

DEXTROMETHORPHANI HYDROBROMIDUM MONOHYDRICUM 25 g

Lot No.: 24H16-F240096

Authorisation:	1890R05413	Date Of Analysis:	05/09/2024
Analytical Reference:	Ph.Eur. [04/2024:0020]	Production Number:	290824-G240032
CNK:	3490-075	Expiry Date:	02/2028

ANALYTICAL TESTS

CHARACTERS	SPECIFICATION	RESULT
Appearance	Almost white, crystalline powder	Complies
IDENTIFICATION	SPECIFICATION	RESULT
Identification B	The spectrum complies with the spectrum obtained with dextromethorphan hydrobromide CRS	Complies
Identification C	Enantiomeric purity	Complies
Identification E	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
Enantiomeric purity		
Impurity E	≤ 0.10%	0.09%
Related substances		
Impurity A	≤ 0.5%	< 0.05%
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%	< 0.05%
Total	≤ 1.0%	0.14%
<i>N,N</i> -Dimethylaniline	≤ 10 ppm	Complies
Water	4.0% to 5.5%	5.0%
Sulfated ash	≤ 0.1%	0.01%
ASSAY	SPECIFICATION	RESULT
Potentiometric titration	99.0% to 101.0% (anhydrous substance)	100.1%
Manufacturer identification code: S/GS/032		

CONCLUSION: COMPLIES

RESPONSIBLE PHARMACIST: