

Certificate of Analysis

Product name: **Benzocainum**
Batch number / Weight: **22G25-B01-226582 / 100 G**
Analysed according to: **Ph.Eur.11.0**
Number of analysis / Inspection Code **22G25-B01 / INS-22-6262**
Reference Code / No.: **V00588 / C0012201014**

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	$\leq 0,10$	0,079	%	
Total impurities	$\leq 0,2$	0,08	%	
Loss on drying	$\leq 0,5$	0,01	%	
Sulphated ash	$\leq 0,1$	0,03	%	
Assay Benzocaine	99,0 - 101,0 (dried substance)	100,75	% m/m	
TAMC	$\leq 10^3$	<10	CFU/g	
TYMC	$\leq 10^2$	<10	CFU/g	
Residual solvents	acc to the current edition			
R1-CEP 2004-008				
for Changzhou Sunlight Fine Ch				
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	

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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 FAGRON PL lab

Release:

Ewelina Gadzinowska

Qualified Person

18-01-2023

Expiration: 14-01-2025

Conclusion: APPROVED

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