

PRODUCT SPECIFICATIONS SHEET
WORLD/GMP GRADE
ACETONE
 REAGENT ACS, NF, BP, EP Grade
 With USP<232>, EMA and ICH Q3D Test Results
 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%	99.8%
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	Pass
Appearance of Solution	BP/EP	Clear, colorless liquid	
Color (APHA), max	ACS	10, max	5
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	<0.0006%
	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	To Pass Test	Pass
Readily Oxidizable Substances	NF		
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)	BP/EP	NMT 0.05% (v/v)	<0.04%
Impurity A - Methanol		NMT 0.05% (v/v)	<0.0001%
Impurity B - Isopropanol		NMT 2ppm (v/v)	<1ppm
Impurity C - Benzene		NMT 0.05% (v/v)	<0.01%
Any other impurity			

USP <232> ELEMENTAL IMPURITIES— LIMITS

Reported in µg/g (ppm)

Default Concentration Limits for Drug Substances and Excipients

ELEMENT	Concentration Limits (µg/g) for Oral Drug Products with a Maximum Daily Dose of ≤10 g/day	Concentration Limits (µg/g) for Parenteral Drug Products with a Maximum Daily Dose of ≤10 g/day	Concentration Limits (µg/g) for Inhalation Drug Products with a Maximum Daily Dose of ≤10 g/day	TYPICAL RESULT (in µg/g) (ppm)
Cadmium	0.5	0.25	0.34	0.00
Lead	0.5	0.5	0.5	0.00
Inorganic Arsenic	1.5	1.5	0.19	0.00
Inorganic Mercury	1.5	0.15	0.12	0.00
Iridium	10	1.0	0.15	0.00
Osmium	10	1.0	0.15	0.00
Palladium	10	1.0	0.1	0.00
Platinum	10	1.0	0.15	0.00
Rhodium	10	1.0	0.15	0.00
Ruthenium	10	1.0	0.15	0.00
Chromium	*	*	0.29	0.00
Molybdenum	18	9.0	0.76	0.00
Nickel	60	6.0	0.60	0.00
Vanadium	12	1.2	0.12	0.00
Copper	130	13	1.3	0.00

* Not a safety concern

EMA GUIDELINE ON THE SPECIFICATION LIMITS FOR RESIDUES OF METAL CATALYSTS OR METAL REAGENTS

Reported in ppm

Class Exposure and Concentration Limits for Individual Metal Catalysts and Metal Reagents

CLASSIFICATION	ELEMENT	Concentration Limits (ppm) for Oral Exposure	Concentration Limits (ppm) for Parenteral Exposure	TYPICAL RESULT (ppm)
Class 1A	Platinum (Pt)	10	1	0.00
	Palladium (Pd)	10	1	0.00
Class 1B	Iridium (Ir)**	10**	1**	0.00
	Rhodium (Rh)**	10**	1**	0.00
	Ruthenium (Ru)**	10**	1**	0.00
	Osmium (Os)**	10**	1**	0.00
Class 1C	Molybdenum (Mo)	25	2.5	0.00
	Nickel (Ni)	25	2.5	0.00
	Chromium (Cr)	25	2.5	0.00
	Vanadium (V)	25	2.5	0.00
Class 2	Copper (Cu)	250	25	0.00
	Manganese (Mn)	250	25	0.00
Class 3	Iron (Fe)	1300	130	0.00
	Zinc (Zn)	1300	130	0.00

** Subclass limit: the total amount of listed metals should not exceed the indicated limit

ICH Q3D: Metal Impurities¹

Reported in µg/g (ppm)

Permitted concentrations of Metal Impurities in drug products, drug substances and excipients

ELEMENT	Proposed Option 1 Oral Concentrations, (µg/g) (50 kg bw)	Proposed Option 1 Parenteral Concentrations, (µg/g) (50 kg bw)	Proposed Option 1 Inhalation Concentrations, (µg/g) (50 kg bw)	TYPICAL RESULT (in µg/g) (ppm)
Arsenic (As)	0.15	0.15	0.15	0.00
Lead (Pb)	0.5	0.5	0.5	0.00
Thallium (Tl)	1	0.15	0.15	0.00
Gold (Au)	1	0.15	0.15	0.00
Cadmium (Cd)	2.5	0.25	0.15	0.00
Mercury (Hg)	4.0	0.4	0.3	0.00
Platinum (Pt)	10	1	0.15	0.00
Palladium (Pd)	10	1	0.15	0.00
Vanadium (V)	10	1	3	0.00
Cobalt (Co)	10	1	0.15	0.00
Rhodium (Rh)**	10	1	0.15	0.00
Ruthenium (Ru)**	10	1	0.15	0.00
Osmium (Os)**	10	1	0.15	0.00
Iridium (Ir)**	10	1	0.15	0.00
Selenium (Se)	10	10	0.3	0.00
Molybdenum (Mo)	10	1	1	0.00
Nickel (Ni)	50	5	0.15	0.00
Tungsten (W)	75	40	40	0.00
Silver (Ag)	75	7.5	0.75	0.00
Copper (Cu)	100	10	10	0.00
Antimony (Sb)	120	60	1	0.00
Tin (Sn)	600	60	6	0.00
Barium (Ba)	600	60	35	0.00
Lithium (Li)	800	400	8	0.00
Chromium (Cr)	1000	100	2.5	0.00
Boron (B)	2000	2000	150	0.00
Aluminum (Al)	5000	Different regional regulation	0.5	0.00

** Insufficient data to establish an appropriate PDE; limit established based on Pt PDE

¹These specifications are based on the ICH Q3D Preliminary Draft. The final guidance has not been issued.