



CERTIFICADO DE ANÁLISIS (COA)

Producto: Ketamina HCL

CAS N°: 1867-66-9

Certificate of analysis

CAS NO. : 1867-66-9

Product	: Ketamine Hydrochloride USP	License No.	: KD-10
Batch No.	: SLL/KH/0122017	Date of Manufacturing	: Jan.-2022
Batch Qty.	: 570.800 kg	Date of re-test/Expiry	: Dec.-2026
A. R. No.	: SLL/QC/FP/22/0116	Date of Release	: 03/02/2022

Sr.No.	Test	Specifications	Results
1.	Characters		
	i. Description	White crystalline powder, having a slight, characteristic odour.	White crystalline powder having a slight, characteristic odour.
	ii. Solubility	Freely soluble in water and in methanol; soluble in alcohol, sparingly soluble in chloroform.	Conforms
2.	Clarity and colour of solution (20.0%, w/v solution in water)	Solution should be clear and colourless.	The solution is clear and colourless.
3.	Identification		
	i. Test A: IR Absorption	The infrared spectrum of sample should be concordant with IR spectrum of working standard or reference standard.	Complies
	ii. UV absorption.		
	a) Acid solvent	The maximum absorbance at about 269 to 276 nm, do not differ by more than 3.0% between sample and standard solution.	Complies
	b) Basic solvent	The maximum absorbance at about 302 nm, do not differ by more than 3.0% between sample and standard solution.	Complies
4.	pH (10.0% w/v solution)	Between 3.5 and 4.1	3.63

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Sr.No.	Test	Specifications	Results
5.	Residue on ignition (% w/w)	Not more than 0.1	0.06
6.	Related compounds by HPLC (%)		
	i. Impurity A	Not more than 0.1	BDL
	ii. Unknown Impurity	Not more than 0.3	0.02
	iii. Total Impurities	Not more than 1.0	0.03
7.	Assay by HPLC (% w/w)	Not less than 98.0 and not more than 102.0	99.55
8.	Additional Test		
8.1	Residual Solvents by GC-HS (ppm)		
	i. Methanol	Not more than 3000	BDL
	ii. Acetone	Not more than 5000	BDL
	iii. Toluene	Not more than 890	BDL
	iv. Isopropyl alcohol	Not more than 5000	748

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 43** specifications.

Storage: Preserve in well-closed container. Store at 25°C, excursion permitted between 15°C and 30°C.

 04/02/22 Compiled by QC QC Chemist (M.M.Sawant)	 04/02/2022 Checked by QC QC Executive (D.D.Jadhav)	 04/02/22 Approved by QC QC Dy.Sr.Manager (S.U.Takale)
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