



## TECHNICAL DATA SHEET

0618-TDS-ENG-2023

17 ALFA ESTRADIOL		
DESCRIPTION DCI: ESTRADIOL 17 ALPHA		DESCRIPTION DOE: ESTRADIOL 17 ALFA
CAS N°: 57-91-0	EC N°: 200-354-8	AEMPS CODE: 8762B
MOL. WEIGHT: 272.40	MOL. FORMULA: C18H24O2	ARTICLE CODE: 0618

ATTRIBUTES	SHOULD BE
Appearance	White or almost white powder
Solubility	Soluble in alcohol and acetone, slightly soluble in ether and chloroform, insoluble in water
Identification A	Complies
Identification B	Complies
Melting point	217 - 226 °C
Optical rotation	+52 / +60
Loss on drying	= < 0.5 %
Related substances	
Estradiol	= < 0.2 %
Estrone	= < 0.2 %
4-methyl-17-alpha estradiol	= < 0.3 %
Delta 9-alpha estradiol	= < 0.15 %
Unspecified impurities	= < 0.10 %
Total impurities	= < 1.0 %
Assay	97.0 - 102.0 %
Residual solvents	
Ethyl acetate	= < 5000 ppm
Ethanol	= < 5000 ppm
Toluene	= < 890 ppm
Microbiological control	
TAMC	= < 1000 CFU/g
TYMC	= < 100 CFU/g
Escherichia coli	Absence/1g
Candida Albicans	Absence/1g
Pseudomonas aeruginosa	Absence/1g
Staphylococcus aureus	Absence/1g
Salmonella	Absence/10g

### COMPLIES WITH

Manufacturer Specifications

### STORAGE

Keep the container tightly closed in a dry, cool and well-ventilated place.

### REMARKS

17- $\alpha$ -Estradiol is subjected to the requirements of the ICH Q3D "Elemental Impurities" 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

All methods are validated by the official pharmacopoeias and/or by the authorized manufacturer

A080.02.ENG



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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.