

Certificate of Analysis

Product name: **Bismuthi subnitras ponderosum**
Batch number / Weight: **22A26-B11-219702 / 250 G**
Analysed according to: **Ph. Eur.**

Tests	Requirement	Result	Unit	Standard remark
Appearance	White powder	Conform		
Identification A	Black / orange	Conform		
Identification B	Yellow-orange color / orange precipitation	Conform		
Identification C	Violet	Conform		
Identification D	$\leq 2,0$ rozpuszcza się z rozkładem w kwasach nieorganicznych	Conform		
Acidity	Conform	Conform	ml	
Chlorides	≤ 200	< 200	ppm	
Copper	≤ 50	$< 0,7$	ppm	
Lead	≤ 20	$< 0,5$	ppm	
Silver	≤ 25	$< 0,1$	ppm	
Substances not precipit.	$\leq 1,0$	0,1	%	
Loss on drying	$\leq 3,0$	2,3	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Bismuth	71,0 - 74,0	73,4	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Total aerobic microbial count (TA)		< 10	CFU/g	

Analysis performed by the authorized lab.

Release:
Agnieszka Pszczółka
Qualified Person

11-05-2022

Expiration: 13-10-2026

Conclusion: APPROVED

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