

DEPARTMENT OF DRUG ADMINISTRATION
NATIONAL MEDICINES LABORATORY
QUALITY AND METHOD VALIDATION SECTION

Cholecalciferol (Cholecalciferol in gel base) Soft Gelatin Capsules

Analytical Profile No.: Chole C 079/080/AP 117

Cholecalciferol Soft Gelatin Capsules contains not less than 90.0% of the stated amount of Cholecalciferol.

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. Assay: *Determine by liquid chromatography*

2.1 Diluent: Prepare a degassed mixture of 90 volume of methanol and 10 volume of acetonitrile.

2.2 Test solution: Collect solution of 20 capsules and mix well. Accurately weight 700 mg of solution and transfer into 100 ml volumetric flask. Add 70 ml of diluent and sonicate for 15 minutes with intermediate shaking, cool to room temperature and make up the volume with same solvent. Dilute 5 ml of this solution to 25 with same solvent and mix.

2.3 Reference solution: Accurately weigh and transfer about 30.0 mg of Cholecalciferol (40000IU/mg) working standard into a 100 ml volumetric flask. Add about 70 ml of diluent, sonicate to dissolve, cool to room temperature and make up the volume with same solvent. Dilute 5 ml of this solution to 100 ml with same solvent and mix.

2.4 Chromatographic system:

Column: C18 (75mm X 4.6mm, 3 μ)

Flow rate: 1.5ml/min

Wavelength: 265 nm

Injection volume: 20 μ l

Column Temperature: 30°C

Sample Temperature: 15°C

Mobile Phase: A mixture of 50 volume of Mobile Phase A and 50 volume of Mobile Phase B (Binary)

Mobile Phase A: Prepare a degassed mixture of 45 volume of methanol, 45 volume of acetonitrile and 10ml of water.

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Mobile Phase B: Acetonitrile

2.5 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 Cholecalciferol in Cholecalciferol Soft Gelatin Capsules.

3. Other tests: As per pharmacopoeial requirements.

Subject to approval from DAC