Empagliflozin Tablets

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Manufacturers, regulatory authorities, health authorities, researchers, and other stakeholders are invited to provide their feedback and comments on this draft proposal. Comments and samples received after the last date will not be considered by the IPC before finalizing the monograph.

Please send any comments you may have on this draft document to lab.ipc@gov.in, with a copy to Dr. Gaurav Pratap Singh (email: gpsingh.ipc@gov.in) before the last date for comments.

Document History and Schedule for the Adoption Process

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Empagliflozin Tablets

Empagliflozin Tablets contain not less than 90.0 per cent and not more than 110.0 per cent of empagliflozin, $C_{23}H_{27}ClO_7$.

Usual strengths. 10 mg; 25 mg.

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.

Tests

Dissolution (2.5.2).

Apparatus No. 1 (Basket),
Medium. 900 ml of buffer solution prepared by dissolving 6.8 g of *potassium dihydrogen orthophosphate* and 0.9 g of *sodium hydroxide* in 1000 ml of *water*, adjusted to pH 6.8 with *0.1 M sodium hydroxide*,
Speed and time. 100 rpm and 60 minutes.

Withdraw a suitable volume of the medium and filter.

Determine by liquid chromatography (2.4.14).

Solvent mixture. 20 volumes of *water* and 80 volumes of *methanol*.

Test solution. Use the filtrate, dilute if necessary, with the dissolution medium.

Reference solution. A 0.028 per cent w/v solution of *empagliflozin IPRS* with the solvent mixture. Dilute 2.0 ml of the solution to 50.0 ml with dissolution medium. *[NOTE —Sonicate to dissolve, if necessary]*

Chromatographic system
- a stainless steel column 15 cm × 4.6 mm, packed with octylsilane bonded to porous silica (5 µm) (such as Zorbax Eclipse XDB C8),
- mobile phase: a mixture of 70 volumes of a buffer solution prepared by dissolving 1.36 g of *potassium dihydrogen orthophosphate* in 1000 ml of *water*, adjusted to pH 3.0 with *dilute orthophosphoric acid* and 30 volumes of *acetonitrile,*
- flow rate: 1.5 ml per minute,
- spectrophotometer set at 225 nm,
- injection volume: 20 µl.

Inject the reference solution. 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 per cent.

Inject the reference solution and the test solution.

Calculate the content of $C_{23}H_{27}ClO_7$ in the medium.

Q. Not less than 75 per cent of the stated amount of $C_{23}H_{27}ClO_7$.

Related substances. Determine by liquid chromatography (2.4.14).

Solvent mixture. 20 volumes of *water* and 80 volumes of *methanol*.

Test solution. Disperse a quantity of the powdered tablets containing 50 mg of Empagliflozin in the solvent mixture with the aid of ultrasound for 20 minutes with intermittent swirling to disperse the tablets completely and dilute to 200.0 ml with the solvent mixture, filter.

Reference solution (a). A 0.00025 per cent w/v solution of *empagliflozin IPRS* with the solvent mixture. *[NOTE —Sonicate to dissolve, if necessary]*

Reference solution (b). Dilute 5.0 ml of reference solution (a) to 50.0 ml with the solvent mixture

Chromatographic system

- a stainless steel column 25 cm × 4.6 mm, packed with octadecylsilane bonded to porous silica (5 µm), (such as Inertsil ODS 3V),
- mobile phase: A. a mixture of 70 volumes of a buffer solution prepared by dissolving 2.72 g of *potassium dihydrogen orthophosphate* in 1000 ml of *water*, 10 volumes of *acetonitrile* and 20 volumes of *methanol*,
  B. a mixture of 20 volumes of *water*, 60 volumes of *acetonitrile* and 20 volumes of *methanol*,
- a gradient programme using the conditions given below,
- spectrophotometer set at 225 nm,
- injection volume: 15 µl.

Time (in min.)	Flow rate (ml per min.)	Mobile phase A (per cent v/v)	Mobile phase B (per cent v/v)
0	0.55	75	25
3	0.55	75	25
35	0.55	52	48
50	0.55	0	100
52	1.5	0	100
68	1.5	0	100
70	1.5	75	25
75	0.55	75	25
80	0.55	75	25

Inject reference solution (a) and (b). 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, the relative standard deviation for replicate injections is not more than 5.0 per cent in the chromatogram obtained with reference solution (a) and the signal-to-noise ratio for the principal peak is not less than 10.0 in the chromatogram obtained with reference solution (b).

Inject reference solution (a) and the test solution. In the chromatogram obtained with the test solution, the area of any secondary peak is not more than 0.2 times the area of the principal peak in the chromatogram obtained with reference solution (a) (0.2 per cent) and the sum of areas of all the secondary peaks is not more than the area of principal peak in the chromatogram obtained with reference solution (a) (1.0 per cent). Ignore any peak with an area less than 0.1 times the area of the principal peak in the chromatogram obtained with reference solution (a) (0.1 per cent).

Microbial contamination (2.2.9). The total aerobic viable count is not more than 10^3 CFU per g, the total combined molds and yeasts count is not more than 10^2 CFU per g. 1 g is free from *Escherichia coli*.

Uniformity of dosage units (2.5.4). Complies with the test stated under Uniformity of dosage units.

Other tests. Comply with the tests stated under Tablets.

Assay. Determine by liquid chromatography (2.4.14).

Solvent mixture. 20 volumes of *water* and 80 volumes of *methanol*.

Test solution. Weigh and powder 20 tablets. Disperse a quantity of the powdered tablets containing 50 mg of Empagliflozin into a 500-ml volumetric flask. Add 100 ml of *water*, sonicate for 10 minutes with intermittent swirling, add 200 ml of *methanol*, further sonicate for 15 minutes, cool and dilute to volume with *methanol*, filter.

Reference solution. A 0.01 per cent w/v solution of *empagliflozin IPRS* with the solvent mixture. *[NOTE —Sonicate to dissolve, if necessary]*

Use the chromatographic system as described under Dissolution with the following modification.

– injection volume: 10 µl.

Inject the reference solution. 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 per cent.

Inject the reference solution and the test solution.

Calculate the content of $C_{23}H_{27}ClO_7$ in the tablets.

Storage. Store at temperature not exceeding 30º.