

Certificate of Analysis

Product name: Benzocainum

Batch number / Weight: 232144 / 10 G

Analysed according to: FSNE-SPEC-0195, wyd.2

Number of analysis / Inspection Code 22G25-B02 / INS-22-6261

Reference Code / No.: V00588 / C0032203002

Tests	Requirement	Result	Unit	Standard remark
Appearance	White, crystalline powder	Conform		
Identification	Conform	Conform		
Solubility	very slightly soluble in water freely soluble in ethanol (96%)	Conform		
Related substances	Conform			
Unspecified impurities	$\leq 0,10$			
for each impurity	$\leq 0,10$	0,053	%	
Total impurities	$\leq 0,2$	0,05	%	
Loss on drying	$\leq 0,5$	0,01	%	
Sulphated ash	$\leq 0,1$	0,02	%	
Assay	99,0 - 101,0 (dried substance)	100,08	%m/m	
Particle size	$\geq 95\%$ cząstek o wielkości poniżej 200 mesh	99	%	
TAMC	$\leq 10^3$	< 10	CFU/g	
TYMC	$\leq 10^2$	< 10	CFU / g	

fagron.pl

Fagron Services Northern Europe Sp. z o.o.
ul. Armii Krajowej 3
32-540 Trzebinia, Poland
e-mail: fsne@fagron.pl

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 Novasome, Fagron PL, CBM

Release:

Agnieszka Pszczółka

Qualified Person

22-09-2023

Expiration: 26-02-2025

Conclusion: APPROVED

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

fagron.pl

Fagron Services Northern Europe Sp. z o.o.
ul. Armii Krajowej 3
32-540 Trzebinia, Poland
e-mail:fsne@fagron.pl