

**TECHNICAL DATA SHEET**

0619-TDS-ENG-2026

<b>ESTRADIOL HEMIHDRATO (17-BETA ESTRADIOL) (EUR. PH.)</b>		
DESCRIPTION DCI: ESTRADIOL 17-BETA		DESCRIPTION DOE: ESTRADIOL 17-BETA
CAS N°: 35380-71-3	EC N°: 631-198-2	AEMPS CODE: 90164A
MOL. WEIGHT: 281,4	MOL. FORMULA: C <sub>18</sub> H <sub>24</sub> O <sub>2</sub> ·1/2H <sub>2</sub> O	ARTICLE CODE: 0619

<u>ATTRIBUTES</u>	<u>SHOULD BE</u>
Appearance	White or almost white, crystalline powder or colourless crystals
Solubility	Practically insoluble in water, soluble in acetone, sparingly soluble in ethanol (96%) and slightly soluble in methylene chloride
Identification B	Complies
Specific optical rotation	+76.0 / +83.0
Related substances	
Impurity A	=< 0.3 %
Impurity B	=< 0.3 %
Impurity C	=< 0.3 %
Impurity D	=< 0.3 %
Unspecified impurities	=< 0.10 %
Total impurities	=< 0.5 %
Water	2.9 - 3.5 %
Assay	97.0 - 103.0 %

**COMPLIES WITH**

European Pharmacopoeia 12.1

**STORAGE**

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

**REMARKS**

Estradiol Hemihydrate 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.