

| <b>BIOTINA (VITAMINA H) Farma</b> |             |                     |                     |
|-----------------------------------|-------------|---------------------|---------------------|
| PRODUCT CODE: 0246                |             | CAS Nº: 58-85-5     | ANALYSIS Nº: 333/24 |
| MANUFACTURER BATCH:               | CS1-2410036 | CERTIFICATE ID:     | 44.584              |
| SUPPLIER BATCH:                   | ----        | MANUFACTURING DATE: | 22/10/2024          |
| METAPH BATCH:                     | 0201224     | EXPIRY DATE:        | 21/10/2028          |

| 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                                                         | +89.5                    |
| Related substances        |                                                                   |                          |
| Impurity A                | =< 0.5 %                                                          | < 0.05 %                 |
| Impurity E                | =< 0.5 %                                                          | < 0.05 %                 |
| Impurity C                | =< 0.2 %                                                          | Not Detected             |
| Unspecified impurities    | =< 0.10 %                                                         | < 0.05 %                 |
| Total impurities          | =< 2.0 %                                                          | < 0.05 %                 |
| Loss on drying            | =< 1.0 %                                                          | 0.02 %                   |
| Sulfated ash              | =< 0.1 %                                                          | 0.04 %                   |
| Assay                     | 98.5 - 101.0 %                                                    | 100.0 %                  |

#### COMPLIES WITH

European Pharmacopoeia 11.0

#### REMARKS

Product fully analyzed within the EU, in compliance with the current regulations "EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines" Part-II.

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

All data controlled by Metapharmaceutical Industrial SL.

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: 06/02/2025  
Signature: Albert Sánchez López (QP)  
Conclusion: Complies



Manufacturer: 40000311  
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Original certificate available upon request

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