

Certificate of Analysis

Product name: Dextromethorphan hydrobrom.
Batch number / Weight: 21F02-B05-213260 / 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	0,25ml HCl		
Specific optical rotation	+28 - +30	+28	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	4,84	%	
Sulphated ash	<=0,1	0,07	%	
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	%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

18-11-2021

Expiration: 31-12-2025

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.