

Status: Currently Official on 14-Feb-2025
Official Date: Official as of 01-Feb-2022
Document Type: USP Monographs
DocId: GUID-8C3E5E4C-E95F-4AA2-A90E-6B9D7BFDC42F_3_en-US
DOI: https://doi.org/10.31003/USPNF_M43160_03_01
DOI Ref: 45x5i

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Azeotropic Isopropyl Alcohol

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DEFINITION

Azeotropic Isopropyl Alcohol contains NLT 91.0% and NMT 93.0% of isopropyl alcohol, by volume, the remainder consisting of water.

IDENTIFICATION

• **A. INFRARED ABSORPTION:** The IR absorption spectrum of a thin film of it exhibits a strong broad band at 3.0 μm ; a strong region of absorption between 3.35 and 3.5 μm , with its highest peak at 3.36 μm , and others at 3.41 and 3.47 μm ; many weak peaks between 3.6 and 6.0 μm , among the most noticeable being those at 3.68, 3.77, 3.97, 4.17, and 5.26 μm ; a broad band at 6.2 μm ; a strong region of absorption between 6.7 and 7.8 μm , the most prominent features being the peaks at 6.80, 7.09, 7.25 (the highest), 7.46, and 7.63 μm ; a strong region of absorption between 8.5 and 9.2 μm , peaking at 8.6, 8.85, and 9.0 μm ; and strong peaks at 10.5 and 12.3 μm .

Add the following:

▲ B. LIMIT OF METHANOL

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

System suitability solution, Sample solution, Standard solution A, Chromatographic system, and System suitability: Proceed as directed in the *Volatile Impurities* test.

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

Acceptance criteria: Meets the requirements in [Table 3](#) for methanol▲ (RB 1-Feb-2022)

IMPURITIES

• LIMIT OF NONVOLATILE RESIDUE

Sample: 50 mL

Analysis: Evaporate the *Sample* in a tared porcelain dish on a steam bath to dryness, and heat at 105° for 1 h.

Acceptance criteria: The weight of the residue does not exceed 2.5 mg (0.005%).

Change to read:

• VOLATILE IMPURITIES

System suitability solution: ▲200 $\mu\text{L/L}$ of methanol and 1000 $\mu\text{L/L}$ of ethyl acetate in▲ (RB 1-Feb-2022) [USP 2-Propanol System Suitability RS](#)

Sample solution: Azeotropic Isopropyl Alcohol ▲(Substance under test)

Standard solution A: 200 $\mu\text{L/L}$ of methanol in *Sample solution*

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

Standard solution B: 1000 $\mu\text{L/L}$ each of acetone, diisopropyl ether, ethyl ether, 1-propanol, 2-butanol, and ethyl acetate in *Sample solution*▲

(RB 1-Feb-2022)

Chromatographic system

(See [Chromatography \(621\)](#), *System Suitability*.)

Mode: GC

Detector: ▲Flame ionization▲ (RB 1-Feb-2022)

Column: 0.25-mm $\times$ 60-m, coated with a 1.4- μm film of phase G43

Temperature

Injector: 150°

Detector: 200°

Column: See [Table 1](#).

Table 1

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
35	▲ (RB 1-Feb-2022)	35	5
35	1	45	▲ (RB 1-Feb-2022)
45	10	100	▲5 (RB 1-Feb-2022)

Carrier gas: Helium

▲Flow rate: 2.3 mL/min▲ (RB 1-Feb-2022)

Injection ▲volume:▲ (RB 1-Feb-2022) 1 µL

▲Injection type: Split injection; split ratio is about 50:1. [NOTE—A 4-mm straight liner is suitable.]▲ (RB 1-Feb-2022)

Run time: ▲26▲ (RB 1-Feb-2022) min

System suitability

Sample: System suitability solution

▲[NOTE—See [Table 2](#).]

Table 2

Name	Relative Retention Time
Methanol	0.5
Ethyl ether	0.8
Acetone	0.9
Isopropyl alcohol	1.0
Diisopropyl ether	1.3
n-Propyl alcohol (1-propanol)	1.4
Ethyl acetate ^a	1.6
2-Butanol	1.7▲ (RB 1-Feb-2022)

^a Ethyl acetate Reference Standard is not a known impurity. It is used for the calculation of unspecified impurities only.

Suitability requirements

Resolution: NLT 1.5 between acetone and isopropyl alcohol

Signal-to-noise ratio: NLT 10 for any of the following peaks: ▲methanol,▲ (RB 1-Feb-2022) ethyl ether, acetone, isopropyl alcohol, diisopropyl ether, 1-propanol, 2-butanol, ▲and ethyl acetate.▲ (RB 1-Feb-2022)

Tailing factor: NMT 2.0 for the isopropyl alcohol peak

Relative standard deviation: NMT 2.0% for the isopropyl alcohol peak ▲of 6 replicate injections of System suitability solution▲ (RB 1-Feb-2022)

Analysis

Samples: Sample solution, ▲Standard solution A, and Standard solution B

Methanol calculation

[NOTE—To be performed as a part of Identification B.]

$$\text{Result (\% v/v)} = \{[M_U / (M_S - M_U)] \times C_M\} / 10,000$$