

CARBAMAZEPINUM 25 g

Lot No.: 20L15-APR22265

Authorisation:	1890R05836	Date Of Analysis:	20/11/2020
Analytical Reference:	Ph. Eur. 10.0 [01/2017:0543]	Production Number:	130922-GS20120
CNK:	4178-695	Expiry Date:	06/2025

ANALYTICAL TESTS

CHARACTERS	SPECIFICATION	RESULT
Appearance	White or almost white, crystalline powder	Complies
IDENTIFICATION	SPECIFICATION	RESULT
Identification A	189 °C to 193 °C	Complies
Identification B	The spectrum complies with the spectrum obtained with carbamazepine CRS	Complies
TESTS	SPECIFICATION	RESULT
Acidity or alkalinity	Colour reaction complies	Complies
Related substances		
Impurity A	≤ 0.15%	< 0.05%
Impurity E	≤ 0.15%	Not detected
Unspecified impurities	≤ 0.10%	< 0.05%
Total	≤ 0.5%	< 0.05%
Chlorides	≤ 140 ppm	Complies
Loss on drying	≤ 0.5%	0.2%
Sulfated ash	≤ 0.1%	0.01%
ASSAY	SPECIFICATION	RESULT
LC	98.0% to 102.0% (dried substance)	101.2%

CONCLUSION: COMPLIES

RESPONSIBLE PHARMACIST: