

PRODUCT SPECIFICATION SHEET

GMP GRADE

ISOPROPANOL 70%

Made with Purified Water and 0.22 micron filtered
Meets USP/NF REAGENT Monographs
With USP<232>, EMA and ICH Q3D Test Results

Catalog Number: 211000GMP-Package Size*

*Individual package sizes have unique size codes
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Manufactured in compliance with cGMP

TEST	SPECIFICATION	TYPICAL RESULT
Appearance	Clear, Free of Suspended Matter	Pass
Assay (by specific gravity of distillate)	0.950 – 0.955 @25°C	0.953
Assay (by volume)	68.0 - 72.0%	69.7 %
Water (by volume)	32.0 – 28.0%	30.3 %
Specific Gravity @ 20°C	0.872 - 0.883	0.8786
Acidity	NMT 1.0 ml of 0.02N NaOH required for neutralization	0.55 ml
Limit of Non-Volatile Residue	NMT 5 mg	0.20 mg
Color (APHA)	5 max	1
Identification	Confirms to IR Spectrum	Pass

Permitted Concentrations of Elemental Impurities Following Option 1 Guideline in drug products, drug substances and excipients¹

Reported in µg/g (ppm)

Element	Class	Oral Concentration µg/g	Parenteral Concentration µg/g	Inhalation Concentration µg/g	TYPICAL RESULT (in µg/g) (ppm)
Cd (Cadmium)	1	0.5	0.2	0.2	0.00
Pb (Lead)	1	0.5	0.5	0.5	0.00
As (Arsenic)	1	1.5	1.5	0.2	0.00
Hg (Mercury)	1	3	0.3	0.1	0.00
Co (Cobalt)	2A	5	0.5	0.3	0.00
V (Vanadium)	2A	10	1	0.1	0.00
Ni (Nickel)	2A	20	2	0.5	0.00
Tl (Thallium)	2B	0.8	0.8	0.8	0.00
Au (Gold)	2B	10	10	0.1	0.00
Pd (Palladium)	2B	10	1	0.1	0.00
Ir (Iridium)	2B	10	1	0.1	0.00
Os (Osmium)	2B	10	1	0.1	0.00
Rh (Rhodium)	2B	10	1	0.1	0.00
Ru (Ruthenium)	2B	10	1	0.1	0.00
Se (Selenium)	2B	15	8	13	0.00
Ag (Silver)	2B	15	1	0.7	0.00
Pt (Platinum)	2B	10	1	0.1	0.00
Li (Lithium)	3	55	25	2.5	0.00
Sb (Antimony)	3	120	9	2	0.00
Ba (Barium)	3	140	70	30	0.00
Mo (Molybdenum)	3	300	150	1	0.00
Cu (Copper)	3	300	30	3	0.00
Sn (Tin)	3	600	60	6	0.00
Cr (Chromium)	3	1100	110	0.3	0.00

¹Includes all requirements for ICH Q3D-Step 4 version, EMA (EP) 5.2 and USP <232> and <233> General Chapters.

Form Isopropanol 70%-GMP, Rev. 1.7, 06/16, KAD

This product is for further commercial manufacturing, laboratory or research use, and may be used as an excipient or a process solvent for pharmaceutical purposes. It is not intended for use as an active ingredient in drug manufacturing nor as a medical device or disinfectant. Appropriate/legal use of this product is the responsibility of the user.