Herbal Medicines Compendium
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Alcohol

Final Authorized Version 1.0

C_2H_6O 46.07

Ethanol;

Ethyl alcohol [64-17-5].

DEFINITION

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 C_2H_5OH.

IDENTIFICATION

- **A. Specific Gravity <841>:** 0.812–0.816 at 15.56°, indicating 92.3%–93.8% by weight, or indicating 94.9%–96.0% by volume, of C_2H_5OH
- **B. Spectrophotometric Identification Tests,** *Infrared Absorption* **<197F>** or **<197S>:** Neat

IMPURITIES

- **Limit of Nonvolatile Residue**

  Analysis: Evaporate 100 mL in a tared dish on a water bath, dry at 100°–105° for 1 h, and obtain the weight of the residue.

  Acceptance criteria: NMT 2.5 mg
- **Volatile 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 (similar to DB-624)

  Split ratio: 20:1

  Temperatures

  Detector: 280°

  Injector: 200°

  Column: See *Table 1*.

Table 1

Initial Temperature (°)	Temperature Ramp (° /min)	Final Temperature (°)	Hold Time at Final Temperature (min)
40	0	40	12
40	10	240	10

Flow rate: 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 and acetal calculation

$$\text{Result} = \{[A_E/(A_T - A_E)] \times C_S\} + \{[D_E/(D_T - D_E)] \times C_U\}$$

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

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

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

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

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

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

Benzene calculation

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

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

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

C_S = concentration of benzene added 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).]

Other impurities 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*

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.	

SPECIFIC TESTS

- **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 absorption curve is smooth.

- **CLARITY OF SOLUTION**

[NOTE—The *Sample solution* is to be compared to *Reference suspension A* and to *Blank* in diffused daylight 5 min after preparation of *Reference suspension A*.]

Hydrazine solution: 10 mg/mL of hydrazine sulfate in water. [NOTE—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. [NOTE—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. [NOTE—This suspension should not be used beyond 24 h after preparation.]

Reference suspension A: *Opalescence standard* and water (1:20)

Reference suspension B: *Opalescence standard* and water (1:10)

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

Samples: *Reference suspension A, Reference suspension B*, *Sample solution A, Sample solution B,* and *Blank*

Transfer a sufficient portion of each of the *Samples* to individual 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. Compare the *Samples* in diffused daylight, viewing vertically against a black background. (See *Spectrophotometry and Light-Scattering* <851>, *Visual Comparison*.) [NOTE—The diffusion of light must be such that *Reference suspension A* can readily be distinguished from *Blank*, and that *Reference suspension B* can readily be distinguished from *Reference suspension A*.]

Acceptance criteria: *Sample solution A* and *Sample solution B* show the same clarity as that of *Blank* or their opalescence is not more pronounced than that of *Reference suspension A*.

- **ACIDITY OR ALKALINITY**

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

Sample solution: 20 mL of Alcohol

Analysis: To the *Sample solution* 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).

- **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) to volume. [NOTE—Prepare the *Standard solution* immediately before use.]

Sample solution: Substance to be examined

Analysis

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

Transfer a sufficient portion of each of the *Samples* to individual 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. Compare the *Samples* 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*.

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers, protected from light.
- **USP REFERENCE STANDARDS <11>**

USP Alcohol RS [1]