

Certificate of Analysis

Product name: **Benzocainum**

Batch number / Weight: **22A15-B10-218043 / 25 G**

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

Tests	Requirement	Result	Unit	Standard remark
Appearance	White, crystalline powder or colorless crystals	Conform		
Identification	Conform	Conform		
Solubility	very slightly soluble in water	Conform		
	freely soluble in ethanol (96%)	Conform		
Related substances	Conform	Conform		
Unspecified impurities		<0,05		
for each impurity	<= 0,10		%	
Total impurities	<=0,2	0,00	%	
Loss on drying	<=0,5	0,025	%	
Sulphated ash	<= 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
Residual solvents	CPMP/ICH/82 260/06			
Ethanol	<= 5000	Conform	ppm	

Analysis performed by the authorized lab.

Release:
Agnieszka Pszczółka
Qualified Person

30-03-2022

Expiration: 07-06-2024

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.