

**BROMHEXINI HYDROCHLORIDUM 5 g**

Lot No.: 23A10-APR23218

Autorisation :	1890R05600	Date Of Analysis :	01/12/2022
Analytical Reference :	Ph. Eur. 10.8 [04/2017 :0706] Corr. 10.0	Production Number :	100723-GS22153
CNK :	3761-566	Expiry Date :	12/2026

**ANALYTICAL TESTS**

CHARACTERS	SPECIFICATION	RESULT
Appearance	White or almost white, crystalline powder	Complies
IDENTIFICATION	SPECIFICATION	RESULT
Identification A	Spectrum complies with the spectrum obtained with bromhexine hydrochloride CRS	Complies
Identification C	Reaction (a) of chlorides	Complies
TESTS	SPECIFICATION	RESULT
Appearance of solution	Clear and not more intensely coloured than reference solution Y <sub>6</sub>	Complies
Related substances		
Impurity C	≤ 0.15 %	< 0.05 %
Unspecified impurities	≤ 0.10 %	< 0.05 %
Total	≤ 0.2 %	< 0.05 %
Loss on drying	≤ 1.0 %	0.02 %
Sulfated ash	≤ 0.1 %	0.06 %
ASSAY	SPECIFICATION	RESULT
LC-UV	98.0 % to 102.0 % (dried substance)	99.7 %

Manufacturer identification code: S/GS/180

CONCLUSION: COMPLIES

RESPONSIBLE PHARMACIST: