

Alcohol

Add the following:

- Portions of this monograph that are national *USP* text, and are not part of the harmonized text, are marked with symbols (♦) to specify this fact. ■_{1S} (*USP37*)



C₂H₆O 46.07
 Ethanol;
 Ethyl alcohol [64-17-5].

DEFINITION

Change to read:

- _{1S} (*USP37*) Alcohol contains NLT 92.3% and NMT 93.8%, by weight, corresponding to NLT 94.9% and NMT 96.0%, by volume, at 15.56°, of C₂H₅OH. ■♦_{1S} (*USP37*)

IDENTIFICATION

- A.** It meets the requirements of the test for *Specific Gravity* (841).
- B. INFRARED ABSORPTION** (197F) or (197S): Neat

IMPURITIES

- LIMIT OF NONVOLATILE RESIDUE**
 Sample: 100 mL of Alcohol
 Analysis: Evaporate the *Sample* in a tared dish on a water bath, and dry at 100°–105° for 1 h.
 Acceptance criteria: The weight of the residue is NMT 2.5 mg.

Change to read:

- ORGANIC IMPURITIES**
 Sample solution A: Alcohol (substance under test)
 Sample solution B: 300 µL/L of 4-methylpentan-2-ol in *Sample solution A*
 Standard solution A: 200 µL/L of methanol in *Sample solution A*
 Standard solution B: 10 µL/L of methanol and 10 µL/L of acetaldehyde in *Sample solution A*
 Standard solution C: 30 µL/L of acetal in *Sample solution A*
 Standard solution D: 2 µL/L of benzene in *Sample solution A*
Chromatographic system
 (See *Chromatography* (621), *System Suitability*.)
 Mode: GC
 Detector: Flame ionization
 Column: 0.32-mm × 30-m fused-silica capillary; bonded with a 1.8-µm layer of phase G43
 Split ratio: 20:1
Temperatures
 Injection port: 200°
 Detector: 280°
 Column: See *Table 1*.

Table 1

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
40	0	40	12

Table 1 (Continued)

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

Linear velocity: 35 cm/s
 Carrier gas: Helium
 Injection volume: 1.0 µL

System suitability

Sample: *Standard solution B*

Suitability requirements

Resolution: NLT 1.5 between the first major peak (acetaldehyde) and the second major peak (methanol)

Analysis

Samples: *Sample solution A*, *Sample solution B*, *Standard solution A*, *Standard solution B*, *Standard solution C*, and *Standard solution D*

Methanol calculation

$$\text{Result} = (r_U/r_S)$$

r_U = peak area of methanol from *Sample solution A*
 r_S = peak area of methanol from *Standard solution A*

Acetaldehyde calculation (sum of acetaldehyde and acetal)

$$\text{Result} = \{[A_E/(A_T - A_E)] \times C_A\} + \{[D_E/(D_T - D_E)] \times C_D\} \times \frac{M_{r1}}{M_{r2}} \quad \text{■}_{1S} \text{ (USP37)}$$

A_E = peak area of acetaldehyde from *Sample solution A*

A_T = peak area of acetaldehyde from *Standard solution B*

C_A = concentration of acetaldehyde in *Standard solution B*, 10 µL/L

D_E = peak area of acetal from *Sample solution A*

D_T = peak area of acetal from *Standard solution C*

C_D = concentration of acetal in *Standard solution C*, 30 µL/L

■ = molecular weight of acetaldehyde,

M_{r1} 44.05 ■_{1S} (*USP37*)

■ = molecular weight of acetal, 118.2 ■_{1S} (*USP37*)

M_{r2}

Benzene calculation

$$\text{Result} = [B_E/(B_T - B_E)] \times C_B$$

B_E = peak area of benzene from *Sample solution A*

B_T = peak area of benzene from *Standard solution D*

C_B = concentration of benzene in *Standard solution D*, 2 µL/L

[NOTE—If necessary, the identity of benzene can be confirmed using another suitable chromatographic system (stationary phase with a different polarity).]

Any other impurity calculation

$$\text{Result} = (r_U/r_M) \times C_M$$

r_U = peak area of each impurity in *Sample solution B*

r_M = peak area of 4-methylpentan-2-ol in *Sample solution B*

C_M = concentration of 4-methylpentan-2-ol in *Sample solution B*

2 Alcohol

Acceptance criteria: See Table 2.

