Certificate of Analysis

Product Name and grade	:	Dextromethorphan Hydrobromide EP	Mfg. License No.	:	KD-129
IUPAC Name	:	ent-3-Methoxy-17-methylmorphinan Hydrobromide monohydrate.			
Batch No.	:	SLL/DXB/0324008	CAS Number	:	[6700-34-1]
Batch Qty.	:	504.000 kg	Mfg. Date	:	Mar. -2024
Dispatch Qty.	:	25.000 kg	Exp. / ~~Retest~~ Date	:	Feb.- 2029
A. R. No.	:	SLL/QC/FP/24/1013	Date of release	:	31/03/2024

Sr.No.	Test	Specifications	Results
1.	Characters :		
1.1	Appearance	Almost white crystalline powder.	Almost white crystalline powder.
1.2	Solubility	Sparingly soluble in water, freely soluble in ethanol.(96%)	Conforms
1.3	Melting Point	It melts at about 125°C with decomposition.	126
2.	Identification : (first identification A,B,D and second identification A,C,D)		
2.1	A. Specific optical rotation (anhydrous substance) (°)	+28 to +30	+28.1
2.2	B. IR Test	The IR absorption spectrum should be concordant with that of Dextromethorphan Hydrobromide working standard /reference standard.	Complies
2.3	D. Bromides Test	It gives reaction (a) of bromides.	Complies
3.	Appearance of solution	Solution S is clear and colourless.	Solution S is clear and colourless
4.	Acidity or alkalinity	Not more than 0.4 mL of 0.01 M hydrochloric acid is required to change the colour of the indicator to red.	0.3
5.	Specific optical rotation (anhydrous substance) (°)	+28 to +30	+28.1
6.	Related substance by HPLC (%)		
	Any single maximum known impurity from (Impurity A or B or C or D) (Impurity A)	Not more than 0.5	BDL
	Other each known impurity from (Impurity A, B, C, and D) (Impurity B)	Not more than 0.25	BDL

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Tel: +91 22 40332727 / 66942507 I Fax : +91 22 26860011 I GSTIN : 27AALCS8686A1ZX
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Factory : A 5/2, Lote Parshuram Industrial Area, M.I.D.C, Tal. - Khed, Dist.-Ratnagiri, 415 722, Maharashtra, India.
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Sr.No.	Test	Specifications	Results
	Other each known impurity from (Impurity A, B, C, and D) (Impurity C)	Not more than 0.25	BDL
	Other each known impurity from (Impurity A, B, C, and D) (Impurity D)	Not more than 0.25	BDL
	unspecified impurities	Not more than 0.10	BDL
	Total impurities	Not more than 1.0	BDL
7.	Limit of N,N-dimethylaniline (ppm)	Maximum 10	Less than 10
8.	Water by KF (%, w/w)	4.0 to 5.5	5.1
9.	Sulfated ash (%, w/w)	Maximum 0.1	0.04
10.	Assay by potentiometrically on anhydrous basis (%)	99.0 to 101.0	99.7
11.	Additional test		
11.1	Residual solvents by GC-HS (ppm)		
	Methanol	Not more than 3000	Not detected
	Methyl formate	Not more than 1000	Not detected
	Acetone	Not more than 5000	681
	Methyl acetate	Not more than 5000	Not detected
	Isopropyl Alcohol	Not more than 5000	Not detected
	Toluene	Not more than 890	Not detected

Where ,
BDL : Below Disregard Limit For Related Substances by HPLC

Remarks: The product complies with respect to above mentioned test as per grade **EP 11.0.**

Storage Condition: Protected from light.

Prepared by QA	Checked by QA	Approved by QA
01/04/24	01/04/24	01/04/24
Officer (M.M.Ambre)	Sr.Executive (V.A.Sawant)	Asst.Manager (A.C.Joshi)

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