

Certificate of Analysis

Product name: **Amitriptylini hydrochloridum**

Batch number / Weight: **22F28-B04-222243 / 5 G**

Analysed according to: **Ph. Eur. 10.8**

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	<0,01	%	
Unspecified impurities	<=0,10	<0,05		
Total impurities	<=0,3	<0,05	%	
Loss on drying	<=0,5	0,04	%	
Sulphated ash	<=0,1	0,07	%	
Residual solvents	CPMP/ICH/82 260/06	Conform		
Acetone	<=500 ppm	57	ppm	
Tetrahydrofurane	<=500 ppm	<25	ppm	
Toluene	<= 500 ppm	68	ppm	
Assay	99,0 - 101,0	100,8	%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:

Ewelina Gadzinowska

Qualified Person

18-08-2022

Expiration: 12-10-2026

Conclusion: APPROVED

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