

Certificate of Analysis

Product name: Amitriptylini hydrochloridum
Batch number / Weight: 21G23-B03-213366 / 25 G
Analysed according to: Ph. Eur.

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	0,08	%	
Sulphated ash	<=0,1	0,00	%	
Residual solvents	CPMP/ICH/82 260/06	Conform		
Acetone	<=5000 ppm	<5000	ppm	
Tetrahydrofuran	<=720 ppm	<720 ppm		
Toluene	<= 890 ppm	<890	ppm	
Assay	99,0 - 101,0	100,57	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer

Analysis performed by the authorized lab.

Release:
 Dominika Sołtysik
 Qualified Person

29-09-2021

Expiration: 06-10-2025

Conclusion: APPROVED

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