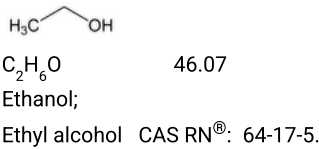


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Dehydrated Alcohol

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.



DEFINITION

†Dehydrated Alcohol contains NLT 99.2% by weight, corresponding to NLT 99.5% by volume, at 15.56°, of ethanol (C₂H₅OH).

IDENTIFICATION

- **A.** It meets the requirements of the test for [Specific Gravity \(841\)](#).
- **B. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy:** 197F or 197S: Neat
- **†C. LIMIT OF METHANOL**

[NOTE—This test must be performed to be in compliance with USP, in addition to *Identification A* and *B* above.]

Sample solution A, Standard solution A, Standard solution B, Chromatographic system, and System suitability: Proceed as directed in *Organic Impurities*.

Analysis: Proceed as directed in the *Organic Impurities* test, *Methanol calculation*.

Acceptance criteria: Meets the requirements in [Table 2](#) for methanol.

IMPURITIES

• LIMIT OF NONVOLATILE RESIDUE

Sample: 100 mL of Dehydrated 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.

• ORGANIC IMPURITIES

Sample solution A: Dehydrated 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*

†[NOTE—To be prepared for use in *Identification C*.]

Standard solution B: 10 µL/L each of methanol and 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

Injection type: Split; 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
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

♦[NOTE—To be performed as a part of *Identification C*.]♦

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

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)

$$\text{Result} = \{[A_E/(A_T - A_E)] \times C_A\} + \{[D_E/(D_T - D_E)] \times C_D \times (M_{r1}/M_{r2})\}$$

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* (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* (µL/L)

M_{r1} = molecular weight of acetaldehyde, 44.05

M_{r2} = molecular weight of acetal, 118.2

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* (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 from *Sample solution B*

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

C_M = concentration of 4-methylpentan-2-ol in *Sample solution B* (µL/L)