METAPHARMACEUTICAL IND SL
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TECHNICAL DATA SHEET

0621-TDS-ENG-2023

ETINILESTRADIOL (EUR. PH.)		
DESCRIPTION DCI: ETINILESTRADIOL	DESCRIPTION DOE: ETHYNILESTRADIOL	
CAS Nº: 57-63-6	EC Nº: 200-342-2	AEMPS CODE: ---
MOL. WEIGHT: 296,41	MOL. FORMULA: C20H24O2	ARTICLE CODE: 0621

ATTRIBUTES	SHOULD BE
Appearance	White or slightly yellowish-white, crystalline powder.
Solubility	Practically insoluble in water, freely soluble in ethanol (96%). It dissolves in dilute alkaline solutions.
Identification A	Complies
Identification B	Complies
Related substances	
Impurity B	<= 0,5 %
Impurity H	<= 0,2 %
Impurity I	<= 0,2 %
Impurity K	<= 0,2 %
Impurity C	<= 0,15 %
Impurity F	<= 0,15 %
Unspecified impurities	<= 0,10 %
Total impurities	<= 0,8 %
Loss on drying	<= 1,0 %
Assay	97,5 - 102,0 %

COMPLIES WITH

European Pharmacopeia 11.0

STORAGE

Keep tightly closed, in a dry and cool place, protected from the light and locked in an area accessible only by authorised peop

REMARKS

It shows polymorphism.

Ethynilestradiol 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.