DEPARTMENT OF DRUG ADMINISTRATION
National Medicines Laboratory
ANALYTICAL METHOD VALIDATION COMMITTEE

Empagliflozin Tablets

Analytical Profile No.: EMPA 075/076/AP044

Empagliflozin Tablet contains not less than 95.0 % and not more than 105.0 % of the stated amount of Empagliflozin.

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. Dissolution:

2.1 Dissolution Parameters:

Apparatus: Paddle

Medium: 900ml of pH 6.8 phosphate buffer

Speed and Time: 75 rpm and 30 minutes

Withdraw a suitable volume of the medium and filter.

Determine by liquid chromatography.

2.2 Test Solution: Dilute the filtrate, if necessary, with dissolution medium.

2.3 Reference Solution: Weigh accurately about 25 mg Empagliflozin WS in 100 ml volumetric flask. Add 5 ml methanol, sonicate to dissolve and make up the volume to 100 ml with dissolution medium. Further dilute 2 ml of this solution to 50 ml with dissolution medium.

2.4 Procedure: Use the chromatographic system as described in the Assay.

Inject the reference solution and the test solution. Measure the peak responses and calculate the % release of the drug.

2.5 Limit:

D. NLT 80.0 % of the stated amount

3. Uniformity of Content

Determine by liquid chromatography, as described in the Assay, using the following solution as the test solution.

Test Solution: Place a tablet in a 50ml volumetric flask, add 30ml of solvent mixture, sonicate for 15 minutes. Cool and make up the volume to 50ml with solvent mixture.

4. Assay:

4.1 Solvent Mixture: Equal volume of water and methanol

4.2 Test Solution: Weigh individually 20 tablets & crush the tablet into fine powder. Weigh a quantity of powder equivalent to 25 mg of Empagliflozin in 100 ml volumetric flask, add 70 ml of solvent mixture, sonicate to dissolve with intermittent shaking and make volume to 100 ml with same solvent.

4.3 Standard Solution: Weigh accurately about 25 mg Empagliflozin WS in 100 ml volumetric flask. Add about 70 ml of solvent mixture and sonicate for about 10 minutes to dissolve and make up the volume to 100 ml with same solvent.

4.4 Chromatographic system:

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

Flow rate: 1.5 ml/min

Detector: UV 227 nm

Injection volume: 20 µl

Column Temperature: 30°C

Mobile Phase: Methanol: Buffer (50:50)

Buffer solution: 0.01M Potassium phosphate buffer of pH 4.0, adjust with phosphoric acid .

4.5 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 content of Empagliflozin in the tablets.

5. Other tests: As per pharmacopoeial requirements.