

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



CH_4O 32.04

Methanol CAS RN®: 67-56-1.

DEFINITION

Methyl Alcohol contains NLT 99.5% of CH_3OH .

[**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 (CH_3OH) 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