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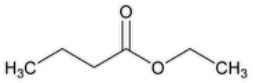
Add the following:

▲Ethyl Butyrate



$C_6H_{12}O_2$ 116.16

Ethyl butyrate CAS RN®: 105-54-4.

DEFINITION

Ethyl Butyrate contains NLT 98.0% of ethyl butyrate ($C_6H_{12}O_2$).

IDENTIFICATION

• **A. Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*:** 197A

• **B. Chromatographic Identity**

System suitability solution, Sample solution, and **Analysis:** Proceed as directed in the *Assay*.

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

ASSAY

• **Procedure**

System suitability solution: Mix quantities of USP Ethyl Acetate RS and USP Ethyl Butyrate RS to obtain a solution containing about 5% ethyl acetate and 95% ethyl butyrate.

Sample solution: Ethyl Butyrate (neat)

Chromatographic system

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

Mode: GC

Detector: Flame ionization

Column: 0.53-mm × 30-m capillary column; bonded with a 3.0-µm layer of phase G43

Temperatures

Injection port: 225°

Detector: 250°

Column: See *Table 1*.

Table 1

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
50	—	50	—
50	5	240	5

Carrier gas: Helium

Flow rate: 1 mL/min

Injection volume: 0.2 µL

Injection type: Splitless

[NOTE—A needle wash with the *Sample solution* is recommended to minimize the carry-over.]

System suitability

Sample: *System suitability solution*

[NOTE—The relative retention times for ethyl acetate and ethyl butyrate are 0.7 and 1.0, respectively.]

Suitability requirements

Tailing factor: NMT 1.8 for the ethyl acetate and ethyl butyrate peaks

Relative standard deviation: NMT 2.5%, using the area ratio of ethyl butyrate to ethyl acetate

Analysis

Sample: *Sample solution*

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

$$\text{Result} = (r_U/r_T) \times 100$$

r_U = peak response of ethyl butyrate from the *Sample solution*

r_T = sum of relevant peak responses from the *Sample solution*

Acceptance criteria: NLT 98.0%

SPECIFIC TESTS

- **FATS AND FIXED OILS ⟨401⟩, *Procedures, Acid Value, Method I***

  Analysis: Dissolve about 10 g of Ethyl Butyrate, accurately weighed, in 50 mL of alcohol.

  Acceptance criteria: NMT 1.0

- **REFRACTIVE INDEX ⟨831⟩:** 1.391–1.394 at 20°
- **SPECIFIC GRAVITY ⟨841⟩:** 0.870–0.877 at 25°

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers, and avoid exposure to excessive heat.
- **USP REFERENCE STANDARDS ⟨11⟩**

  USP Ethyl Acetate RS

  USP Ethyl Butyrate RS▲ (NF 1-May-2024)

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

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

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. 48(5)

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