

Certificate of Analysis

Product name: **Biotinum**

Batch number / Weight: **22C02-B01-216151 / 25 G**

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

Tests	Requirement	Result	Unit	Standard remark
Appearance	White, crystalline powder or colourless crystals	Conform		
Identification A	Conform	Conform		
Appearance of solution	Clear / colourless	Conform		
Specific optical rotation	+89 - +93	+91		
Related substances	Conform	Conform		
Impurity A	<=0,5	<0,05	%	
Impurity E	<=0,5	<0,05	%	
Impurity C	<=0,2	<0,05	%	
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=2,0	<0,05	%	
Loss on drying	<=1,0	0,02	%	
Sulphated ash	<=0,1	0,04	%	
Assay D-Biotin	98,5 - 101,0	99,9	%m/m	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Residual solvents				
Ethanol	<=5000	<5000	ppm	
Toluene		<890		
Chloroform		<60		

Analysis performed by the authorized lab.

Release:

Agnieszka Pszczółka

Qualified Person

01-06-2022

Expiration: 11-01-2024

Conclusion: APPROVED

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