

# **D-Biotin**

### Coversheet for Certificate of Analysis

Productcode : Lot No. : Analysis No. :	5011655 UE01501003 04419244
CFC Number :	02714432
Articlecode :	5011655010
Sales Name :	0.005 KG SAMPLES: D-BIOTIN
Manufacturing Date :	25-JAN-2015
Best Use Before Date :	24-JAN-2018



# d-Biotin

### **CERTIFICATE OF ANALYSIS**

Productcode	: 5011655
Lot No.	: UE01501003
Analysis No.	: 04419244

Test	Result	Limits / Specification	Dimension / Units
Appearance			
Appearance Visual inspection	crystalline powder	crystalline powder	
Visual Colour			
Colour Visual inspection	white	white	
Visual Colour of a solution 1pc			
in NaOH 0.1N Visual inspection	colourless	colourless	
Visual Clarity of a solution 1pc			
in NaOH 0.1N Visual inspection	clear	clear	
Melting Point			
Melting Point Ph. Eur.	231	229 to 232	°C
Specific Optical Rotation, 589 nm, 20°C			
C=1 in NaOH 0.1N (dried) Ph. Eur.	90.5	89.0 to 93.0	o
Identity			
Identity IR / Ph. Eur.	corresponds	corresponds	
Sulphated Ash			
Sulphated Ash Ph. Eur.	<0.1	max. 0.1	%
Heavy Metals			
Heavy metals ICP-AES / Ph. Eur.	<10	<10	ppm
Lead			
Lead ICP-AES / Ph. Eur.	<2	<2	ppm
Loss on drying			



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Test	Result	Limits / Specification	Dimension / Units
Loss on drying Ph. Eur.	0.25	max. 1.0	%
<b>Residual solvents</b>			
Ethanol GC / Ph. Eur.	229	max. 5000	ppm
Cyclohexane GC / Ph. Eur.	10	max. 50	ppm
Related substances			
Diamino derived HPLC I	0.08	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	0.08	max. 1.5	%
Assay (dried)			
d-Biotin HPLC I	100.0	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	%

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:



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Ph. Eur + USP + FCC

DSM Nutritional Products France SAS The Quality Assurance Manager

3. Herfold

Philippe Herfeld

**Product Information** 



### **D-Biotin**

#### **GMO Statement**

We hereby confirm that the product D-Biotin is manufactured by conventional processes\*\* and therefore does not contain GMO-DNA.

\*\* The term "conventional process" refers to chemical synthesis, fermentation using non GMM, extraction from conventional plants.

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