

**SUPRIYA LIFESCIENCE LTD.**

Creating true values that binds global health

**Certificate of Analysis**

Product Name and grade	: Dextromethorphan Hydrobromide EP	License No.	: KD-129
Batch No.	: SLL/DXB/1222033	Month of Manufacturing	: Dec. -2022
Batch Qty.	: 525.000 kg	Month of re-test / expiry	: Nov- 2027
Dispatch Qty	: 25.000 kg		
A. R. No.	: SLL/QC/FP/23/1408	Date of Release	: 15/06/2023

Sr.No.	Test	Specification	Result
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.	125.4
2.	IDENTIFICATION : (First identification A, B, D and Second identification A,C,D)		
2.1	A. Specific optical rotation (anhydrous substance) (°)	+28 to +30	+28.90
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) (°) (2.2.7)	+28 to +30	+28.90
6.	Related substances by HPLC (%)		
	Any single maximum known impurity from (Impurity A or B or C or D) (Impurity A)	Not more than 0.5	0.20
	Other each known impurity from (Impurity A, B, C, and D) (Impurity D)	Not more than 0.25	0.08

QA/011/F03-03 /Effective date 15/12/2022

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

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CIN : L51900MH2008PLC180452 | Email: [supriya@supriyalifescience.com](mailto:supriya@supriyalifescience.com) | Website: [www.supriyalifescience.com](http://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 672300 / 200 Fax : +91 2356 272178 E-Mail : [factory@supriyalifescience.com](mailto:factory@supriyalifescience.com)**GOVT. RECOGNISED EXPORT HOUSE**



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Sr.No.	Test	Specification	Result
	Other each known impurity from (Impurity A, B, C, and D) (Impurity B)	Not more than 0.25	BDL
	Other each known impurity from (Impurity A, B, C, and D) (Impurity C)	Not more than 0.25	BDL
	unspecified impurities	Not more than 0.10	BDL
	Total impurities	Not more than 1.0	0.27
7.	Limit of N,N-dimethylaniline (ppm)	Maximum 10	Less than 10
8.	Water by KF (% w/w)	4.0 to 5.5	5.12
9.	Sulfated ash (% w/w)	Maximum 0.1	0.03
10.	Assay by potentiometrically on anhydrous basis (%)	99.0 to 101.0	100.46
11.	Additional test		
11.1	Residual solvents by GC-HS (ppm)		
	Methanol	Not more than 3000	BDL
	Methyl formate	Not more than 1000	BDL
	Acetone	Not more than 5000	271
	Methyl acetate	Not more than 5000	BDL
	Isopropyl Alcohol	Not more than 5000	BDL
	Toluene	Not more than 890	10

Where ,

BDL : Below Detection Limit For Residual Solvents by GC-HS

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.

 15/06/23 Prepared by QA Chemist (M.M.Ambre)	 15/06/23 Checked by QA Sr. Executive (V.A.Sawant)	 15/06/23 Approved by Head-QA/Designee Head-QA (Sheshhu Kumar Kalidindi)
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