

Wockhardt Limited (Bulk Drug Division)
 Factory : Plot No. 138,
 GIDC Estate, Ankleshwar - 393 002.
 Dist. Bharuch, Gujarat, India.
 Tel. : +91-2646-661444
 Fax : +91-2646-661555
 Website : www.wockhardt.com

CERTIFICATE OF ANALYSIS

DRUG SUBSTANCE : Dextromethorphan Hydrobromide EP	BATCH QUANTITY : 935 Kg
BATCH NO. : EPS11003	DATE OF MFG. : AUG. 2014
DATE OF ANALYSIS : AUG. 2014	RETEST DATE : JUL. 2019
	PAGE NO. : 1 Of 2

Sr. No.	TESTS	STANDARDS	RESULTS
PHARMACOPOEIAL TESTS			
1.	Characters		
a.	Appearance (Description)	Almost white, crystalline powder	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 126.4°C, with decomposition.
2.	Identification First Identification: A,B,D. A) Specific optical rotation B) Infrared Absorption Spectrophotometry D) Test for bromide	The specific optical rotation should be +28° to +30° calculated with reference to the anhydrous substance. 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. It should give reaction of bromides.	+29.1° The transmission minima (absorption maxima) in the spectrum obtained with the sample correspond in position and relative size to those in the spectrum obtained with the Dextromethorphan hydrobromide-working standard. 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 red.	0.3 ml of 0.01 M hydrochloric acid is required to change the colour of the indicator to red.
5.	Specific optical rotation	The specific optical rotation should be +28.0° to +30° calculated with reference to the anhydrous substance.	+29.1°
6.	Related Substances i) Known impurities Impurity A Impurity B Impurity C Impurity D ii) Any unknown impurity iii) Total impurities	Not more than 0.5 % Not more than 0.25 % Not more than 0.25 % Not more than 0.25 % Not more than 0.10 % Not more than 1.0 %	Not detected Not detected Not detected BDL** Not detected Nil
7.	N, N-Dimethylaniline*	Maximum 10 ppm.	---
8.	Water (Determined on 0.200 g of sample)	Between 4.0% and 5.5% w/w	5.1 %

(Signature)
 25/08/2014.
 Checked by

(Signature)
 Approved by

Format No.: DM/EP/303712/1

Effective Date: 11.03.2013

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Sr. No.	TESTS	STANDARDS	RESULTS
9.	Sulphated Ash	Maximum 0.1 % w/w	0.05 %
10.	Assay (Calculated with reference to the anhydrous substance)	Between 99.0 and 101.0 %.	99.6 %
ADDITIONAL IN-HOUSE TESTS			
11.	Residual Solvents Isopropyl alcohol Toluene	Not more than 1000 ppm Not more than 300 ppm	77 Not detected
12.	Particle size	Not less than 98 % should pass through 60 mesh (250 µm)	100 % passes through 60 mesh (250 µm)
13.	Tapped Density	Between 0.5 and 0.9 g/cc.	0.87
14.	Formaldehyde content	Not more than 0.3ppm	Not detected

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

** Below Disregard Limit is 0.05%.

Remarks: Dextromethorphan Hydrobromide LP Batch No.: EPS11003 conforms to FP-LP 303712/1 Specification.

Storage: Protected from light.

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