



PRODUCT SPECIFICATIONS SHEET
WORLD GRADE ®

ACETONE

Meets REAGENT ACS, NF, BP, EP Grade Monographs

WORLD/GMP GRADE

Catalog Number: 329WORLD-Size Code*

*Individual package sizes have unique size codes

Manufactured in compliance with cGMP

TEST	MONO-GRAPH	SPECIFICATION	TYPICAL RESULT
Assay (corrected for water)	ACS	NLT 99.5%	99.8%
Assay (on the anhydrous basis)	NF	NLT 99.0%	99.9%
Identification A – Infrared Absorption	NF	Conforms to Infrared Spectra	Pass
Identification B – GC	NF	Conforms to Reference Chromatogram	Pass
Specific Gravity @ 25°C	NF	NMT 0.789	0.7870
Identification A – Relative Density	EP/BP	0.790 – 0.793@ 20°C	0.792
Identification B	EP/BP	An intense red color is produced, and becomes violet.	Pass
Identification C	EP/BP	A greenish-blue color is produced	Pass
Appearance	ACS	Clear liquid with characteristic odor	
Appearance of Solution	BP/EP	Clear, colorless liquid	Pass
Color (APHA), max	ACS	10 max	1
Solubility in Water	ACS	The solution remains clear for 30 min.	Pass
Matter Insoluble in Water	BP/EP	The solution is clear	Pass
Residue After Evaporation	ACS	0.001%, max	<0.001%
	BP/EP	50 ppm, max	< 5 ppm
Nonvolatile Residue	NF	NMT 2 mg /50mL (0.004%)	0.3mg
Titration Acid,	ACS	0.0003 meq/g, max	0.0002meq/g
Titration Base	ACS	0.0006 meq/g, max	0.0001meq/g
Acidity or Alkalinity	BP/EP	To Pass Test	Pass
Aldehyde (as HCHO)	ACS	0.002%, max	< 0.002%
Isopropyl Alcohol	ACS	0.05%, max	< 0.0001%
Methanol	ACS	0.05%, max	<0.04%
Substances Reducing Permanganate	ACS		
Readily Oxidizable Substances	NF	To Pass Test	Pass
Reducing Substances	BP/EP		
Water	ACS/NF	0.5%, max	0.20%
Water	BP/EP	NMT 3g/L	2 g/L
Related Substances (by GC)			
Impurity A - Methanol	BP/EP	NMT 0.05% (v/v)	<0.04%
Impurity B - Isopropanol		NMT 0.05% (v/v)	<0.0001%
Impurity C - Benzene		NMT 2ppm (v/v)	<1ppm
Any other impurity		NMT 0.05% (v/v)	<0.01%

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

Form Acetone-ACS-NF-BP-EP, Rev. 2.3, 04/20, RAC

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

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.