

## Certificate of analysis

**Product name:** L-5-Hydroxytryptophan  
**Description:** L-5-Hydroxytryptophan  
**Code:** ITR  
**Batch:** 50814001  
**Net Weight:** 25.00 Kg

**Certificate n.** 047966  
**Date of manufacture:** 11-2012  
**Date of expiry:** 11-2017

| <u>Parameters</u>                   | <u>Results</u> | <u>Units</u> | <u>Method</u>                                 | <u>Specifications</u>                                    |
|-------------------------------------|----------------|--------------|-----------------------------------------------|----------------------------------------------------------|
| Aspect                              | Complies       | --           | Internal Method                               | White to grey white powder                               |
| IR Identification                   | Complies       | --           | Internal Method                               | Complies with reference standard                         |
| pH                                  | 5.7            | --           | Internal Method                               | Between 4.0 and 6.0                                      |
| Solubility                          | Complies       | --           | Internal Method                               | Slightly soluble in water, insoluble in organic solvents |
| Loss on drying                      | 0.6            | %            | Internal Method                               | Not more than 2.0 %                                      |
| Specific Optical Rotation           | -33.4          | °            | Internal Method                               | Between -38.0 and -30.0                                  |
| Assay (HClO <sub>4</sub> titration) | 100.7          | %            | Internal Method                               | Between 99.0 % and 101.0 %                               |
| Related substances:                 |                |              |                                               |                                                          |
| L-tryptophan                        | 0.1            | %            |                                               | Not more than 0.2 %                                      |
| Total impurities                    | 0.2            | %            | Internal Method                               | Not more than 0.5 %                                      |
| Sulphated ash                       | 0.1            | %            | 2.4.14 Ph Eur, current edition                | Not more than 0.2 %                                      |
| Heavy metals                        | Complies       | --           | 2.4.8 Ph Eur, current edition                 | Not more than 15 ppm                                     |
| Residual solvents:                  |                |              |                                               |                                                          |
| Methanol                            | <10            | ppm          | Internal Method according to EP monograph 5.4 | Not more than 1000 ppm                                   |
| Methyl t-butyl ether                | <5             | ppm          | Internal Method according to EP monograph 5.4 | Not more than 100 ppm                                    |
| Informative parameter:              |                |              |                                               |                                                          |
| Tapped density                      | 0.5            | g/ml         | 2.9.15 Ph Eur, current edition                | Preferible: Not less than 0.40 g/ml                      |

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|---------------------------------------------|----------------|--------------|-------------------------------------------|----------------------------|
| Microbiology                                |                |              |                                           |                            |
| <i>Total aerobic microbial count</i>        | Complies       | --           | 2.6.12 Ph Eur, current edition            | Not more than $10^3$ cfu/g |
| <i>Total combined yeast/mould count</i>     | Complies       | --           | 2.6.12 Ph Eur, current edition            | Not more than $10^2$ cfu/g |
| <i>Escherichia coli</i>                     | Complies       | --           | 2.6.13 Ph Eur, current edition            | Absent/10 g                |
| <i>Bile tolerant Gram-negative bacteria</i> | Complies       | --           | 2.6.13 Ph Eur, current edition            | Not more than $10^2$ cfu/g |
| <i>Salmonella</i>                           | Complies       | --           | 2.6.13 and 2.6.31 Ph Eur, current edition | Absent/25 g                |

Remarks:

Released on: 25.02.2014

Order Number: 14/033

**APPROVED**

Quality Unit Manager  
 Georgia Tossi

