



TECHNICAL DATA SHEET

1490-TDS-ENG-2024

| PREDNISOLONA BASE (EUR. PH.) | | |
|-------------------------------|--|-------------------------------|
| DESCRIPTION DCI: PREDNISOLONE | | DESCRIPTION DOE: PREDNISOLONA |
| CAS N°: 50-24-8 | EC N°: 200-021-7 | AEMPS CODE: 887A |
| MOL. WEIGHT: 360,45 | MOL. FORMULA: C ₂₁ H ₂₈ O ₅ | ARTICLE CODE: 1490 |

| ATTRIBUTES | SHOULD BE |
|---------------------------|---|
| Appearance | White or almost white, crystalline, hygroscopic powder |
| Solubility | Very slightly soluble in water, soluble in ethanol (96 %) and in methanol, sparingly soluble in acetone, slightly soluble in methylene chloride |
| Identification A | Complies |
| Identification B | Complies |
| Specific optical rotation | +113 / +119 |
| Related substances | |
| Impurity A | =< 1.0 % |
| Impurity F | =< 0.5 % |
| Impurity B | =< 0.3 % |
| Impurity C | =< 0.3 % |
| Impurity J | =< 0.3 % |
| Unspecified impurities | =< 0.10 % |
| Total impurities | =< 1.5 % |
| Loss on drying | =< 1.0 % |
| Assay | 96.5 - 102.0 % |

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

Keep the container tightly closed, in a cool, dry place. Protected from air and light.

REMARKS

It shows polymorphism (5.9).

Prednisolone 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.