

Certificate of Analysis

Product name: Biotinum
Batch number / Weight: 21G16-B10-213981 / 5 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	+90		
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	0,05	%	
Sulphated ash	<=0,1	0,10	%	
Assay D-Biotin	98,5 - 101,0	100,6	%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	37	ppm	
Cyclohexane	<=50	2,5	ppm	

Analysis performed by the authorized lab.

Release:
 Ewelina Gadzinowska
 Qualified Person

30-11-2021

Expiration: 14-06-2023

Conclusion: APPROVED

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