

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

Analytical profile of Tapentadol HCl Capsules

Analytical Profile No.: Tap 074/075/ AP 020

Tapentadol HCl Capsules contains not less than 90.0% and not more than 110.0% of the stated amount of Tapentadol HCl.

Usual Strength: 100 mg

1. Identification:

In the assay, the principle peak in the chromatogram obtained with the sample solution should correspond to the peak in the chromatogram obtained with the reference solution.

2. Dissolution:

2.1 Dissolution Parameters:

Apparatus: Basket

Medium: 900ml of 0.1 N HCl

Speed and Time: 75 rpm and 60 minutes

Withdraw a suitable volume of the medium and filter.

2.2 Test Solution: Dilute 10 ml of the filtrate to 20 ml with dissolution medium.

2.3 Empty shell solution: To one of the dissolution vessel, add an empty capsule shell, proceed the test similar to the sample, filter and collect the filtrate. Dilute 10 ml of this solution to 20 ml with dissolution medium.

2.4 Reference Solution: Weigh accurately about 27.5 mg of Tapentadol HCl RS 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 filtrate to 25 ml with dissolution medium.

2.5 Procedure: Measure the absorbance at 272.0 nm using dissolution medium as blank. Subtract the absorbance value of empty capsule shell from the test sample solution. Calculate the percent release of Tapentadol HCl.

2.6 Limit: Not Less than 80 % D of the stated amount.

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3. Assay:

3.1 Test Solution: Weigh individually 20 capsules & remove the content of each capsule. Mix the content of all the capsules. Weigh powder eq. to 50 mg of Tapentadol HCl and transfer into 50 ml volumetric flask. Add about 70 ml of mobile phase and dissolve by sonicating for about 10 minutes. Filter the resulting solution and dilute 5 ml of the filtrate to 25 ml with mobile phase.

3.2 Reference Solution: Weigh accurately about 25 mg of Tapentadol HCl RS and transfer into 25 ml volumetric flask. Dissolve with mobile phase and make up the volume to 25 ml with mobile phase. Dilute 5 ml of the resulting solution to 25 ml with mobile phase.

3.3 Chromatographic system

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

Flow rate: 1.0 ml/min

Detector: UV Detector

Wavelength: 215 nm

Injection volume: 20 µl

Oven temperature: 40 °C

Mobile phase: 75 volume of Buffer and 25 volume of methanol

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 HCl.

4. Other tests: As per pharmacopoeial requirements.