

Certificate of Analysis

Product name: Benzocainum

Batch number / Weight: 21G17-B07-215093 / 100 G

Analysed according to: Ph. Eur.

Tests	Requirement	Result	Unit	Standard remark
Appearance	White, crystalline powder	Conform		
	or colorless crystals			
Identification	Conform	Conform		
Related substances	Conform	Conform		
Unspecified impurities				
for each impurity	<= 0,10	0,057	%	
Total impurities	<=0,2	0,057	%	
Loss on drying	<=0,5	0,02	%	
Sulphated ash	<= 0,1	0,01	%	
Assay Benzocaine	99,0 - 101,0 (dried substance)	100,03	% m/m	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06			
Ethanol	<= 5000	Conform	ppm	

Analysis performed by the authorized lab.

Release:

Dominika Sołtysik Qualified Person

07-10-2021

Expiration: 29-03-2023

Conclusion: APPROVED

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