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

Analytical profile of Tapentadol Tablets

Analytical Profile No.: Tap T 075/076/AP 056

Tapentadol Tablets contain not less than 90.0% & not more than 110.0% of the stated amount of Tapentadol.

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 reference solution.

2. Dissolution: *Determine by UV Spectroscopy*

2.1 Dissolution Parameters:

Apparatus: Basket

Medium: 900 ml of **:** 0.1 M Hydrochloric acid

Speed and Time: 75 rpm and 60 minutes

Withdraw a suitable volume of the medium and filter.

Wavelength : 272 nm

2.2 Test Solution: Use the filtrate.

2.3 Reference Solution: Weigh accurately about 55 mg of Tapentadol hydrochloride WS and transfer into 100 ml volumetric flask. Dissolve with dissolution medium and make up the volume to 100 ml with dissolution medium. Dilute 5 ml of the solution to 50 ml with dissolution medium.

2.4 Procedure: Measure the absorbance of sample and standard solution at 272 nm using UV/VIS Spectrophotometer. Use dissolution medium as blank. Calculate the content of release of tapentadol

2.5 Limit: NLT 80.0 % (D) of the stated amount

3. Assay: *Determine by Liquid Chromatography*

3.1 Test Solution: Weigh individually 20 tablets and crush them to fine powder. Weigh powder eq. to 50 mg of Tapentadol and transfer into 100 ml volumetric flask. Add about 70 ml mobile phase and dissolve by sonicating for about 10 minutes, cool at room temperature and make up

the volume to 100 ml with same solvent. Dilute 10 ml of this solution to 25 ml with mobile phase.

3.2 Reference Solution: Weigh accurately about 50 mg of Tapentadol hydrochloride WS and transfer into 100 ml volumetric flask. Dissolve with mobile phase by sonicating for about 10 minutes and make up the volume to 100 ml with mobile phase. Dilute 10 ml of the resulting solution to 25 ml with mobile phase.

3.3 Chromatographic system

Column: Octylsilane (C8), (150 x 4.6 mm), 5 µm

Flow rate: 2.0 ml/min

Wavelength: 215 nm

Injection volume: 20 µl

Column temperature: Ambient

Mobile phase: Buffer:Methanol (80:20)

Buffer solution: Dissolve 2.72 gm of potassium dihydrogen orthophosphate in 1000 ml of water, add 2 ml of triethylamine, and mix. Adjust the pH to 2.5 with 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 Tapentadol in Tapentadol Tablets.

4. Other tests: As per pharmacopoeial requirements.