

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

Analytical Profile of Albendazole and Praziquantel Tablet

Analytical Profile No.: Alben Prazi 082/083 AP 184

Albendazole and Praziquantel Tablet contains not less than 90.0% and not more than 110.0% of the stated amount of Albendazole and Praziquantel.

Usual Strength: Albendazole 300 mg and Praziquantel 50 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. Assay: *Determine by liquid chromatography*

2.1 Test solution: Weigh and powder 20 tablets. Disperse the quantity of powder containing 100 mg of Albendazole and 16 mg of Praziquantel in 100 ml volumetric flask and make up the volume to 100 ml with methanol. Dilute 5 ml of the resulting solution to 50 ml with methanol.

2.2 Reference solution: Dissolve an accurately weighed quantity of 100 mg of Albendazole RS and 16 mg of Praziquantel RS in 100 ml volumetric flask and make up the volume to 100 ml with methanol. Dilute 5 ml of the resulting solution to 50 ml with methanol.

2.3 Chromatographic system:

Column: C18 (4.6mm X 250 mm, 5µm)

Wavelength: 225 nm

Injection volume: 10 µl

Flow Rate: 1.2 ml/minute

Column Temperature: 28°C

Mobile phase: A mixture of Acetonitrile and Water in the ratio of 60:40, pH adjusted to 3.0 with the aid of orthophosphoric acid.

2.4 Procedure: Inject the reference solution five times, followed by the test solution. The test is not valid unless the resolution between the peaks due to Albendazole and Praziquantel is not less than 4.0, the column efficiency is not less than 2000 theoretical plates, the tailing factor is not more than 2.0, and the

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relative standard deviation for replicate injections is not more than 2.0%. Measure the peak responses. Calculate the content of Albendazole and Praziquantel.

3. Other tests: As per Pharmacopoeial requirements.

Subject to approval from DAC