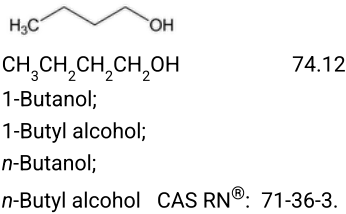


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# Butyl Alcohol



**DEFINITION**  
Butyl Alcohol is *n*-butyl alcohol. It contains NLT 99.5% of *n*-butyl alcohol (C<sub>4</sub>H<sub>10</sub>O).

## IDENTIFICATION

Change to read:

- **A.** [▲SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 197F▲](#) (CN 1-MAY-2020)
- **B.** The retention time of the major peak from the *Sample solution* corresponds to the 1-butanol peak from the *System suitability solution*, as obtained in the Assay.

## ASSAY

- **PROCEDURE**  
**System suitability solution:** [USP 1-Butanol RS](#) and [USP 2-Methyl-1-Propanol RS](#) (1:1)  
**Reference solution:** 0.1% of Butyl Alcohol in water  
**Sample solution:** Butyl 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 thickness of 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, 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 shows at about 11 min, and the 1-butanol peak at about 15 min. See [Table 2.](#)]

**Table 2**

Component	Relative Retention Time (RRT)
2-Methyl-1-propanol	0.7
1-Butanol	1.0

**System 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 butyl alcohol in the portion of sample taken:

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

$r_U$  = peak response of butyl alcohol

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

**Acceptance criteria:** NLT 99.5%

**IMPURITIES**

• **LIMIT OF BUTYRALDEHYDE, 2-BUTANOL, ISOBUTYL ALCOHOL (2-METHYL-1-PROPANOL), AND BUTYL ETHER**

**Reference solution:** 0.1% of Butyl Alcohol in water

**Standard solution:** 0.2% of [USP Butyraldehyde RS](#), 0.2% of butyl ether, 0.1% of [USP 2-Methyl-1-Propanol RS](#), and 0.1% of [USP 2-Butanol RS](#) in Butyl Alcohol

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

**System suitability**

**Sample:** *Standard solution*

[NOTE—See [Table 3](#).]

**Table 3**

Component	Relative Retention Time (RRT)
Butyraldehyde	0.45
2-Butanol	0.5
2-Methyl-1-propanol	0.7
1-Butanol	1.0
Butyl ether	1.8

**System suitability requirements**

**Resolution:** NLT 1.5 between all adjacent peaks

**Analysis**

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

If any peaks are present in the chromatogram from the *Sample solution* that have the same retention times as the peaks due to butyraldehyde, 2-butanol, isobutyl alcohol (2-methyl-1-propanol), and butyl ether, subtract the areas of any such peaks from the peak areas at these retention times in the chromatogram from the *Standard solution*.

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

$r_S$  = peak response of each individual impurity (butyraldehyde, 2-butanol, isobutyl alcohol, or butyl ether) in the *Standard solution*

$r_U$  = peak response of each individual impurity (butyraldehyde, 2-butanol, isobutyl alcohol, or butyl ether), if present, in the *Sample solution*

**Acceptance criteria:** See [Table 4](#). 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 4

Impurity	Percentage (%)
Butyraldehyde	In the chromatogram from the <i>Sample solution</i> , the area of any peak corresponding to butyraldehyde, $r_U$ , is NMT half of the difference ( $\Delta r$ ) between the area of the peak due to butyraldehyde in the chromatogram from the <i>Standard solution</i> and the area of the peak due to butyraldehyde in the chromatogram from the <i>Sample solution</i> , corresponding to NMT 0.1%.
2-Butanol	In the chromatogram from the <i>Sample solution</i> , the area of any peak corresponding to 2-butanol, $r_U$ , is NMT the difference ( $\Delta r$ ) between the area of the peak due to 2-butanol in the chromatogram from the <i>Standard solution</i> and the area of the peak due to 2-butanol in the chromatogram from the <i>Sample solution</i> , corresponding to NMT 0.1%.
Isobutyl alcohol (2-Methyl-1-propanol)	In the chromatogram from the <i>Sample solution</i> , the area of any peak corresponding to 2-methyl-1-propanol, $r_U$ , is NMT the difference ( $\Delta r$ ) between the area of the peak due to 2-methyl-1-propanol in the chromatogram from the <i>Standard solution</i> and the area of the peak due to 2-methyl-1-propanol in the chromatogram from the <i>Sample solution</i> , corresponding to NMT 0.1%.
Butyl ether	In the chromatogram from the <i>Sample solution</i> , the area of any peak corresponding to butyl ether, $r_U$ , is NMT the difference ( $\Delta r$ ) between the area of the peak due to butyl ether in the chromatogram from the <i>Standard solution</i> and the area of the peak due to butyl ether in the chromatogram from the <i>Sample solution</i> , corresponding to NMT 0.2%.

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 0.1%
- **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 (0.004%).

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers, and prevent exposure to excessive heat.
- **USP REFERENCE STANDARDS (11).**  
[USP Butyraldehyde RS](#)  
[USP 1-Butanol RS](#)  
[USP 2-Butanol RS](#)  
[USP 2-Methyl-1-Propanol RS](#)

Topic/Question	Contact	Expert Committee
BUTYL ALCOHOL	<a href="#">Documentary Standards Support</a>	SE2020 Simple Excipients

Chromatographic Database Information: [Chromatographic Database](#)

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