ANALYTICAL METHOD VALIDATION COMMITTEE FOR NON PHARMACOPOEIAL PRODUCT
DEPARTMENT OF DRUG ADMINISTRATION
National Medicines Laboratory

Tapentadol Capsules

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

Tapentadol Capsules contain not less than 90 percent and not more than 110 percent 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

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.

2.2 Test Solution:

Dilute 10 ml of filtrate to 20 ml with dissolution medium.

2.3 Reference Solution:

Weigh accurately about 27.5 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 this solution to 25 ml with dissolution medium.

2.4 Procedure:

Measure the absorbance at 272.0 nm using dissolution medium as blank.

Calculate the content of % release of tapentadol.

2.6 Limit:

D. Not less than 80 percent of the stated amount of tapentadol.

3. Assay: Determine by liquid chromatography

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 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 hydrochloride WS 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: C8, (150*4.6 mm), 5 µm

Flow rate: 1.0 ml/min

Wavelength: 215 nm

Injection volume: 20 µl

Column temperature: 40 °C

Detector: UV

Mobile phase:

A mixture of 75 volumes of Buffer and 25 volumes 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 dilute orthophosphoric acid.

3.4 Procedure: Inject the reference solution. 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 in not more than 2.0%.

Inject the reference solution and the test solution.

Calculate the content of Tapentadol in the capsules.

4. Other tests: As per pharmacopoeial requirements.