

# CERTIFICATE OF ANALYSIS

## MELATONIN F

N-(2-(5-methoxy-1H-indol-3-yl)ethyl)acetamide

|                     |                  |              |            |
|---------------------|------------------|--------------|------------|
| BATCH:              | 0020092165       | QUANTITY:    | 20 KG      |
| MANUFACTURING SITE: | CHIGNOLO D'ISOLA | RETEST DATE: | 05/13/2025 |
| MANUFACTURING DATE: | 06/08/2020       | REF.:        | BP         |
| CODE MATERIAL:      | FC00000019       | SPEC.REV.:   | 20         |
| ANALYSIS REF. NO.:  | 040000008636     |              |            |
| CAS NO.:            | 73-31-4          |              |            |

| TESTS                             | SPECIFICATIONS     | UM     | RESULTS            | ANALYTICAL METHOD<br>REFERENCES |
|-----------------------------------|--------------------|--------|--------------------|---------------------------------|
| Aspect                            | Crystalline powder |        | Crystalline Powder |                                 |
| Colour                            | Ivory to beige     |        | Ivory              |                                 |
| Identification (IR)               | Must comply        |        | Complies           |                                 |
| Identification (HPLC)             | Must comply        |        | Complies           |                                 |
| Solubility (5% w/v ethyl alcohol) | Complete           |        | Complete           |                                 |
| Appearance of solution            | Clear, <BY3 EP     |        | Clear, <BY3 EP     | Ph. Eur. <2.2.1>                |
| Melting Point                     | 116.0 - 118.5      | °C     | 118.2              |                                 |
| Water Content                     | <= 0.3             | %      | 0.1                |                                 |
| Assay (HPLC)                      | 98.0 - 102.0       | % d.b. | 99.7               |                                 |
| Purity (HPLC)                     | >= 99.0            | %      | 100.0              |                                 |
| Each Unknown Impurity (HPLC)      | <= 0.10            | %      | < 0.05             |                                 |
| 5-Methoxytryptamine (HPLC)        | <= 0.10            | %      | < 0.05             |                                 |
| Total Impurities (HPLC)           | <= 1.0             | %      | 0.0                |                                 |
| Sulphated Ash                     | <= 0.1             | %      | 0.0                |                                 |
| Residual Methyl Alcohol           | <= 1 000           | ppm    | < 51               |                                 |
| Residual 2-Propanol               | <= 2 000           | ppm    | 405                |                                 |
| Residual Tert Butyl Methylether   | <= 1 000           | ppm    | < 16               |                                 |
| Ethyl Acetate (GC)                | <= 1 000           | ppm    | 57                 |                                 |

### Electronically signed by:

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Quality Control  
06/23/2020 - APPROVED

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Qualified Person  
06/25/2020 - RELEASED

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