

GUAIFENESINUM 250 g

Lot No.: 23F30-APR23207

Autorisation :	1890R05420	Date Of Analysis :	30/05/2023
Analytical Reference :	Ph. Eur. 10.6 [04/2018:0615] corr. 9.6	Production Number :	030723-GS23053
CNK :	3490-281	Expiry Date :	01/2028

ANALYTICAL TESTS

CHARACTERS	SPECIFICATION	RESULT
Appearance	White or almost white, crystalline powder	Complies
IDENTIFICATION	SPECIFICATION	RESULT
Identification B	The spectrum complies with the spectrum obtained with guaifenesin CRS	Complies
TESTS	SPECIFICATION	RESULT
Appearance of solution	Clear and colourless	Complies
Acidity or alkalinity	≤ 0.1 mL sodium hydroxide (0.01 M)	0.05 mL
	≤ 0.1 mL hydrochloric acid (0.01 M)	0.02 mL
Related substances		
Impurity B	≤ 0.5 %	0.1%
Impurity C	≤ 0.1 %	< 0.03%
Impurity D	≤ 0.1 %	< 0.03%
Any other impurity	≤ 0.05 %	< 0.03%
Total	≤ 0.7 %	0.1%
Chlorides and monochlorhydrins	≤ 250 ppm	Complies
Loss on drying	≤ 0.5 %	0.01%
Sulfated ash	≤ 0.1 %	0.05%
ASSAY	SPECIFICATION	RESULT
LC	98.0 % to 102.0 % (dried substance)	101.1%

Manufacturer identification code: S/GS/003

CONCLUSION: COMPLIES

RESPONSIBLE PHARMACIST: