

Certificate of Analysis

Productname: Biotinum
Number of analysis/Inspection Code: 1 / KEUR-187417B
Batchnumber: 20K09-F02-375265
Reference code / No.: 3757 / UE02005010
Analysed according to: PH.EUR10.2

Tests	Requirement	Result	Unit	Standard remark
Appearance	Almost white, crystalline powder or colourless crystals	Conform		
Identification A	Conform	Conform		IR-spectrum
Appearance of solution	Clear / colourless	Conform		1%m/V in NaOH 0.4%m/V
Specific optical rotation	+89 - +93	+91		1%m/V NaOH 0.4%m/V; dried
Related substances	Conform	Conform	%	
Impurity A	<=0,5	<0,05	%	
Impurity C	<=0,2	<0,05	%	
Impurity E	<=0,5	0,1	%	
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=2,0	0,1	%	
Loss on drying	<=1,0	<0,1	%	105 °C
Sulphated ash	<=0,1	0,1	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay D-Biotin	98,5 - 101,0	100,0	%m/m	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Proxylabs.

Release:
Paul Hofman
Pharmacist - Qualified Person

11/30/20

Expiration: 05-2023

Conclusion: APPROVED

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