Acetone

World/GMP. WORLD Grade ®

Grade: ACS/NF/EP/BP **Catalog number:** 329WORLD

Test	Mono-graph	Specification	Typical Result
Assay (corrected for water)	ACS	NLT 99.5%	99.71 %
Assay (on the anhydrous basis)	NF	NLT 99.0%	99.98 %
Color (APHA)	ACS	10 max.	1
Appearance of Solution	EP/BP	The solution is clear and colorless	Pass
Characters	EP/BP	Appearance: volatile, clear, colorless liquid. Solubility: miscible with water and with ethanol (96 per cent).The vapour is flammable.	Pass
Residue after Evaporation	ACS	0.001%, max	0.000 %
Nonvolatile Residue	NF	NMT 2 mg/50mL (0.004%)	0 mg
Residue on Evaporation	EP/BP	50 ppm, max	0 ppm
Solubility in Water	ACS	The solution remains clear for 30 min.	Pass
Titrable Acid	ACS	0.0003 meq/g, max	0.0000 meq/g
Acidity or Alkalinity	EP/BP	To Pass Test	Pass
Titrable Base	ACS	0.0006 meq/g, max	0.0000 meq/g
Aldehyde (as HCHO)	ACS	0.002%, max	LT 0.002%
Isopropyl Alcohol	ACS	0.05%, max	0.00 %
Related Substances Impurity B – Isopropanol	EP/BP	NMT 0.05% (v/v)	0.00 %

Test	Mono-graph	Specification	Typical Result
Methanol	ACS	0.05%, max	0.02 %
Related Substances Impurity A - Methanol	EP/BP	NMT 0.05% (v/v)	0.02 %
Related Substances Impurity C – Benzene	EP/BP	NMT 2ppm (v/v)	0 ppm
Related Substances - Any other impurity	EP/BP	NMT 0.05% (v/v)	0.00 %
Matter Insoluble in Water	EP/BP	The solution is clear	Pass
Substances Reducing Permanganate	ACS	To Pass Test	Pass
Reducing substances	EP/BP	To Pass Test	Pass
Water	ACS	0.5%, max	0.27 %
Water	NF	0.5%, max	0.27 %
Water	EP/BP	NMT 3g/L	2.2 g
Identification A - Infrared Absorption	NF	Conforms to Infrared Spectra	Pass
Identification B - GC	NF	Conforms to Reference Chromatogram	Pass
Identification A - Relative Density	EP/BP	0.790 - 0.793 @ 20°C	0.791
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
Specific Gravity @ 25°C	NF	NMT 0.789	0.787
Readily Oxidizable Substances	NF	To Pass Test	Pass
Ag (Silver)	USP<232>	Lot Analysis	0.00 ppm
As (Arsenic)	USP<232>	Lot Analysis	0.00 ppm
Au (Gold)	USP<232>	Lot Analysis	0.00 ppm

Test	Mono-graph	Specification	Typical Result
Ba (Barium)	USP<232>	Lot Analysis	0.00 ppm
Cd (Cadmium)	USP<232>	Lot Analysis	0.00 ppm
Co (Cobalt)	USP<232>	Lot Analysis	0.00 ppm
Cr (Chromium)	USP<232>	Lot Analysis	0.00 ppm
Cu (Copper)	USP<232>	Lot Analysis	0.00 ppm
Hg (Mercury)	USP<232>	Lot Analysis	0.00 ppm
Ir (Iridium)	USP<232>	Lot Analysis	0.00 ppm
Li (Lithium)	USP<232>	Lot Analysis	0.00 ppm
Mo (Molybdenum)	USP<232>	Lot Analysis	0.00 ppm
Ni (Nickel)	USP<232>	Lot Analysis	0.00 ppm
Os (Osmium)	USP<232>	Lot Analysis	0.00 ppm
Pb (Lead)	USP<232>	Lot Analysis	0.00 ppm
Pd (Palladium)	USP<232>	Lot Analysis	0.00 ppm
Pt (Platinum)	USP<232>	Lot Analysis	0.00 ppm
Rh (Rhodium)	USP<232>	Lot Analysis	0.00 ppm
Ru (Ruthenium)	USP<232>	Lot Analysis	0.00 ppm
Sb (Antimony)	USP<232>	Lot Analysis	0.00 ppm
Se (Selenium)	USP<232>	Lot Analysis	0.00 ppm
Sn (Tin)	USP<232>	Lot Analysis	0.00 ppm
Tl (Thallium)	USP<232>	Lot Analysis	0.00 ppm

Test	Mono-graph	Specification	Typical Result
V (Vanadium)	USP<232>	Lot Analysis	0.00 ppm

Certification and Compliance Statements

This product is processed and packaged in compliance with excipient Good Manufacturing Practices.

This product complies with all of the current requirements listed in the National Formulary, European Pharmacopoeia, and British Pharmacopoeia monographs.

This product is not derived, nor does it come in contact with, any materials derived from bovine or other animal sources.

No chemicals whatsoever are used as solvents at any point in the manufacture, processing, or packaging of Acetone. Acetone may contain trace amounts of Benzene. Benzene is not used as a solvent but may appear in Acetone as a by-product. The typical level for Benzene content in Acetone is <2ppm. Class 2 and Class 3 residual solvents may appear as impurities / related substances / low level contaminants in Acetone. Concentration of Class 2 Option 1 and Class 3 residual solvents is below limits in the current USP/NF General Chapter <467> and ICH Q3C Impurities: Residual Solvents.

Greenfield products are for further commercial manufacturing, laboratory use, or research. Greenfield is not registered with the United States Food and Drug Administration (FDA) as a drug manufacturing facility. Greenfield products are not registered with the FDA as active pharmaceutical ingredients in drug manufacturing. Appropriate/legal use of all products are the responsibility of the user and subject to applicable local laws and regulations.