



## TECHNICAL DATA SHEET

1496-TDS-ENG-2024

| PROGESTERONA BASE (EUR. PH.)  |  |                               |
|-------------------------------|--|-------------------------------|
| DESCRIPTION DCI: PROGESTERONE |  | DESCRIPTION DOE: PROGESTERONA |
| CAS Nº: 57-83-0               | EC Nº: 200-350-6   | AEMPS CODE: 2209A             |
| MOL. WEIGHT: 314,47           | MOL. FORMULA: C <sub>21</sub> H <sub>30</sub> O <sub>2</sub> | ARTICLE CODE: 1496            |

| ATTRIBUTES                        | SHOULD BE   |
|-----------------------------------|---|
| Appearance                        | White or almost white, crystalline powder or colourless crystals  |
| Solubility                        | Practically insoluble in water, freely soluble in anhydrous ethanol, sparingly soluble in acetone and in fatty oils |
| Identification A                  | Complies  |
| Identification B                  | Complies  |
| Specific optical rotation         | +186 / +194   |
| Related substances                |   |
| Impurity I (sum of the 2 epimers) | <= 0.6 %  |
| Impurity C                        | <= 0.3 %  |
| Impurity B                        | <= 0.2 %  |
| Sum of impurities D and E         | <= 0.15 %   |
| Impurity G                        | <= 0.15 %   |
| Impurity J                        | <= 0.15 %   |
| Impurity K                        | <= 0.15 %   |
| Impurity L                        | <= 0.15 %   |
| Impurity M                        | <= 0.15 %   |
| Impurity H at 286 nm              | <= 0.15 %   |
| Unspecified impurities            | <= 0.10 %   |
| Sum of impurities other than H    | <= 1.0 %  |
| Loss on drying                    | <= 0.5 %  |
| Assay                             | 97.0 - 102.0 %  |

### COMPLIES WITH

European Pharmacopoeia 11.0

### STORAGE

Store locked up in cool place. Keep continue tightly closed in a dry and well-ventilated place.

### REMARKS

**VEGETAL ORIGIN** Progesterone is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006 - ICH Q3C (R6) "Residual solvents".

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.