

DEXTROMETHORPHANI HYDROBROMIDUM 100 g

Lot No.: 23I05-APR23269

Autorisation :	1890R05413	Date Of Analysis :	10/08/2023
Analytical Reference :	Ph. Eur. 10.7 [07/2016:0020]	Production Number :	050923-GS23080
CNK :	3889-516	Expiry Date :	11/2027

ANALYTICAL TESTS

CHARACTERS	SPECIFICATION	RESULT
Appearance	Almost white, crystalline powder	Complies
IDENTIFICATION	SPECIFICATION	RESULT
Identification A	+ 28 to + 30 (anhydrous substance)	+29
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	Complies
	≤ 0.4 mL hydrochloric acid (0.01 M)	Complies
Specific optical rotation	+ 28 to + 30 (anhydrous substance)	+29
Related substances		
Impurity A	≤ 0.5 %	0.17%
Impurity B	≤ 0.5 %	< 0.05%
Impurity C	≤ 0.5 %	< 0.05%
Impurity D	≤ 0.5 %	< 0.05%
Impurities A, B, C and D	≤ 1 peak is greater than 0.25 %	Complies
Unspecified impurities	≤ 0.10 %	0.00%
Total	≤ 1.0 %	0.2%
<i>N,N</i> -Dimethylaniline	≤ 10 ppm	Complies
Water	4.0 % to 5.5 %	5.1%
Sulfated ash	≤ 0.1 %	0.1%
ASSAY	SPECIFICATION	RESULT
Potentiometric titration	99.0 % to 101.0 % (anhydrous substance)	100.7%
Manufacturer identification code: S/GS/032		

CONCLUSION: COMPLIES

RESPONSIBLE PHARMACIST: