

Certificate of Analysis

Product name: Benzocainum
Batch number / Weight: 22H30-B01-235519 / 100 G
Analysed according to: Ph.Eur.11.2
Number of analysis / Inspection Code 22H30-B01 / INS-22-7256
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	<=0,10	0,079		
Total impurities	<=0,2	0,08	%	
Loss on drying	<=0,5	0,01	%	
Sulphated ash	<= 0,1	0,03	%	
Assay Benzocaine	99,0 - 101,0 (dried substance)	100,75	% 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

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,CBMiA

Release:
Agnieszka Pszczółka
Qualified Person

27-11-2023

Expiration: 14-01-2025

Conclusion: APPROVED

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