METAPHARMACEUTICAL IND SL
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ESTRONA (USP)

PRODUCT CODE: 626	CAS Nº: 53-16-7	ANALYSIS Nº: 303/24	
MANUFACTURER BATCH:	ZEONy23002-M1	CERTIFICATE ID:	44.286
SUPPLIER BATCH:	----	MANUFACTURING DATE:	01/10/2023
METAPH BATCH:	0281124	RETEST DATE:	30/09/2026

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white crystalline powder	White crystalline powder
Clarity of solution	Clear	Clear
Identification A	Complies	Complies
Identification B	Complies	Complies
	+158º / +165º	+159º
Loss on drying	=< 0.5 %	0.2 %
Residue on ignition	=< 0.5 %	0.3 %
Limit of equilenin and equilin	Complies	Complies
Ordinary impurities	Complies	Complies
Assay	97.0 % - 103.0 %	99.7 %

COMPLIES WITH

USP 2024

REMARKS

Product fully analyzed within the EU, in compliance with the currents regulations "EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines" Part-II.

Estrone is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

All data controlled by Metapharmaceutical Industrial SL.

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.

STORAGE

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

Analysis date: 20/12/2024
Signature: Albert Sanchez Lopez (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40000916
SYMBIOTEC PHARMALAB PVT. LIMITED
Plot No.5, 6, 7 &SEZ Phase- II, Pharma Zone
454774 Pithampur Dist. Dhar. (M.P)
(India)