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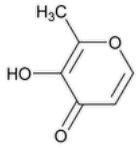
Maltol



$C_6H_6O_3$ 126.11

4*H*-Pyran-4-one, 3-hydroxy-2-methyl-;

3-Hydroxy-2-methyl-4*H*-pyran-4-one CAS RN®: 118-71-8.

DEFINITION

Maltol contains NLT 98.0% and NMT 102.0% of 3-hydroxy-2-methyl-4*H*-pyran-4-one, calculated on the anhydrous basis.

IDENTIFICATION

- **A. Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*:** 197K
- **B. Chromatographic Identity**

Analysis: Examine the chromatograms obtained in the *Assay*.

Acceptance criteria: The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*.

ASSAY

- **Procedure**

Diluent: Alcohol, absolute

Internal standard solution: 0.5 mg/mL of USP Benzyl Alcohol RS (internal standard) in *Diluent*

System suitability solution: 1.0 mg/mL of USP Maltol RS and 0.2 mg/mL of USP Ethyl Maltol RS in *Internal standard solution*

Standard solution: 1.0 mg/mL of USP Maltol RS in *Internal standard solution*

Sample solution: 1.0 mg/mL of Maltol in *Internal standard solution*

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: GC

Detector: Flame ionization

Column: 0.32-mm × 30-m capillary; bonded with a 0.5-µm layer of phase G42

Temperatures

Detector: 300°

Injection port: 280°

Column: See *Table 1*.

Table 1

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
100	10	180	5
180	20	300	5

Carrier gas: Helium

Flow rate: 2 mL/min (constant flow mode)

Injection volume: 1.0 µL

Injection type: Split, split ratio 10:1

Liner: Ultra inert with glass wool, low pressure drop[1]

System suitability

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

[NOTE—The approximate relative retention time of ethyl maltol with reference to maltol is 1.2.]

Suitability requirements

Resolution: NLT 1.5 between the maltol and ethyl maltol peaks, *System suitability solution*

Tailing factor: NMT 2.0, determined from the maltol peak, *System suitability solution*

Relative standard deviation: NMT 1% for the peak response ratio of maltol to the internal standard, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of Maltol in the portion of the sample taken:

$$\text{Result} = (R_U/R_S) \times (C_S/C_U) \times 100$$

R_U = peak response ratio of maltol to the internal standard from the *Sample solution*

R_S = peak response ratio of maltol to the internal standard from the *Standard solution*

C_S = concentration of USP Maltol RS in the *Standard solution* (mg/mL)

C_U = concentration of Maltol in the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%–102.0% on the anhydrous basis

IMPURITIES

• **ORGANIC IMPURITIES**

Diluent and **Chromatographic system:** Proceed as directed in the *Assay*.

Protectant solution: 1.0 mg/mL of 4-hydroxy-6-methyl-2-pyrone (protectant) in *Diluent*

System suitability solution: 1 mg/mL of USP Maltol RS and 0.2 mg/mL of USP Ethyl Maltol RS in *Protectant solution*

Standard solution: 0.02 mg/mL of USP Maltol RS in *Protectant solution*

Sample solution: 20.0 mg/mL of Maltol in *Protectant solution*

System suitability

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

[NOTE—The approximate relative retention time of ethyl maltol with reference to maltol is 1.2.]

Suitability requirements

Resolution: NLT 1.5 between the maltol and ethyl maltol peaks, *System suitability solution*

Relative standard deviation: NMT 5.0%, determined from the maltol peak, *Standard solution*

Signal-to-noise ratio: NLT 10, determined from the maltol peak, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each individual unidentified impurity in the portion of sample taken:

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

r_U = peak area of any individual unidentified impurity from the *Sample solution*

r_S = peak area of maltol from the *Standard solution*

C_S = concentration of USP Maltol RS in the *Standard solution* (mg/mL)

C_U = concentration of Maltol in the *Sample solution* (mg/mL)

Acceptance criteria: See *Table 2*.

Table 2

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Maltol	1.0	—
Any individual unidentified impurity	—	0.1
Total impurities	—	1.0

• **RESIDUE ON IGNITION ⟨281⟩:** NMT 0.2%, determined on 1.0 g

Change to read:

• ▲**Lead** ⟨251⟩, *Procedures, Procedure 1*▲ (CN 1-Jun-2023) **:** NMT 10 ppm

SPECIFIC TESTS

• **Melting Range or Temperature** ⟨741⟩, *Procedures, Procedure for Class Ia*: 160°–164°

• **Water Determination** ⟨921⟩, *Method I*: NMT 0.5%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers protected from light, and avoid contact with metals. No storage requirements are specified.

• **USP Reference Standards** ⟨11⟩
USP Benzyl Alcohol RS
USP Ethyl Maltol RS
USP Maltol RS

[1] Agilent PN 5190-2295 liner has been used. Other equivalent liners can be also used.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

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

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. 46(2)

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