

Product Specification

Meets U.S.P Requirements, Meets J.P. Chemical Specifications, Meets B.P. Chemical Specifications, Meets E.P. Chemical Specifications, GMP Manufactured Product

Test	Specification
USP – Identification A	Passes Test
USP – Identification B	Passes Test
USP – Identification C (Methanol)	≤ 0.02 %
USP – Specific Gravity at 25°/25°C	0.783 – 0.787
USP – Refractive Index, n ²⁰ D	1.376 – 1.378
USP – Acidity	Passes Test
USP – Nonvolatile Residue	≤ 0.005 %
USP – Assay	≥ 99.0 %
USP – Water (H ₂ O)	≤ 0.5 %
USP – Volatile Impurities – Methanol	≤ 0.02 %
USP – Volatile Impurities – Ethyl ether	≤ 0.1 %
USP – Volatile Impurities – Acetone	≤ 0.1 %
USP – Volatile Impurities – Diisopropyl ether	≤ 0.1 %
USP – Volatile Impurities – 1-Propanol	≤ 0.1 %
USP – Volatile Impurities – 2-Butanol	≤ 0.1 %
USP – Volatile Impurities – Total	≤ 1.0 %
USP – Individual unspecified impurities	≤ 0.1 %
USP – Benzene	≤ 2 ppm
EP/BP – Identification B	Passes Test
EP/BP – Identification C	Passes Test
Appearance	Passes Test
EP/BP – Acidity or Alkalinity	Passes Test
EP/BP – Benzene (C ₆ H ₆)	≤ 2 ppm
EP/BP – Any peak other than 2-butanol	≤ 0.3 %
EP/BP – Peroxide	Passes Test
EP/BP – Nonvolatile Matter	≤ 20 ppm
EP/BP – Water (H ₂ O)	≤ 0.5 %
EP/BP – UV Absorbance – 310 nm	≤ 0.01

>>> Continued on page 2 >>>

Isopropyl Alcohol, U.S.P.
Multi-Compendial
(2-propanol)



Material No.: 9037-20

Test	Specification
EP/BP – UV Absorbance – 290 nm	≤ 0.02
EP/BP – UV Absorbance – 270 nm	≤ 0.03
EP/BP – UV Absorbance – 250 nm	≤ 0.10
EP/BP – UV Absorbance – 230 nm	≤ 0.30
EP/BP – Spectrum Appearance	Passes Test
JP – Identification A	Passes Test
JP – Identification B	Passes Test
JP – Specific Gravity at 20°/20°C	0.785 – 0.788
JP – Clarity of Solution	Passes Test
JP – Acidity	Passes Test
JP – Residue on Evaporation, mg/20mL	≤ 1.0
JP – Water (H ₂ O)	≤ 0.75 %
JP – Distilling Range(Lower)	81 – 83 °C
JP – Distilling Range (Upper)	81 – 83 °C

>>> Continued on page 3 >>>

Isopropyl Alcohol, U.S.P.
Multi-Compendial
(2-propanol)



Material No.: 9037-20

Test

Specification

GMP Manufactured Product
Bulk Pharmaceutical Chemical

CAUTION: For Manufacturing, processing or repackaging

Residual solvents " Only the Class 2 solvent cyclohexane and Class 3 solvents are likely to be present. Cyclohexane is controlled below the USP 467 Option 1 limit. All Class 3 solvents are less than 0.5%.

Packaging Site: Paris Mfg Ctr & DC