

TECHNICAL DATA SHEET

1850-TDS-ENG-2026

| TRIPTOFANO-L (EUR. PH.) | | |
|--------------------------------|---|-------------------------------|
| DESCRIPTION DCI: L-TRYPTOPHAN | | DESCRIPTION DOE: L-TRIPTOFANO |
| CAS Nº: 73-22-3 | EC Nº: 200-795-6 | AEMPS CODE: --- |
| MOL. WEIGHT: 204,23 | MOL. FORMULA: C ₁₁ H ₁₂ N ₂ O ₂ | ARTICLE CODE: 1850 |

| <u>ATTRIBUTES</u> | <u>SHOULD BE</u> |
|---|--|
| Appearance | White or almost white, crystalline or amorphous powder |
| Solubility | Sparingly soluble in water, slightly soluble in ethanol (96 per cent). It dissolves in dilute solutions of mineral acids and alkali hydroxides |
| Identification A | Complies |
| Identification B | Complies |
| Appearance of solution | Clear and not more intensely coloured than ref. sol. BY6 |
| Specific optical rotation | -33.0 / -30.0 |
| Ninhydrin-positive substances | |
| Any ninhydrin-positive substance | =< 0.2 % |
| Total substances | =< 0.5 % |
| Impurity A and other related substances | |
| Impurity A | =< 10 ppm |
| Sum of impurities RT < Impurity A | =< 100 ppm |
| Sum of impurities RT > Impurity A | =< 300 ppm |
| Chlorides | =< 200 ppm |
| Sulfates | =< 300 ppm |
| Ammonium | =< 0.02 % |
| Iron | =< 20 ppm |
| Loss on drying | =< 0.5 % |
| Sulfated ash | =< 0.1 % |
| Assay | 98.5 - 101.0 % |

COMPLIES WITH

European Pharmacopoeia 12.2

STORAGE

Store in a cool place. Keep the container tightly closed in a dry and well-ventilated place.

REMARKS

L-Tryptophan is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

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

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product before use.