

**SUPRIYA LIFESCIENCE LTD.***Creating true values that bind global health***Certificate of analysis**

Product	: Dextromethorphan Hydrobromide USP	License No.	: KD-129
Batch No.	: SLL/DMH/1216004	Date of Manufacturing	: Dec -2016
Batch Qty.	: 24.0kg	Date of re-test/Expiry	: Nov -2021
A. R. No.	: SLL/QC/FP/16/1037	Date of Release	: 31/12/2016

Sr. No.	Test	Specification	Result
1.	Description	Practically white crystals or crystalline powder, having a faint odor.	White crystalline powder
2.	Solubility	Freely soluble in alcohol and chloroforms, sparingly Soluble in water, practically in soluble in ether.	Confirm
3.	Melting Point	It melts at about 126°C with decomposition.	129.4
4.	Identification:		
	i. IR Absorption	The IR absorption spectrum should be concordant with that of Dextromethorphan Hydrobromide working standard /reference standrd.	Positive
	ii. UV Absorption	Do not differ by more than 3.0 % on anhydrous basis.	0.18
	iii. Colour Test	A yellowish white precipitate should be formed.	Positive
5.	pH (1 g in 100 mL water)	Between 5.2 and 6.5	5.32
6.	Water determination by KF (% w/w)	Between 3.5 and 5.5	4.95
7	Residue on ignition (% w/w)	NMT 0.1	0.06

QA/011/F03-02/Effective date 05/08/2015

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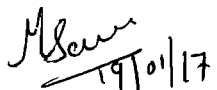
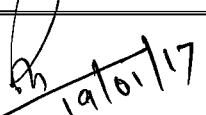
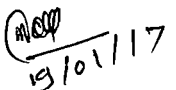
CIN: U51900MH2008PLC180452 | E-mail: supriya@supriyalifescience.com | Website: www.supriyalifescience.com**Factory** : A-5/2, Lote Parshuram Industrial Area, M.I.D.C., Tal.- Khed, Dist.- Ratnagiri, Pin: 415 722, Maharashtra, India.Tel: +91 2356 272299 | Fax : +91 2356 272178 | E-Mail: factory@supriyalifescience.com**GOVT. RECOGNISED EXPORT HOUSE**

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S.No.	Test	Specifications	Results
8.	Limit of N,N-dimethylaniline (ppm)	NMT 10	Complies
9.	Limit of phenolic compound	No blue colour should be develops.	Complies
10	Specific rotation (°)	Determined photoelectrically at 325 nm, does not differ from that of the similarly prepared solution of USP Dextromethorphan Hydrobromide RS by more than 1.0%	Complies
11.	Assay by HPLC (%)	98.0 to 102.0 on anhydrous basis.	100.04
12.	Additional test		
12.1	Residual solvent by GC-HS (ppm)		
	i. Methanol	Not more than 3000	BDL
	ii. Acetone	Not more than 5000	396
	iii Toluene	Not more than 890	BDL

Remarks: The product is complies with respect to above mentioned test as per USP 39 specification.**Storage:** Preserve in tight containers.

 Compiled by QC QC Chemist (M.M.Sawant)	 Checked by QC QC Dy. Sr Manager (S.U.Takale)	 Approved by Head – QC QC Head (S.H.Kambale)
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