



ESTRIOL PH.EUR

PRODUCT CODE: 002185	CAS N°: 50-27-1	ANALYSIS N°: 203/22
MANUFACTURER BATCH: ESTZ01A007	CERTIFICATE ID: 35.916	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 01/06/2020	
METAPH BATCH: 0070122	RETEST DATE: 30/05/2024	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white crystalline powder	White crystalline powder
Solubility	Practically insoluble in water, sparingly soluble in ethanol (96 %)	Complies (*)
Identification A	Complies	Complies
Identification B	Complies	Complies
Specific optical rotation	+60 / +65	+64.4
Related substances		
Impurity F	=< 0.5 %	0.36 %
Impurity E	=< 0.3 %	0.26 %
Impurity A	=< 0.2 %	< 0.05 %
Impurity D	=< 0.2 %	< 0.05 %
Unspecified impurities	=< 0.10 %	< 0.05 %
Total impurities	=< 1.0 %	0.62 %
Loss on drying	=< 0.5 %	< 0.01 %
Assay	97.0 - 102.0 %	100.8 %
Residual solvents		(*) (**)
Methanol	=< 3000 ppm	196 ppm
DMF	=< 880 ppm	Not Detected
1,2-Dichloroethane	=< 5 ppm	Not Detected
Particle size		(*)
D90	< 10 µm	Complies
Microbiological control		(*)
TAMC	< 1000 CFU/g	60 CFU/g
TYMC	< 100 CFU/g	30 CFU/g

COMPLIES WITH

European Pharmacopoeia 10.0

REMARKS

Estriol is subjected to the requirements of the ICH Q3D "Elemental Impurities".

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.

(*) Data adapted from the certificate of analysis of the manufacturer.

(**) According to the requirements of guides EMA/CHMP/ICH/82260/2006.

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

Analysis date: 02/11/2022
Signature: Ferran Gonzalez de Rivera Riera (QA/QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40001162

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

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