

Certificate of Analysis

Productname: Amitriptylini hydrochloridum
Number of analysis/Inspection Code: 2 / KEUR-180664B
Batchnumber: 19C08-B02-366812
Reference code / No.: 1116 / 1901746
Analysed according to: PH.EUR 9.7

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white powder or colorless crystals	Conform		
Identification A	Conform	Conform		IR-spectrum
Identification B	Conform	Conform		Chloride
Appearance of solution	Clear / <B7	Conform		5% <i>m/V</i>
Acidity or alkalinity	Conform	Conform		
Related substances	Conform	Conform		HPLC
Impurity B	<=0,1	<0,05	%	
Impurity A	<=0,05	<0,05	%	
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=0,3	<0,05	%	
Loss on drying	<=0,5	0,1	%	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 Amitriptyline hydrochloride	99,0 - 101,0	100,4	% <i>m/m</i>	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Pharma Cosmetic Polen.

Release:
dr. M.J. Vincenten - van Maanen
Pharmacist - Qualified Person

02/24/20

Expiration: 02-2024

Conclusion: APPROVED

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