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

Analytical profile of Tetrabenazine Tablet

Analytical Profile No.: Tetrab 080/81/AP 152

Tetrabenazine Tablets contains not less than 90.0% and not more than 110.0% of the stated amount of Tetrabenazine.

Usual Strength: 25 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. Dissolution: *Determine by UV/VIS Spectroscopy.*

2.1 Dissolution Parameters:

Apparatus: Basket

Medium: 900 ml of 0.1N Hydrochloric Acid

Speed & Time: 100 rpm & 30 minutes

Withdraw a suitable volume of the medium and filter.

2.2 Test Solution: Use the filtrate.

2.3 Reference Solution: Weigh accurately 25 mg of Tetrabenazine WS and transfer in 100 ml completely dried volumetric flask, add 60 ml of methanol and dissolve it. Dilute to volume with methanol and mix. Dilute 5 ml of the solution to 50 ml with dissolution media and mix.

2.4 Procedure: Measure the absorbance of reference and test solution at 282 nm using UV/VIS Spectrophotometer. Use dissolution media as blank.

Calculate the percent release of Tetrabenazine.

2.5 Limit: NLT 70 % (Q) of stated amount.

3. Assay: *Determine by liquid chromatography*

3.1 Test solution: Weigh and grind 20 tablets and mix thoroughly. Weigh accurately a quantity of powder equivalent to 25 mg of Tetrabenazine and transfer to 25 ml volumetric flask. First add few ml of water and then add 15-20 ml of acetonitrile. Sonicate for 15 minutes. Cool to room temperature, make up the volume with acetonitrile. Centrifuge the solution. Discard the first portion of filtrate. Transfer 5 ml of this solution to 20 ml volumetric flask and make up the volume with acetonitrile.

3.2 Reference solution: Weigh accurately 25 mg of Tetrabenazine WS and transfer in 100 ml completely dried volumetric flask, dissolve and dilute to volume with acetonitrile.

3.3 Chromatographic system:

Column: C18 (4.6mmX 250-mm, 5µ)

Flow rate: 1.0 ml/min

Wavelength: 282 nm

Injection volume: 20 µl

Mobile Phase: A mixture of 50 volumes of buffer and 50 volumes Acetonitrile.

Buffer: Dissolve 1.32 gm. of Di ammonium hydrogen phosphate in 1000 ml water and mix well. Adjust the pH to 6.5±0.05 with dilute orthophosphoric acid.

3.4 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 Tetrabenazine in Tetrabenazine Tablets.

4. Other tests: As per Pharmacopoeial requirements.