DEPARTMENT OF DRUG ADMINISTRATION

NATIONAL MEDICINES LABORATORY

ANALYTICAL METHOD VALIDATION COMMITTEE

Oxyclozanide and Levamisole HCl Suspension

Analytical Profile No.: Oxyclo Levami 079/080/AP 127

Oxyclozanide and Levamisole HCl Suspension contains not less than 90.0% and not more than 110.0% of the stated amount of Oxyclozanide and Levamisole HCl.

Usual Strength: Each 100 ml contains:

Oxyclozanide 3 gm

Levamisole HCl 3 gm

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. Wt/ml: As per manufacturer's specification

4. Microbial Limit Test: As per IP latest edition

5. Absence of specified Microorganism: As per IP latest edition

6. Assay: *Determine by liquid chromatography*

6.1 Diluent: Water: Methanol: (10:50)

6.2 Test solution: Weigh accurately sample equivalent to 75 mg of either Oxyclonazide or Levamisole to 100 ml volumetric flask, add about 50 ml of diluent, sonicate to dissolve, cool to room temperature and make up the volume with same solvent and further shake for about 10 minutes with magnetic stirrer. Dilute 5 ml of the solution to 50ml with mobile phase.

6.3 Reference solution: Weigh accurately 75 mg of Oxyclonazide WS and 75 mg of Levamisole WS in 100ml of volumetric flask, add about 50 ml of diluent, sonicate, cool to room temperature and make up the volume with same solvent. Dilute 5 ml of this solution to 50 ml with mobile phase.

6.4 Chromatographic system:

- **Column:** C18 (4.6mmX 250mm, 5µ)
- **Flow rate:** 1.0 ml/min
- **Injection volume:** 10 µl

- **Detector:** UV
- **Wavelength:** 230 nm
- **Column temperature:** 35°C
- **Mobile Phase:** A mixture of 30 volume of buffer, 40 volume of Acetonitrile and 30 volume of Methanol

  Buffer: 0.05 M phosphate buffer prepared by dissolving 6.8 gm of Potassium Dihydrogen orthophosphate in 1000 ml of water pH adjusted to 3.5 with dilute orthophosphoric acid.

6.5 Procedure: Inject the reference solution five times. 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%. Inject the test solution. Measure the peak responses. Calculate the content of Oxyclozanide and Levamisole HCl in suspension.

7. Other tests: As per pharmacopoeial requirements.