DEPARTMENT OF DRUG ADMINISTRATION
National Medicines Laboratory
ANALYTICAL METHOD VALIDATION COMMITTEE

Cholecalciferol Chewable Tablets

Analytical Profile No.: Chole 078/079/AP 105

Cholecalciferol Chewable Tablets contains not less than 90.0% and not more than 125.0% of the stated amount of Cholecalciferol.

Usual Strength: 60,000 IU

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. Uniformity of Content

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

2.1 Test Solution: Place a tablet in a 100ml volumetric flask, add 70ml of methanol, sonicate to disperse whole tablet with intermittent shaking. Cool, make up the volume to 100 ml with same solvent.

2.2 Reference Solution: Weigh accurately about 20 mg of Cholecalciferol WS in 100 ml volumetric flask. Add about 60 ml of methanol, sonicate to dissolve, cool and make volume to 100 ml with same solvent. Further dilute 2 ml of this solution to 20 ml with same solvent.

3. Assay: *Determine by liquid chromatography*

3.1 Test Solution: Weigh and powder 20 tablets. Weigh a quantity of powder about 2.0 g into 50 ml volumetric flask, add about 30 ml of methanol, sonicate, cool and make volume to 50 ml with same solvent.

3.2 Reference Solution: Weigh accurately about 50 mg of Cholecalciferol WS in 50 ml volumetric flask. Add about 30 ml of methanol, sonicate to dissolve, cool and make volume to 100 ml with same solvent. Further dilute 5 ml of this solution to 25ml with same solvent.

3.3 Chromatographic system:

- **Column:** C18, (250 x 4.6 mm), 5 µ particle size

- **Flow rate:** 1.0 ml/min
- **Wavelength:** 265 nm
- **Column Oven Temperature:** 30 ºC
- **Injection volume:** 20 µl
- **Detector:** UV
- **Mobile Phase:** Methanol

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 Cholecalciferol in the tablets.

4. Other tests: As per pharmacopoeial requirements.