

Certificate of Analysis

Product name: **Bismuthi subnitratis ponderosum**
Batch number / Weight: **19B19-B04-195159 / 250 G**
Analysed according to: **Ph. Eur.**

Tests	Requirement	Result	Unit	Standard remark
Appearance	White powder	Conform		
Identification A	Black / orange	Conform		Bismuth
Identification B	Yellow-orange color / orange precipitation	Conform		Bismuth
Identification C	Violet	Conform		Nitrate
Identification D	<=2,0	Conform		pH
Acidity	Conform	Conform		
Chlorides	<=200	Conform	ppm	
Copper	<=50	<20	ppm	AAS
Lead	<=20	<10	ppm	AAS
Silver	<=25	<3	ppm	AAS
Substances not precipit. by amm	<=1,0	Conform	%	
Loss on drying	<=3,0	0,2	%	105 °C
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	72,8	%m/m	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:
Dorota Sutkowska
Qualified Person

22-11-2019

Expiration: 06-09-2023

Conclusion: APPROVED

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