

DEPARTMENT OF DRUG ADMINISTRATION
National Medicines Laboratory
ANALYTICAL METHOD VALIDATION COMMITTEE

Sodium Picosulfate Tablets

Analytical Profile No.: SODP 076/077/AP065

Sodium Picosulfate tablets contains not less than 90 % and not more than 110 % of the stated amount of Sodium Picosulfate.

1. Identification: The final solution obtained in the assay shows concordant spectrums with that of the reference spectrum and the maxima at about 263 nm.

Tests:

2. Dissolution: *Determine by UV Spectroscopy*

2.1 Dissolution Parameters:

Apparatus: Paddle

Medium: 900 ml of 0.1 N HCl

Speed and Time: 50 rpm & 30 minutes

Temperature: 37+/-0.5°C

Withdraw a suitable volume of the medium and filter

2.2 Test Solution: Use the filtrate.

2.3 Reference Solution: Weigh accurately about 27.5 mg of Sodium Picosulfate reference standard in 50 ml volumetric flask. Add about 30 ml of dissolution medium and sonicate to dissolve and finally make up the volume with dissolution media. Further dilute 1 ml of this solution to 50 ml with the dissolution media.

2.4 Procedure: Measure the absorbance of both reference solution and test solution on UV-Vis Spectrophotometer at a wavelength of 263 nm against dissolution medium as blank. Calculate the % release of Sodium Picosulfate.

2.5 Limit: Not less than 80 % (D) of the stated amount.

3. Uniformity of Content: *Determine by UV Spectroscopy*

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Proceed as described in the Assay, using the following solution as the test solution.

3.1 Test solution: Weigh 10 tablets individually and transfer each into 100 ml volumetric flask. Add 70 ml of water, sonicate for about 15 minutes to dissolve the tablet; cool and make up the volume to the mark with water. Filter and further dilute 5 ml of filtrate to 20 ml with water.

3.2 Limit: 85 % - 115 % of the stated amount

4. Assay: *Determine by UV Spectroscopy*

4.1 Test Solution: Determine the average weight of 20 tablets. Crush them into homogeneous mixture in mortar and pestle. Transfer carefully powder equivalent to 25 mg of Sodium Picosulfate into 100 ml volumetric flask, add 70 ml of water, sonicate for about 15 minutes to dissolve, cool and make up the volume to the mark with water. Filter and further dilute 5 ml of filtrate to 50 ml with water.

4.2 Reference Solution: Weigh accurately about 25 mg of Sodium Picosulfate reference standard in 100 ml volumetric flask. Add 70 ml of water, and sonicate; cool and make up the volume to 100 ml with water. Further dilute 5 ml of this solution to 50 ml with water.

4.3 Procedure: Measure the absorbance of both reference and test solution in UV-Vis Spectrophotometer at a wavelength of 263 nm against water as blank. Calculate the content of Sodium Picosulfate in the tablets.

5. Other tests: As per pharmacopoeial requirement.