

Certificate of Analysis

Product name: **Bismuthi subnitratis ponderosum**

Batch number / Weight: **22G19-B10-223720 / 250 G**

Analysed according to: **Ph. Eur. 10.8**

Number of analysis / Inspection Code **22G19-B10 / INS-22-7062**

Reference Code / No.: **V00589 / 222000034**

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	$\leq 2,0$	Conform		
Acidity	Conform	0,15mlNaOH	ml	
Chlorides	≤ 200	<200	ppm	
Copper	≤ 50	<2	ppm	
Lead	≤ 20	<5	ppm	
Silver	≤ 25	<1	ppm	
Substances not precipit. by ammonia	$\leq 1,0$	0,11	%	
Loss on drying	$\leq 3,0$	2,30	%	
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	73,77	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

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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, EI Spol, CBMiA

Release:

Agnieszka Pszczółka

Qualified Person

31-10-2022

Expiration: 21-06-2027

Conclusion: APPROVED

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