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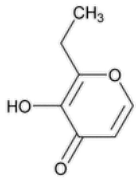
Ethyl Maltol

Change to read:



$C_7H_8O_3$ 140.14

▲4*H*-Pyran-4-one, 2-ethyl-3-hydroxy-;▲ (NF 1-Dec-2020)

2-Ethyl-3-hydroxy-4*H*-pyran-4-one;

2-Ethyl pyromeconic acid CAS RN®: 4940-11-8.

DEFINITION

Change to read:

Ethyl Maltol contains ▲NLT 97.5% and NMT 102.5% of 2-ethyl-3-hydroxy-4*H*-pyran-4-one,▲ (NF 1-Dec-2020) calculated on the anhydrous basis.

IDENTIFICATION

Change to read:

• **A.** ▲Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*▲ (NF 1-Dec-2020): 197S, 1:50 solution in chloroform

Add the following:

▲• **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*.▲ (NF 1-Dec-2020)

ASSAY

Change to read:

• **Procedure**

▲**Diluent:** Absolute alcohol

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 Ethyl Maltol RS and 0.2 mg/mL of USP Maltol RS in *Internal standard solution*

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

Sample solution: 1.0 mg/mL of Ethyl 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: 2 mL/min (constant flow mode)

Injection volume: 1.0 µL

Injection type: 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 times of related substances are listed in *Table 2*.]

Suitability requirements

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

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

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

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of ethyl maltol in the portion of sample taken:

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

R_U = peak response ratio of ethyl maltol to the internal standard (peak response of ethyl maltol/peak response of the internal standard) from the *Sample solution*

R_S = peak response ratio of ethyl maltol to the internal standard (peak response of ethyl maltol/peak response of the internal standard) from the *Standard solution*

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

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

Acceptance criteria: 97.5%–102.5% on the anhydrous basis ▲(NF 1-Dec-2020)

IMPURITIES

Add the following:

▲• **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: 1.0 mg/mL of USP Ethyl Maltol RS and 0.2 mg/mL of USP Maltol RS in *Protectant solution*

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

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

System suitability

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

[NOTE—The approximate relative retention times of related substances are listed in *Table 2*.]

Suitability requirements

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

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

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

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of maltol 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 maltol 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 Ethyl Maltol in the *Sample solution* (mg/mL)

Calculate the percentage of each individual unspecified 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 unspecified impurity from the *Sample solution*

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

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

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

Acceptance criteria: See *Table 2*.

Table 2.

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Maltol	0.83	0.3
Ethyl maltol	1.0	—
Any individual unspecified impurity	—	0.1
Total of all impurities	—	1.0▲ (NF 1-Dec-2020)

• **Residue on Ignition ⟨281⟩:** NMT 0.2% at 800° for 15 min

SPECIFIC TESTS

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

ADDITIONAL REQUIREMENTS

Change to read:

• **Packaging and Storage:** Preserve in tight containers ▲and avoid contact with metals.▲ (NF 1-Dec-2020)

Change to read:

• **USP Reference Standards ⟨11⟩**

▲ USP Benzyl Alcohol RS▲ (NF 1-Dec-2020)

USP Ethyl Maltol RS

▲ USP Maltol RS▲ (NF 1-Dec-2020)

[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
ETHYL MALTOL	Documentary Standards Support	SE2020 Simple Excipients

Chromatographic Database Information: Chromatographic Database

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