

Geldig van 27 DEC 2018
tot 27 DEC 2021

QUALITY CONTROL DEPARTMENT

HYOSCINI BUTYLBROMIDUM

ANALYSIS REPORT: 20D29-APR20083

AUTHORISATION	1890R05573	DATE OF ANALYSIS	18/02/2020
LOT NUMBER	20D29-APR20083	EXPIRY DATE	08/2024
PRODUCTION NUMBER	130520-GS20025	ANALYTICAL REFERENCE	PH. EUR. 10.0 [07/2018:0737] CORR. 9.6

ANALYTICAL TESTS

CHARACTERS	SPECIFICATION	RESULT
Appearance	White or almost white, crystalline powder	Complies
IDENTIFICATION	SPECIFICATION	RESULT
Identification A	- 20 to - 18 (dried substance)	Complies
Identification B	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 %	0.2 %
Sulfated ash	≤ 0.1 %	0.02 %
ASSAY	SPECIFICATION	RESULT
Potentiometric titration	98.0 % to 101.0 % (dried substance)	100.2 %

CONCLUSION: COMPLIES

RESPONSIBLE PHARMACIST:


 Maxime Brits

DATE:

02 JUNI 2020