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

Tiamulin Hydrogen Fumarate Oral Powder [Veterinary]

Analytical Profile No.: Tiamu 079/080/AP 133

Tiamulin Hydrogen Fumarate oral powder contains contains not less than 90.0% and not more than 110.0% of the stated amount of Tiamulin Hydrogen Fumarate.

Usual Strength: Each gm contains

Tiamulin Hydrogen Fumarate 800 mg

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 certified reference solution.

2. Assay: *Determine by liquid chromatography*

2.1 Test solution: Weigh accurately 50.0 mg of Tiamulin Hydrogen Fumarate WS and transfer to 50 ml volumetric flask and add 20 ml of mobile phase and sonicate for 10 minutes and make up the volume with mobile phase. Then, filter the solution through 0.22 micron filter paper.

2.2 Reference solution: Weigh accurately 50.0 mg of Tiamulin Hydrogen Fumarate and transfer to 50 ml volumetric flask and add 20 ml of mobile phase and sonicate for 10 minutes and make up the volume with mobile phase. Then, filter the solution through 0.22 micron filter paper.

2.3 Chromatographic system:

Column: C18 (4.6mmX 150-mm, 5µ)

Flow rate: 1.0 ml/min

Wavelength: 212 nm

Injection volume: 50 µl

Column Temperature: 35ºC

Mobile Phase: Methanol: Acetonitrile: 1% ammonium carbonate solution (50:25:25)

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 Tiamulin Hydrogen Fumarate in Tiamulin Hydrogen Fumarate oral powder.

5. Other tests: As per pharmacopoeial requirements.