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

Analytical profile of Sodium Valproate SR Tablet

Analytical Profile No.: SVT 074/075/ AP 031

Sodium Valproate SR Tablet contains not less than 90.0% and not more than 110.0% of the stated amount of Sodium Valproate.

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: *Deteremine by liquid chromatography*

2.1 Dissolution Parameters:

Apparatus: Paddle

Medium: 1000ml of Water

Speed and Time: 50 rpm and 1st hour, 4th hour, 8th hour, 12th hour & 20th hour

Withdraw a suitable volume of the medium and filter.

2.2 Diluent: 50 volume of Water and 50 volume of Acetonitrile

2.3 Test Solution: Use the filtrate.

2.4 Reference Solution: Weigh accurately about 25 mg of Sodium Valproate RS in 50 ml volumetric flask. Add 30 ml of diluent and sonicate for 15 min and make up volume with same solvent. Dilute 5 ml of this solution to 50 ml with same diluent.

2.5 Procedure: Use the chromatographic system as described in the Assay using 25 µl as injection volume. Inject the reference solution and the test solution.

Calculate the percent release of Sodium Valproate.

2.6 Limit

1st hour – NLT 15% and NMT 35%

4th hour – NLT 35% and NMT 55%

8th hour – NLT 55% and NMT 70%

12th hour – NLT 70 and NMT 85%

20th hour - NLT 75% of the stated amount

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3. Assay:

3.1 Diluent: 50 volume of Water and 50 volume of Acetonitrile

3.2 Test Solution: Weigh and powder 20 tablets. Weigh powder eq. to 250 mg of Sodium Valproate in 100ml volumetric flask. Add about 70ml of diluent and sonicate for 15 minutes, make up the volume to 100 ml with diluent. Filter and dilute 5 ml of the filtrate to 25 ml with diluent. (500 ppm)

3.3 Reference Solution: Weigh accurately about 12.5 mg of Sodium Valproate RS in 25 ml volumetric flask and add 15 ml diluent in it. Sonicate for about 10 min and make volume with diluent. (500 ppm)

3.4 Chromatographic system

Column: Octyldecylsilane (C18), (250 x 4.6 mm), 5 µm

Flow rate: 1.0 ml/min

Detector: UV Detector

Wavelength: 220 nm

Injection volume: 25 µl

Oven temperature: 35 °C

Mobile phase: 45 volume of Buffer and 55 volume of Acetonitrile

Buffer: 0.32% Potassium dihydrogen phosphate, adjust pH 3.0 ± 0.05 with Orthophosphoric acid

3.5 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 Sodium Valproate in Sodium Valproate SR Tablet.

4. Other tests: As per pharmacopoeial requirements.