

Lot: 0140618

D-Biotin



Coversheet for Certificate of Analysis

Productcode : 5011655
Lot No. : UE01705015
Analysis No. : 04483535



C/ Terra, 42 P.I. Els Bellots
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CfC Number : 03475094
Articlecode : 5011655270
Sales Name : D-Biotin, 1 KG TIN
Manufacturing Date : 09-MAY-2017
Best Use Before Date : 08-MAY-2020
Delivery Note No. 2422048831
Destination : Spain
Customer Ref. No : PC1800931
Customer Article No: 1522
Customer Name: DISPROQUIMA,S.A.
C/Terra 42, Pol. Ind. Els
Bellots
Terrassa

Comment

CERTIFICATE OF ANALYSIS

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Test	Result	Limits / Specifications	Dimension / Units
Appearance			
Appearance	crystalline powder	crystalline powder	
Visual inspection			
Visual Colour			
Colour	white	white	
Visual inspection			
Visual Colour of a solution 1 pc in NaOH 0.1N			
Visual inspection	colourless	colourless	
Visual Clarity of a solution 1 pc in NaOH 0.1N			
Visual inspection	clear	clear	
Melting Point			
Melting Point	231	229 to 232	°C
Ph. Eur.			
Specific Optical Rotation, 589 nm, 20°C			
C=1 in NaOH 0.1 N (dried)	90.7	89.0 to 93.0	°
Ph. Eur.			
Identity			
Identity	corresponds	corresponds	
IR / Ph. Eur.			
Sulphated Ash			
Sulphated Ash	<0.1	max. 0.1	%
Ph. Eur.			
Heavy Metals			
Heavy Metals	<10	<10	ppm
ICP-AES / Ph. Eur.			
Lead			
Lead	<2	<2	ppm
ICP-AES / Ph. Eur.			

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Test	Result	Limits / Specifications	Dimension / Units
Loss on drying			
Loss on drying Ph. Eur.	0.05	max. 1.0	%
Residual Solvents			
Ethanol GC / Ph. Eur.	167	max. 5000	ppm
Cyclohexane GC / Ph. Eur.	3	max. 50	ppm
Related substances			
Diamino derived HPLC I	<0.05	max. 0.20	%
Biotinyl Biotin HPLC I	<0.05	max. 0.50	%
Monobenzyl Biotin HPLC I	<0.05	max. 0.50	%
Any unspecified impurity HPLC I and II	<0.10	max. 0.10	%
Total of the impurities HPLC I and II	0.00	max. 1.5	%
Assay (dried)			
d-Biotin HPLC I	99.7	98.5 to 100.5	%
Powder fineness			
Through sieve 20 USP Laser diffraction	100	100	%
Chlorides			
Chlorides Ph. Eur.	< 0.047	< 0.047	%
Sulphates			
Sulphates Ph. Eur.	< 0.032	< 0.032	%

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This lot was analysed and released by our authorized Quality Control Department and was found to meet the specifications as given above.

The product meets all requirements of the following valid compendia when tested accordingly :

Ph. Eur + USP + FCC

DSM Nutritional Products France SAS
The Quality Assurance Manager

A handwritten signature in blue ink, appearing to be "V. Wirth-Koenig".

Valérie Wirth-Koenig