

Certificate of Analysis

Product name: Tetracainum
Batch number / Weight: 22K19-B02-002010 / 25 g
Producer / Producer Batch Number: Venkata Narayana Active Ing. Pvt. Ltd / TC0310822
Analyzed according to: USP
Number of Analysis / Certificate no.: 22K19-B02 / QO0004516

	Requirement	Result	Unit	Standard remark
Metallic residues	CHMP/ICH/353369/2013	Conform		
Residual solvents	CPMP/ICH/82 260/06	Conform		
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		
Appearance	white or light yellow, waxy solid	Conform		
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Assay	98,0 - 102,0	98,69	% m/m	
Sulfated ash	<= 0,1	0,00	%	
Loss on drying	<= 0,5	0,01	%	
Organic impurities	Conform	Conform		
Impurity A	<= 0,4	0,00	%	
Impurity B	<= 0,4	0,00	%	
Impurity C	<= 0,4	0,00	%	
Unspecified impurities	<= 0,4	0,07	%	
Total impurities	<= 0,8	0,07	%	

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

Release:

27-9-2024
 Ewelina Gadzinowska
 Qualified Person

Expiration: 31-7-2025

Conclusion: APPROVED

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