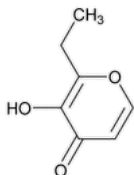


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Ethyl Maltol

Change to read:



$C_7H_8O_3$ 140.14

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

2-Ethyl-3-hydroxy-4H-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-4H-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 drop¹

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*