

Certificate of Analysis

Product name: **Dextromethorphan hydrobrom.**
Batch number / Weight: **18B09-B02-217116 / 25 G**
Analysed according to: **Ph.Eur.**

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	+29	Â°	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	%	
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	<0,1	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		
Assay Dextromethorphan hydrobro	99,0 - 101,0	100,2	%m/m	Anhydrous
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:
 Ewelina Gadzinowska
 Qualified Person

10-12-2021

Expiration: 30-11-2022

Conclusion: APPROVED

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