Xylitol

Published on: 17.03.2023 **Last date for comments:** 16.04.2023

This draft proposal contains monograph 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. Manufacturers are also invited to submit samples of their products to the IPC to ensure that the proposed monograph adequately controls the quality of the product(s) they manufacture. 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	2.0
Monograph proposed for inclusion	IP Addendum 2024
Tentative effective date of monograph	April, 2024
First draft published on IPC website for public comments	18 October, 2022
Draft revision published on IPC website for public comments	Version 2.0 17.03.2023
Further follow-up action as required.	

Xylitol

$C_5H_{12}O_5$ Mol. Wt. 152.2

Xylitol contains not less than 98.5 per cent and not more than 101.0 per cent of $C_5H_{12}O_5$, calculated on the anhydrous basis.

Category. Pharmaceutical aid.

Description. A 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 reference solution (a).

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: 80º,
- 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. Transfer 0.5 g of the substance under examination to a 10-ml conical flask and dissolve in 2.0 ml of *water*.

Reference solution. A 0.05 per cent w/v solution of *dextrose* in *water*. Transfer 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, determined on 1.0 g.

Assay. Determine by liquid chromatography (2.4.14).

Test solution. Dissolve 0.25 g 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 $C_5H_{12}O_5$.

Storage. Store protected from moisture.

Solubility. Page 297

Insert before **Xylometazoline Hydrochloride**

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