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Add the following:

^Testosterone Compounded Cream

DEFINITION
Testosterone Compounded Cream contains NLT 90.0% and NMT 110.0% of the labeled amount of testosterone (C₁₉H₂₈O₂).
Prepare Testosterone Compounded Cream, 5 mg/g and 100 mg/g, as follows (see [Pharmaceutical Compounding—Nonsterile Preparations \(795\)](#)).
To prepare a Testosterone Compounded Cream containing 5 mg/g of testosterone:

Testosterone (micronized) powder	0.5 g
Propylene Glycol	5 mL
HRT Supreme Cream Base, ^a a sufficient quantity to make	100 g

^a FAGRON, St. Paul, MN.

To prepare a Testosterone Compounded Cream containing 100 mg/g of testosterone:

Testosterone (micronized) powder	10 g
Propylene Glycol	10 mL
HRT Supreme Cream Base, ^a a sufficient quantity to make	100 g

^a FAGRON, St. Paul, MN.

Accurately measure all ingredients. Wet the *Testosterone (micronized) powder* with *Propylene Glycol* in a suitable container. Geometrically add the *HRT Supreme Cream Base*, triturating after each addition.
Alternatively, the formulation may be prepared as follows. In an appropriately sized electronic mortar and pestle container, add 50 g of *HRT Supreme Cream Base*, place the *Testosterone (micronized) powder* and *Propylene Glycol* on top, and then add sufficient *HRT Supreme Cream Base* to bring to final weight. Mix the mixture with an electronic mortar and pestle for 2 min at a speed of about 1500 rpm. Process through an ointment mill once at the middle setting and once at the finest setting to reduce the particle size of the active ingredient and reduce the air content of the preparation. Return the mixture to the electronic mortar and pestle container and mix again for 1 min at a speed of about 1100 rpm.

ASSAY

- PROCEDURE**
Mobile phase: Dissolve 1.82 g of potassium phosphate monobasic in 1300 mL of water. Adjust to a pH of 7.5 using potassium hydroxide. Add 140 mL of methanol and 560 mL of acetonitrile. Pass through a filter of 0.22-µm pore size.
Standard solution: 0.05 mg/mL of [USP Testosterone RS](#) in methanol. Sonicate for 1 min.
Sample solution
For 5 mg/g of Cream: Transfer approximately 2 mL of Cream into a 3-mL syringe. Transfer this Cream to fill a 1-mL syringe to minimize air bubbles, and move the piston to the 1-mL mark. Weigh the syringe and tare, recording the weight to 0.01 mg (initial). Precharge a 100-mL volumetric flask with approximately 4–16 mL of 2-propanol, ensuring that the neck of the flask is wetted. Transfer the Cream from the 1-mL syringe into a 100-mL volumetric flask. Keep the syringe at the center of the flask to minimize the Cream sticking to the neck of the flask. Weigh the empty syringe again, recording the weight to 0.01 mg (final). The difference between initial and final weight should be between 900 mg and 1100 mg. An additional 2–4 mL of 2-propanol may be used to dissolve any Cream stuck in the neck of the

volumetric flask. Vortex the volumetric flask for 1 min until the Cream is evenly distributed. Add approximately 70 mL of methanol and sonicate for 4 min, and wait for the Cream to mostly dissolve (approximately 10–15 min, vortexing sporadically). Bring to volume with methanol and mix. Pass through a polyvinylidene fluoride (PVDF) filter of 0.22-μm pore size, discarding the first 30 drops.

For 100 mg/g of Cream: Transfer approximately 2 mL of Cream into a 3-mL syringe. Transfer this Cream to fill a 1-mL syringe to minimize air bubbles and move the piston to the 1-mL mark. Weigh the syringe and tare, recording the weight to 0.01 mg (initial). Precharge a 100-mL volumetric flask with approximately 4–16 mL of 2-propanol, ensuring that the neck of the flask is wetted. Transfer the Cream from the 1-mL syringe into a 100-mL volumetric flask. Keep the syringe at the center of the flask to try to minimize the Cream sticking to the neck of the flask. Weigh the empty syringe again, recording the weight to 0.01 mg (final). The difference between the initial and final weight should be between 900 and 1100 mg. An additional 2–4 mL of 2-propanol may be used to dissolve Cream stuck in the neck of the volumetric flask. Vortex the volumetric flask for 1 min until the Cream is evenly distributed. Add approximately 70 mL of methanol and sonicate for 4 min, and wait for the Cream to mostly dissolve (approximately 10–15 min, vortexing sporadically). Bring to volume with methanol and mix. Transfer 1 mL of the resultant solution using a class A “To Contain” glass pipette into a 20-mL volumetric flask. Rinse the pipette with NLT 3 mL of methanol and bring to volume with methanol. Shake well. Pass through a PVDF filter of 0.22-μm pore size, discarding the first 30 drops.

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 245 nm

Column: 4.6-mm × 15-cm; 3-μm packing [L1](#)

Column temperature: 40°

Flow rate: 1 mL/min

Injection volume: 10 μL

System suitability

Sample: *Standard solution*

[NOTE—The retention time for testosterone is about 21.3 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 testosterone ($C_{19}H_{28}O_2$) in the portion of Cream taken:

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

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

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

C_S = concentration of [USP Testosterone RS](#) in the *Standard solution* (mg/g)

C_U = nominal concentration of testosterone in the *Sample solution* (mg/g)

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

- [pH \(791\)](#): 5.9–6.9

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Package in a tight, light-resistant, and 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 for external use only and to state the *Beyond-Use Date*.
- **USP REFERENCE STANDARDS (11)**
[USP Testosterone RS](#) ▲ (USP 1-May-2022)

Topic/Question	Contact	Expert Committee
TESTOSTERONE COMPOUNDED CREAM	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	CMP2020 Compounding 2020

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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