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

Analytical profile of Cinacalcet Tablet

Analytical Profile No.: Cinacal 080/81/AP 151

Cinacalcet Tablets contains not less than 90.0% and not more than 110.0% of the stated amount of Cinacalcet.

Usual Strength: Cinacalcet Hydrochloride eq. to Cinacalcet 30 mg

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 certified reference solution.

2. Dissolution: *Determine by UV/VIS Spectroscopy.*

2.1 Dissolution Parameters:

Apparatus: Paddle

Medium: 900 ml 0.05N Hydrochloric Acid

Speed: 75 rpm

Time: 30 minutes

Withdraw a suitable volume of the medium and filter.

2.3 Test Solution: Use the filtrate.

2.4 Reference Solution: Weigh accurately 30.5 mg of Cinacalcet Hydrochloride WS and transfer in 100 ml completely dried volumetric flask, add 5 ml of methanol and dissolve it. Dilute to volume with dissolution media and mix. Dilute 3 ml of the solution to 25 ml with dissolution media and mix.

2.5 Procedure: Measure the absorbance of reference and test solution at 282 nm using UV/VIS Spectrophotometer. Use dissolution media as blank.

Calculate the percent release of Cinacalcet.

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

3. Uniformity of Content

Determine by liquid chromatography, as described in the Assay, using the following test solution.

3.1 Test Solution: Take individually 10 tablets and transfer each tablet to 100 ml volumetric flask, disperse in 70 ml of diluent and sonicate for about 15 minutes. Cool and dilute to volume with mobile phase and mix.

3.2 Reference Solution: Transfer an accurately weighed quantity of about 55 mg Cinacalcet Hydrochloride WS into 50 ml volumetric flask. Dissolve and dilute to volume with diluent and mix. Dilute 3.0 ml of this solution to 10.0 with diluent.

3.3 Limit: NLT 85.0% and NMT 115.0% of the obtained average content Cinacalcet.

4. Assay: *Determine by liquid chromatography*

4.1 Test solution: Transfer an accurately weighed of 6 whole tablets into 250 ml volumetric flask. Add about 150 ml of diluent and sonicate for 15 minutes. Cool and dilute to volume with diluent and mix. Dilute 10.0 ml of filtrate to 25.0 ml with diluent and mix.

4.2 Reference solution: Weigh accurately 31.8 mg of Cinacalcet Hydrochloride WS and transfer in 100 ml completely dried volumetric flask, dissolve and dilute to volume with diluent and mix.

4.3 Chromatographic system:

Column: C18 (4.6mmX 250-mm, 5µ)

Flow rate: 1.5 ml/min

Wavelength: 270 nm

Injection volume: 10 µl

Column Temperature: 30ºC

Mobile Phase: A mixture of 75 volumes of Acetonitrile and 25 volumes buffer.

Buffer: Transfer 5.0 ml of Triethylamine into 1000 ml of water. Adjust the pH to 5.8 with dilute Orthophosphoric acid.

Diluent: 50:50: Buffer: Acetonitrile.

4.4 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, 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 Cinacalcet in Cinacalcet Tablets.

5. Other tests: As per Pharmacopoeial requirements.