



17 ALFA ESTRADIOL

MANUFACTURER BATCH: 20171201		SUPPLIER BATCH: ----	METAPH BATCH: 0060218
CERTIFICATE ID:	23.081	PRODUCT CODE:	0618
MANUFACTURING DATE:	11/12/2017	CAS N°:	57-91-0
EXPIRY DATE:	10/12/2020	ANALYSIS N°:	026/18

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	221 - 224 °C
Optical rotation	+52° / +60°	+57°
Loss on drying	=< 0.5 %	0.12 %
Related substances		
Estradiol	=< 0.2 %	Not Detected
Estrone	=< 0.2 %	0.11 %
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 %	0.16 %
Assay	97.0 - 102.0 %	101.3 %
Residual solvents		(**)
Ethyl acetate	=< 5000 ppm	< 10 ppm
Toluene	=< 890 ppm	224 ppm

COMPLIES WITH

Manufacturer Standard

REMARKS

17- α -estradiol is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE are available upon request.

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

(**) According to the requirements of guides CPMP/ICH/283/95.

STORAGE

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

Analysis date: 01/03/2018
Signature: Ferran Gonzalez de Rivera Riera (QA/QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40000349