

Certificate of Analysis

Product name: **Dextromethorphan hydrobrom.**

Batch number / Weight: **23L12-B03-234555 / 25 G**

Analysed according to: **Ph.Eur.11.3**

Number of analysis / Inspection Code **23L12-B03 / INS-24-0944**

Reference Code / No.: **V02418 / DXT230011AFP**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification A	+28 - +30	+28,9		
Identification B	Conform	Conform		
Identification D	White yellow	Conform		
Appearance of solution	Clear / colourless	Conform		
Acidity or alkalinity	Conform	0,15	ml	
Specific optical rotation	+28 - +30	+28,9		
Related substances	Conform	Conform		
Impurity A	<=0,5	0,07	%	
Impurity B	<=0,5	<0,05	%	
Impurity C	<=0,5	0,00	%	
Impurity D	<=0,5	0,05	%	
Imp.A,B,C,D	1 peak <=0,25%	Conform		
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=1,0	0,11	%	
N,N- Dimethylaniline	<=10	Conform	ppm	
Water (Karl Fischer)	4,0 - 5,5	5,10	%	
Sulphated ash	<=0,1	0,00	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Dextromethorphan hydro	99,0 - 101,0	100,23	%m/m	
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 FAGRON PL lab

Release:
Ewelina Gadzinowska
Qualified Person

23-02-2024

Expiration: 31-10-2026

Conclusion: APPROVED

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