

HYOSCINI BUTYLBROMIDUM 5 g

Lot No.: 23E15-APR23152

Autorisation :	1890R05573	Date Of Analysis :	13/04/2023
Analytical Reference :	Ph. Eur. 10.7 [07/2018 :0737] Corr. 9.6	Production Number :	160523-GS23039
CNK :	3490-869	Expiry Date :	10/2027

ANALYTICAL TESTS

CHARACTERS	SPECIFICATION	RESULT
Appearance	White or almost white, crystalline powder	Complies
IDENTIFICATION	SPECIFICATION	RESULT
Identification A	– 20 to – 18 (dried substance)	-20
Identification C	The spectrum complies with the spectrum obtained with hyoscine butylbromide CRS	Complies
Identification F	Reaction (a) of bromides	Complies
TESTS	SPECIFICATION	RESULT
Appearance of solution	Clear and colourless	Complies
Acidity or alkalinity	≤ 0.5 mL HCl (0.01 M) is required to change the colour of the indicator to reddish-violet	Complies
Specific optical rotation	– 20 to – 18 (dried substance)	-20
Related substances		
Impurity A	≤ 0.15 %	< 0.05%
Unspecified impurities	≤ 0.10 %	< 0.05%
Total	≤ 0.4 %	< 0.05%
Loss on drying	≤ 2.5 %	0.4%
Sulfated ash	≤ 0.1 %	0.04%
ASSAY	SPECIFICATION	RESULT
Potentiometric titration	98.0 % to 101.0 % (dried substance)	100.4%

Manufacturer identification code: S/GS/055

CONCLUSION: COMPLIES

RESPONSIBLE PHARMACIST: