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

# Analytical Profile of Bempedoic Acid Tablets

**Analytical Profile No.:** Bempe 082/083/AP 182

Bempedoic Acid Tablets contain not less than 90.0% and not more than 110.0% of the stated amount of Bempedoic Acid.

Usual Strength: 180 mg

**1. Identification:**

In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.

**2. Dissolution:** *Determine by liquid chromatography*

**2.1 Dissolution Parameters:**

**Apparatus:** Paddle

**Medium:** 900 ml of 0.05 M Phosphate Buffer pH 6.6 (Dissolve 6.80 g of potassium dihydrogen phosphate in 1000 ml of water and adjust the pH to 6.6 with 1 M Sodium hydroxide)

**Speed and Time:** 50 rpm and 30 minutes

Withdraw a suitable volume of the medium and filter.

**2.2 Test Solution:** Use the filtrate

**2.3 Reference Solution:** Weigh 20 mg of Bempedoic acid RS accurately and transfer into a 100 mL volumetric flask. Add 70 ml of dissolution medium, and sonicate for 5 minutes to dissolve. Make up the volume with the dissolution medium. (200 ppm)

**2.4 Procedure:** Use the chromatographic system as described in the Assay. Inject the reference solution and the test solution. Calculate the percent release of Bempedoic acid.

**2.5 Limit:** NLT 80 % (Q) of the stated amount of Bempedoic acid.

**3. Assay:** *Determine by liquid chromatography*

**3.1 Diluent:** Same as Mobile Phase

**3.2 Test solution:** Weigh the contents of 20 tablets and calculate the average weight. Weigh the powder equivalent to 180 mg of Bempedoic acid in 200 ml volumetric flask, add 150 ml of diluent, and sonicate for 15 minutes to dissolve with intermittent shaking. Cool the sample solution to room temperature, then

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make up the volume with diluent and mix. Dilute 3 ml of the resulting solution to 10 ml with diluent. (270 ppm)

**3.3 Reference solution:** Weigh accurately about 27 mg of Bempedoic acid WS and transfer to a 100 ml volumetric flask. Dissolve in 70 ml of diluent with the aid of sonication. Cool and make up to the volume with diluent. (270 ppm)

**3.4 Chromatographic system:**

**Column:** Phenyl, 150 x 4.6mm, 3.5 µm

**Flow rate:** 1.0 ml/min

**Wavelength:** 230 nm

**Injection volume:** 100 µl

**Column Temperature:** Ambient

**Mobile phase:** A mixture of 50 volume of Buffer and 50 volume of Acetonitrile

**Buffer:** 0.1% Formic Acid

**3.5 Procedure:** Inject the reference solution five times and test the solutions. The test is not valid unless the column efficiency is not less than 2000 theoretical plates, the 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 content of Bempedoic Acid.

**4. Other tests:** As per Pharmacopoeial requirements.

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