Draft Proposal for Comments and Inclusion in The Indian Pharmacopoeia

Empagliflozin

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This draft proposal contains general chapter text for inclusion in the Indian Pharmacopoeia (IP). The content of this draft document is not final, and the text may be subject to revisions before publication in the IP. This draft does not necessarily represent the decisions or the stated policy of the IP or Indian Pharmacopoeia Commission (IPC).

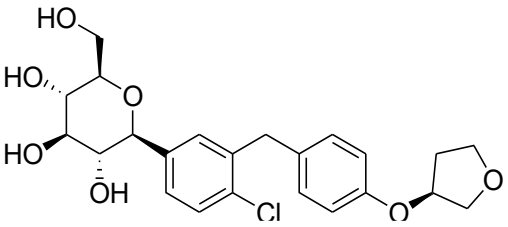
Manufacturers, regulatory authorities, health authorities, researchers, and other stakeholders are invited to provide their feedback and comments on this draft proposal. Comments and samples received after the last date will not be considered by the IPC before finalizing the monograph.

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

Description	**Details**
Document version	1.0
Monograph proposed for inclusion	Addendum to IP 2026
Tentative effective date of monograph	April, 2028
First draft published on IPC website for public comments	
Draft revision published on IPC website for public comments	
Further follow-up action as required.	

Empagliflozin



$C_{23}H_{27}ClO_7$ Mol. Wt. 450.9

Empagliflozin is (2*S*,3*R*,4*R*,5*S*,6*R*)-2-[4-chloro-3-[[4-[(3*S*)-oxolan-3- yl]oxyphenyl]methyl]phenyl]-6-(hydroxymethyl) oxane-3,4,5-triol.

Empagliflozin contains not less than 98.0 per cent and not more than 102.0 per cent of $C_{23}H_{27}ClO_7$, calculated on the anhydrous and solvent free basis.

Category. Anti-diabetic.

Description. A White to yellowish coloured powder.

Identification

A. Determine by infrared absorption spectrophotometry (2.4.6). Compare the spectrum with that obtained with *empagliflozin IPRS* or with the reference spectrum of empagliflozin.

B. 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

Specific optical rotation (2.4.22). + 16.0° to + 20.0°, determined in a 1 per cent w/v solution in *methanol*.

Related substances. Determine by liquid chromatography (2.4.14).

Solvent mixture. Equal volumes of mobile phase A and mobile phase B.

Test solution. Dissolve 25 mg of the substance under examination in the solvent mixture with the aid of ultrasound and dilute to 50.0 ml with the solvent mixture.

Reference solution. A 0.0005 per cent w/v solution of *empagliflozin IPRS* in the solvent mixture. Dilute 5.0 ml of the solution to 50.0 ml with the solvent mixture. *[NOTE —Sonicate to dissolve, if necessary]*

Chromatographic system
- a stainless steel column 15 cm × 4.6 mm, packed with octadecylsilane bonded to porous silica (3.5 µm), (such as Zorbax SB-C18),
- column temperature: 25°,
- mobile phase: A. a buffer solution prepared by dissolving 1.38 g of *sodium dihydrogen phosphate* in 1000 ml of *water*, adjusted to pH 3.0 with *orthophosphoric acid*,
  B. *acetonitrile*,
- a gradient programme using the conditions given below,
- flow rate: 1 ml per minute,
- spectrophotometer set at 225 nm,
- injection volume: 10 µl.

Time (in min.)	Mobile phase A (per cent v/v)	Mobile phase B (per cent v/v)
0	75	25
8	65	35
15	55	45
26	35	65
30	10	90
38	10	90
38.1	75	25
45	75	25

Name	Relative retention time	Correction factor
Empagliflozin impurity A[1]	0.56	1.04
Empagliflozin impurity B[2]	0.67	1.29
Empagliflozin impurity C [3]	0.86	1.05
Empagliflozin	1.0	---
Empagliflozin impurity D [4]	1.13	1.10
Empagliflozin impurity E[5]	1.19	0.97
Empagliflozin impurity F[6]	3.23	0.78

