



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 240803

| | |
|--------------------|--------------------------------|
| Product: | 17-alpha ESTRADIOL |
| Lot: | 240803 |
| Expiry date: | 04/04/2029 |
| Reference: | Especificaciones de fabricante |
| Synonyms: | Alfatradiol. |
| Formule: | C18H24O2 |
| Poids moléculaire: | 272,37 g/mol |

| Assay | Result | Specification | |
|-------------------------------|---------------|-------------------|---|
| Identification | Conform (A,B) | Test (A,B) | |
| Organoleptic properties | Conform | | |
| Melting point | 225 °C | 222 - 226 °C | |
| Loss on drying | 0,08 % | <= 0,5 % | |
| Specific rotation | + 53,0 | (+51,0) - (+56,0) | |
| Sulphated ashes | 0,00% | =< 0,1% | |
| Related substances (HPLC) | Conform | Test | |
| Elemental impurities | Conform | Test | # |
| Assay | 100,1% | 97,0 - 102,0 % | |
| Impurity A | < 0,05 % | <= 0,2 % | |
| Impurity B | < 0,05 % | <= 0,15 % | |
| Impurity C | ND | <= 0,2 % | |
| Impurity D | ND | <= 0,3 % | |
| Unspecified Impurities | < 0,05 % | <= 0,10 % | |
| Total impurities | < 0,05 % | <= 1,0 % | |
| Residual solvent: Ethanol | < 5000 ppm | <= 5000 ppm | # |
| Residual solvent: Cyclohexane | < 3880 ppm | <= 3880 ppm | # |
| Residual solvent: Methanol | < 3000 ppm | <= 3000 ppm | # |
| Residual solvent: Toluene | < 890 ppm | <= 890 ppm | # |
| Nitrosamine impurities | Conform | Test | # |

Organoleptic characteristics: White or almost white, crystalline powder. Practically insoluble in water, freely soluble in ethanol and in hot alkaline solution.

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 10/05/2024

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00343 CHIRACON GmbH

Manufacturer batch: 21-22-I-91P6527

| Produit | Nom | Capacité | Lot |
|---------|---------------------------------|----------|------------|
| 1130262 | ESTRADIOL 17-alfa (BIOIDENTICA) | 0,25 g | 240803-B-1 |
| 1130262 | ESTRADIOL 17-alfa (BIOIDENTICA) | 0,25 g | 240803-B-2 |
| 1130263 | ESTRADIOL 17-alfa (BIOIDENTICA) | 0,5 g | 240803-C-1 |
| 1130263 | ESTRADIOL 17-alfa (BIOIDENTICA) | 0,5 g | 240803-C-2 |
| 1130264 | ESTRADIOL 17-alfa (BIOIDENTICA) | 1 g | 240803-D-1 |
| 1130264 | ESTRADIOL 17-alfa (BIOIDENTICA) | 1 g | 240803-D-2 |
| 1130265 | ESTRADIOL 17-alfa (BIOIDENTICA) | 5 g | 240803-E-1 |
| 1130265 | ESTRADIOL 17-alfa (BIOIDENTICA) | 5 g | 240803-E-2 |

This certificate is not initialled as it is computer processed, it is validated with the originals available at Acofarma.

Original manufacturer's certificate available on request.

(#) Parameter controlled by the manufacturer

(=) UE certificate

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