

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

Analytical profile of Bromhexine HCl Oral Solution [Veterinary]

Analytical Profile No.: Brom 079/80/ AP 132

Bromhexine Hydrochloride oral solution contains not less than 90.0% and not more than 110.0% of the stated amount of Bromhexine Hydrochloride.

Usual Strength: 10 mg/ml

1. Identification:

The light absorbance in the range from 200 nm to 800 nm of the solution obtained in the assay for Bromhexine HCl exhibits maximum absorbance at about 317 nm.

2. Assay: *Determine by UV Spectrometry*

Diluent: 0.1 M Methanolic Hydrochloric acid. [Dissolve 8.5 ml of concentrated hydrochloric acid in 1000 ml of methanol].

2.1 Test solution: Weigh accurately 2.0 gm of solution (i.e., equivalent to 20 mg of Bromhexine hydrochloride) and transfer to 50 ml volumetric flask and add 20 ml of diluent and shake for 10 minutes and make up the volume with same solvent. Filter the solution through what man filter paper no 4; further dilute 5 ml to 25 ml with the same solvent.

2.2 Reference solution: : Weigh accurately 40.0 mg of Bromhexine hydrochloride WS and transfer to 50 ml volumetric flask and add 20 ml of diluent and shake for 10 minutes and make up the volume with diluent. Further dilute 5 ml to 50 ml with same solvent.

2.3 Procedure: Measure the absorbance of standard and sample at 317 nm using diluent as blank. Calculate the percentage content of bromhexine HCl in the oral solution.

3. Other tests: As per pharmacopoeial requirements.