

Certificate of Analysis

Productname: Dextromethorphan hydrobrom.
Number of analysis/Inspection Code: 1 / KEUR-180769B
Batchnumber: 19A08-B03-367765
Reference code / No.: 4112 / S-2321118
Analysed according to: PH.EUR 9.6

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification A	+28 - +30	Conform		Specific optical rotation
Identification B	Conform	Conform		IR-spectrum
Identification D	White yellow	Conform		Bromide
Appearance of solution	Clear / colourless	Conform		5% m/V in alcohol
Acidity or alkalinity	Conform	Conform		
Specific optical rotation	+28 - +30	+28,8		2% m/V HCl 0.1M; anhydrous
Related substances	Conform	Conform		HPLC
Impurity A	<=0,5	<0,05	%	
Impurity B	<=0,5	<0,05	%	
Impurity C	<=0,5	<0,05	%	
Impurity D	<=0,5	<0,05	%	
<=1 peak >=0,25%	<=1	<0,05		
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=1,0	<0,05	%	
N,N- Dimethylaniline	<=10	Conform	ppm	
Water (Karl Fischer)	4,0 - 5,5	5,0	%	
Sulphated ash	<=0,1	0,04	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		
Assay Dextromethorphan hydrobromide	99,0 - 101,0	99,9	%m/m	Anhydrous
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Quercus BE.

Release:
dr. M.J. Vincenten - van Maanen
Pharmacist - Qualified Person

02/27/20

Expiration: 10-2023

Conclusion: APPROVED

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