Raffinose

1 Nonproprietary Names

None adopted.

2 Synonyms

Gossypose; melitose; melitriose; D-raffinose; D-(+)-raffinose.

3 Chemical Name and CAS Registry Number

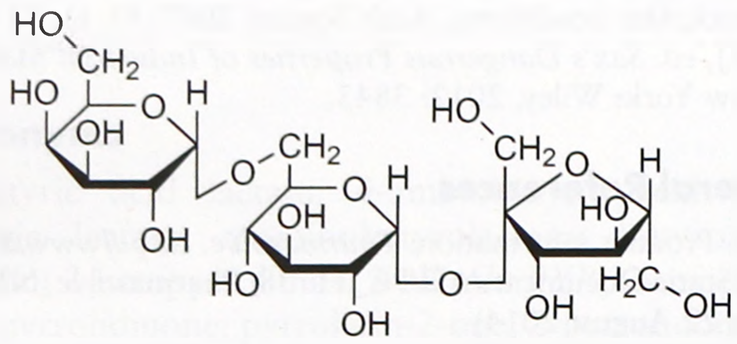
β-D-Fructofuranosyl-O-α-D-galactopyranosyl-(1→6)-α-D-glucopyranoside, anhydrous [512-69-6]

β-D-Fructofuranosyl-O-α-D-galactopyranosyl-(1→6)-α-D-glucopyranoside pentahydrate [17629-30-0]

4 Empirical Formula and Molecular Weight

$C_{18}H_{32}O_{16}$ 504.44 (for anhydrous)
$C_{18}H_{32}O_{16}·5H_2O$ 594.52 (for pentahydrate)

5 Structural Formula



D-Raffinose anhydrous

6 Functional Category

Lyophilization aid.

7 Applications in Pharmaceutical Formulation or Technology

Raffinose is a trisaccharide carbohydrate that is used as a bulking agent, stabilizing agent, and water scavenger in freeze-drying where it acts as a stabilizer for freeze-dried formulations.[1–4] It is also used as a crystallization inhibitor in sucrose solutions.[5,6]

Raffinose has also been investigated for use in spray-dried powders for oral inhalation formulations.[7–9]

8 Description

Raffinose is a white crystalline powder. It is odorless and has a sweet taste approximately 10% that of sucrose.[10]

9 Pharmacopeial Specifications

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10 Typical Properties

Collapse temperature –26°C[2]
Decomposition temperature 118–119°C (anhydrous); 130°C (pentahydrate).[11]
Density (bulk) 0.67 g/cm^3 (pentahydrate)
Density (tapped) 0.98 g/cm^3 (pentahydrate)
Density (true) 1.465 g/cm^3 (anhydrous)
Diffusion coefficient (infinite dilution) 0.33×10^{-5} cm^2/s (water at 15°C)[12]
Glass transition temperature 114°C (amorphous)[13]
Heat of solution at infinite dilution (25°C) 52 kJ/mol (crystalline pentahydrate); –38 kJ/mol (amorphous)[1]
Melting point 80°C (pentahydrate);[11] 118°C (anhydrous)[14]
Optical rotation 105° (pentahydrate); 123° (anhydrous)[15]
Specific gravity 1.465 (pentahydrate)[11]
Solubility in methanol 0.10 g/mL[15]
Solubility in water 0.14 g/mL[11]
Solubility Soluble 1 in 10 of methanol, in pyridine and 1 in 7.1 of water; slightly soluble in ethanol (95%); insoluble in diethyl ether.

The data for the crystal structure,[16,17] NMR structure,[18] powder x-ray diffraction pattern,[19] water vapor sorption isotherms,[19,20] glass transition temperature as a function of water,[19] heat capacity,[1] heat of solution properties,[1] vapor pressure,[21] and osmotic pressure[22] are described in the literature.

SEM 1: Excipient: D-(+)-raffinose pentahydrate; manufacturer: Sigma-Aldrich (Lot No. 092K01211); magnification: 100×.

SEM 2: Excipient: D-(+)-raffinose pentahydrate; manufacturer: Sigma-Aldrich (Lot No. 092K01211); magnification: 500×.

11 Stability and Storage Conditions

Raffinose is stable under ordinary conditions of use and storage. Excessive heat should be avoided to prevent degradation. Thermal