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

Analytical profile of Fenbendazole Tablets

Analytical Profile No.: Fenben 080/81/AP 156

Fenbendazole Tablets contains not less than 90.0% and not more than 110.0% of the stated amount of Fenbendazole.

Usual Strength: 200 mg

1. Identification:

In the Assay, the principle peak in the chromatogram obtained with the test solution corresponds to the

2. Assay: *Determine by liquid chromatography*

2.1 Test solution: Weigh 20 tablets and calculate average weight. Weigh accurately the powder equivalent to 100 mg of Fenbendazole in 100 ml of dry volumetric flask, add 50 ml of 0.1M methanolic hydrochloric acid and sonicate for 30 minute. Make up the volume with methanol (65%) and filter. Dilute 5 ml of the solution to 50 ml with 0.1M hydrochloric acid in methanol (85%).

2.2 Reference solution: Weigh accurately 100 mg of Fenbendazole WS and transfer in 100 ml completely dried volumetric flask. Add 50 ml of 0.1M methanolic Hydrochloric acid, sonicate for 30 minutes to dissolve. Make up the volume with methanol (65%). Dilute 5 ml of the solution to 50 ml with 0.1M hydrochloric acid in methanol (85%).

2.3 Chromatographic system:

Column: C18 (4.6mmX 250-mm, 5µ)

Flow rate: 1.0 ml/min

Wavelength: 280 nm

Injection volume: 20 µl

Mobile Phase: 350 volumes of 0.5% w/v solution of sodium dihydrogen orthophosphate and 650 volumes of methanol containing 1.88 gm. of sodium hexane sulfonate. Adjust pH 3.5 with orthophosphoric acid.

2.4 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 Fenbendazole in Fenbendazole Tablets.

3. Other tests: As per Pharmacopoeial requirements.