Acetone

Grade: ACS/USP/NF/EP/BP **Catalog number:** ZP3290000EP

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	ACS	Clear liquid with characteristic odor	Pass
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
Acidity or Alkalinity	EP/BP	To Pass Test	Pass
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%

Test	Mono-graph	Specification	Typical Result
Related Substances Impurity B – Isopropanol	EP/BP	NMT 0.05% (v/v)	0.00 %
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/L
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

Certification and Compliance Statements

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.

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