [ ] Limited Quantity
- [ ] Consumer Commodity, ORM-D
- [ ] Small Quantity (49 CFR 173.4)
- [ ] Special Permit; DOT-SP
- [ ] Special Provision (listed in Column 7 of 49 CFR 172.101);

SP#

### SDS Hazard Classification

- [X] Organic
- [ ] Inorganic
- [ ] Steroid/Androgen
- [ ] Corrosive
- [ ] Oxidizer
- [ ] Contact Hazard
- [ ] Aerosol Class; Identify NFPA Storage Level:

Is the product a NIOSH hazardous drug? No

If yes, indicate which:

### Hazardous Waste Identification

EPA Hazardous Waste Code:

### REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product? No

If Yes, is it managed with a pharmacy registry?

Website URL:

Comments / Details: (For example, iPledge program?)

**REMS:**

REMS Program Manager Name: Phone:

Supplier Manages REMS registry exclusively:

Wholesale distributor support:

Provider Name:

Site Enrollment Number assigned by Supplier:

DEA #:

PCPDP #:

NPI #:

Comments

**Registry:**

Registry Program Contact Name: Phone:

Comments

## ADD'L STORAGE INFORMATION

Is the Product…

| | |
|---|---|
| Controlled Substance? | No |
| Controlled by State(s)? | No |
| ARCOS Reportable? | |
| Schedule No. (inc. N for non-narcotic) | |
| Controlled Substance Code | |
| Listed Chemical (List I or II) | |
| If yes, indicate which: | |
| Is it a scheduled listed chemical product?: | |

## CLASS OF TRADE RESTRICTION:

| | |
|---|---|
| No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices | |
| Restricted to retail pharmacy only: | |
| Restricted to hospital, clinics, and physician offices only: | |
| Restricted from US territories? (explain in comments) | |

Comments:

## RETURN INSTRUCTIONS

Contact tel. # if product received damaged: 631-524-5509

Is product returnable for credit:

URL/Link to returns policy:

Special regulations or returns requirements for this product in certain states? No

If so, which states? Other requirements? Comments?

## MISCELLANEOUS NOTES and/or Image of Product Barcode:

Release DATE

# Standard Pharmaceutical Product Information (Page 3)

**FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.**

## Order Method for Designated Drop Ship Product

Purchase orders may be accepted by:

a. EDI
b. Autofax — Fax Number:
c. Fax — Fax Number:
d. Phone only — Phone No.:
e. Supplier Web Site only — Site Address:

Minimum Order Quantity:
Supplier's Customer Service Number:
Contracted 3PL company / contact #: Name:
Phone:

## Standard Order Receipt and Processing

**Purchase order daily receipt cut off time by supplier**
Cut off time:

Shipping lead time of PO: Hours Days

Ships same day for next day receipt:
Ships for second day receipt:
Ships regular ground for 3-10 days receipt:

## Expedited Freight Charges or Other Designated Drop Ship Fees:

Expedited freight fees billed with each order:
Drop Ship service fee billed with each order:
Drop Ship miscellaneous fees billed:
Comments:

## Overnight and Priority Overnight PO Processing

**Overnight receipt available:**
PO Receipt cut off time:
Days of week overnight is available:
Monday
Tuesday
Wednesday
Thursday
Friday

**Priority Overnight receipt available:**
PO Receipt Cut off time:

**Saturday Overnight receipt available:**
PO Receipt Cut off time:

Order receipt method: Phone: Phone #:
Fax: Fax #:
EDI:

Overnight Fees apply:
Other fees apply:

## Class of Trade Restriction:

No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices
Restricted to retail pharmacy only:
Restricted to hospital, clinics, and physician offices only:
Restricted from US territories? (explain in comments)
Comments:

## Other Data Information Required to Process PO:

Patient Procedure Date:
Physician Name:
Physician/Clinic Phone #
Physician State License #
Physician/Clinic DEA #:
Physician/Clinic Specialty:

## Return Instructions

Contact # if product is received damaged:
Is product returnable for credit:
URL/Link to returns policy:
Special regulations or returns requirements for this product in certain states?
If so, which states? Other requirements? Comments?

## Miscellaneous Notes:

## ADDITIONAL INFORMATION

Is product order for scheduled patient procedure?
Is product order for restocking purposes?