

Xylitol

C₅H₁₂O₅

Mol. Wt. 152.2

Xylitol contains not less than 98.5 per cent and not more than 101.0 per cent of C₅H₁₂O₅, calculated on the anhydrous basis.

Category. Pharmaceutical aid.

Description. White crystals or crystalline powder.

Identification.

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

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

Limit of other Polyols. Determine by liquid chromatography (2.4.14).

Test solution. Dissolve 1 g of the substance under examination in the mobile phase and dilute to 100.0 ml with the mobile phase.

Reference solution (a). A 10.0 per cent w/v solution of *xylitol IPRS* in the mobile phase.

Reference solution (b). A solution containing 0.05 per cent w/v, each of, *L-arabinitol IPRS*, *galactitol IPRS*, *mannitol IPRS*, and *sorbitol IPRS* in the mobile phase.

Chromatographic system

- a stainless steel column 30 cm x 8.0 mm, packed with strong cation-exchange resin consisting of sulphonated cross-linked styrene-divinylbenzene copolymer (7 µm) (Such as Shodex SUGAR SP 0810)
- column temperature: 80°,
- mobile phase: a mixture of 20 volumes of *acetonitrile* and 80 volumes of *water*.
- flow rate: 0.5 ml per minute,
- spectrophotometer set at 192 nm,
- injection volume: 25 µl.

The relative retention time with reference to xylitol, for *L-arabinitol*, *mannitol*, *galactitol*, and *sorbitol* is about 0.76, 0.81, 1.12, and 1.22, respectively.

Inject reference solution (a) and (b). The test is not valid unless the resolution between all adjacent polyol peaks is not less than 1.5 in the chromatogram obtained with reference solution (b) and the relative standard deviation for replicate injections is not more than 5.0 per cent, for *galactitol* peak, in the chromatogram obtained with reference solution (a).

Inject reference solution (a) and the test solution.

Calculate the percentage of each polyols (*L-arabinitol*, *galactitol*, *mannitol* and *sorbitol*). The sum of the polyols is not more than 2.0 per cent, calculated on the anhydrous basis.

Reducing sugars. Not more than 0.2 per cent reducing sugar, as dextrose.

Test solution. Dissolve 0.5 g of the substance under examination in 2.0 ml of *water*, in a 10 ml of conical flask.

Reference solution. A 0.05 per cent w/v solution of *dextrose* in *water*. Pipet 2.0 ml of the solution to a 10 ml conical flask.

To each flask, add 1 ml of *alkaline cupric tartrate solution*, heat to boiling and cool. Any turbidity in the test solution is not more than that in the reference solution, in which reddish-brown precipitate forms.

Heavy metal (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 0.5 per cent.

Water (2.3.43). Not more than 0.5 per cent.

Assay. Determine by liquid chromatography (2.4.14).

Test solution. Dissolve 0.25g of the substance under examination in the mobile phase and dilute to 10.0 ml with the mobile phase.

Reference solution (a). A 2.5 per cent w/v solution of *xylitol IPRS* in the mobile phase.

Reference solution (b). A solution containing 0.25 per cent w/v of *galactitol IPRS* and 2.5 per cent w/v of *xylitol IPRS* in the mobile phase.

- Use the chromatographic system as described under Limit of other polyols.

The relative retention time with reference to xylitol, for galactitol is about 1.1.

Inject reference solution (a) and (b). The test is not valid unless the resolution between the peaks due to galactitol and xylitol is not less than 2.0 in the chromatogram obtained with reference solution (b) and the relative standard deviation for replicate injections is not more than 2.0 per cent in the chromatogram obtained with reference solution (a).

Inject reference solution (a) and the test solution.

Calculate the content of $C_5H_{12}O_5$.

Solubility. Page 297

Insert before, Xylometazoline Hydrochloride

Xylitol. Very soluble in *water*, sparingly soluble in *ethanol*.