



Certificate of analysis

CAS # 1867-66-9

Product	:	Ketamine Hydrochloride USP	License No.	:	KD-10
Batch No.	:	SLL/KH/0822147	Date of Manufacturing	:	Aug.-2022
Batch Qty.	:	546.120 kg	Date of Expiry	:	July- 2027
A. R. No.	:	SLL/QC/FP/22/1291	Date of Release	:	14/09/2022

Sr.No.	Test	Specifications	Results
1.	Description	White crystalline powder, having a slight, characteristic odour.	White crystalline powder, having a slight, characteristic odour.
2.	Solubility	Freely soluble in water and in methanol; soluble in alcohol, sparingly soluble in chloroform.	Conforms
3.	Clarity and colour of solution (20.0%, w/v solution in water)	Resultant Solution should be clear and colourless.	Resultant solution is clear and colourless.
4.	Identification		
4.1	Test A: IR Absorption	The Infrared spectrum of sample should be concordant with IR spectrum of working standard or reference standard.	Complies
4.2	Test B: UV absorption	Acid solvent: The respective absorptivities at the wavelengths of maximum absorbance at about 269 and 276 nm, do not differ by more than 3.0% between sample and standard solution.	Complies
		Basic solvent: The respective absorptivities at the wavelength of maximum absorbance at about 302 nm, do not differ by more than 3.0% between sample and standard solution.	Complies
5.	pH (10.0% , w/v solution)	Between 3.5 and 4.1	3.87
6.	Residue on ignition (% , w/w)	Not more than 0.1	0.04

QA/011/F03-02/Effective date 05/08/2015

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Corporate Office : 207/208, Udyog Bhavan, Sonawala Road, Goregaon (East), Mumbai - 400 063. Maharashtra, India.

Tel: +91 22 40332727 / 66942507 | Fax : +91 22 26860011 | GSTIN : 27AALCS8686A1ZX

CIN : L51900MH2008PLC180452 | Email: supriya@supriyalifescience.com | Website: www.supriyalifescience.com

Factory : A 5/2, Lote Parshuram Industrial Area, M.I D.C, Tal. - Khed, Dist.-Ratnagiri, 415 722, Maharashtra, India.

Tel. : +91 2356 272299 | Fax : +91 2356 272178 | E-mail: factory@supriyalifescience.com

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SUPRIYA LIFESCIENCE LTD.
Creating true values that binds global health

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Sr.No.	Test	Specifications	Results
7.	Related Compounds by HPLC (%)		
	i. Related compound A	Not more than 0.1	BDL
	ii. Unknown Impurity	Not more than 0.3	0.02
	iii. Total unknown impurity	Not more than 1.0	0.02
8.	Assay by HPLC (% w/w)	Not less than 98.0 and not more than 102.0	100.3
9.	Additional Test		
9.1	Residual Solvents by GC-HS (ppm)		
	i. Methanol	Not more than 3000	BDL
	ii. Acetone	Not more than 5000	BDL
	iii. Isopropyl alcohol	Not more than 5000	44
	iv. Toluene	Not more than 890	BDL
Where, BDL : Below Disregard Limit For Related Compounds by HPLC BDL : Below Detection Limit For Residual Solvent by GC			
Remarks: The product complies with respect to above mentioned test as per USP NF 2022 specifications.			
Storage: Preserve in well-closed container. Store at 25°C, excursion permitted between 15°C and 30°C.			
Compiled by QC QC Chemist (M.M.Sawant)		Checked by QC QC Sr.Officer (D.B.Pol)	Approved by - QC QC Dy.Sr.Manager (S.U.Takale)

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