2-Deoxy-D-Glucose Sachet

2-Deoxy-D-Glucose Sachet contains not less than 95.0 per cent and not more than 105.0 per cent of the stated amount of 2-Deoxy-D-Glucose, $C_6H_{12}O_5$.

Usual strengths. 2.34 g; 5.85 g.

Identification

A. Determine by infrared absorption spectrophotometry (2.4.6). Compare the spectrum with that obtained with *2-deoxy-D-glucose IPRS* or with the reference spectrum of 2-deoxy-D-glucose.

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). + 44.0° to + 48.0°, determined in a 1.0 per cent w/v solution.

Related substances. Determine by liquid chromatography (2.4.14).

Test solution. Mix the contents of 5 sachets and disperse a quantity of mixed content containing 1.0 g of 2-deoxy-D-glucose in *water,* with the aid of vortex for 6 minutes, and dilute to 50.0 ml with *water*. Centrifuge at 10,000 RPM for 10 minutes and filter.

Reference solution. A 0.002 per cent w/v solution of *2-Deoxy-D-Glucose IPRS* in *water.*

Chromatographic system

- a stainless steel column 25 cm x 4.6 mm, packed with octadecylsilane bonded to porous silica (5µm) (Such as Inert sustain AQ-C18),
- column temperature: 55˚,
- mobile phase: *water*,
- flow rate: 0.5 ml per minute,
- refractive index detector,
- detector cell temperature: 50˚,
- injection volume: 10 µl,

Name	Relative retention time	Correction factor
Glucose impurity*	0.8	
2-Deoxy-D-Glucose	1.0	
Glucol impurity*	1.8	1.17
Furan diol impurity*	4.3	

* These are process impurities and are controlled in drug substances and no need to control in the formulation.

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 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 secondary peak 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 sum of the areas of all the secondary peaks is not more than 20 times the area of the principal peak in the chromatogram obtained with the reference solution (2.0 per cent).

Other tests. Comply with the tests stated under Granules.

Water (2.3.43). Not more than 5.0 per cent, determined on 0.5 g.

Seal test *(only for sachets).* Loosely bundle 10 sachets with a rubber band and submerge the bundle under water in a vacuum desiccator maintained at a pressure not exceeding 18 kPa for one minute. Examine the bundle for any fine stream of bubbles. Re-establish normal pressure and open the bundle. No penetration of water is observed in any sachet.

Assay. Determine by liquid chromatography (2.4.14).

Test solution. Mix the contents of 5 sachets and disperse a quantity of mixed content containing 0.25 g of 2-deoxy-D-glucose in *water,* with the aid of vortex for 6 minutes, and dilute to 250.0 ml with *water*. Centrifuge at 10,000 RPM for 10 minutes and filter.

Reference solution. A 0.1 per cent w/v solution of *2-deoxy-D-glucose IPRS* in *water*.

Chromatographic system as described under Related substances.

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 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 $C_6H_{12}O_5$ in sachets.

Storage. Store protected from moisture.