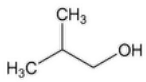
Status: Currently Official on 18-Feb-2025
Official Date: Official as of 01-Feb-2023
Document Type: NF Monographs
DocId: GUID-1D3E52BD-E487-4D19-AD35-16092E026124_3_en-US
DOI: https://doi.org/10.31003/USPNF_M4791_03_01
DOI Ref: wsq1d

Isobutyl Alcohol



$CH_3CH(CH_3)CH_2OH$ 74.12
2-Methyl-1-propanol;
2-Methylpropyl alcohol;
1-Isobutanol CAS RN®: 78-83-1.

DEFINITION

Isobutyl Alcohol contains NLT 98.0% of 2-methyl-1-propanol ($C_4H_{10}O$).

IDENTIFICATION

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

• **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the 2-methyl-1-propanol peak of the *System suitability solution*, as obtained in the *Assay*.

ASSAY

Change to read:

• **Procedure**

System suitability solution: USP 1-Butanol RS and USP 2-Methyl-1-Propanol RS (1:1)

Reference solution: 0.1% of Isobutyl Alcohol in water

Sample solution: Isobutyl Alcohol (neat)

Chromatographic system

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

Mode: GC

Detector: Flame ionization

Column: 0.53-mm × 30-m; coated with a 3.0-µm layer of thickness phase G43

Temperatures

Detector: 250°

Injection port: 140°

Column: See *Table 1*.

Table 1

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
40	—	40	20
40	10	240	20

Carrier gas: Helium

Flow rate: 4.8–4.9 mL/min

Injection volume: 1 µL

Injection type: Split injection. The split ratio is 30:1. [Note—A needle wash with the *Sample solution* is recommended to minimize the carry over.]

System suitability

Sample: *System suitability solution*

[Note—The 2-methyl-1-propanol peak typically elutes at about 11 min, and 1-butanol at about 15 min. The relative retention times for 2-methyl-1-propanol and 1-butanol are 0.7 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 2.0 between 2-methyl-1-propanol and 1-butanol

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Reference solution* and *Sample solution*

Calculate the percentage of 2-methyl-1-propanol ($C_4H_{10}O$) in the portion of Isobutyl Alcohol taken:

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

r_U = peak response of isobutyl alcohol

r_T (ERR 1-Feb-2023) = sum of all the peaks except those each of which with an area less than 0.1 times the area of the major peak from the *Reference solution*

Acceptance criteria: NLT 98.0%

IMPURITIES

• **Limit of Isobutyraldehyde, Butyraldehyde, 2-Butanol, 1-Butanol, and Other Volatile Impurities**

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

Reference solution: 0.1% of Isobutyl Alcohol in water

Standard solution: 0.2% of USP Isobutyraldehyde RS, 0.2% of USP Butyraldehyde RS, 0.1% of USP 1-Butanol RS, and 0.1% of USP 2-Butanol RS in the *Sample solution*

System suitability

Sample: *Standard solution*

[Note—See *Table 2* for relative retention times.]

Table 2

Component	Relative Retention Time
Isobutyraldehyde	0.4
Butyraldehyde	0.5
2-Butanol	0.6
2-Methyl-1-propanol	0.8
1-Butanol	1.0

Suitability requirements

Resolution: NLT 1.5 between all adjacent peaks

Analysis

Samples: *Sample solution*, *Reference solution*, and *Standard solution*

If any peaks of the *Sample solution* have the same retention times as the peaks due to isobutyraldehyde, butyraldehyde, 2-butanol, and 1-butanol, subtract the areas of any such peaks from the peak areas of the *Standard solution* at these retention times. The difference is calculated below:

$$\text{Result } (\Delta r) = r_S - r_U$$

r_S = peak response of each individual impurity (isobutyraldehyde, butyraldehyde, 2-butanol, or 1-butanol) from the *Standard solution*

r_U = peak response of each individual impurity (isobutyraldehyde, butyraldehyde, 2-butanol, or 1-butanol), if present, from the *Sample solution*

Calculate the percentage of each impurity other than isobutyraldehyde, butyraldehyde, 2-butanol, and 1-butanol in the portion of Isobutyl Alcohol taken:

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

r_U = peak response of each impurity other than isobutyraldehyde, butyraldehyde, 2-butanol, and 1-butanol from the *Sample solution*

r_T = sum of all the peaks from the *Sample solution*, except those each of which with an area less than 0.1 times the area of the major peak from the *Reference solution*)

Acceptance criteria: See *Table 3*. Disregard any peak with an area less than 0.1 times the area of the major peak from the *Reference solution*, corresponding to 0.01%.

Table 3

Impurity	Percentage (%)
Isobutyraldehyde	The area of any peak of the *Sample solution* corresponding to isobutyraldehyde, r_U, is NMT half of the difference (Δr) between the area of the peak due to isobutyraldehyde in the *Standard solution* and the area of the peak due to isobutyraldehyde in the *Sample solution*, corresponding to NMT 0.1%.
Butyraldehyde	The area of any peak of the *Sample solution* corresponding to butyraldehyde, r_U, is NMT half of the difference (Δr) between the area of the peak due to butyraldehyde in the *Standard solution* and the area of the peak due to butyraldehyde in the *Sample solution*, corresponding to NMT 0.1%.
2-Butanol	The area of any peak of the *Sample solution* corresponding to 2-butanol, r_U, is NMT the difference (Δr) between the area of the peak due to 2-butanol in the *Standard solution* and the area of the peak due to 2-butanol in the *Sample solution*, corresponding to NMT 0.1%.
1-Butanol	The area of any peak of the *Sample solution* corresponding to 1-butanol, r_U, is NMT the difference (Δr) between the area of the peak due to 1-butanol in the *Standard solution* and the area of the peak due to 1-butanol in the *Sample solution*, corresponding to NMT 0.1%.
Total impurities	NMT 2.0%

- **Limit of Nonvolatile Residue**

  Sample: 100 mL

  Analysis: Evaporate the *Sample* in a tared porcelain dish on a steam bath, and dry at 105° for 30 min.

  Acceptance criteria: The weight of the residue does not exceed 4 mg, corresponding to NMT 0.004%.

SPECIFIC TESTS

- **Acidity**

  Sample: 74 mL (60 g)

  Analysis: Titrate the *Sample* with 0.020 N alcoholic potassium hydroxide, using phenolphthalein TS as the indicator, until a pink color persists for NLT 15 s.

  Acceptance criteria: NMT 2.5 mL is consumed.

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

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight containers, and prevent exposure to excessive heat.

- **USP Reference Standards ⟨11⟩**

  USP 1-Butanol RS
  USP 2-Butanol RS
  USP Butyraldehyde RS
  USP Isobutyraldehyde RS
  USP 2-Methyl-1-Propanol RS

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

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

Topic/Question	Contact	Expert Committee
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SE2020 Simple Excipients

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 38(4)

Current DocID: GUID-1D3E52BD-E487-4D19-AD35-16092E026124_3_en-US

DOI: https://doi.org/10.31003/USPNF_M4791_03_01

DOI ref: wsq1d