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

Analytical profile of Deflazacort Tablets

Analytical Profile No.: DEFLA 075/076/AP045

Deflazacort Tablets contains not less than 90.0% & not more than 110.0% of the stated amount of Deflazacort.

1. Identification:

In the assay, the principle peak in the chromatogram obtained with the sample solution should correspond to the peak in the chromatogram obtained with the reference standard solution of Deflazacort.

2.0 Dissolution:

2.1 Dissolution Parameters:

Apparatus: Paddle

Medium: 900 ml of Water

Speed and Time: 75 rpm and 45 minutes

Withdraw a suitable volume of the medium and filter.

2.2 Test Solution: Use the filtrate.

2.3 Standard Solution: Weigh accurately about 30 mg Deflazacort WS in 100 ml volumetric flask. Add 25 ml methanol, sonicate to dissolve and make up the volume to 100 ml with water. Further dilute 1 ml of this solution to 50 ml with water.

2.4 Procedure: Proceed the process as described in assay method using 100 µl injection volume and obtain the respective chromatograms. Measure the peak responses and calculate the % release of the drug.

[Note: Inject the solution immediately after preparation or within 18 hour stored in an autosampler at 10ºC.]

2.5 Limit: NLT 70.0 % (D) of the stated amount

3.0 Uniformity of Content

Determine by liquid chromatography, as described in the Assay, using the following test solution.
Test Solution: Place a tablet in a 25ml volumetric flask, add 15ml of mobile phase, sonicate for 30 minutes. Cool and make up the volume to 25ml with mobile phase. Centrifuse for 3 minutes and filter it through 0.2 µm membrane filter.

4.0 Assay:

4.1 Test Solution: Weigh individually 20 tablets & crush the tablet into fine powder. Weigh a quantity of powder equivalent to 12 mg of Deflazacort in 50 ml volumetric flask, add 30 ml of mobile phase, sonicate for 30 minutes to dissolve and make volume to 50 ml with same solvent.

4.2 Standard Solution: Weigh accurately about 24 mg Deflazacort WS in 100 ml volumetric flask. Add about 70 ml of mobile phase and sonicate for about 10 minutes to dissolve and make up the volume to 100 ml with same solvent.

4.3 Chromatographic system:

Column: Octyldecylsilane (C18), (250 x 4.6 mm), 5 µm

Flow rate: 1.0 ml/min

Wavelength: 244 nm

Injection volume: 20 µl

Column Temperature: 35°C

Mobile Phase: A mixture of 55 volume of Water & 45 volume of ACN

4.4 Procedure: Inject the reference solution five/six 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 Deflazacort.

5. Other tests: As per pharmacopoeial requirements.