Department of Drug Administration
National Medicines Laboratory
ANALYTICAL METHOD VALIDATION COMMITTEE FOR NON PHARMACOPOEIAL PRODUCT

Deflazacort Tablets

Analytical Profile No.:DEFLA075/076/AP045

Deflazacort Tablet contains 90% to 110% of Deflazacort of stated amount.

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 reference solution.

2. Dissolution:

2.1Dissolution Parameters: Determine by liquid chromatography.

Apparatus:	Paddle
Medium:	900ml of Water
Speed and Time:	75rpm and 45 minutes
Temperature:	37+/-0.5℃

Withdraw a suitable volume of the medium and filter.

2.2 Test Solution:

Dilute the filtrate, if necessary, with dissolution medium.

2.3Reference 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:Chromatographic System:

Use the chromatographic system as described in the Assay except injection volume of 100 µl.

2.5 Procedure:

Inject the reference solution and the test solution.

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

Calculate the % release of Deflazacort.

2.6Limit:

D. NLT 70.0 % of the stated amount

3. Uniformity of Content

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

3.1 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. Centrifuge for 3 minutes and filter it through 0.2 µm membrane filter.

3.2 Uniformity of content:

85-115% of stated amount.

4. Assay: Determine by Liquid Chromatography

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 Reference 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.

4.3Chromatographic system:

- Column: C18, (250*4.6 mm), 5 µm
- Injection volume: 20 µl
- Flow rate: 1.0 ml/min
- Wavelength: 244 nm
- Detector: UV
- Column Temperature: 35°C

Mobile Phase: Water:ACN (55:45)

4.4 Procedure:

Inject the reference solution. 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%.

Calculate the content of Deflazacort in the tablets.

5. Other tests: As per pharmacopoeial requirements.