



## MELATONINA (EUR. PH.)

|                                 |                                |                     |
|---------------------------------|--------------------------------|---------------------|
| PRODUCT CODE: 46433078          | CAS Nº: 73-31-4                | ANALYSIS Nº: 161/24 |
| MANUFACTURER BATCH: MTN20240401 | CERTIFICATE ID: 42.517         |                     |
| SUPPLIER BATCH: ----            | MANUFACTURING DATE: 07/04/2024 |                     |
| METAPH BATCH: 0070624           | EXPIRY DATE: 06/04/2029        |                     |

| ATTRIBUTES             | SHOULD BE                                                                                                                     | IS                                 |
|------------------------|-------------------------------------------------------------------------------------------------------------------------------|------------------------------------|
| Appearance             | White to slightly yellowish powder                                                                                            | White to slightly yellowish powder |
| Solubility             | Slightly soluble in water, soluble in ethanol (96 %), sparingly soluble in ethyl acetate and practically insoluble in heptane | Complies                           |
| Identification         | Complies                                                                                                                      | Complies                           |
| Related substances     |                                                                                                                               |                                    |
| Unspecified impurities | =< 0.10 %                                                                                                                     | < 0.05 %                           |
| Total impurities       | =< 0.5 %                                                                                                                      | < 0.05 %                           |
| Water                  | =< 0.3 %                                                                                                                      | 0.2 %                              |
| Sulfated ash           | =< 0.1 %                                                                                                                      | < 0.1 %                            |
| Assay                  | 98.0 - 102.0 %                                                                                                                | 99.5 %                             |

### COMPLIES WITH

European Pharmacopoeia 11.0

### REMARKS

Melatonin is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006 - ICH Q3C (R6) "Residual solvents".

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 the container tightly closed, in a cool, dry place. Protected from air and light.

Analysis date: 18/07/2024  
Signature: Albert Sanchez Lopez (QP)  
Conclusion: Complies  
Original certificate available upon request

Manufacturer: 40000349