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	CERTIFICATE OF ANALYSIS	

Name of the Product	:	CISAPRIDE MONOHYDRATE			
Batch Number	:	ACIS/2501001	Analyzed on	:	31/01/2025
Manufacturing Date	:	JAN'2025	Expiry Date	:	DEC'2029
Quantity	:	113.80Kg	A.R.No.	:	FP/25127

S.No.	TEST	RESULT	SPECIFICATION
1.0	Description	White powder	White or almost white powder.
2.0	Solubility	Complies	Freely soluble in dimethylformamide; soluble in methylene chloride; sparingly soluble in methanol; practically insoluble in water.
3.0	Completeness of solution	Complies	To meet the test.
4.0	Identification by Infrared absorption	Complies	To match with Working / Reference standard.
5.0	Specific Rotation (at 20°C)	-0.08°	Between -10° and +10°
6.0	Water content	3.77% w/w	Between 3.4% and 4.0% w/w
7.0	Residue on ignition	0.03% w/w	Not more than 0.1% w/w
8.0	Chromatographic purity by HPLC		
	Any single maximum Impurity	0.09%	Not more than 0.50%
	Total Impurities	0.24%	Not more than 1.00%
9.0	Assay by HPLC (on anhydrous basis)	100.5% w/w	Not less than 99.0% and not more than 101.0% w/w
10.0	ADDITIONAL TEST		
10.1	Residual solvents by GC HS		
	Methanol	29 ppm	Not more than 3000 ppm
	Methyl isobutyl ketone	BDL (LOD: 0.90 ppm)	Not more than 2260 ppm
	Toluene	BDL (LOD: 0.16 ppm)	Not more than 890 ppm

BDL: Below Detection Limit.

REMARKS: The material complies as per USP Specification.

	Prepared By QC	Checked By QC	Approved By QC
Signature & date	<u>K. Teja</u> 31/01/2025	<u>[Signature]</u> 31/01/2025	<u>[Signature]</u> 31/01/2025
Name	K. TEJA SWARUPA CHARI	P. GOVARDHAN	B. SRINIVASA RAJU
Designation	Executive-QC	Asst Manager-QC	Head-QC

