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

Analytical profile of Thiocolchicoside Tablets

Analytical Profile No.: Thioco 080/81/AP 161

Thiocolchicoside Tablets contain not less than 90.0% and not more than 110.0% of the stated amount of Thiocolchicoside.

Usual Strength: 4 mg

1. Identification:

In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.

2. Dissolution: *Determine by liquid chromatography*

2.1 Dissolution Parameters:

Apparatus: Paddle

Medium: 900 ml Phosphate Buffer pH 7.5

Speed: 100 rpm

Time: 45 minutes

2.3 Test Solution: After completion of the test withdraw a specimen from the dissolution medium, and filter through a 0.2 µm membrane filter.

2.4 Reference Solution: Weigh 44.0 mg of Thiocolchicoside WS accurately and transfer in 100 ml of a completely dried volumetric flask. Add 70 ml of water and sonicate to dissolve and make up the volume with the same and mix. Dilute 5 ml of the solution to 50 ml with the dissolution medium. Again, dilute 5 ml of the solution to 50 ml with the dissolution medium and, mix, and filter through a 0.2 µm membrane filter.

2.5 Procedure: Use the chromatographic system described in the Assay using 100 µl as injection volume. Inject the reference solution and the test solution. Calculate the percent release of Thiocolchicoside.

2.6 Limit: NLT 85 % (Q) of the stated amount.

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

3. Assay: *Determine by liquid chromatography*

3.1 Test solution: Weigh the content of 20 tablets and calculate the average weight. Weigh the powder equivalent to 4 mg of Thiocolchicoside in 100 ml of dry volumetric flask, add 70 ml of water, and sonicate to dissolve. Cool the sample solution to room temperature and make up the volume with water. Then stir for 10 minutes and filter the solution through 0.25-micron filter paper.

3.2 Reference solution: Weigh accurately about 40.0 mg of Thiocolchicoside WS and transfer to a 100 ml completely dried volumetric flask. Dissolve in 70 ml of water with the aid of ultrasound and make up the volume with water. Again, dilute 5 ml of the solution to 50 ml with the water and, mix, and filter through a 0.25-micron filter paper.

3.3 Chromatographic system:

Column: C8 (4.6mmX 250-mm, 5µm)

Wavelength: 370 nm

Injection volume: 20 µl

Column Temperature: 30ºC

Gradient Program

Mobile Phase A: Water

Mobile Phase B: HPLC grade acetonitrile

Diluent: Water

Time (in minutes)	Flow (ml/min)	Mobile Phase A (%v/v)	Mobile Phase B (%v/v)
0	1.0	90	10
10	1.0	90	10
11	1.0	75	25

12	1.8	75	25
15	1.8	75	25
17	1.8	70	30
18	1.8	70	30
20	1.8	90	10
22	1.0	90	10

3.4 Procedure: Inject the reference solution five times and test the solutions. The test is not valid unless the column efficiency is not less than 2000 theoretical plates, the 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 Thiocolchicoside.

3.5 Acceptance criteria: NLT 90.0% and NMT 110.0% of the stated amount.

4. Uniformity of content: Determine by HPLC as described in the test for assay

4.1 Test Solution: Place one tablet in each of 10 separate 100 ml volumetric flasks. Dissolve in about 70 ml water with the aid of sonication to fully disperse and make up the volume to 100 ml with water. Stir for 10 minutes then filter through 0.25-micron filter paper.

4.2 Reference solution: Use the standard solution prepared in the assay.

4.3 Acceptance criteria: NLT 85.0% and NMT 115.0% of the stated amount.

5. Other tests: As per Pharmacopoeial requirements.