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

Sucralfate and Oxetacaine Suspension

Analytical Profile No.: Oxe Sucral 079/080/AP 121

Sucralfate and Oxetacaine Suspension contains not less than 90.0% and not more than 110.0% of the stated amount of Sucralfate and Oxetacaine.

Usual Strength: Each 5 ml contains:

Sucralfate 500 mg

Oxetacaine 10 mg

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 Assay of Sucralfate

6.1.1 Test solution: Weigh accurately suspension equivalent to about 500 mg of Sucralfate in 25 ml volumetric flask. Add about 10 ml of 1,1 mixture of 2M sulphuric cid and 2,2M sodium hydroxide, sonicate, keeping the temperature below 30°. Make up the volume to 25 ml with 0.1M sodium hydroxide.

6.1.2 Reference solution: Weigh accurately 450 mg of Sucralfate WS in 25 ml volumetric flask. Add about 10 ml of 1:1 mixture of 2M Sulphuric acid and 2.2M Sodium hydroxide, sonicate to dissolve, keeping the temperature below 30°C. Make up the volume to 25 ml with 0.1M sodium hydroxide.

6.1.3 Chromatographic system:

- **Column:** Aminopropylsilane chemically bonded to porous silica (5µm) column of 25 cm x 4.6mm

- **Flow rate:** 1.0 ml/min
- **Injection volume:** 20 µl
- **Detector:** Refractive index
- **Detector temperature:** 30°C
- **Column temperature:** 40°C
- **Mobile Phase:** A buffer solution prepared by dissolving 132 gm ammonium sulphate in 900 ml of water and dilute to 1000 ml with water and adjust to pH 3.5 with orthophosphoric acid.

6.1.4 Procedure: Inject the reference solution five times. The test is not valid unless the column efficiency is not less than 400 theoretical plates, tailing factor is not more than 4.0 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 Sucralfate in suspension.

6.2 Assay of Oxetacaine

6.2.1 Test solution: Weigh accurately suspension equivalent to about 5 mg of Oxetacaine in 100 ml volumetric flask. Add about 60ml of mobile phase, sonicate and finally make the volume up to the mark with same solvent. Further dilute 5 ml of this solution to 25 ml with same solvent.

6.2.2 Reference solution: Weight accurately 25 mg of Oxetacaine WS in 100 ml volumetric flask. Add about 60ml of mobile phase, sonicate to dissolve and finally make the volume up to the mark with same solvent. Further dilute 2 ml of this solution to 50 ml with same solvent.

6.2.3 Chromatographic system:

- **Column:** C18 (5µm) column of 25 cm x 4.6mm
- **Flow rate:** 1.0 ml/min
- **Wavelength:** 220 nm
- **Injection volume:** 50 µl
- **Detector:** UV
- **Mobile Phase:** A mixture of 78 volumes of Acetonitrile and 22 volumes of buffer.
    - **Buffer:** 0.01M KH_2PO_4 (pH 6.5 ± 0.1 with Orthophosphoric Acid)

6.2.4 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 Oxetacaine in suspension.

7. Other tests: As per pharmacopoeial requirements.