Table 2

Name	Acceptance Criteria
Methanol	NMT 0.5, corresponding to 200 µL/L
Acetaldehyde and acetal	NMT 10 µL/L, expressed as acetaldehyde
Benzene	NMT 2 µL/L
Sum of all other impurities ^a	NMT 300 µL/L

^a Disregard any peaks of less than 9 µL/L (0.03 times the area of the peak corresponding to 4-methylpentan-2-ol in the chromatogram obtained with *Sample solution B*).^{■15 (USP37)}

SPECIFIC TESTS

Change to read:

- ^{■15 (USP37)} **SPECIFIC GRAVITY (841):** 0.812–0.816 at 15.56°, indicating 92.3%–93.8%, by weight, or 94.9%–96.0%, by volume, of C₂H₅OH.^{■15 (USP37)}
- **ULTRAVIOLET ABSORPTION**
Analytical wavelength: 235–340 nm
Cell: 5 cm
Reference: Water
Acceptance criteria
Absorbance: NMT 0.40 at 240 nm; NMT 0.30 between 250 nm and 260 nm; NMT 0.10 between 270 nm and 340 nm
Curve: [■]The spectrum shows a steadily rising curve with no observable peaks or shoulders.^{■25 (USP37)}

Change to read:

- ^{■15 (USP37)} **CLARITY OF SOLUTION**
[NOTE—The *Sample solution* is to be compared to *Standard suspension A* and to water in diffused daylight 5 min after preparation of *Standard suspension A*.]
Hydrazine solution: 10 mg/mL of hydrazine sulfate in water. Allow to stand for 4–6 h.
Methenamine solution: Transfer 2.5 g of methenamine to a 100-mL glass-stoppered flask, add 25.0 mL of water, insert the glass stopper, and mix to dissolve.
Primary opalescent suspension: Transfer 25.0 mL of *Hydrazine solution* to the *Methenamine solution* in the 100-mL glass-stoppered flask. Mix, and allow to stand for 24 h. This suspension is stable for 2 months, provided it is stored in a glass container free from surface defects. The suspension must not adhere to the glass and must be well mixed before use.
Opalescence standard: Transfer 15.0 mL of the *Primary opalescent suspension* to a 1000-mL volumetric flask, and dilute with water to volume. This suspension should not be used beyond 24 h after preparation.
Standard suspension A: *Opalescence standard* and water (1 in 20)
Standard suspension B: *Opalescence standard* and water (1 in 10)
Sample solution A: Substance to be examined
Sample solution B: Dilute 1.0 mL of *Sample solution A* with water to 20 mL, and allow to stand for 5 min before testing.

Blank: Water

Analysis: Transfer a sufficient portion of *Sample solution A* and *Sample solution B* to separate test tubes of colorless, transparent, neutral glass with a flat base and an internal diameter of 15–25 mm to obtain a depth of 40 mm. Similarly transfer portions of *Standard suspension A*, *Standard suspension B*, and *Blank* to separate matching test tubes. Compare *Sample solution A*, *Sample solution B*, *Standard suspension A*, *Standard suspension B*, and *Blank* in diffused daylight, viewing vertically against a black background (see *Spectrophotometry and Light-Scattering (851)*, *Visual Comparison*). The diffusion of light must be such that *Standard suspension A* can readily be distinguished from water, and *Standard suspension B* can readily be distinguished from *Standard suspension A*.

Acceptance criteria: *Sample solution A* and *Sample solution B* show the same clarity as that of water or their opalescence is not more pronounced than that of [■]*Standard suspension A*.^{■15 (USP37)}

• ACIDITY OR ALKALINITY

Phenolphthalein solution: Dissolve 0.1 g of phenolphthalein in 80 mL of alcohol, and dilute with water to 100 mL.

Sample: 20 mL of Alcohol

Analysis: To the *Sample* add 20 mL of freshly boiled and cooled water and 0.1 mL of *Phenolphthalein solution*. The solution is colorless. Add 1.0 mL of 0.01 N sodium hydroxide.

Acceptance criteria: The solution is pink (30 µL/L, expressed as acetic acid).

Change to read:

• ^{■15 (USP37)} COLOR OF SOLUTION

Standard stock solution: Combine 3.0 mL of ferric chloride CS, 3.0 mL of cobaltous chloride CS, 2.4 mL of cupric sulfate CS, and 1.6 mL of dilute hydrochloric acid (10 g/L).

Standard solution: Transfer 1.0 mL of *Standard stock solution* to a 100-mL volumetric flask, and dilute with dilute hydrochloric acid (10 g/L). Prepare the *Standard solution* immediately before use.

Sample solution: Substance to be examined

Blank: Water

Analysis: Transfer a sufficient portion of the *Sample solution* to a test tube of colorless, transparent, neutral glass with a flat base and an internal diameter of 15–25 mm to obtain a depth of 40 mm. Similarly transfer portions of the *Standard solution* and *Blank* to separate, matching test tubes. Compare the *Sample solution*, *Standard solution*, and *Blank* in diffused daylight, viewing vertically against a white background (see *Spectrophotometry and Light-Scattering (851)*, *Visual Comparison*).

Acceptance criteria: The *Sample solution* has the appearance of water or is not more intensely colored than the *Standard solution*.^{■15 (USP37)}

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers, protected from light.
- **USP REFERENCE STANDARDS (11)**
USP Alcohol RS