



TECHNICAL DATA SHEET

0246-TDS-ENG-2024

BIOTINA (VITAMINA H) (EUR. PH.)		
DESCRIPTION DCI: BIOTIN		DESCRIPTION DOE: BIOTINA
CAS Nº: 58-85-5	EC Nº: 200-399-3	AEMPS CODE: 499A
MOL. WEIGHT: 244,31	MOL. FORMULA: C ₁₀ H ₁₆ N ₂ O ₃ S	ARTICLE CODE: 0246

ATTRIBUTES	SHOULD BE
Appearance	A white or almost white crystalline powder or colourless crystals
Solubility	Very slightly soluble in water and in alcohol, practically insoluble in acetone. It dissolves in dilute solutions of alkali hydroxides
Identification A	Complies
Appearance of solution	Clear and colourless
Specific optical rotation	+89 / +93
Related substances	
Impurity A	=< 0.5 %
Impurity E	=< 0.5 %
Impurity C	=< 0.2 %
Unspecified impurities	=< 0.10 %
Total impurities	=< 2.0 %
Loss on drying	=< 1.0 %
Sulfated ash	=< 0.1 %
Assay	98.5 - 101.0 %

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

Keep tightly closed. In a well-ventilated place, cool, dry and protected from light.

REMARKS

Biotin is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.