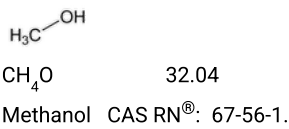


Status: Currently Official on 15-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: NF Monographs
DocId: GUID-DA6ACB2D-1929-4E1D-BEEE-38CB6C5E98A7_2_en-US
DOI: https://doi.org/10.31003/USPNF_M52000_02_01
DOI Ref: g2gf7

© 2025 USPC
Do not distribute

Methyl Alcohol



DEFINITION

Methyl Alcohol contains NLT 99.5% of CH₃OH.

[CAUTION—Methyl Alcohol is poisonous.]

IDENTIFICATION

Change to read:

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

ASSAY

- **PROCEDURE**
System suitability solution: Dilute 1.0 mL of [USP Methyl Alcohol RS](#) and 1.0 mL of [USP Acetone RS](#) with tetrahydrofuran to 50 mL.
Internal standard solution: 2% (v/v) acetonitrile in tetrahydrofuran
Standard solution: 15.8 mg/mL of [USP Methyl Alcohol RS](#) in *Internal standard solution*
Sample solution: 15.8 mg/mL of Methyl Alcohol in *Internal standard solution*
Chromatographic system
(See [Chromatography \(621\), System Suitability.](#))
Detector: Flame ionization
Column: 0.32-mm × 30-m fused-silica capillary column, coated with a 1.8-μm layer of phase G43
Temperature
Injector: 200°
Detector: 280°
Column: See [Table 1](#).

Table 1

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
40	—	40	5
40	20	240	—

Carrier gas: Helium
Linear velocity: 35 cm/s
Injection type: Split ratio, 20:1
Injection size: 1 μL

System suitability

Samples: *System suitability solution* and *Standard solution*
[NOTE—The relative retention times for methyl alcohol, acetone, and acetonitrile are 1.0, about 1.6, and about 1.8, respectively.]

Suitability requirements

Resolution: NLT 15 between methyl alcohol and acetone, *System suitability solution*
Tailing factor: NMT 1.5 for methyl alcohol, *System suitability solution*
Relative standard deviation: NMT 2.0% for the ratio of the peak area of methyl alcohol to acetonitrile, *Standard solution*

Analysis**Samples:** *Standard solution* and *Sample solution*Calculate the percentage of methyl alcohol (CH₃OH) in the portion of Methyl Alcohol taken:

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

 R_U = peak area ratio from the *Sample solution* R_S = peak area ratio from the *Standard solution* C_S = concentration of [USP Methyl Alcohol RS](#) in the *Standard solution* (mg/mL) C_U = concentration of Methyl Alcohol in the *Sample solution* (mg/mL)**Acceptance criteria:** NLT 99.5%**IMPURITIES**• **NONVOLATILE RESIDUE****Sample:** 250 mL of Methyl Alcohol**Analysis:** Evaporate the *Sample* in a 600-mL beaker on a steam bath, in a well-ventilated hood, until the volume is reduced to about 100 mL.

Cool, transfer a portion of the liquid to a suitable, tared 50-mL platinum dish on a steam bath, and evaporate. Repeat the process until all of the liquid has been transferred, and then evaporate to dryness. Dry at 105° for 30 min, cool, and weigh.

Acceptance criteria: The weight of the residue does not exceed 2 mg, corresponding to NMT 0.001% (w/w).• **ACETONE AND ALDEHYDES** (as acetone)**Standard solution:** Dilute 1.9 mL (1.5 g) of acetone with water to 1000 mL, then dilute 1.0 mL of this solution with water to 100 mL. Dilute 2 mL of the resulting solution with water to 5 mL. The *Standard solution* contains 30 µg of acetone and is freshly prepared.**Sample solution:** Dilute 1.25 mL (1 g) of Methyl Alcohol with water to 5 mL.**Analysis:** Adjust to and maintain each solution at 20°. Add 5 mL of alkaline mercuric–potassium iodide TS to each of the *Standard solution* and *Sample solution*.**Acceptance criteria:** Any turbidity produced in the *Sample solution* is not greater than that produced in the *Standard solution* (NMT 0.003%).• **READILY CARBONIZABLE SUBSTANCES** (271).**Sample:** 5 mL**Analysis:** Cool 5 mL of sulfuric acid, contained in a small conical flask, to 10°, and add the *Sample* dropwise with constant mixing, maintaining the temperature below 20° throughout the test.**Acceptance criteria:** No discoloration develops.• **READILY OXIDIZABLE SUBSTANCES****Sample:** 20 mL of Methyl Alcohol**Analysis:** Cool the *Sample* to 15°, add 0.1 mL of 0.1 N potassium permanganate, and allow to stand at 15°.**Acceptance criteria:** The pink color does not completely disappear within 5 min.**SPECIFIC TESTS**• **ACIDITY****Sample solution:** Mix 25 mL of water with 10 mL of alcohol and 0.5 mL of phenolphthalein TS, and add 0.02 N sodium hydroxide until a slight pink color persists after shaking for 30 s. Taking precautions to avoid absorption of carbon dioxide, add 19 mL (15 g) of Methyl Alcohol.**Analysis:** Titrate the *Sample solution* with 0.020 N sodium hydroxide.**Acceptance criteria:** NMT 0.45 mL of 0.020 N sodium hydroxide is required to produce a pink color.• **ALKALINITY** (as ammonia)**Sample:** 28.6 mL (22.6 g) of Methyl Alcohol**Analysis:** Mix the *Sample* with 25 mL of water, add 1 drop of methyl red TS, and titrate with 0.020 N sulfuric acid.**Acceptance criteria:** NMT 0.20 mL of 0.020 N sulfuric acid is required to produce a pink color (3 ppm).• **WATER DETERMINATION, Method I (921):** NMT 0.1%**ADDITIONAL REQUIREMENTS**• **PACKAGING AND STORAGE:** Preserve in tight containers, remote from heat, sparks, and open flames.• **USP REFERENCE STANDARDS** (11).[USP Acetone RS](#)[USP Methyl Alcohol RS](#)

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

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. PF 34(5)

Current DocID: GUID-DA6ACB2D-1929-4E1D-BEEE-38CB6C5E98A7_2_en-US

DOI: https://doi.org/10.31003/USPNF_M52000_02_01

DOI ref: [g2gf7](#)

OFFICIAL