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

Analytical Profile of Oxyclozanide & Levamisole Hydrochloride Bolus

Analytical Profile No.: Oxyclo Levami B 081/082/AP 167

Oxyclozanide & Levamisole Hydrochloride Bolus contain not less than 90.0% and not more than 110.0% of the stated amount of Oxyclozanide and Levamisole Hydrochloride.

Usual Strength: 150 mg (Oxyclozanide) and 75 mg (Levamisole Hydrochloride)

1. Identification:

In the Assay, the principal peaks in the chromatogram obtained with the test solution correspond to the peaks in the chromatogram obtained with the reference solution.

2. Assay: *Determine by liquid chromatography*

2.1 Diluent: Water: Methanol (10:50)

2.2 Test solution: Weigh the content of 20 bolus and calculate the average weight. Weigh the powder equivalent to 100 mg of Oxyclozanide in a 100 ml dry volumetric flask, add 70 ml of diluent, and sonicate for 10-20 minutes to dissolve. Cool the sample solution to room temperature make up the volume with the same diluent and mix. Dilute 5 ml of the resulting solution to 50 ml with mobile phase, and mix.

2.3 Reference solution: Weigh accurately about 50.0 mg of Levamisole Hydrochloride WS and 100 mg of Oxyclozanide WS. Then, transfer them to a 100 ml completely dried volumetric flask. Dissolve in 70 ml of diluent with the aid of ultrasound and make up the volume with the diluent. Dilute 5 ml of the resulting solution to 50 ml with mobile phase and mix

2.4 Chromatographic system:

Column: C18 (4.6mmX 250-mm, 5µm)

Wavelength: 230 nm

Injection volume: 10 µl

Flow Rate: 1.0 ml/minute

Column Temperature: 35ºC

Mobile phase: A mixture of 30 volumes of buffer, 40 volumes of Acetonitrile, and 30 volumes of Methanol.

Buffer: 0.05 M of phosphate buffer prepared by dissolving 6.8 g of potassium dihydrogen orthophosphate in 1000 ml of water pH adjusted to 3.5 with dilute orthophosphoric acid.

2.5 Procedure: Inject the reference solution five times and test the solutions. The test is not valid unless the column efficiency is not less than 2000 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 Oxyclozanide and Levamisole Hydrochloride.

3. Other tests: As per Pharmacopoeial requirements.