



FORMULA NUMBER: 2753

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

DOSAGE FORM: Cream

FORMULA (Rx):

Ingredients	For: 100 grams	Lot#	RPh Initials
Testosterone	Neat, USP 10 g	_____	_____
Ethoxydiglycol	10 mL	_____	_____
Pentravan™ PLUS [Cream]	qs 100 g	_____	_____

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.

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8. Package in tubes and label.

LABELING:

Apply Exact Dose Topically as Directed

For Veterinary Use

Pregnant Women Must Not Handle this Medicine

For External Use Only

Keep Out of Reach of Children

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

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More information about this formula and its components available at the formula section of www.CompoundingToday.com

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