Remogliflozin Tablets

Remogliflozin Etabonate Tablets

Remogliflozin Tablets contain not less than 90.0 per cent and not more than 110.0 per cent of the stated amount of Remogliflozin Etabonate, $C_{26}H_{38}N_2O_9$.

Usual strength. 100 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. 2 (Paddle),
Medium. 900 ml of a buffer solution prepared by dissolving 2.72 g of *potassium dihydrogen orthophosphate* in 1000 ml of *water*, adjusted to pH 3.0 with *orthophosphoric acid.* Add 1 g of *cetyltrimethylammonium bromide (CTAB)* and mix to dissolve,
Speed and time. 75 rpm and 45 minutes.

Withdraw a suitable volume of the medium and filter.

Determine by liquid chromatography (2.4.14).

Solvent mixture. 60 volumes of a buffer solution prepared by dissolving 2.72 g of *potassium dihydrogen orthophosphate* in 1000 ml of water, adjusted to pH 3.0 with *orthophosphoric acid* and 40 volumes of *acetonitrile*.

Test solution. Dilute the filtrate, if necessary, with the dissolution medium.

Reference solution. Dissolve 28 mg of *remogliflozin etabonate IPRS* in 30 ml of the solvent mixture with the aid of ultrasound for 10 minutes and dilute to 50.0 ml with the solvent mixture. Dilute 5.0 ml of the solution to 25.0 ml with the dissolution medium.

Chromatographic system
- a stainless steel column 15 cm x 4.6 mm, packed with phenyl group bonded to porous silica (3.5 µm) (Such as Zorbax SB-Phenyl),
- column temperature: 35°,
- mobile phase: a mixture of 40 volumes of 0.05 per cent v/v of *trifluoroacetic acid* in *water* and 60 volumes of *methanol*,
- flow rate: 1.5 ml per minute,
- spectrophotometer set at 278 nm,
- injection volume: 50 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 $C_{26}H_{38}N_2O_9$ in the medium.

Q. Not less than 75 per cent of the stated amount of $C_{26}H_{38}N_2O_9$.

Related substances. Determine by liquid chromatography (2.4.14).

Solvent mixture. 60 volumes of a buffer solution prepared by dissolving 2.72 g of *potassium dihydrogen orthophosphate* in 1000 ml of water, adjusted to pH 3.0 with *orthophosphoric acid* and 40 volumes of *acetonitrile*.

Test solution. Disperse a quantity of powdered tablets containing 100 mg of Remogliflozin Etabonate in the solvent mixture, with the aid of ultrasound for about 15 minutes and dilute to 100.0 ml with the solvent mixture, filter.

Reference solution (a). Dissolve 25 mg of *remogliflozin etabonate IPRS* in the solvent mixture with the aid of ultrasound for 10 minutes and dilute to 50.0 ml with the solvent mixture. Dilute 2.0 ml of the solution to 200.0 ml with the solvent mixture.

Reference solution (b). Dilute 2.0 ml of reference solution (a) to 25.0 ml with the solvent mixture.

Chromatographic system
- a stainless steel column 15 cm x 4.6 mm, packed with phenyl group bonded to porous silica (3.5 µm) (Such as Zorbax SB-Phenyl),
- column temperature: 35°,
- mobile phase: A. a 0.05 per cent v/v solution of *trifluoroacetic acid* in *water*,

B. *methanol*,

- a gradient programme using the conditions given below,
- flow rate: 1.5 ml per minute,
- spectrophotometer set at 227 nm,
- injection volume: 10 µl.

Time (in min.)	Mobile phase A (per cent v/v)	Mobile phase B (per cent v/v)
0	50	50
20	25	75
25	5	95
25.1	50	50
30	50	50

Name	Relative retention time	Correction factor
Remogliflozin etabonate impurity A[1]	0.59	0.88
Remogliflozin etabonate	1.0	---

[1]*5-methyl-1-(propan-2-yl)-4-[4-(propan-2-yloxy)benzyl]-1H-pyrazol-3-yl β-D-glucopyranoside*

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 is not less than 10 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 peak due to remogliflozin etabonate impurity A is not more than twice the area of the principal peak in the chromatogram obtained with reference solution (a) (1.0 per cent). The area of any secondary peak is not more than the area of the principal peak in the chromatogram obtained with reference solution (a) (0.5 per cent) and the sum of the area of all the secondary peaks is not more than 4 times the area of the principal peak in the chromatogram obtained with reference solution (a) (2.0 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 (b) (0.05 per cent).

Other tests. Comply with the tests stated under Tablets.

Assay. Determine by liquid chromatography (2.4.14), as described under dissolution with the following modification.

Test solution. Weight and powder 20 tablets. Disperse a quantity of powdered tablets containing 100 mg of Remogliflozin Etabonate in the solvent mixture, with the aid of ultrasound for about 15 minutes and dilute to 200.0 ml with the solvent mixture, filter.

Reference solution. Dissolve 25 mg of *remogliflozin etabonate IPRS* in the solvent mixture with the aid of ultrasound for 10 minutes and dilute to 50.0 ml with the solvent mixture.

Chromatographic system

- 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 $C_{26}H_{38}N_2O_9$ in the tablets.

Microbial contamination (2.2.9). Total aerobic viable count is not more than 10^3 CFU per g and total Yeast and Mould count is not more than 10^2 CFU per g, determined by plate count. 1 g is free from *Escherichia coli.*

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