Certificate of Analysis

Product name: **Dextromethorphani hydrobrom.**

Batch number / Weight: **21F02-B05-225290 / 25 G**

Analysed according to: **Ph. Eur.**

Number of analysis / Inspection Code **21F02-B05 / INS-21-4021**

Reference Code / No.: **V01390 / S-A-0100221**

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, an
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 hydro	99,0 - 101,0	100	%m/m	Anhydrous
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

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All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab EL Spol

Release:
Agnieszka Pszczółka
Qualified Person

26-11-2022

Expiration: 31-12-2025

Conclusion: APPROVED

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