



TECHNICAL DATA SHEET

626-TDS-ENG-2024

ESTRONA (USP)		
DESCRIPTION DCI: estrone		DESCRIPTION DOE: ESTRONA
CAS N°: 53-16-7	EC N°: 200-164-5	AEMPS CODE: 1457A
MOL. WEIGHT: 270,37	MOL. FORMULA: C18H22O2	ARTICLE CODE: 626

ATTRIBUTES	SHOULD BE
Appearance	White or almost white crystalline powder
Clarity of solution	Clear
Identification A	Complies
Identification B	Complies
	+158° / +165°
Loss on drying	= < 0.5 %
Residue on ignition	= < 0.5 %
Limit of equilenin and equilin	Complies
Ordinary impurities	Complies
Assay	97.0 % - 103.0 %

COMPLIES WITH

USP 2024

STORAGE

Keep tightly closed, in a dry and cool place and protected from the light.

REMARKS

Estrone 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.