

Certificate of Analysis

Product name: **Bismuthi subgallas (90)**
Batch number / Weight: **23C31-B07-234212 / 100 G**
Analysed according to: **Ph.Eur.11.2**
Number of analysis / Inspection Code **23C31-B07 / INS-23-3311**
Reference Code / No.: **V00788 / 2023001183**

Tests	Requirement	Result	Unit	Standard remark
Appearance	Fine, yellow powder	Conform		
Particle size	99% < 90 µm	Conform		
Identification A	Blackblue	Conform		
Identification B	Orange-yellow	Conform		
Acidity	<= 0,15	0,05	ml	
Chlorides	<= 200	<200	ppm	
Nitrates	<= 0,2	<0,2	%	
Copper	<= 50	<2	ppm	
Lead	<= 20	<5	ppm	
Silver	<= 25	<1	ppm	
Substances not precipitated by a	<=1,0	0,47	%	
Loss on drying	<= 7,0	5,68	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay	48,0 - 51,0 (dried substance)	49,61	%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:
Dominika Soltysik
Qualified Person

22-11-2023

Expiration: 17-01-2028

Conclusion: APPROVED

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