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

Analytical profile of Finerenone Tablets

Analytical Profile No.: Finere 081/82/AP 173

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

Usual Strength: 10 mg & 20 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 (For 10 mg tablets):

Apparatus: Paddle

Medium: 900 ml Acetate Buffer pH 4.5

Speed: 75 rpm

Time: 30 minutes

Note - Preparation of Acetate buffer pH 4.5: Dissolve 2.99 g of Sodium Acetate trihydrate in 1000 ml of water and add 1.59 ml of Acetic acid. Maintain pH to 4.5 with acetic acid if required

Diluent: Water: Acetonitrile (70:30)

2.2 Test Solution: After completion of the test withdraw a specimen from the dissolution medium, and filter through a 0.2 µm membrane filter.

2.3 Reference Solution: Weigh 20.0 mg of Finerenone WS accurately and transfer in 100 ml of a completely dried volumetric flask. Add 70 ml of diluent and sonicate to dissolve and make up the volume with the same and mix. Dilute 1 ml of the solution to 20 ml with the dissolution medium then, filter through a 0.2 µm membrane filter.

2.4 Dissolution Parameters (For 20 mg tablets):

Apparatus: Paddle

Medium: 900 ml Acetate Buffer pH 4.5 with 0.1% Polysorbate 20

Speed: 75 rpm

Time: 30 minutes

Note - Preparation of Acetate buffer pH 4.5: Dissolve 2.99 g of Sodium Acetate trihydrate in 1000 ml of water and add 1.59 ml of Acetic acid. Maintain pH to 4.5 with acetic acid if required. Then add 1 ml of Polysorbate 20 to the media.

Diluent: Water: Acetonitrile (70:30)

2.5 Test Solution: After completion of the test withdraw a specimen from the dissolution medium, and filter through a 0.2 µm membrane filter.

2.6 Reference Solution: Weigh 20.0 mg of Finerenone WS accurately and transfer in 100 ml of a completely dried volumetric flask. Add 70 ml of diluent and sonicate to dissolve and make up the volume with the same and mix. Dilute 2 ml of the solution to 20 ml with the dissolution medium then, filter through a 0.2 µm membrane filter.

2.7 Procedure: Use the chromatographic system described in the Assay. Inject the reference solution and the test solution. Calculate the percent release of Finerenone.

2.8 Limit: NLT 75 % (Q) of the stated amount.

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 20 mg of Finerenone in 100 ml of dry volumetric flask, add 80 ml of diluent, and sonicate for 10 minutes with occasional shaking. Cool the sample solution to room temperature and make up the volume with diluent. Dilute 2 ml of this solution to 10 ml with diluent and mix. Filter the solution through 0.25-micron filter paper.

3.2 Reference solution: Weigh accurately about 20.0 mg of Finerenone WS and transfer to a 100 ml completely dried volumetric flask. Dissolve in 80 ml of diluent with the aid of ultrasound and make up the volume with diluent. Again, dilute 2 ml of the solution to 10 ml with the diluent and, mix, and filter through a 0.25-micron filter paper.

3.3 Chromatographic system:

Column: C18 (4.6mmX 150-mm, 3µm)

Wavelength: 250 nm

Injection volume: 10 µl

Column Temperature: 30ºC

Mobile Phase: Buffer: Acetonitrile (60:40)

Buffer: 0.02 M/L di-potassium hydrogen phosphate in water, pH 7.0 adjusted with sodium hydroxide if necessary

Diluent: Water: Acetonitrile (70:30)

3.4 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 Finerenone.

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 50 ml volumetric flasks. Dissolve in the diluent with the aid of sonication to fully disperse and make up the volume to 50 ml with diluent. Stir for 10 minutes then further dilute with diluent to make a final concentration of 0.04 mg/ml. Filter through 0.25-micron filter paper.

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

5. Other tests: As per Pharmacopoeial requirements.