

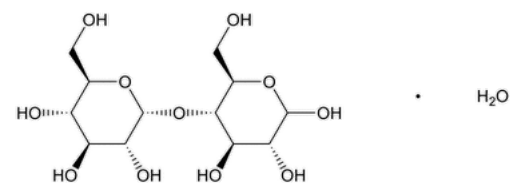
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Maltose

To view the Notice from the Expert Committee that posted in conjunction with this accelerated revision, please click

<https://www.uspnf.com/rb-maltose-20221216>.



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

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

4-O- α -D-Glucopyranosyl- β -D-glucose monohydrate CAS RN[®]: 6363-53-7.

4-O- α -D-Glucopyranosyl- β -D-glucose CAS RN[®]: 69-79-4.

DEFINITION

Maltose is a sugar. It contains one molecule of water of hydration or is anhydrous. It contains NLT 92.0% of maltose, calculated on the anhydrous basis. The amounts of other sugars, if detected, are not included in the requirements or the calculated amount in [General Notices, 5.60.10 Other Impurities in USP and NF Articles](#).

IDENTIFICATION

- **A.** Perform this test for Anhydrous Maltose only.

Sample solution: 50 mg/mL

Analysis: Add 2–3 drops of the *Sample solution* to 5 mL of hot [alkaline cupric tartrate TS](#).

Acceptance criteria: A red precipitate is formed.

- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.
- **C. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy:** 197K

Perform the test for Maltose Monohydrate only. Use the undried sample and [USP Maltose Monohydrate RS](#).

ASSAY

Change to read:

PROCEDURE

Mobile phase: Water

System suitability solution: 10 mg/g each of maltotriose, maltose, and glucose

Standard solution: Dissolve [USP Maltose Monohydrate RS](#) in water to obtain a solution having a concentration of about 10 mg/g ▲ of maltose ▲ (RB 1-Jan-2023) .

Sample solution: Dissolve 0.10 g of Maltose in water, and dilute with water to 10 g. Record the final solution weight, and mix thoroughly.

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: LC

Detector: Refractive index

Column: 7.8-mm × 30-cm; packing [L58](#)

Temperatures

Column: 80 ± 2°

Detector: 40°

Flow rate: 0.35 mL/min; adjust so that the resolution between maltotriose and maltose is NLT 1.6.

Injection volume: 20 µL

System suitability

Samples: *System suitability solution* and *Standard solution*

[NOTE—The relative retention times for maltotriose, maltose, and glucose are about 0.9, 1.0, and 1.2, respectively.]

Suitability requirements

Resolution: NLT 1.6 between maltotriose and maltose, *System suitability solution*

Relative standard deviation: NMT 2.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate ▲ the percentage of maltose ($C_{12}H_{22}O_{11}$) in the portion▲ (RB 1-Jan-2023) of Maltose taken:

$$\text{Result} = [(r_U / r_S) \times (C_S / C_U)] / [(100 - W) / 100] \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of [USP Maltose Monohydrate RS](#) in the *Standard solution*▲ (RB 1-Jan-2023) (mg/g)

C_U = concentration of Maltose in the *Sample solution* (mg/g)

W = percentage of water from the test for *Water Determination*

Acceptance criteria: NLT 92.0% on the anhydrous basis

IMPURITIES

- [RESIDUE ON IGNITION \(281\)](#).

Sample: 2 g

Acceptance criteria: NMT 0.05%

SPECIFIC TESTS

- **DEXTRIN, STARCH, AND SULFITE**

Sample solution: 1.0 g of Maltose in 10 mL of water

Analysis: Add 1 drop of [iodine TS](#) to the *Sample solution*.

Acceptance criteria: A yellow color develops. Then add 1 drop of [starch TS](#); a blue color develops.

- [pH \(791\)](#).

Sample solution: 100 mg/mL in [carbon dioxide-free water](#)

Acceptance criteria

Anhydrous form: 3.7–4.7

Monohydrate form: 4.0–5.5

- [WATER DETERMINATION \(921\), Method I](#)

Anhydrous: NMT 1.5%

Monohydrate: 4.5%–6.5%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers. No storage requirements specified.

- [USP REFERENCE STANDARDS \(11\)](#).

[USP Maltose Monohydrate RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
MALTOSE	Documentary Standards Support	SE2020 Simple Excipients

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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