[1](2S,3R,4R,5S,6R)-2-(4-chloro-3-(4-hydroxybenzyl)phenyl)-6-(hydroxymethyl)tetrahydro-2H-pyran-3,4,5-triol; (Des furan impurity),
[2](2R,3S,4R,5R,6S)-2-(hydroxymethyl)-6-(3-(4-(((S)-tetrahydrofuran-3-yl)oxy)benzyl)phenyl)tetrahydro-2H-pyran-3,4,5-triol; (Des Chloro impurity),
[3](1R,2S,3R,4R,5R)-1-(4-chloro-3-(4-(((S)-tetrahydrofuran-3-yl)oxy)benzyl)phenyl)hexane-1,2,3,4,5,6-hexaol; (Open ring impurity),
[4](2S,3R,4S,5S,6R)-2-(4-chloro-3-(4-(((S)-tetrahydrofuran-3-yl)oxy)benzyl)phenyl)-6-(hydroxymethyl)-2-methoxytetrahydro-2H-pyran-3,4,5-triol; (Empa Methoxy compound),
[5](2R,3R,4R,5S,6R)-2-(4-chloro-3-(4-(((S)-tetrahydrofuran-3-yl)oxy)benzyl)phenyl)-6-(hydroxymethyl)tetrahydro-2H-pyran-3,4,5-triol; (Alpha isomer of empagliflozin),
[6](3S)-3-[4-[(5-bromo-2-chlorophenyl) methyl] phenoxy] tetrahydrofuran; (Bromofuran).

Inject the reference solution. The test is not valid unless the column efficiency is not less than 10000 theoretical plates, the tailing factor is not less than 0.8 and not more than 2.0 and the relative standard deviation for replicate injections is not more than 5.0 per cent.

Inject the reference solution and the test solution. In the chromatogram obtained with the test solution, the area of any peak corresponding to empagliflozin impurity A, empagliflozin impurity B, empagliflozin impurity C, empagliflozin impurity D, empagliflozin impurity E and empagliflozin impurity F, each of, is not more than 1.5 times the area of the principal peak in the chromatogram obtained with the reference solution (0.15 per cent), the area of any other secondary peak is not more than the area of the principal peak in the chromatogram obtained with the reference solution (0.1 per cent) and the sum of all the secondary peaks is not more than 5 times the area of the principal peak in the chromatogram obtained with the reference solution (0.5 per cent) and the relative standard deviation for replicate injections is not more than 5.0 per cent.

Sulphated ash (2.3.18). Not more than 0.1 per cent.

Water (2.3.43). Not more than 0.5 per cent, determined on 0.3 g.

Assay. Determine by liquid chromatography (2.4.14),

Buffer solution. Dissolve 1.38 g of *sodium dihydrogen phosphate monohydrate* in 1000 ml of *water*, adjusted to pH 3.0 with *orthophosphoric acid*.

Solvent mixture. Equal volumes of the buffer solution and *acetonitrile*.

Test solution. Dissolve 25 mg of the substance under examination in the solvent mixture with the aid of ultrasound and dilute to 50.0 ml with the solvent mixture. Dilute 5.0 ml of the solution to 25.0 ml with the solvent mixture.

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

Chromatographic system
- a stainless steel column 15 cm × 4.6 mm, packed with octadecylsilane bonded to porous silica (3.5 µm), (such as Zorbax SB-C18),
- mobile phase: a mixture of 70 volumes of the buffer solution and 30 volumes of *acetonitrile*,
- flow rate: 1.5 ml per minute,
- spectrophotometer set at 225 nm,
- injection volume: 5 µl.

Inject the reference solution. The test is not valid unless the column efficiency is not less than 2000 theoretical plates and the relative standard deviation for replicate injections is not more than 1.0 per cent.

Inject the reference solution and the test solution.

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

Storage. Store protected from moisture, at a temperature not exceeding 30°.

Solubility: **S**oluble in *dimethylformamide* and *dimethyl sulphoxide*.