Certificate of analysis

Product	:	Dextromethorphan Hydrobromide EP	License No.	:	KD-129
Batch No.	:	SLL/DXB/0722004	Date of Manufacturing	:	July -2022
Batch Qty.	:	272.100 kg	Date of Expiry	:	June -2027
A. R. No.	:	SLL/QC/FP/22/1161	Date of Release	:	20/08/2022

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 :		
2.1	A. Specific optical rotation (anhydrous substance) (°)	+28 to +30	+29.25
2.2	B. Infrared absorption spectrophotometry Test	The IR absorption spectrum should be concordant with that of Dextromethorphan Hydrobromide working standard /reference standard.	Complies
2.3	C. Thin Layer Chromatography	The principal spot in the chromatogram obtained with the test solution should be similar in position and size to the principal spot in the chromatogram obtained with the reference solution.	Complies
2.4	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 (ml)	Not more than 0.4 ml of 0.01M hydrochloric acid is required to change the colour of the indicator to red.	0.3
5.	Specific optical rotation (anhydrous substance) (°)	+28 to +30	+29.25

Corporate Office : 207/208, Udyog Bhavan, Sonawala Road, Goregaon (East), Mumbai - 400 063. Maharashtra, India.
Tel: +91 22 40332727 / 66942507 I Fax : +91 22 26860011 I GSTIN : 27AALCS8686A1ZX
CIN : L51900MH2008PLC180452 I Email: supriya@supriyalifescience.com I Website: 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 272299 I Fax : +91 2356 272178 I E-mail: factory@supriyalifescience.com

Certificate of analysis

Product	:	Dextromethorphan Hydrobromide EP	License No.	:	KD-129
Batch No.	:	SLL/DXB/0722004	Date of Manufacturing	:	July -2022
Batch Qty.	:	272.100 kg	Date of Expiry	:	June -2027
A. R. No.	:	SLL/QC/FP/22/1161	Date of Release	:	20/08/2022

Sr.No.	Test	Specification	Result
6.	Related substances by HPLC (%)		
	i. Impurity A	Not more than 0.5	0.11
	ii. Impurity B	Not more than 0.5	BDL
	iii. Impurity C	Not more than 0.5	BDL
	iv. Impurity D	Not more than 0.5	0.09
	v. unspecified impurities	Not more than 0.10	0.06
	vi. Total impurities	Not more than 1.0	0.26
7.	Limit of N,N-dimethylaniline (ppm)	Maximum 10	Less than 10
8.	Water determination by KF (%, w/w)	4.0 to 5.5	5.16
9.	Sulphated ash (%, w/w)	Maximum 0.1	0.04
10.	Assay by potentiometrically (%)	99.0 to 101.0 on anhydrous basis.	100.08
11.	Additional test		
11.1	Residual solvent by GC-HS (ppm)		
	i. Methanol	Not more than 3000	39
	ii. Methyl formate	Not more than 1000	21
	iii. Acetone	Not more than 5000	546
	iv. Methyl acetate	Not more than 5000	BDL
	v. Methylene chloride	Not more than 600	BDL
	vi. Chloroform	Not more than 60	BDL
	vii. Toluene	Not more than 890	5

Remarks: The product complies with respect to above mentioned test as per **EP 10.0** specification.

Where ,
BDL : Below Detection Limit For Residual Solvent by GC
BDL : Below Disregard Limit For Related Substances by HPLC

Storage: Protected from light.

28/10/22	28/10/22	28/10/22
Compiled by QC QC Chemist (M.M.Sawant)	Checked by QC QC Sr.Officer(D.B.Pol)	Approved by QC QC Dy.Sr.Manager (S.U.Takale)

SUPRIYA LIFESCIENCE LTD. MUMBAI

Corporate Office : 207/208, Udyog Bhavan, Sonawala Road, Goregaon (East), Mumbai - 400 063. Maharashtra, India.
Tel: +91 22 40332727 / 66942507 I Fax : +91 22 26860011 I GSTIN : 27AALCS8686A1ZX
CIN : L51900MH2008PLC180452 I Email: supriya@supriyalifescience.com I Website: 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 272299 I Fax : +91 2356 272178 I E-mail: factory@supriyalifescience.com