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Estradiol Cypionate Injection

DEFINITION

Estradiol Cypionate Injection is a sterile solution of Estradiol Cypionate in a suitable oil. It contains NLT 90.0% and NMT 110.0% of the labeled amount of estradiol cypionate ($C_{26}H_{36}O_3$).

IDENTIFICATION

• **A.**

Sulfanilic acid solution: Mix 50 mg of sulfanilic acid with 2 mL of 3 N hydrochloric acid, warm the mixture, then cool it in ice water, and slowly add, with agitation, 0.3 mL of sodium nitrite solution (1 in 10).

Sample solution: Transfer a volume of Injection, equivalent to 5 mg of estradiol cypionate, to a glass-stoppered, 50-mL test tube, and add 30 mL of alcohol.

Analysis: Shake the *Sample solution* vigorously for 5 min, centrifuge until the two layers have separated, and transfer the alcohol layer, with the aid of a hypodermic syringe, to a 50-mL beaker. Evaporate on a steam bath to dryness, add 5 mL of potassium hydroxide solution (1 in 10), and heat on the steam bath for 15 min. Add the *Sulfanilic acid solution* to the saponified estradiol cypionate.

Acceptance criteria: A red color is produced.

ASSAY

• **Procedure**

Mobile phase: 0.8 g/L of ammonium nitrate. Dissolve in 300 mL of water, and combine with 700 mL of acetonitrile.

Internal standard solution: 2.0 mg/mL of testosterone benzoate in tetrahydrofuran

Standard solution: 0.1 mg/mL of USP Estradiol Cypionate RS in tetrahydrofuran, prepared as follows. Transfer 10 mg of USP Estradiol Cypionate RS to a 100-mL volumetric flask, add 10.0 mL of the *Internal standard solution*, and dilute with tetrahydrofuran to volume. Shake vigorously to dissolve.

Sample solution: Using a "to contain" pipet, transfer an accurately measured volume, in mL, of Injection, equivalent to 10 mg of estradiol cypionate, to a 100-mL volumetric flask. Rinse the pipet with small portions of tetrahydrofuran, collecting the washings in the volumetric flask. Add 10.0 mL of the *Internal standard solution*, and dilute with tetrahydrofuran to volume.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 280 nm

Column: 3.9-mm × 30-cm; packing L1

Flow rate: 1 mL/min

Injection size: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Resolution: NLT 3.0 between the peaks for estradiol cypionate and the internal standard

Relative standard deviation: NMT 1.5%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of estradiol cypionate ($C_{26}H_{36}O_3$) in the portion of Injection taken:

$$\text{Result} = (R_U/R_S) \times (C_S/C_U) \times 100$$

R_U = peak response ratio of estradiol cypionate to the internal standard from the *Sample solution*

R_S = peak response ratio of estradiol cypionate to the internal standard from the *Standard solution*

C_S = concentration of the *Standard solution* (mg/mL)

C_U = nominal concentration of the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

• **Injections and Implanted Drug Products ⟨1⟩:** Meets the requirements

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in single-dose or in multiple-dose, light-resistant containers, preferably of Type I glass.

• **USP Reference Standards ⟨11⟩**

USP Estradiol Cypionate RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
ESTRADIOL CYPIONATE INJECTION	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

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