

BIOTINA (VITAMINA H) Farma			
PRODUCT CODE: 0246		CAS Nº: 58-85-5	ANALYSIS Nº: 216/23
MANUFACTURER BATCH:	CS1-2306006	CERTIFICATE ID:	39.225
SUPPLIER BATCH:	----	MANUFACTURING DATE:	31/05/2023
METAPH BATCH:	0060823	EXPIRY DATE:	30/05/2027

ATTRIBUTES	SHOULD BE	IS
Appearance	A white or almost white crystalline powder or colourless crystals	White crystalline powder
Identification A	Complies	Complies
Appearance of solution	Clear and colourless	Clear and colourless (*)
Specific optical rotation	+89 / +93	+ 91 (*)
Related substances		(*)
Impurity A	=< 0.5 %	< 0.5 %
Impurity E	=< 0.5 %	< 0.5 %
Impurity C	=< 0.2 %	< 0.2 %
Unspecified impurities	=< 0.10 %	< 0.10 %
Total impurities	=< 2.0 %	< 2.0 %
Loss on drying	=< 1.0 %	0.02 %
Sulfated ash	=< 0.1 %	< 0.10 %
Assay	98.5 - 101.0 %	99.5 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

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

(*) Data adapted from the manufacturer's certificate of analysis.

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.

STORAGE

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

Release date: 06/09/2023
Signature: Albert Sánchez López (QP)
Conclusion: Complies



Manufacturer: 40000311
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Original certificate available upon request

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