Deflazacort Tablets

Analytical Profile No.: DEFLA 075/076/AP045

Deflazacort Tablet contains not less than 90 % and not more than 110 % of the stated amount of Deflazacort.

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.

Tests:

2. Dissolution: *Determine by liquid chromatography.*

2.1 Dissolution Parameters:

Apparatus:	Paddle
Medium:	900 ml of Water
Speed and Time:	75 rpm and 45 minutes
Temperature:	37 ± 0.5°C

Withdraw a suitable volume of the medium and filter.

2.2 Test Solution: Dilute the filtrate, if necessary, with dissolution medium. Filter the resulting solution through 0.2 µm membrane filter.

2.3 Reference Solution: Weigh accurately about 30 mg Deflazacort reference standard 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 and Procedure: Use the chromatographic system and procedure as described in the Assay using injection volume of 100 µl.

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

Calculate the percentage release of Deflazacort in each tablet.

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

3. Uniformity of Content: *Determine by liquid chromatography*

3.1 Test Solution: Place a tablet in a 25 ml volumetric flask, add 15 ml of mobile phase, sonicate for 30 minutes. Cool and make up the volume to 25 ml with mobile phase. Centrifuge for 3 minutes and filter it through 0.2 µm membrane filter.

3.2 Reference Solution: Same as Assay

3.3 Chromatographic System and Procedure: Proceed as directed under the Assay

3.4 Limit: 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. Filter the resulting solution through 0.2 µm membrane filter.

4.2 Reference Solution: Weigh accurately about 24 mg Deflazacort reference standard 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. Filter the resulting solution through 0.2 µm membrane filter.

4.3 Chromatographic 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 five times and test 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.