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

Analytical profile of Prucalopride Tablets

Analytical Profile No.: Prucal 080/81/AP 160

Prucalopride Tablets contain not less than 90.0% and not more than 110.0% of the stated amount of Prucalopride.

Usual Strength: 1 mg

1. Identification:

In the Assay, the principal 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 0.1 N HCL

Speed: 50 rpm

Time: 30 minutes

2.3 Test Solution: After completion of the test withdraw a specimen from the zone midway between the surface of the dissolution medium and the top of the rotating blade, not less than 1 cm from the vessel wall, and filter through a 0.2 µm membrane filter. (2 ppm)

2.4 Reference Solution: Weigh 20.0 mg of Prucalopride Succinate RS accurately and transfer in 100 ml of a completely dried volumetric flask. Add 15 ml of dissolution medium and shake to dissolve and make up the volume with the same and mix. Dilute 1 ml of the solution to 100 ml with the same diluent, mix, and filter through a 0.2 µm membrane filter. (2 ppm)

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

2.6 Limit: NLT 80 % (Q) of the stated amount.

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3. Assay: *Determine by liquid chromatography*

3.1 Test solution: Weigh the content of 20 tablets and calculate the average weight. Weigh the powder equivalent to 408 mg (4 mg equivalent of Prucalopride) in 100 ml of dry volumetric flask, add 70 ml of the mobile phase, sonicate for 15 minutes, and cool the sample solution to room temperature. Make up the volume with the mobile phase and filter the solution through filter paper. (40 ppm)

3.2 Reference solution: Weigh accurately about 26.5 mg of Prucalopride Succinate RS (20 mg equivalent of Prucalopride) and transfer to a 100 ml completely dried volumetric flask. Dissolve in 70 ml of the mobile phase with the aid of ultrasound for 15 minutes and make up the volume with the mobile phase. Dilute 2 ml of the solution to 10 ml using the mobile phase and filter through a 0.2 µm membrane filter. (40 ppm)

3.3 Chromatographic system:

Column: C8 (4.6mmX 150-mm, 5µm)

Flow rate: 1.0 ml/min

Wavelength: 215 nm

Injection volume: 20 µl

Column Temperature: 30ºC

Sample Temperature: 25ºC

Mobile Phase: Buffer: Acetonitrile: 80:20 (V/V)

Buffer: Weigh 2.72 g of potassium dihydrogen phosphate in 1000 ml of HPLC grade water, and mix. Adjust pH 3.0 (+/- 0.05) with a 33% w/v solution of orthophosphoric acid.

Acetonitrile: HPLC grade acetonitrile

Diluent: Mobile phase

3.4 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, the 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 Prucalopride.

3.5 Acceptance criteria: NLT 90.0% and NMT 110.0% of the stated amount.

4. Uniformity of content: Determine by HPLC as described in the test for assay

4.1 Test Solution: Place one tablet in each of 10 separate 25 ml volumetric flasks. Dissolve in about 15 ml mobile phase with the aid of sonication for 10 minutes and make up the volume to 25 ml with the same solvent. (40 ppm)

4.2 Reference solution: Use the standard solution prepared in the assay.

4.3 Acceptance criteria: NLT 85.0% and NMT 115.0% of the stated amount.

5. Other tests: As per Pharmacopoeial requirements.