

Certificate of Analysis

Product Name and grade	: Ketamine Hydrochloride USP	Mfg. License No.	: KD-10
IUPAC Name	: (±)-2-(o-Chlorophenyl)-2-(methylamino) cyclohexanone hydrochloride.		
Batch No.	: SLL/KH/1025167	CAS Number	: [1867-66-9]
Batch Qty.	: 568.690 kg	Mfg. Date	: Oct - 2025
Dispatch Qty.	: 25.000 kg	Exp. / Retest Date	: Sep - 2030
A. R. No.	: SLL/QC/FP/25/3180	Date of release	: 10/10/2025

Sr.No.	Test	Specifications	Results
1.	Description	White crystalline powder, having a slight, characteristic odour.	White crystalline powder.
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)	The solution is clear and colourless	The 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 in water)	Between 3.5 and 4.1	3.9
6.	Residue on ignition (% w/w)	Not more than 0.1	0.02
7.	Related Compounds by HPLC (%)		
	Related compound A	Not more than 0.1	Not detected
	Unknown Impurity	Not more than 0.3	BLQ
	Total unknown impurity	Not more than 1.0	0.02

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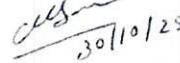
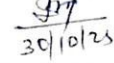

Sr.No.	Test	Specifications	Results
8.	Assay by HPLC (% w/w)	Not less than 98.0 and not more than 102.0	99.9
9.	Additional Test		
9.1	Residual Solvents by GC-HS (ppm)		
	Methanol	Not more than 3000	Not detected
	Acetone	Not more than 5000	Not detected
	Isopropyl alcohol	Not more than 5000	75
	Toluene	Not more than 890	Not detected
	2-Chloropropane	Not more than 33	1

Where;

BLQ: Below Limit of Quantification.

Remarks: The product complies with respect to above mentioned test as per grade **USP NF 2025**.

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

 30/10/25 Prepared by QA Executive (M.M.Ambre)	 30/10/25 Checked by QA Executive (D.B.Pol)	 30/10/2025 Approved by QA Dy. Manager (S.H.Mengade)
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