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Suggested Formula	Methylprednisolone Acetate 80 mg/mL Intramuscular Injection (Suspension, 100 mL)	FIN	F 004 811v2

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Methylprednisolone Acetate (Micronized), USP	8.000	g				
Polyethylene Glycol 3350, NF	2.82	g				
Sodium Phosphate, Monobasic, Anhydrous, USP	0.66	g				
Sodium Phosphate, Dibasic, USP	0.14	g				
Benzyl Alcohol, NF §	0.9	mL				
Sodium Chloride, USP	0.23	g				
Polysorbate 80, NF	0.2	mL				
Sterile Water For Injection, USP	5.0	mL				
Sterile Water For Injection, USP	80.0	mL				
Sterile Water For Injection, USP	q.s. to 100.0	mL				

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SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Light sensitive *(protect from light whenever possible):*	*Methylprednisolone Acetate, Polysorbate 80, Benzyl Alcohol*
Hygroscopic *(protect from moisture whenever possible):*	*Polysorbate 80, Sodium Phosphate, Dibasic*
Oxygen Sensitive *(protect from oxygen whenever possible):*	*Polysorbate 80*

Suggested Preparatory Guidelines

☐ Non-Sterile Preparation ■ Sterile Preparation

Processing Error / Testing Considerations: To account for processing error, pH testing, sterility and endotoxin testing considerations during preparation, it is suggested to measure an additional **5 to 9%** 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 100 mL)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Methylprednisolone Acetate (Micronized), USP §	8.000	g			
Polyethylene Glycol 3350, NF §	2.82	g			
Sodium Phosphate, Monobasic, Anhydrous, USP §	0.66	g			
Sodium Phosphate, Dibasic, USP §	0.14	g			
Benzyl Alcohol, NF §	0.9	mL			
Sodium Chloride, USP §	0.23	g			
Polysorbate 80, NF §	0.2	mL			
Sterile Water For Injection, USP §	5.0	mL			
Sterile Water For Injection, USP §	80.0	mL			
Sterile Water For Injection, USP §	q.s. to 100.0	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-Liquid preparation:** A. Combine and mix the following ingredients together to form a homogeneous liquid-like solution: -Benzyl Alcohol -Polysorbate 80 -Sterile Water For Injection (5.0 mL *plus* processing error adjustments). B. Levigate the Methylprednisolone Acetate with the homogeneous liquid-like solution (Step 2A) to form a homogeneous liquid-like dispersion.

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3.	**Medium integration:** A In the given order, sequentially add the following ingredients to the Sterile Water For Injection (80.0 mL *plus* processing error adjustments). -Homogeneous liquid-like dispersion (Step 2B) -Polyethylene Glycol 3350 -Sodium Phosphate, Monobasic, Anhydrous -Sodium Phosphate, Dibasic -Sodium Chloride Specifications: Continuously mix. End result: Homogeneous liquid-like dispersion.
4.	**Filling to Volume:** A. Add additional Sterile Water For Injection to the above mixture to fill to the required batch size (100.0 mL *plus* processing error adjustments). Specifications: Continuously mix. End result: Homogeneous liquid-like dispersion. B. Test the pH of the product. It should lie between 3.5 and 7.0. If the pH does not lie in the range, use either NaOH or HCl solution to adjust to the range.
5.	**Product Transfer into dispensing container:** A. Transfer the final product into the recommended dispensing container (see Packaging requirements). **Note 1: After sterilization, a sample is to be used as the Test sample for sterility and endotoxin testing.** **Note 2: Continuously mix the final product during the transfer process into the recommended dispensing containers in order to maintain homogeneity.**
6.	**Sterilization:** Following the manufacturer's specifications, autoclave sterilize the mixture, then return to ambient temperature and pressure. Specifications: Heating temperature: 121°C Heating time: 15 minutes Pressure: 15 psi IMPORTANT: The temperature of the heated chamber must reach 121°C before the exposure duration is timed.
7.	**Sterility testing:** Validate the Test sample for sterility and endotoxins, in accordance to current USP 797 regulatory guidelines.

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SUGGESTED PRESENTATION

Estimated Beyond-Use Date		14 days, refrigerated, as per USP. BUD based on a successful sterility and endotoxin test result.	Packaging Requirements		Sterile, light-resistant, heat stable unit dose injection vials.
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	Keep refrigerated. Do not freeze.		9	Do not use if product changes color.
	4	**Shake to homogenous before use. Discard the product if the solid doesn't redisperse upon shaking.**		10	Consult your health care practitioner if any other prescription or over-the-counter medications are currently being used or are prescribed for future use.
	5	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.		11	May produce psychological and/or physical dependence.
	6	Equilibrate to room temperature before use.			
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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