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FORMULATION CHEMISTRY DEPARTMENT
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Suggested Formula	Testosterone 100 mg/mL Intramuscular Injection (Solution, 50 mL)	FIN	F 004 571v2

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Testosterone (micronized), USP	5.000	g				
Benzyl Benzoate, NF	22.5	mL				
Benzyl Alcohol, NF	5.0	mL				
Sesame Oil, NF	q.s. to 50.0	mL				

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Controlled substance *(adhere to proper handling and documentation procedures)*

Testosterone (micronized)

Light sensitive *(protect from light whenever possible):*

Testosterone (micronized), Benzyl alcohol, Benzyl Benzoate, Sesame oil

Suggested Preparatory Guidelines

☐ Non-Sterile Preparation ■ Sterile Preparation

Processing Error / Testing Considerations: To account for processing error, sterility and endotoxin testing considerations during preparation, it is suggested to measure an additional **10 to 12%** of the required quantities of ingredients.

Special Instruction: This formula must be prepared within the appropriate facilities under adequate environmental conditions, following the necessary guidelines and procedures as stated within *USP 797*. Only trained and qualified personnel must prepare this formula.

All heat stable, reusable materials and equipment must be sterilized and depyrogenated by dry heat sterilization at 250°C for 2 hours prior to use.

Every batch of final product compounded using this procedure must be sterility and endotoxin tested before being dispensed.

Protective apparel, such as a sterile gown, sterile gloves, shoe covers, head cap, eyewear and face-masks should always be worn. In addition, proper personnel cleansing must be done before entering the buffer or clean area.

Filter integrity must be validated by performing a filter stress test. If the test demonstrates that the filter might be defective, the solution must be discarded and remade.

This procedure requires the use of very small quantities of ingredients. All calculations and preparation techniques must be verified before dispensing the final product.

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SUGGESTED PREPARATION (for 50 mL)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Testosterone (micronized), USP §	5.000	g			
Benzyl Benzoate, NF §	22.5	mL			
Benzyl Alcohol, NF §	5.0	mL			
Sesame Oil, NF §	q.s. to 50.0	mL			

* Takes into account increased batch size conversions and density conversions, if required.
§ Weigh / measure just prior to use.

Preparatory Instruction **IMPORTANT: All preparatory procedures must be performed using proper Aseptic Technique**	
1.	**Equipment sterilization:** Following the manufacturer's specifications, sterilize and depyrogenate all heat stable, reusable materials and equipment, then return to ambient temperature.
2.	**Powder preparation:** A. Combine the following ingredients together to form a homogeneous liquid-like solution: -Benzyl Benzoate -Benzyl Alcohol B. Incrementally add the Testosterone (micronized) to the homogeneous liquid-like solution (Step 2A). Specifications: Continuously mix. End result: Homogeneous liquid-like dispersion.
3.	**Filling to volume:** A. Add Sesame Oil to the mixture (Step 2B) to fill to the required batch size (50.0 mL *plus* processing error adjustments). Specifications: Continuously mix until all solid particles have completely dissolved. Warming the oil to 40°C will facilitate the dissolution. End result: Homogeneous liquid-like solution.
4.	**Product transfer:** Transfer the final product into the specified dispensing container (see "Packaging requirements"). Transfer the remainder into a separate dispensing container. After sterilization, this is to be used as the Test sample for sterility and endotoxin testing.

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5.	**Product sterilization:** A. Following the manufacturer's specifications, dry heat sterilize the finished product (Step 4), then return to ambient temperature. Specifications: Heating temperature: 160°C Heating time: 120 minutes IMPORTANT: The temperature of the heated chamber must reach 160°C before the exposure duration is timed.
6.	**Sterility testing:** Validate the Test sample for sterility and endotoxins, in accordance to current USP 797 regulatory guidelines.

SUGGESTED PRESENTATION

Estimated Beyond-Use Date		14 days, as per USP 797 BUD based on a successful sterility and endotoxin test result.	Packaging Requirements	Sterile, light-resistant unit-dose serum vials sealed with serum bottle stopper chlorobutyl.
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	7	Protect from light.
	2	Keep out of reach of children.	8	Discard container after use.
	3	**Controlled substance. Dangerous unless used as directed.**	9	Keep in a dry place.
	4	Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use.	10	Discard in the presence of particulate matter.
	5	Storage at low temperatures may result in the separation of some solid material which redissolves readily on warming.	11	Do not use if product changes color.
	6	Keep at room temperature (20°C – 23°C).		
Pharmacist Instructions	Add any auxiliary labels specific to the API to the dispensing container as deemed necessary.			
Patient Instructions	Contact your pharmacist in the event of adverse reactions.			

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REFERENCES

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