



Specification

Concerning Product:	
Article number	58855BN
Trade name / designation / denomination	D-Biotin
CAS number	58-85-5
Other names / synonyms	•5-(2-oxo-1,3,3a,4,6,6a-hexahydrothieno[3,4-d]imidazol-4-yl)pentanoic acid; •Biotine 2%; •Biotine pure; •biotin; •vitamin H;
EC number	200-399-3
Customs tariff number / CN code / TARIC	29362900
Molecular weight [g / mol]	244.31064
Formula	C ₁₀ H ₁₆ N ₂ O ₃ S

Parameter	Test Method	Specification	Unit
Organoleptic test			
Appearance of solution	1% in 0,1N NaOH	clear and colourless	
Appearance		white crystalline powder	
Physical parameter			
Loss on drying		≤ 1,0	%
Specific Optical Rotation	on dry material	89 – 93	°
Melting range	with decomposition	229 – 232	°C
Solubility		Very slightly soluble in water and in ethanol, practically insoluble in organic solvents	
Identity			
Assay		97,5 – 101	%
Identification		complies	
Impurities			
Heavy Metals (as Pb)		≤ 10	ppm
Sulphated ash		≤ 0,1	%
Related substances		conforms to Ph. Eur requirements	% [w/w]
Residual Solvents			
Residual solvents		Toluene ≤ 890	ppm
Elemental Impurities			
Arsenic (As)		≤ 2	ppm
Cadmium (Cd)		≤ 1	ppm
Mercury (Hg)		≤ 0,1	ppm
Lead (Pb)		≤ 2	ppm
Organic volatile impurities			
Org. volat. Imp. Total		comforms to USP requirements	

Microbiological data			
Coliform bacteria		negativ	
Escherichia Coli.		Negative	CFU/g
Salmonella		Negative	
Staphylococcus Aureus		Negative	
Total Plate Count		≤ 99	CFU/g
Yeast and Mould		≤ 49	CFU/g

Supplemental information:

Shelf life: 36 month

Storage conditions: Protect from light and store cool and dry in well-closed original packaging. The temperature should not exceed 25 °C.

Complies with monographie: USP, FCC, Ph. Eur

Regional origin: CN

Usage: Pharma, food, feed and veterinary

Chemische Werke Hommel GmbH & Co.KG

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Waltrop, 12. May. 2020

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