DEPARTMENT OF DRUG ADMINISTRATION

NATIONAL MEDICINES LABORATORY

QUALITY AND METHOD VALIDATION SECTION

Tramadol Hydrochloride Injection

Analytical Profile No.: Trama 078/079/AP 104

Tramadol Hydrochloride Injection contains not less than 90.0% and not more than 110.0% of the stated amount of Tramadol Hydrochloride.

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. pH: As per manufacturer's specification

3. Particulate Matter: As per IP latest edition

4. Sterility: As per IP latest edition

5. Bacterial Endotoxin Test: As per IP latest edition.

Limit: NMT 0.875 EU/mg

6. Assay: *Determine by liquid chromatography*

6.1 Test solution: Dilute 2 ml of injection sample to 100 ml volumetric flask witb mobile phase. Further dilute 5 ml of this solution to 50 ml with same solvent.

6.2 Reference solution: Weigh accurately about 50 mg of Tramadol HCl WS and transfer into 50 ml volumetric flask. Dissolve in mobile phase by sonication and make up the volume with same solvent. Further dilute 5 ml of this solution to 25 ml with same solvent.

6.3 Chromatographic system:

- **Column:** C18, (250 x 4.6 mm), 5 µ particle size
- **Flow rate:** 1.0 ml/min
- **Wavelength:** 270 nm
- **Injection volume:** 20 µl
- **Detector:** UV

- **Mobile Phase:** Add 1.4 m l of trifluoroacetic acid in 705 ml of water, mix and add 295 ml of acetonitrile

6.4 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 Tramadol Hydrochloride in Injection.

7. Other tests: As per pharmacopoeial requirements.