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

Analytical profile of Cefixime and Potassium Clavulanate Powder for Oral

Analytical Profile No.: Cefix Clavu 080/81/AP 139

Cefixime and Potassium Clavulanate Powder for Oral Suspension contains not less than 90.0% and not more than 120.0% of the stated amount of Cefixime and Potassium Clavulanate.

Cefixime and Potassium Clavulanate Powder for Oral Suspension contains not less than 90.0% of the stated amount of Cefixime and Potassium Clavulanate after 3 days of reconstitution when stored in refrigerator.

Usual Strength: Each 5 ml of reconstituted suspension contains

Cefixime Trihydrate USP eqv. to Anhydrous Cefixime 50 mg

Potassium Clavulanate Diluted IP eqv. to Clavulanic Acid 31.25 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. Assay: *Determine by liquid chromatography*

2.1 Solvent Mixture: Dissolve 7.10 gm of disodium hydrogen phosphate in 500 ml of water and adjust pH 1.0 with potassium dihydrogen phosphate solution

2.2 Test solution:

Slowly add distilled water up to the ring make on the bottle. Shake vigorously. Adjust the volume up to the make by adding more water, if necessary. Weigh accurately as near as about 2.7 gm of the suspension in a tared 50 ml volumetric flask. Add about 20 ml of solvent mixture sonicate for about 10 minutes and make up the volume with diluent. Shake well and filter. Dilute 5 ml of the solution to 100 ml with solvent mixture and mix well.

2.3 Reference solution:

Weigh accurately about 28 mg Cefixime Trihydrate WS and 37 mg Potassium Clavulanate WS and transfer to 50 ml volumetric flask. Add about 40 ml of solvent mixture and sonicate for 20

minutes, make up the volume with solvent mixture, shake well and filter. Dilute 5 ml of the solution to 100 ml with diluent and shake well.

2.4 Chromatographic conditions:

Column: C18, 25 cm x 4.6 mm, 5µm column or equivalent.

Detector: UV

Detector wavelength: 220 nm

Flow rate: 1.0 ml per minute

Injection volume: 20 µL

Column temperature: Ambient

Mobile phase: Dissolve 3.408 gm. of disodium hydrogen phosphate in 800 ml water. Add 200 ml methanol. Adjust pH 5.5 with dilute orthophosphoric acid.

2.5 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 percentage of Cefixime and Clavulanic acid in the reconstituted suspension.

Note: While calculating the content of Clavulanic acid note that 2 mg of Potassium clavulanate diluted is equivalent to 1 mg of Potassium Clavulanate. So divide the content by 2.

3. **Other tests:** As per Pharmacopoeial Requirement