

17 ALFA ESTRADIOL			
PRODUCT CODE: 0618		CAS Nº: 57-91-0	ANALYSIS Nº: 070/25
MANUFACTURER BATCH:	AFE20241201	CERTIFICATE ID:	45.573
SUPPLIER BATCH:	----	MANUFACTURING DATE:	18/12/2024
METAPH BATCH:	0220325	EXPIRY DATE:	17/12/2027

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white powder	White powder
Solubility	Soluble in alcohol and acetone, slightly soluble in ether and chloroform, insoluble in water	Complies (*)
Identification A	Complies	Complies
Identification B	Complies	Complies
Melting point	217 - 226 °C	224.6 °C
Optical rotation	+52 / +60	+55
Loss on drying	=< 0.5 %	0.04 %
Sulfated ash	=< 0.1 %	0.04 %
Related substances		
Estradiol	=< 0.2 %	0.1 %
Estrone	=< 0.2 %	Not Detected
4-methyl-17-alpha estradiol	=< 0.3 %	Not Detected
Delta 9-alpha estradiol	=< 0.15 %	Not Detected
Unspecified impurities	=< 0.10 %	< 0.05 %
Total impurities	=< 1.0 %	0.1 %
Assay	97.0 - 102.0 %	99.6 %
Residual solvents		
Ethyl acetate	=< 5000 ppm	< 50 ppm
Ethanol	=< 5000 ppm	481 ppm
Methanol	=< 3000 ppm	< 50 ppm
Isopropyl alcohol	=< 5000 ppm	< 50 ppm
Tetrahydrofuran	=< 720 ppm	< 50 ppm
Toluene	=< 890 ppm	< 50 ppm
Microbiological control		
TAMC	=< 1000 CFU/g	< 10 CFU/g
TYMC	=< 100 CFU/g	< 10 CFU/g
Escherichia coli	Absence/1g	Absence/1g
Candida Albicans	Absence/1g	Absence/1g
Pseudomonas aeruginosa	Absence/1g	Absence/1g
Staphylococcus aureus	Absence/1g	Absence/1g
Salmonella	Absence/1g	Absence/1g

COMPLIES WITH

Manufacturer Specifications

Release date: 04/12/2025
Signature: Albert Sánchez López (QP)
Conclusion: Complies



Manufacturer: 40000349
H. G. (WAICOME PHARMA)
No. 138 YuWu Road
XinMin Town
408302 Chongqing

Original certificate available upon request

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REMARKS

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

17-a-Estradiol is subjected to the requirements of the ICH Q3D "Elemental Impurities" and the requirements of guides EMA/CHMP/ICH/82260/2006.

All data controlled by Metapharmaceutical Industrial SL.

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

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

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