PRODUCT SPECIFICATIONS SHEET

WORLD/GMP GRADE
ACETONE

Meets REAGENT ACS, NF, BP, EP Grade Monographs

With USP<232>, EMA and ICH Q3D Elemental Impurities 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) Assay (on the anhydrous basis)	ACS NF	NLT 99.5% NLT 99.0%	99.8% 99.9%
Identification A – Infrared Absorption Identification B – GC	NF NF	Conforms to Infrared Spectra Conforms to Reference Chromatogram	Pass Pass
Specific Gravity @ 25^0C	NF	NMT 0.789	0.7870
Identification A – Relative Density Identification B Identification C	EP/BP EP/BP EP/BP	0.790 – 0.793@ 20^0C An intense red color is produced, and becomes violet. A greenish-blue color is produced	0.792 Pass Pass
Appearance Appearance of Solution	ACS BP/EP	Clear liquid with characteristic odor Clear, colorless liquid	 Pass
Color (APHA), max	ACS	10 max	1
Solubility in Water Matter Insoluble in Water	ACS BP/EP	The solution remains clear for 30 min. The solution is clear	Pass Pass
Residue After Evaporation	ACS BP/EP	0.001%, max 50 ppm, max	<0.001% < 5 ppm
Nonvolatile Residue	NF	NMT 2 mg /50mL (0.004%)	0.3mg
Titrable Acid,	ACS	0.0003 meq/g, max	0.0002meq/g
Titrable 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 Readily Oxidizable Substances Reducing Substances	ACS NF BP/EP	To Pass Test	Pass
Water Water	ACS/NF BP/EP	0.5%, max NMT 3g/L	0.20% 2 g/L
Related Substances (by GC) Impurity A - Methanol Impurity B - Isopropanol Impurity C - Benzene Any other impurity	 BP/EP	 NMT 0.05% (v/v) NMT 0.05% (v/v) NMT 2ppm (v/v) NMT 0.05% (v/v)	 <0.04% <0.0001% <1ppm <0.01%

Permitted Concentrations of Elemental Impurities Following Option 1 Guideline in drug products, drug substances and excipients[1]

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. 2.1, 02/17, SKKS

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