

CERTIFICATE OF ANALYSIS

DRUG SUBSTANCE	: Dextromethorphan Hydrobromide EP	BATCH QUANTITY	: 897.520 KG
BATCH NO.	: EUS10016	DATE OF MFG.	: JAN . 2019
DATE OF ANALYSIS	: JAN . 2019	RETEST DATE	: DEC . 2023
		PAGE NO	: 1 OF 3

Sr.No	TESTS	STANDARDS	RESULTS
1	Characters		
	a. Appearance (Description)	Almost white, crystalline powder.	Almost white crystalline powder.
	b. Solubility	Sparingly soluble in water, freely soluble in alcohol.	Sparingly soluble in water, freely soluble in alcohol.
	c. Melting Point	It melts at about 125°C, with decomposition.	It melts at 125.5°C with decomposition.
2	Identification		
	A) Specific optical rotation	The specific optical rotation should be +28° to +30° calculated with reference to the anhydrous substance.	+29°
	B) Infrared Absorption Spectrophotometry	The transmission minima (absorption maxima) in the spectrum obtained with the sample should correspond in position and relative size to those in the spectrum obtained with the Dextromethorphan hydrobromide CRS/ working standard.	The transmission minima (absorption maxima) in the spectrum obtained with the sample corresponds in position and relative size to those in the spectrum obtained with the Dextromethorphan hydrobromide working standard.
	D) Test for bromide	It should give reaction of bromides.	It gives reaction of bromides.
3	Appearance of solution	Solution 'S' should be 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 should be required to change the colour of the indicator to	0.2 ml of 0.01 M hydrochloric acid is required to change the colour of the indicator to red.



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Checked by



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Sr.No	TESTS	STANDARDS	RESULTS
		red.	
5	Specific optical rotation	The specific optical rotation should be +28° to +30°,calculated with reference to the anhydrous substance.	+29°
6	Related substances		
	i) Known impurities		
	Impurity A	Not more than 0.5%	0.09 %
	Impurity B	Not more than 0.25%	Not detected
	Impurity C	Not more than 0.25%	Not detected
	Impurity D	not more than 0.25%	Not detected
	ii) Any unknown impurity	Not more than 0.10%	**BDL
	iii) Total impurities	Not more than 1.0%	0.09 %
7	Limit of N,N-dimethylaniline*	Maximum 10 ppm.	-----
8	Water (Determined on about 0.200 g of sample)	Between 4.0% and 5.5% w/w.	5.0% w/w
9	Sulphated Ash	Maximum 0.1% w/w.	0.03% w/w
10	Assay (calculated with reference to the anhydrous substance)	Between 99.0 and 101.0%,	99.9% w/w
11	ADDITIONAL IN HOUSE TESTS		
	Residual Solvents		
	Isopropyl alcohol	Not more than 1000 ppm	83 ppm
	Toluene	Not more than 300 ppm	Not detected


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12	Particle size	Not less than 98.0% should pass through 60 mesh (250µm).	99.9% passes through 60 mesh (250µm).
13	Tapped density	Between 0.5 and 0.9 g/cc.	0.83 g/cc
14	Formaldehyde content	Not more than 0.3 ppm	***BDL


*Based on the knowledge of manufacturing process, there is no potential for presence of N,N-Dimethylaniline.


**Below disregard limit is 0.05%.

***Below disregard limit is 0.0629 ppm.

Remarks : The Material Complies With Specification No : FP/EP/305144/L.

Storage: Preserve in tight containers.


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