

Certificate of Analysis

Product name: Amitriptylini hydrochloridum

Batch number / Weight: 23C04-B07-226703 / 5 G

Analysed according to: Ph.Eur.11.1

Number of analysis / Inspection Code 23C04-B07 / INS-23-2297

Reference Code / No.: V01409 / 2301192

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder / crystals	Conform		
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Appearance of solution	Clear / <B7	Conform		
Acidity or alkalinity	Conform	Conform		
Related substances	Conform	Conform		
Impurity B	<=0,1	<0,05	%	
Impurity A	<=0,05	<0,05	%	
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=0,3	0,00	%	
Loss on drying	<=0,5	0,05	%	
Sulphated ash	<=0,1	0,00	%	
Residual solvents	CPMP/ICH/82 260/06	Conform		
Assay	99,0 - 101,0	99,92	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer

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All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab FAGRON PL lab

Release:

Ewelina Gadzinowska

Qualified Person

19-04-2023

Expiration: 30-01-2028

Conclusion: APPROVED

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