FORMULA NUMBER: 2753

FORMULA NAME: Testosterone 100-mg/g in Pentravan™ Gel-Cream, Preserved, Human, Veterinary

DOSAGE FORM: Cream

FORMULA (Rx):

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>For: 100 grams</th>
<th>Lot#</th>
<th>RPh Initials</th>
</tr>
</thead>
<tbody>
<tr>
<td>Testosterone</td>
<td>Neat, USP</td>
<td>10 g</td>
<td></td>
</tr>
<tr>
<td>Ethoxydiglycol</td>
<td>10 mL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pentravan™ PLUS [Cream]</td>
<td>qs</td>
<td>100 g</td>
<td></td>
</tr>
</tbody>
</table>

SYNONYMS:
Testosterone in PLO; Testosterone 10% Cream

USE/TYPE:
Human Use
Veterinary Use
Non-Sterile Preparation
Chemo-Therapeutic Agent

CATEGORY:
Androgen and Androgen-like

NOTES:
The concentration of testosterone may be increased up to 50-mg/g or decreased according to patient response. This preparation may be used topically or vaginally. Disposable vaginal applicators may be prefilled with the correct dose for the patient. This preparation should be prepared in a vertical airflow hood in a biological safety cabinet or barrier isolation technology.

SPECIALIZED EQUIPMENT:
Biohazard or Chemo Materials Equipment
EMP - Electric Mortar & Pestle

METHOD OF PREPARATION:

1. Calculate the required quantity of each ingredient for the total amount to be prepared.

2. Accurately weigh and/or measure each ingredient.

3. Mix the ethoxy diglycol with the testosterone powder in the mortar until a snappy paste forms.

4. Tare an empty dispensing jar on a balance.

5. Place the ketoprofen mixture for the mortar to the dispensing jar.

6. Add the Pentravan™ to the testosterone mixture with the dispensing jar on the balance, bring to final weight.

7. Mix the gel-cream well twice with the electronic mortar and pestle.
8. Package in tubes and label.

**LABELING:**
- Apply Exact Dose Topically as Directed  
  - For External Use Only
- For Veterinary Use  
  - Keep Out of Reach of Children
- Pregnant Women Must Not Handle this Medicine

**PRESERVATION, PACKAGING AND STORAGE:**
- Tight, Light Resistant Container  
  - Store at Room Temperature Away from Excessive Heat
- Do Not Use After ________________

**STABILITY:**
A beyond-use date of 30 days can be used for this preparation.

**ENDOTOXIN ASSESSMENT:**

**USE:**
Testosterone gel is used in hormone replacement therapy when a gel or cream is desired. A calibrated dispensing device must be supplied with the solution for accurate measurement by the patient or caregiver.

**STANDARD OPERATING PROCEDURE FOR QUALITY CONTROL:**
Assessments may include theoretical weight compared to actual weight, pH, specific gravity, active drug assay and color. Other observations: texture-surface, texture-spatula spread, appearance, feel, rheological properties and physical macroscopic observations should be noted.

**REGULATORY CONTROL:**
- United States DEA - Controlled Substance
- International IOC - International Olympic Committee Banned Substance
- International IOC - International Olympic Committee Restricted or Measured
REFERENCES:
1. ..
23. Vermeulen A. Androgen in the aging male. Journal of Clinical Endocrinology & Metabolism. 73( ); 1991:221-224.
More information about this formula and its components available at the formula section of [www.CompoundingToday.com](http://www.CompoundingToday.com)

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