

Certificate of Analysis

Product name: **Tetracaini hydrochloridum**

Batch number / Weight: **22J19-B01-217492 / 25 G**

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

Number of analysis / Inspection Code **22J19-B01 / INS-22-8920**

Reference Code / No.: **V01433 / TH0111021**

Tests	Requirement	Result	Unit	Standard remark
Appearance	White, crystalline powder, slightly hygroscopic	Conform		
Identification A	Conform	Conform		
Identification D	White	Conform		
Appearance of solution	Clear and colourless	Conform		
pH	4,5 - 6,5	5,45		
Related substances	Conform	Conform		
Impurity A	<=0,05	0,001	%	
Impurity B	<=0,1	<0,05	%	
Impurity C	<=0,1	<0,05	%	
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=0,5	0,00	%	
Loss on drying	<=1,0	0,08	%	
Sulphated ash	<= 0,1	0,02	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Tetracaine hydrochloride	99,0 - 101,0	100,06	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Residual solvents				
Methanol	<= 3000 ppm	<150	ppm	
Acetone	<= 5000 ppm	<250	ppm	
Hexane	<= 290 ppm	0,0	ppm	
Toluene	<= 890 ppm	0,0	ppm	

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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:

Agnieszka Pszczółka

Qualified Person

26-11-2022

Expiration: 30-09-2026

Conclusion: APPROVED

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