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

Tapentadol Tablets

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

TapentadolTabletcontainsnot less than 90 % and not more than 110 % of the stated amount of Tapentadol.

1. Identification:

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

2. Dissolution: Determine by UV Spectroscopy

2.1 Dissolution Parameter

Apparatus:	Basket
Medium:	900ml 0.1 M Hydrochloric acid
Speed and Time:	75 rpm and 60 minutes
Temperature:	37+/-0.5℃

2.2Test Solution:

Withdraw a suitable volume of the sample after 60 minutes.

2.3 ReferenceSolution:

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 dissolution medium as blank. Calculate the content of release of Tapentadol in each tablet.

2.5 Limit:

D. Not less than 80% of the stated amount

3. Assay: Determine by Liquid Chromatography

3.1Solvent Mixture:

Same as Mobile Phase.

3.2TestSolution:

Weigh individually 20 tablets and crush them to fine powder. Weighpowder eq. to 50 mg of Tapentadoland 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. Filter the resulting solution through 0.2 µm membrane filter paper.

3.3 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. Filter the resulting solution through 0.2 µm membrane filter paper.

3.4 Chromatographic system

Column:	C8, (150 x 4.6 mm), 5 µm
Flow rate:	2.0 ml/min
Injection volume:	20 µl
Wavelength:	215nm
Column temperature:	Ambient
Detector:	UV

Mobile phase

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.

Mobile phase: Buffer:Methanol (80:20)

3.5Procedure:

Inject 20 µl of standard and sample solution separately and obtain the respective chromatogram. In the chromatogram obtained from the standard preparation, thecolumn efficiency determined from the major peak should not be less than 2000 theoreticalplates, the tailing factor should be not more than 2.0 and the relative standard deviation ofreplicate injections should not be more than 2.0 %.

Calculate the content of Tapentadol per tablet.

4. Other tests: As per pharmacopoeial requirement