

Certificate of Analysis

Productname: Tetracaini hydrochloridum
Number of analysis/Inspection Code: 1 / KEUR-183249B
Batchnumber: 20A17-F10-370803
Reference code / No.: 4153 / TH0060219
Analysed according to: PH.EUR10.1

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		Slightly hygroscopic !
Identification A	Conform	Conform		IR-spectrum
Identification B	About 131	131	°C	
Identification D	White	Conform		Chloride
Appearance of solution	Clear and colourless	Conform		2%m/V
pH	4,5 - 6,5	5,4		1%m/V
Related substances	Conform	Conform		HPLC
Impurity A	<=0,05	<0,05	%	
Impurity B	<=0,1	<0,05	%	
Impurity C	<=0,1	<0,05	%	
Unspecified impurities	<=0,10	0,07	%	
Total impurities	<=0,5	0,1	%	
Loss on drying	<=1,0	0,1	%	105 °C
Sulphated ash	<=0,1	0,0	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		
Assay Tetracaine hydrochloride	99,0 - 101,0	100,5	%m/m	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Pharma Cosmetic Polen.

Release:
Wai Lung Chung
Pharmacist - Qualified Person

06/09/20

Expiration: 01-2024

Conclusion: APPROVED

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