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

Analytical profile of Granisetron Syrup

Analytical Profile No.: Grani 075/076/AP059

Granisetron Syrup contains not less than 92.0% & not more than 108.0% of the stated amount of Granisetron.

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. pH: As per manufacturer's specification

3. wt/ml: As per manufacturer's specification

4. Assay

4.1 Diluent: Buffer (Weigh 15.6 gm of Sodium dihydrogen orthophosphate in 900 ml water, dissolve it, adjust pH to 2.0 with dilute phosphoric acid. Dilute with water to 1000 ml.)

4.2 Test Solution: Weigh about 27 gm of syrup eq. to 5 mg of Granisetron in 100 ml volumetric flask. Add about 70 ml of diluents and sonicate for about 10-15 minutes, cool at room temperature and make up the volume to 100 ml with same solvent.

4.3 Standard solution: Weigh accurately Granisetron HCl WS equivalent to 50 mg of Granisetron into 50 ml volumetric flask, add about 30 ml of diluents and sonicate for about 10 minutes to dissolve, cool at room temperature and make up the volume to 50 ml with same solvent. Dilute 1 ml of this solution to 20 ml with same solvent.

4.4 Chromatographic Condition

Column: Octadecylsilane (C18), (150 x 4.6 mm), 5 µm

Flow rate: 1.2 ml/min

Wavelength: UV 300 nm

Injection volume: 20 µl

Column temperature: 35° C

Mobile phase: Buffer:Methanol:Tetrahydrofuran (75:24:1.1)

Buffer solution: Weigh 15.6 gm of Sodium dihydrogen orthophosphate (NaH_2PO_4) in 900 ml water, dissolve it, adjust pH to 2.0 with dilute phosphoric acid. Dilute with water to 1000 ml.

4.5 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. The tailing factor is not more than 2.0 and the relative standard deviation for replicate injections in not more than 2.0%. Measure the peak response. Calculate the content of Granisetron in syrup

5. Other tests: As per pharmacopoeial requirement.