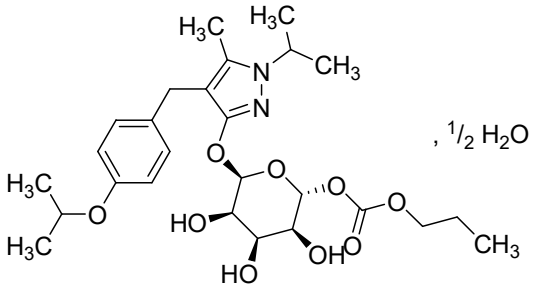
Remogliflozin Etabonate



$C_{26}H_{38}N_2O_9$. ½ H_2O Mol Wt. 531.6

Remogliflozin Etabonate is 5-methyl-1-(propan-2-yl)-4-[4-(propan-2-yloxy)benzyl]-1*H*-pyrazol-3-yl 6-*O*-(ethoxycarbonyl)-b-*D*-glucopyranoside hemihydrate.

Remogliflozin Etabonate contains not less than 97.0 per cent and not more than 102.0 per cent of $C_{26}H_{38}N_2O_9$, calculated on the anhydrous basis.

Category. Sodium-glucose co-transporter 2 (SGLT2).

Description. A white to off white powder.

Identification

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

B. In the Assay, the principal peak in the chromatogram obtained with test solution (b) corresponds to the principal peak in the chromatogram obtained with reference solution (a).

Tests

Related substances. Determine by liquid chromatography (2.4.14).

Solvent mixture. 70 volumes of *0.02 M potassium dihydrogen orthophosphate*, adjust pH 3.0 with *orthophosphoric acid* and 35 volumes of *acetonitrile*.

Test solution (a). Dissolve 75 mg of substance under examination in the solvent mixture and dilute to 50.0 ml with the solvent mixture.

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

Reference solution (a). A 0.015 per cent w/v solution of *remogliflozin etabonate IPRS* in the solvent mixture.

Reference solution (b). Dilute 3.0 ml of reference solution (a) to 100.0 ml with the solvent mixture.

Reference solution (c). A solution containing 0.15 per cent w/v of *remogliflozin etabonate IPRS* and 0.00045 per cent w/v of *remogliflozin etabonate impurity A IPRS* in the solvent mixture.

Chromatographic system

- a stainless steel column 25 cm x 4.6 mm, packed with octadecylsilane bonded to porous silica (5µm) (Such as Insersil ODS-3V),
- mobile phase: A. a 0.1 per cent v/v perchloric acid in *water*,
  B. a mixture of 80 volumes of acetonitrile and 20 volumes of methanol,
- a gradient programme using the conditions given below,
- flow rate: 1.4 ml per minute,
- spectrophotometer set at 227 nm,
- injection volume: 20 µl.

Time (in min.)	Mobile phase A (per cent v/v)	Mobile phase B (per cent v/v)
0.0	60	40
40	45	55
60	30	70
70	30	70
72	60	40
80	60	40

Name	Relative retention time	Correction factor
Remogliflozin etabonate impurity A[1]	0.40	0.82
Remogliflozin etabonate (Retention time about 30 minutes)	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 (b). The test is not valid unless the column efficiency is not less than 5000 theoretical plates, the tailing factor is not more than 2.0 and the relative standard deviation for replicate injections is not more than 5.0 per cent.

Inject reference solution (c) to identify the peak due to remogliflozin etabonate impurity A.

Inject reference solution (b) and test solution (a). In the chromatogram obtained with test solution (a), the area of any peak due to remogliflozin etabonate impurity A is not more than 1.67 times the area of the principal peak in the chromatogram obtained with reference solution (b) (0.5 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 (b) (0.3 per cent) and the sum of the area of all the secondary peaks is not more than 3.34 times the area of the principal peak in the chromatogram obtained with reference solution (b) (1.0 per cent). Ignore any peak with an area less than 0.066 times the area of the principal peak in the chromatogram obtained with reference solution (b) (0.02 per cent).

Heavy metals (2.3.13). 1.0 g complies with limit test for heavy metals, Method B (20 ppm)

Sulphated ash (2.3.18). Not more than 0.20 per cent.

Water (2.3.43). Not more than 3.0 per cent, determined on 0.5 g.

Assay. Determine by liquid chromatography (2.4.14), Use chromatographic conditions as described under related substances with the following modification.

Inject reference solution (a). The test is not valid unless the tailing factor is not more than 2.0, the column efficiency is not less than 5000 theoretical plates and the relative standard deviation for five replicate injections is not more than 1.0 per cent.

Inject reference solution (a) and test solution (b).

Calculate the content of $C_{26}H_{38}N_2O_9$, ½ H_2O.

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

2.4.26. Solubility. Page 291

Insert after **Repaglinide**

Remogliflozin Etabonate. Soluble in *acetone* and *methanol* and practically insoluble in *water*.
