

QUALITY CONTROL DEPARTMENT

DEXTROMETHORPHANI HYDROBROMIDUM

ANALYSIS REPORT: 20G01-APR22026

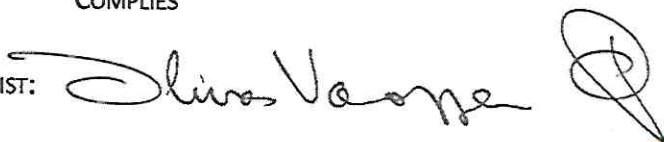
AUTHORISATION	1890R05413	DATE OF ANALYSIS	17/03/2020
LOT NUMBER	20G01-APR22026	EXPIRY DATE	12/2023
PRODUCTION NUMBER	180122-GS20029	ANALYTICAL REFERENCE	PH. EUR. 10.0 [07/2016:0020]

ANALYTICAL TESTS

CHARACTERS	SPECIFICATION	RESULT
Appearance	Almost white, crystalline powder	Complies
IDENTIFICATION	SPECIFICATION	RESULT
Identification A	+28 to + 30 (anhydrous substance)	Complies
Identification B	The spectrum complies with the spectrum obtained with dextromethorphan hydrobromide CRS	Complies
Identification D	Reaction (a) of bromides	Complies
TESTS	SPECIFICATION	RESULT
Appearance of solution	Clear and colourless	Complies
Acidity or alkalinity	Solution is yellow ≤ 0.4 mL hydrochloric acid (0.01 M)	Complies 0.3 mL
Specific optical rotation	+ 28 to + 30 (anhydrous substance)	+ 28
Related substances		
Impurity A	≤ 0.5%	Not detected
Impurity B	≤ 0.5%	Not detected
Impurity C	≤ 0.5%	Not detected
Impurity D	≤ 0.5%	Not detected
Impurities A, B, C and D	≤ 1 peak is greater than 0.25%	Complies
Unspecified impurities	≤ 0.10%	Not detected
Total	≤ 1.0%	Not detected
N,N-Dimethylaniline	≤ 10 ppm	Complies
Water	4.0% to 5.5%	5.0%
Sulfated ash	≤ 0.1%	0.06%
ASSAY	SPECIFICATION	RESULT
Potentiometric titration	99.0% to 101.0% (anhydrous substance)	100.3%

CONCLUSION: COMPLIES

RESPONSIBLE PHARMACIST:



DATE:

27 JAN. 2022