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

Analytical Profile of Lurasidone Tablets

Analytical Profile No.: Luras 081/082/AP 170

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

Usual Strength: 40 mg, 80 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: 900 ml of Mcllvaine Buffer, pH 3.8
Speed and Time: 50 rpm and 30 minutes

2.2 Media Preparation: Dissolve 5.25 g of Citric acid monohydrate and 7.098 g of disodium hydrogen phosphate anhydrous in 1000 ml of water, mix, and adjust the resulting solution with Orthophosphoric acid to a pH of 3.8.

2.3 Test Solution: Withdraw a specimen from the dissolution medium. Dilute, if necessary, with dissolution media. Filter through a 0.45micron nylon filter paper.

2.4 Reference Solution: Weigh 22.2 mg of Lurasidone Hydrochloride WS accurately and transfer in 100 ml of a completely dried volumetric flask. Add 40 ml of methanol, and sonicate for 5 minutes to dissolve. Make up the volume with the methanol, and mix. Dilute 5 ml of the solution to 50 ml with the dissolution medium. Mix, and filter through a 0.45micron nylon filter paper.

2.5 Procedure: Use the chromatographic system as described in the Assay. Inject the reference solution and the test solution.

Calculate the percent release of Lurasidone Hydrochloride.

2.6 Limit: NLT 70 % (Q) of the stated amount.

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3. Assay: *Determine by liquid chromatography*

3.1 Diluent: Same as Mobile Phase

3.2 Test solution: Weigh the content of 20 tablets and calculate the average weight. Weigh the powder equivalent to 50 mg of Lurasidone Hydrochloride in 200 ml of dry volumetric flask, add 100 ml of diluent, and sonicate for 20 minutes to dissolve with intermittent shaking. Cool the sample solution to room temperature then, make up the volume with diluent and mix. Dilute 10 ml of the solution to 50 ml with diluent. Mix and filter the solution through 0.45micron nylon filter paper.

3.3 Reference solution: Weigh accurately about 25 mg of Lurasidone Hydrochloride WS and transfer to a 100 ml completely dried volumetric flask. Dissolve in 50 ml of diluent with the aid of ultrasound for 5 minutes. Cool and up to the volume with diluents. Dilute 10 ml of the solution to 50 ml with the diluent and, mix, and filter through a 0.45micron nylon filter paper.

3.4 Chromatographic system:

Column: C18 (250-mm X 4.6mm, 5µm)
Flow rate: 1.0 ml/min
Wavelength: 230 nm
Injection volume: 10 µl
Column Temperature: 35ºC
Mobile phase: A mixture of 40 volumes of buffer solution, 30 volumes of Methanol, and 30 volumes of Acetonitrile.

Buffer Solution: It is prepared by dissolving 0.4 ml of perchloric acid (60%v/v) in 400 ml of HPLC water

3.5 Procedure: Inject the reference solution five times and test the 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 Lurasidone.

4. Other tests: As per Pharmacopoeial requirements.