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

Analytical profile of Cefoperazone & Sulbactam for injection

Analytical Profile No.: CEF SUL 075/076/AP 043

Cefoperazone & Sulbactam for injection contains not less than 90.0% & not more than 110.0% of the stated amount of Cefoperazone & Sulbactam.

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 (By Light Obscuration Particle Counter): As per Indian Pharmacopoeia (latest edition)

4. Bacterial Endotoxin Test: As per Indian Pharmacopoeia (latest edition)

Limit: Not more than 0.20 USP EU/mg of Cefoperazone

5. Sterility test: As per Indian Pharmacopoeia (latest edition)

6. Assay:

6.1 Test Solution: Weigh twenty units taken randomly, and record their fill weight. Empty the content of the entire ten containers and mix all the content and keep the content in the air tight container. Weigh the sample equivalent to 40 mg of Cefoperazone and transfer into 20 ml volumetric flask. Dissolve it with mobile phase and make up the volume with same solvent. Dilute 5 ml of the resulting solution to 25 ml with mobile phase.

6.2 Reference Solution: Weigh accurately about 42 mg of Cefoperazone Sodium WS and 44 mg of Sulbactam Sodium WS in 20 ml volumetric flask. Dissolve with mobile phase and make up the volume with same solvent. Dilute 5 ml of the resulting solution to 25 ml with mobile phase.

6.3 Chromatographic System

Column: Octadecylsilane (C18), (150*4.6 mm), 5 µm

Flow rate: 0.8 ml/min

Wavelength: 230nm

Injection volume: 20 µl

Detector: UV

Mobile Phase: A mixture of 70 volume of Buffer & 30 volume of Acetonitrile

Buffer: Transfer 3.3 ml of Tetrabutyl ammonium hydroxide (40% in water) in 1000ml of water and adjust the pH to 6.6 ± 0.05 with orthophosphoric acid.

6.4 Procedure:

Inject the reference solution five/six 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, the relative standard deviation for replicate injections is not more than 2.0% and the resolution between sulbactam and Cefoperazone is not less than 5. Measure the peak responses. Calculate the content of Cefoperazone & Sulbactam.

7. Other tests: As per pharmacopoeial requirements.