

**TECHNICAL DATA SHEET**

1847-TDS-ENG-2026

| <b>TRIMETOPRIM (EUR. PH.)</b> |                          |                               |
|-------------------------------|--------------------------|-------------------------------|
| DESCRIPTION DCI: trimethoprim |                          | DESCRIPTION DOE: TRIMETOPRIMA |
| CAS N°: 738-70-5              | EC N°: 212-006-2         | AEMPS CODE: 90A               |
| MOL. WEIGHT: 290,32           | MOL. FORMULA: C14H18N4O3 | ARTICLE CODE: 1847            |

| <b>ATTRIBUTES</b>      | <b>SHOULD BE</b>   |
|------------------------|--|
| Appearance             | White or yellowish-white powder  |
| Solubility             | Very slightly soluble in water, slightly soluble in ethanol (96 %), practically insoluble in heptane |
| Identification C       | Complies   |
| Appearance of solution | Not more intensely coloured than ref. sol. BY7   |
| Related substances     |  |
| Unspecified impurities | =< 0.10 %  |
| Total impurities       | =< 0.2 %   |
| Impurity K             | =< 5 ppm   |
| Loss on drying         | =< 1.0 %   |
| Sulfated ash           | =< 0.1 %   |
| Assay                  | 99.0 - 101.0 %   |

**COMPLIES WITH**

European Pharmacopoeia 12.1

**STORAGE**

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

**REMARKS**

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

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

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 product before use.