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

Analytical profile of Hydrocortisone Acetate and Lidocaine Suppositories

Analytical Profile No.: Hydro Lido 080/81/AP 147

Hydrocortisone Acetate and Lidocaine Suppositories contains not less than 95.0% and not more than 105.0% of the stated amount of Hydrocortisone Acetate and Lidocaine.

Usual Strength: Each Suppositories contains

Hydrocortisone Acetate 5 mg

Lidocaine USP 60 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. Uniformity of Content

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

2.1 Test Solution: Weigh and take one suppository in 200 ml volumetric flask. Add 100 ml of acetonitrile, sonicate for 20 minutes with aid if heating (temperature should not be greater than 38 ˚C). Cool the solution and make up the volume using purified water to 200 ml and mix thoroughly. Cool the solution in ice batch for 30 minutes to settle the solution and cool the solution at room temperature. Filter the supernatant solution. Further dilute 5 ml of the filtrate to 10 ml with diluent.

2.2 Limit: NLT 85.0% and NMT 115% of the obtained average content Hydrocortisone acetate and Lidocaine.

3. Assay: *Determine by liquid chromatography*

3.1 Test solution: Melt 10 suppositories in a glass beaker on a water bath. Mix thoroughly using a glass rod and cool to room temperature under stirring for uniform mixing. Weigh accurately about 2.6000 gm. of sample equivalent to 5.0 mg of Hydrocortisone and 60.0 mg of Lidocaine in a 200 ml volumetric flask, add about 100 ml of acetonitrile and sonicate with heating (37 ˚C to 38 ˚C), for 10 minutes, cool, make up the volume 200 ml with water. Filter the solution. Further dilute 5 ml of filtered solution to 10 ml with diluent.

3.2 Reference solution:

(a). Weigh accurately 25 mg of Hydrocortisone Acetate WS and transfer in 100 ml completely dried volumetric flask, add about 50 ml of acetonitrile and sonicate till it dissolves. Make up the volume to 100 ml with water and mix thoroughly.

(b). Weigh accurately 75 mg of Lidocaine WS and transfer in 50 ml completely dried volumetric flask, add about 25 ml of acetonitrile and sonicate till it dissolves. Make up the volume to 100 ml with water and mix thoroughly.

Composite Standard Solution: Further dilute 5 ml of Hydrocortisone Acetate standard solution and10 ml of Lidocaine standard solution to 100 ml with diluent.

3.3 Chromatographic system:

Column: C18 (4.6mmX 250-mm, 5µ)

Flow rate: 1.0 ml/min

Wavelength: 230 nm

Injection volume: 20 µl

Sample Temperature: 5ºC

Column Temperature: 30˚C

Diluent: 50:50: Acetonitrile: Water

Mobile Phase: Mixture of Buffer Solution and Acetonitrile in the ratio 60:40

Buffer: Weigh accurately about 6.80 gm. of Potasium Dihydrogen Phosphate dissolved in 1000 ml water adjust the pH to 4.5 with dilute orthophosphoric acid.

3.4 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 Hydrocortisone Acetate and Lidocaine in Hydrocortisone Acetate and Lidocaine Suppository.

5. Other tests: As per Pharmacopoeial requirements.