

PRODUCT SPECIFICATIONS SHEET
WORLD/GMP GRADE

n-Propyl Alcohol

Meets ACS/FCC/EP Grade Monographs
With USP<232>, EMA and ICH Q3D Elemental Impurities Test Results

Catalog Number: 334WORLD-Size Code*

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

TEST	MONO-GRAPH	SPECIFICATION	TYPICAL RESULT
Assay Assay (by GC, corrected for water)	FCC ACS	NLT 99.0% of C ₃ H ₈ O 99.5% min	99.99%
Identification A – Refractive Index	EP FCC	1.384 – 1.387 @ 20° C 1.383 – 1.388 @ 20° C	1.386
Identification B – Boiling Point	EP	96° C – 98° C	Pass
Identification C – Infrared Absorption Identification	EP FCC	Conforms to Reference Spectra	Pass
Identification D	EP	Meets Requirement of Test	Conforms
Solubility in Water	ACS	To pass test	Pass
Specific Gravity	FCC	0.800 – 0.805 @ 25° C	0.804
Color (APHA)	ACS	10 max	2
Appearance	EP	Clear and colorless	Pass
Residue after Evaporation Non-volatile Matter	ACS EP	0.001% max 0.004% max	<0.001%
Acidity or Alkalinity	EP	The solution is pink	Pass
Titration Acid	ACS	0.0004 meq/g max	<0.0004 meq/g
Related Substances	EP	Any Impurity 0.1% max Total Impurities 0.3% max Disregard Limit 0.01% max	Pass Pass Pass
Ethyl Alcohol	ACS	0.01% max	<0.001%
Methanol	ACS	0.01% max	<0.001%
Isopropyl Alcohol	ACS	0.05% max	<0.001%
Carbonyl Compounds (as Propionaldehyde)	ACS	0.03% max	<0.001%
Absorbance	EP	230 nm 0.30 max. 250 nm 0.10 max 270 nm 0.03 max. 290 nm 0.02 max. 310 nm 0.01 max. The absorption curve does not show any peaks	0.15 0.05 0.00 0.00 0.00 Pass
Reducing Substances	EP	To Pass Test	Pass
Water	ACS/EP	0.2% max	0.03%

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: n-Propanol, ACS-FCC-EP Rev. 2.1, 08/17, MB

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.