

MANUFACTURING SITE Via Bedeschi, 22 - 24040 CHIGNOLO D'ISOLA (BG) - Italy



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## CERTIFICATE OF ANALYSIS

### MELATONIN F

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

|                    |             |                       |            |
|--------------------|-------------|-----------------------|------------|
| BATCH              | 170014      | CODE                  | FC00000019 |
| QUANTITY           | KG - 230,99 | SPEC. CODE            | FC00000019 |
| MANUFACTURING DATE | 23/11/2017  | REV.                  | 14         |
| RETEST DATE        | 28/10/2022  | REFERENCE             | BP         |
| ANALYSIS DATE      | 22/12/2017  | ANALYTICAL REPORT NR. | 2017003124 |

| TESTS                             | LIMITS |       |       | RESULTS            |
|-----------------------------------|--------|-------|-------|--------------------|
|                                   | M.U.   | MIN   | MAX   |                    |
| ASPECT                            |        |       |       | CRYSTALLINE POWDER |
| COLOUR                            |        |       |       | CRYSTALLINE POWDER |
| IDENTIFICATION (IR)               |        |       |       | COMPLIES           |
| IDENTIFICATION (HPLC)             |        |       |       | COMPLIES           |
| SOLUBILITY (5% w/v ethyl alcohol) |        |       |       | COMPLIES           |
| CLARITY, COLOUR SOLUTION          |        |       |       | COMPLIES           |
| MELTING POINT                     | °C     | 116.0 | 118.5 | CLEAR, <Y4 EP      |
| WATER CONTENT                     | %      |       | 0.3   | 117.4              |
| ASSAY (HPLC)                      | % d.b. | 98.0  | 102.0 | 0.0                |
| PURITY (HPLC)                     | %      | 99.0  |       | 99.6               |
| EACH UNKNOWN IMPURITY (HPLC)      | %      |       | 0.10  | 100.0              |
| 5-METHOXYTRYPTAMINE (HPLC)        | %      |       | 0.10  | < 0.05             |
| TOTAL IMPURITIES (HPLC)           | %      |       | 1.0   | < 0.05             |
| HEAVY METALS                      | ppm    |       | 10    | 0.0                |
| SULPHATED ASH                     | %      |       | 0.1   | < 10               |
| RESIDUAL METHYL ALCOHOL           | ppm    |       | 1000  | 0.1                |
| RESIDUAL 2-PROPANOL               | ppm    |       | 2000  | 0                  |
| RESIDUAL TERT BUTYL METHYLETHYL   | ppm    |       | 1000  | 467                |
| ETHYL ACETATE (GC)                | ppm    |       | 1000  | 7                  |
|                                   |        |       |       | 74                 |

NOTES: Colour: Ivory 23/11/17 FB  
Test Purity, each unknown impurity, 5-Methoxytryptamine and total impurities: disregard limit 0.05% 28/11/2017 MK

APPROVED

QUALITY CONTROL  
Dr. Stefano Gobbato

NOTE: This certificate of analysis has been generated electronically and it is valid without a signature  
Unique identification is assigned by batch number + compound code