

AMITRIPTYLINI HYDROCHLORIDUM 100 g

Lot No.: 24I09-F240123

Authorisation:	1890R05756	Date Of Analysis:	26/07/2024
Analytical Reference:	Ph.Eur. [01/2017:0464]	Production Number:	230924-G240052
CNK:	4614-327	Expiry Date:	01/2029

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%	< 0.5%
Sulfated ash	≤ 0.1%	< 0.1%
ASSAY	SPECIFICATION	RESULT
Titration	99.0% to 101.0%	100.9%

Manufacturer identification code: S/GS/082

CONCLUSION: COMPLIES

RESPONSIBLE PHARMACIST: