

AMITRIPTYLINI HYDROCHLORIDUM 5 g

Lot No.: 23C22-APR23108

Autorisation :	1890R05756	Date Of Analysis :	02/02/2023
Analytical Reference :	Ph. Eur. 10.7 [01/2017 :0464]	Production Number :	230323-GS23011
CNK :	3968-955	Expiry Date :	10/2027

ANALYTICAL TESTS

CHARACTERS	SPECIFICATION	RESULT
Appearance	White or almost white powder or colourless crystals	Complies
IDENTIFICATION	SPECIFICATION	RESULT
Identification A	The spectrum complies with the spectrum obtained with amitriptyline hydrochloride CRS	Complies
Identification B	Reaction (a) of chlorides	Complies
TESTS	SPECIFICATION	RESULT
Appearance of solution	Clear and not more intensely coloured than reference solution B ₇	Complies
Acidity or alkalinity	Solution should be yellow with NaOH and red with HCl	Complies
Related substances		
Impurity B	≤ 0.1%	< 0.05%
Impurity A	≤ 0.05%	< 0.05%
Unspecified impurities	≤ 0.10%	< 0.05%
Total	≤ 0.3%	< 0.05%
Loss on drying	≤ 0.5%	0.15%
Sulfated ash	≤ 0.1%	0.08%
ASSAY	SPECIFICATION	RESULT
Titration	99.0% to 101.0%	99.6%
Manufacturer identification code: S/GS/082		

CONCLUSION: COMPLIES

RESPONSIBLE PHARMACIST: