

Government of Nepal
Ministry of Health and Food Safety
Department of Drug Administration
National Medicines Laboratory
Quality and Method Validation Section
Analytical Profile of Tilmicosin Oral Solution

Analytical Profile No.: Tilmi 082/083 AP 185

Tilmicosin Oral Solution contains not less than 90.0% and not more than 110.0% of the stated amount of Tilmicosin.

Usual Strength: 30% w/v

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: Shake well and weigh sample equivalent to 50 mg of Tilmicosin and transfer into 50 ml volumetric flask. Add about 30 ml of acetonitrile and sonicate, cool at room temperature and make up the volume to 50 ml with same solvent. Dilute 2 ml of above solution to 100 ml with mobile phase.

2.2 Reference solution: Weigh accurately about 10 mg of Tilmicosin RS and transfer into a 50 ml volumetric flask. Add about 30 ml of acetonitrile and sonicate, cool at room temperature and make up the volume to 50 ml with same solvent. Dilute 5 ml of above solution to 50 ml with mobile phase.

2.3 Chromatographic system:

Column: C18 (4.6mmX 250-mm, 5µm)

Wavelength: UV-280 nm

Injection volume: 50 µl

Flow Rate: 0.8 ml/minute

Column Temperature: 30°C

Mobile phase: Acetonitrile: 0.1 M orthophosphoric acid (60:40, V/V). Adjust pH of the mobile phase to 3.0 with 2M NaOH.

2.4 Procedure: Inject the reference solution five times, followed by the test solution. The test is not valid unless the column efficiency is not less than 1500 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 Tilmicosin.

3. Other tests: As per Pharmacopoeial requirements.