

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

Granisetron Mouth Dissolving Tablets

Analytical Profile No.: Grani 075/076/AP058

Granisetron Mouth Dissolving Tablets contain 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. Dissolution: *Determine by liquid chromatography*

2.1 Dissolution Parameters:

Apparatus: Paddle

Medium: 500 ml of Phosphate Buffer pH 6.5 (Dissolve 6.8 g of Potassium Dihydrogen Orthophosphate in 800 ml of water. Adjust pH 6.5 with 1 N NaOH and dilute to 1000 ml with water.

Speed and Time: 50 rpm and 10 minutes

Withdraw a suitable volume of the medium and filter.

2.2 Test solution: Use the filtrate.

2.3 Reference Solution: Weigh accurately Granisetron Hydrochloride WS equivalent to 20 mg of Granisetron into 100 ml volumetric flask, add about 70 ml of diluents and sonicate for about 10 minutes to dissolve, cool at room temperature and make up the volume to 100 ml with same solvent. Dilute 1 ml of this solution to 100 ml with same solvent.

2.4 Procedure: Use the chromatographic system as described in the Assay using 50 µl as injection volume. Inject the reference solution and the test solution. Calculate the percent release of Granisetron.

2.5 Limit: NLT 75% (D) of the stated amount

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3. Uniformity of Content

Determine by liquid chromatography as described under assay, using following solution as test solution.

Test Solution: Place 1 tablet in a 20ml volumetric flask, add about 10ml of diluents and sonicate for 10-15 minutes, cool at room temperature and make up the volume up to mark with same solvent, mix well.

4. Assay: *Determine by Liquid Chromatography*

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 individually 20 tablets and crush them to fine powder. Weigh powder eq. to 5 mg of Granisetron and transfer into 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. Filter the resulting solution through 0.2 µm membrane filter.

4.3 Reference Solution: Weigh accurately Granisetron Hydrochloride 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. Filter the solution through 0.2 µm membrane filter.

4.4 Chromatographic Condition:

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

Flow rate: 1.2 ml/min

Wavelength: 300 nm

Injection volume: 20 µl

Column temperature: 35° C

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

Buffer solution: 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.

4.5 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 Granisetron in Granisetron Mouth Dissolving Tablets.

5. Other tests: As per pharmacopoeial requirements.