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Add the following:

▲Estriol Compounded Vaginal Cream

DEFINITION

Estriol Compounded Vaginal Cream contains NLT 90.0% and NMT 110.0% of the labeled amount of estriol ($C_{18}H_{24}O_3$). Prepare Estriol Compounded Vaginal Cream, 0.5 mg/g (0.05%), as follows (see *Pharmaceutical Compounding—Nonsterile Preparations ⟨795⟩*).

Estriol	50 mg
Propylene Glycol	5 mL
Emollient Cream Base,[a] a sufficient quantity to make	100 g

[a] PCCA, Houston, TX.

Wet the *Estriol* with the *Propylene Glycol* in a suitable container and mix until smooth and homogenous. Add the *Emollient Cream Base* by geometric dilution until final weight is achieved. Mix after each addition of the *Emollient Cream Base*.

ASSAY

• **Procedure**

Solution A: 25 mM monobasic potassium phosphate

Solution B: Acetonitrile and methanol (50:50)

Mobile phase: See *Table 1*.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	80	20
5	80	20
30	40	60
31	80	20
35	80	20

Diluent: Methanol and water (80:20)

Standard stock solution: Transfer about 20 mg of USP Estriol RS to a 250-mL volumetric flask and dilute with *Diluent* to final volume.

Standard solution: 0.005 mg/mL of estriol prepared from *Standard stock solution* and *Diluent*

Sample solution: Weigh about 3 mL of Vaginal Cream and transfer into a 100-mL volumetric flask, add about 5 mL of chloroform, and sonicate until the cream is broken down. Dilute with *Diluent* to final volume and pass through a filter of 0.45-µm pore size.

Chromatographic system

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

Mode: LC

Detector: UV 230 nm

Column: 4.6-mm × 15-cm; 3-µm packing L11

Column temperature: 60°

Flow rate: 1.0 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

[NOTE—The retention time for estriol is about 17.2 min.]

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0% for replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of estriol ($C_{18}H_{24}O_3$) in the portion of Vaginal Cream taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of estriol from the *Sample solution*

r_S = peak response of estriol from the *Standard solution*

C_S = concentration of USP Estriol RS in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Package in a tight, light-resistant suitable calibrated dispenser. Store at controlled room temperature.
- **BEYOND-USE DATE:** NMT 90 days after the date on which it was compounded when stored at controlled room temperature
- **LABELING:** Label it to indicate that it is for vaginal use only, and to state the *Beyond-Use Date*.
- **USP REFERENCE STANDARDS ⟨11⟩**
  USP Estriol RS▲ (USP 1-Aug-2019)

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

Topic/Question	Contact	Expert Committee
ESTRIOL COMPOUNDED VAGINAL CREAM	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020

Chromatographic Database Information: Chromatographic Database

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