

Certificate of Analysis

Product name: **Benzocainum**
Batch number / Weight: **21J21-B01-217139 / 25 G**
Analysed according to: **Ph. Eur.**

Tests	Requirement	Result	Unit	Standard remark
Appearance	White, crystalline powder or colorless crystals	Conform		
Identification	Conform	Conform		
Related substances	Conform	Conform		
Unspecified impurities for each impurity	$\leq 0,10$	$<0,05$	%	
Total impurities	$\leq 0,2$	0,00	%	
Loss on drying	$\leq 0,5$	0,025	%	
Sulphated ash	$\leq 0,1$	0,005	%	
Assay Benzocaine	99,0 - 101,0 (dried substance)	100,25	% m/m	
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:
Dominika Sołtysik
Qualified Person

22-12-2021

Expiration: 07-06-2024

Conclusion: APPROVED

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