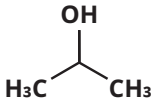
Technical Data Sheet

Isopropyl alcohol (2- Propanol)

IP, BP, Ph.Eur, USP, CDMF



Applications

Isopropyl alcohol (2- Propanol) is used in cosmetics and pharmaceutical formulations, primarily as a solvent in topical formulations. Isopropyl alcohol is also used as a solvent both for tablet film-coating and for tablet granulation, where the isopropyl alcohol is subsequently removed by evaporation.

General Information

Pharmacopeia Status	:	IP, BP, Ph.Eur, USP, CDMF
CAS No.	:	67-63-0
EC No.	:	200-661-7
Appearance/Description	:	Transparent, clear, colorless, mobile, volatile liquid having a characteristic odor & flammable.
Molecular Formula	:	C_3H_8O
Molecular Mass	:	60.10 g/mol

Marketed Formulation

- Amoxicillin trihydrate 500 mg capsule
- Atomoxetine Hydrochloride 18 mg tablet
- Gabapentin 300 mg capsule
- Temazepam 30 mg tablet & many more...

Quality and Regulatory Support

- GMP and ISO certification
- EXCiPACT certification
- Nitrosamine impurity risk assessment
- Elemental impurity risk assessment
- Residual solvent declaration
- Genotoxic impurity declaration
- Vendor questionnaire and site audit
- CMC documentation
- Regulatory queries

Key Product Attributes

- Manufacturing and packing under GMP environment
- Control of sub-visible particles

Pack Mode

- 2.5 Litre glass bottle
- 25 Litre, 20 Kg GI drum
- 160 kg, 200 Litre MS drum

DMF (Drug Master File)

CDMF registered product (CDE # F20200000010)

Stability and Storage Conditions

Isopropyl alcohol should be stored in an airtight container in a cool & dry place.

Safety and Handling Information

Observe normal precautions appropriate to the circumstances and quantity of material handled. Isopropyl alcohol may be irritant to the skin, eyes, and mucous membranes upon inhalation. Eye protection and gloves are recommended. Isopropyl alcohol should be handled in a well-ventilated environment. OSHA standards state that IPA 8-hour time weighted average airborne level in the workplace cannot exceed 400 ppm. Isopropyl alcohol is flammable and produces toxic fumes on combustion.

Pharmaceutical Specifications

Description /Appearance	A transparent, clear, colourless mobile liquid having a characteristic odour and flammable (BP, Ph.Eur, USP)
Solubility	Miscible with water, alcohol, ethanol (96%), methanol with chloroform and ether (IP, USP/Ph.Eur, CDMF)
Acidity or Alkalinity	Not more than 1.4ml of 0.01 mol/L sodium hydroxide is required (CDMF)
	NMT 0.7 mL of 0.020N sodium hydroxide should require for Neutralization (USP)
	Not more than 0.6 mL of 0.01 M sodium hydroxide should require to change the color of the indicator to pale pink (BP, Ph.Eur)
Aldehydes & ketones	Not more than 2.0 mL of 0.1M sodium hydroxide should require
Assay (GC)	Not less than 99.0% (USP)
Benzene and related substances (Benzene)	0.0002% v/v max / 2ppm max. (BP, Ph.Eur, USP)
Benzene and related substances, (Total impurity apart from 2-butanol)	0.3% max. (BP, Ph.Eur)
Carbonyl compounds	The dark red colour produce should not be more intense than that of 0.50ml of the reference solution obtained in the same way (CDMF)
Clarity and colour of solution	The solution should be clear and colorless (CDMF)
Distillation range (95%)	NLT 95% v/v should distil between 81°C-83°C
Identification (By Chemical test)	A white or yellowish white precipitate should produce (IP)
	The sulfuric acid layer should turn violet (BP, Ph.Eur)
Identification (By GC Chromatogram)	The retention time of the major peak of the sample solution corresponds to the 2- propanol peak of the standard solution, as obtained in the assay (USP)
Identification (By IR)	IR spectra of the sample should be concomitant with IR spectra of the standard (BP, Ph.Eur, USP)
Identification (Refractive index, 20±0.5°C)	1.376 to 1.379 (BP, Ph.Eur)
Identification (Relative density, 20°C)	0.785 to 0.789 (BP, Ph.Eur)
Limit of Non-volatile residue	0.005% max. (USP)
Limit of volatile impurities (Each individual impurity)	Not more than 0.1% (USP)
Limit of volatile impurities (Total impurity)	Not more than 1.0% (USP)
Non-volatile matter	Not more than 0.002% w/v / 20 ppm max. (USP, CDMF, BP, Ph.Eur)
Peroxides	No color should develop (BP, Ph.Eur)
Readily carbonizable substances	Any colour produced should not be more intense than that of the reference solution Y1 (CDMF)
Readily oxidizable substances	The pink colour of the solution should not disappear completely (CDMF)
Refractive index,20° C	1.377-1.378
Refractive index,20° C	Between 1.376 - 1.378 (CDMF)
Relative density, 20°C	0.785 to 0.788 (CDMF)
Specific gravity,25°C	Between 0.783 - 0.787 (USP)
UV absorbance profile (10mm cell) at 230nm	0.30 max (BP, Ph.Eur)
UV absorbance profile (10mm cell) at 250nm	0.10 max (BP, Ph.Eur)
UV absorbance profile (10mm cell) at 270nm	0.03 max (BP, Ph.Eur)
UV absorbance profile (10mm cell) at 290nm	0.02 max (BP, Ph.Eur)
UV absorbance profile (10mm cell) at 310nm	0.01 max (BP, Ph.Eur)

Pharmaceutical Specifications

Water	0.5% max. (BP, Ph.Eur, USP)
Water (By KF)	NMT 0.2% (CDMF)
Water insoluble matter	No opalescence should produce
Water insoluble substances	The solution should maintain clear (CDMF)
Wt. per ml (20°C)	0.782g to 0.786g

Regulatory Information

Included in the FDA Inactive Ingredients Database (oral capsules, tablets, and topical preparations), in the non-parenteral medicines licensed in the UK and the Canadian List of Acceptable Non-medicinal Ingredients.

Shipping Information

By Sea, Air and Road
Nature: Hazardous
UN Number: UN1219
Class: 3
Packaging group: II

See the Material Safety Data Sheet on www.finarchemicals.com

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