

**Government of Nepal
Ministry of Health and Population
Department of Drug Administration
National Medicines Laboratory
Quality and Method Validation Section**

Analytical profile of Solifenacin Succinate Tablets

Analytical Profile No.: Solf 076/077/AP 080

Solifenacin Succinate Tablets contains not less than 90.0% and not more than 110.0% of the stated amount of Solifenacin Succinate.

Usual Strength: Solifenacin Succinate 5 mg

1. Identification:

In the Assay, the principle peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.

2. Dissolution:

2.1 Dissolution Parameters:

Apparatus: Paddle

Medium: 900ml of water

Speed and Time: 50 rpm and 45 minutes

Withdraw a suitable volume of the medium and filter.

Determine by liquid chromatography.

2.2 Test Solution: Dilute the filtrate, if necessary, with dissolution medium.

2.3 Reference Solution: Weigh accurately about 27.5 mg of Solifenacin succinate WS in 50 ml volumetric flask. Add about 30ml of dissolution medium, sonicate to dissolve, allow to cool and make up the volume to 50 ml with dissolution medium. Further dilute 1 ml of this solution to 100 ml with dissolution medium.

2.4 Procedure: Use the chromatographic system as described in the Assay.

Inject the reference solution and the test solution. Calculate the percent release of Solifenacin Succinate.

2.5 Limit: NLT 70.0 % (D) of the stated amount

3. Uniformity of Content

Determine by liquid chromatography, as described in the Assay, using the following solution as the test solution.

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Test Solution: Place a tablet in a 50ml volumetric flask, disperse in 2 ml of water and add 30ml of methanol, sonicate for 30-45 minutes. Cool and make up the volume to 50 ml with methanol. Further dilute 2 ml to 20 ml of this solution to 10 ml with methanol.

4. Assay: *Determine by liquid chromatography*

4.1 Test Solution: Weigh individually 20 tablets & crush the tablet into fine powder. Weigh a quantity of powder equivalent to 10 mg of Solifenacin succinate in 100 ml volumetric flask, disperse in 2 ml of water and add about 70 ml of methanol, sonicate for about 30 minutes, allow to cool and make volume to 100 ml with methanol. Further dilute 2 ml of this solution to 20 ml with methanol.

4.2 Reference Solution: Weigh accurately about 20 mg of Solifenacin succinate WS in 100 ml volumetric flask. Add about 10ml of methanol, sonicate to dissolve, allow to cool and make up the volume with methanol. Further dilute 1 ml of this solution to 20 ml with methanol.

4.3 Chromatographic system:

- **Column:** C8, (250 x 4.6 mm), 5 μ m
- **Flow rate:** 1.0 ml/min
- **Wavelength:** 210 nm
- **Injection volume:** 20 μ l
- **Detector:** UV
- **Column Temperature:** 25°C
- **Mobile Phase:** A mixture of 60 volume of buffer and 40 volume of Acetonitrile
- **Buffer:** 10 mM Potassium Dihydrogen phosphate (i.e; 136.09x gm) with 0.1% v/v Triethylamine in water, adjust pH to 3.0 with phosphoric acid

4.4 Procedure: Inject the reference solution five times and sample solutions. The test is not valid unless the column efficiency is not less than 2000 theoretical plates, tailing factor is not more than 2.0 and the relative standard deviation for replicate injections is not more than 2.0%. Measure the peak responses. Calculate the content of Solifenacin succinate in the tablets.

5. Other tests: As per pharmacopoeial requirements.