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

Analytical profile of Sucralfate Suspension

Analytical Profile No.: Sucral 076/077/AP 057

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

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. Total aerobic microbial count: As per Indian Pharmacopoeia (latest edition)

5. Test for specific microorganism (E. Coli & Salmonella): As per Indian Pharmacopoeia (latest edition)

6. Neutralizing Capacity:

Weigh accurately 2.6 g of suspension in 250 ml stoppered conical flask. Add about 100 ml of 0.1 M Hydrochloric acid, which is previously heated and maintained at 37^0C. The conical flask is then placed in a magnetic stirrer maintained at 37^0C, stirring continuously for 1 hour. The solution is then cooled to room temperature and 20 ml of the resulting solution is transferred to another conical flask. Add about 30 ml of water and titrate the resulting solution with 0.1 M Sodium hydroxide to a pH of 3.5.

Carry out blank titration using a mixture of 30 ml water and 20 ml of 0.1 M hydrochloric acid.

Calculate mEq of acid consumed per gram of Sucralfate suspension taken by the formula.

$$= \frac{5 * Molarity\ of\ sodium\ hydroxide * (Volume\ consumed\ by\ blank - Volume\ consumed\ by\ spl)}{Weight\ of\ sample\ (in\ g) * 0.5} * wt\ per\ ml * 5$$

Limit: NLT 12 mEq of acid is consumed

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7. Assay: *Determine by Liquid Chromatography*

7.1 Test Solution: Weigh accurately 5 g of Sucralfate suspension in 25 ml volumetric flask. About 10 ml of mixture of 2M Sulphuric acid and 2.2M Sodium hydroxide is added and sonicated for 5 minutes, keeping the temperature of the mixture below 30^0C. The volume of the solution is made up to 25 ml with 0.1M Sodium hydroxide. Centrifuge the resulting solution and filter the supernatant liquid through nylon filter of 0.2 µm porosity.

7.2 Reference Solution: Weigh accurately about 450 mg of Sucralfate WS in a 100 ml beaker. About 10 ml of a mixture of 2M Sulphuric acid and 2.2M Sodium hydroxide is added and sonicated for 5 minutes, keeping the temperature of the mixture below 30^0C. The solution is maintained at pH 2.0 with 0.1M NaOH solution. The solution is transferred to 25 ml volumetric flask and make up the volume to 25 ml with water. Filter the resulting solution through nylon filter of 0.2 µm porosity.

6.3 Chromatographic system

- **Column:** Aminopropylsilane chemically bonded to porous silica 5 µm, (250 x 4.6 mm) column
- **Flow rate:** 1.0 ml/min
- **Detector:** Refractive Index Detector
- **Injection volume:** 80 µl
- **Detector & Column temperature**: 30^0 C
- **Mobile Phase:** A buffer solution prepared by mixing 35 g of ammonium sulphate in 900 ml water and dilute to 1000 ml with water and adjust to pH 3.5 with orthophosphoric acid.

7.4 System Suitability: 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 response. Calculate the content of Sucralfate in the suspension.

7. Other tests: As per pharmacopoeial requirement.