

## Certificate of Analysis

|                 |                       |                     |            |
|-----------------|-----------------------|---------------------|------------|
| Certificate n.: | 4495                  |                     |            |
| INN:            | L-5-Hydroxytryptophan |                     |            |
| Code:           | ITR1                  | Manufacturing date: | 28-04-2023 |
| Batch:          | 23002                 | Expiry date:        | 28-04-2028 |
| Net weight:     | 60.00 KG              | Order Number:       | OC0001192  |

| <u>Test</u>                                  | <u>Result</u> | <u>Method</u>                           | <u>Limits</u>                                            |
|----------------------------------------------|---------------|-----------------------------------------|----------------------------------------------------------|
| Appearance                                   | Complies      | In-house (visual)                       | White to grey white powder                               |
| Loss on drying                               | 0.8 %         | Ph. Eur. (2.2.32) current ed.           | Not more than 2.0 %                                      |
| pH                                           | 5.8           | Ph. Eur. (2.2.3) current ed.            | Between 4.0 and 6.0                                      |
| Solubility                                   | Complies      | In-house                                | Slightly soluble in water, insoluble in organic solvents |
| Specific optical rotation                    | -33.4         | Ph. Eur. (2.2.7) current ed.            | Between -38.0 and -30.0                                  |
| Related substances:                          |               | In-house (HPLC)                         |                                                          |
| <i>L-tryptophan</i>                          | 0.1 %         |                                         | Not more than 0.2 %                                      |
| <i>Any unspecified impurity (max single)</i> | <0.05 %       |                                         | Not more than 0.10 %                                     |
| <i>Total</i>                                 | 0.1 %         |                                         | Not more than 0.5 %                                      |
| Assay (dried substance)                      | 100.0 %       | In-house (potentiometric titration)     | Between 99.0 and 101.0 %                                 |
| Identification (IR)                          | Complies      | Ph. Eur. (2.2.24) current ed.           | Complies with reference standard                         |
| Sulfated ash                                 | 0.0 %         | Ph. Eur. (2.4.14) current ed.           | Not more than 0.2 %                                      |
| Heavy metals                                 | Complies      | Ph. Eur. (2.4.8 - method C) current ed. | Not more than 10 ppm                                     |
| Residual solvents:                           |               | In-house (GC)                           |                                                          |
| <i>Methanol</i>                              | 34 ppm        |                                         | Not more than 1000 ppm                                   |
| <i>Terz-butylmetylether</i>                  | <5 ppm        |                                         | Not more than 100 ppm                                    |
| Tapped density                               | 0.54 g/mL     | Ph. Eur. (2.9.15) current ed.           | Not less than 0.40 g/mL                                  |
| Total aerobic microbial count                | <10 CFU/g     | Ph. Eur. (2.6.12) current ed.           | Not more than 10 <sup>3</sup> CFU/g                      |
| Total combined yeast/mould count             | <10 CFU/g     | Ph. Eur. (2.6.12) current ed.           | Not more than 10 <sup>2</sup> CFU/g                      |
| Bile-tolerant Gram-negative bacteria         | 0 CFU/g       | Ph. Eur. (2.6.13) current ed.           | Not more than 10 <sup>2</sup> CFU/g                      |
| Escherichia coli                             | Complies      | Ph. Eur. (2.6.13) current ed.           | Absent/10g                                               |
| Salmonella                                   | Complies      | Ph. Eur. (2.6.31) current ed.           | Absent/25g                                               |

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The Batch has been manufactured and controlled in accordance with the requirements of GMPs and meets the Specifications

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**Approved**

Release date and time (UTC): 06-06-2023 07:08:19

*Quality Unit Manager*

**Giorgia Tossi**

*The electronic signature used to release the lot is equivalent to a handwritten signature due to the compliance of the software used, to the international rules concerning electronic records and electronic signature management (FDA CFR21 p11, EU Annex 11).*