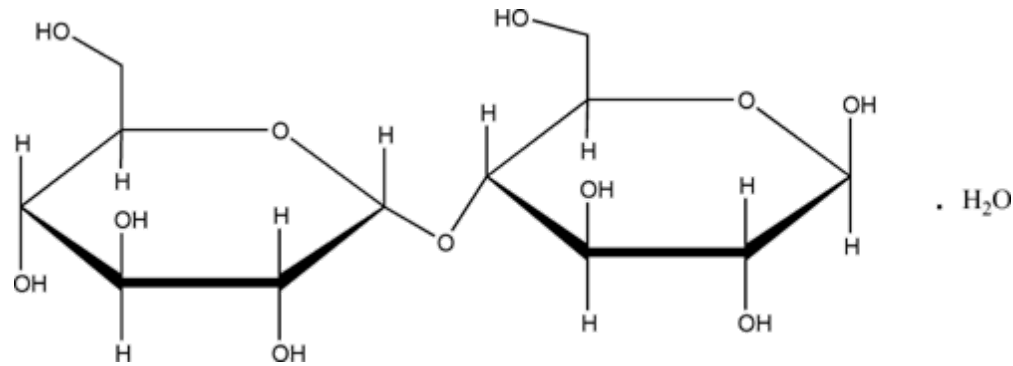


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Maltose



$C_{12}H_{22}O_{11} \cdot H_2O$ 360.31

and $C_{12}H_{22}O_{11}$ 342.30

4-O- α -D-Glucopyranosyl- β -D-glucopyranose.

» Maltose is a sugar. It contains one molecule of water of hydration or is anhydrous. It contains not less than 92.0 percent of maltose, calculated on the anhydrous basis. The amounts of other sugars, if detected, are not included in the requirements or the calculated amount under *Other Impurities*.

Packaging and storage— Preserve in well-closed containers. No storage requirements specified.

USP Reference standards [〈 11 〉](#) — [USP Maltose Monohydrate RS](#).

Identification—

A: Add 2 to 3 drops of a solution of Maltose (1 in 20) to 5 mL of hot alkaline cupric tartrate TS. A red precipitate is formed.

B: The retention time of the major peak in the chromatogram of the *Assay preparation* corresponds to that in the chromatogram of the *Standard preparation*, as obtained in the *Assay*.

pH [〈 791 〉](#) — Prepare a 1 in 10 solution in carbon dioxide-free water. For the anhydrous form, it is between 3.7 and 4.7; and for the monohydrate form, it is between 4.0 and 5.5.

Water, Method I [〈 921 〉](#) — The anhydrous form contains not more than 1.5%. The monohydrate form contains not less than 5.0% and not more than 6.5%.

Residue on ignition [〈 281 〉](#) : not more than 0.05%, determined on a 2-g portion, accurately weighed.

Heavy metals, Method I [〈 231 〉](#) : not more than 5 μ g per g.

Dextrin, starch, and sulfite— Dissolve 1.0 g of Maltose in 10 mL of water, and add 1 drop of iodine TS: a yellow color develops. Then add 1 drop of starch TS to this portion: a blue color develops.

Residual solvents [〈 467 〉](#): meets the requirements.

(Official January 1, 2007)

Assay—

Mobile phase— Use degassed water.

Resolution solution— Dissolve accurately weighed quantities of maltotriose, maltose, and glucose in water to obtain a solution having concentrations of about 10 mg of each per g.

Standard preparation— Dissolve an accurately weighed quantity of [USP Maltose Monohydrate RS](#) in water to obtain a solution having a concentration of about 10 mg per g. Calculate the exact concentration on the anhydrous basis.

Assay preparation— Dissolve about 0.10 g of Maltose, accurately weighed, in water, and dilute with water to about 10 g. Accurately record the final solution weight, and mix thoroughly.

Chromatographic system (see [Chromatography 〈 621 〉](#))— The liquid chromatographic system is equipped with a refractive index detector maintained at a constant temperature of about 40 °, and a 7.8-mm × 30-cm column that contains packing L58 (see [Chromatography 〈 621 〉](#)). The column temperature is maintained at about 80 °, controlled to within ±2 °. Chromatograph the *Resolution solution*, and record the peak responses as directed for *Procedure*. Adjust the flow rate to about 0.35 mL per minute so that the resolution, *R*, between maltotriose and maltose is not less than 1.6. Chromatograph the *Standard preparation*, and record the peak responses as directed for *Procedure*: the relative retention times are about 0.9 for maltotriose, 1.0 for maltose, and 1.2 for glucose; and the relative standard deviation for replicate injections is not more than 2.0%.

Procedure— Separately inject equal volumes (about 20 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the percentage of Maltose on the anhydrous basis, taken by the formula:

$$[10,000(C_S / C_U)(r_U / r_S)] / (100 - W),$$

in which C_S is the concentration, in mg per g, on the anhydrous basis of [USP Maltose Monohydrate RS](#) in the *Standard preparation*; C_U is the concentration, in mg per g, of Maltose in the *Assay preparation*; r_U and r_S are the peak responses obtained from the *Assay preparation* and the *Standard preparation*, respectively; and W is the percentage obtained in the test for *Water*.

Auxiliary Information— *Staff Liaison* : [Catherine Sheehan, B.Sc., Scientist](#)

Expert Committee : (EM105) Excipient Monographs 1

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