

Certificate of Analysis

Productname: Carbamazepinum
Number of analysis/Inspection Code: 1 / KEUR-182270B
Batchnumber: 19K28-F06-369684
Reference code / No.: 1305 / 101101926
Analysed according to: PH.EUR10.1

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification A	189 - 193	191	°C	Melting point
Identification B	Conform	Conform		IR-spectrum
Acidity or alkalinity	Conform	Conform		
Related substances	Conform	Conform		HPLC
Impurity A	<=0,15	0,08	%	
Impurity E	<=0,15	<0,05	%	
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=0,5	0,1	%	
Chlorides	<=140	Conform	ppm	
Loss on drying	<=0,5	0,0	%	2 h 105 °C
Sulphated ash	<=0,1	0,0	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Carbamazepin	98,0 - 102,0	99,2	%m/m	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Pharma Cosmetic Polen.

Release:
Wai Lung Chung
Pharmacist - Qualified Person

04/24/20

Expiration: 10-2022

Conclusion: APPROVED

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