MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
TOLL-FREE: 866-333-7811
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Suggested Formula	Amitriptyline Hydrochloride 10% Transdermal PLO Gel (Emulsion, 100 mL)	FIN	F 008 219

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Amitriptyline Hydrochloride, USP	10.000	g				
Ethoxy Diglycol	5.0	mL				
Medisca PLO Gel Mediflo™ 30 (Pre-Mixed)	q.s. to 100.0	mL				

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SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Light Sensitive *(protect from light whenever possible):* *Amitriptyline Hydrochloride*

Hygroscopic *(protect from moisture whenever possible):* *Ethoxy Diglycol*

Suggested Preparatory Guidelines

■ Non-Sterile Preparation ☐ Sterile Preparation

Processing Error / Testing Considerations: To account for processing error considerations during preparation, it is suggested to measure an additional **5 to 9%** of the required quantities of ingredients.

Special Instruction: This formula may contain one or more Active Pharmaceutical Ingredients (APIs) that may be classified as hazardous, please refer & verify the current NIOSH list of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2016. **General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings** was formally published February 1, 2016 in the First Supplement to USP 39-NF 34 and has a delayed **official implementation date of December 31st, 2019**.

This formula must be prepared within the appropriate facilities under adequate environmental conditions, following the necessary guidelines and procedures as stated within *USP 795* and *USP 800*, when handling hazardous drugs. Only trained and qualified personnel must prepare this formula.

All required personal protective equipment (hazardous if applicable), such as but not limited to, lab coat, protective sleeves, gloves both inner and outer if applicable, dedicated shoe covers, hairnet, beard cover, eyewear, appropriate face mask, respirator and face shield, etc., where applicable must be worn at all times.

If applicable, follow all required procedures for hazardous drug handling including but not limited to procurement, transport, storage, preparation, dispensing, administration, clean up (spills) & disposal.

If you are a registered 503B facility, please refer to all relevant guidance documents including but not limited to the Code of Federal Regulations (CFR), Guidance for Industry (GFIs) and Compliance Policy Guides (CPGs).

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
Amitriptyline Hydrochloride, USP §	10.000	g			
Ethoxy Diglycol	5.0	mL			
Medisca PLO Gel Mediflo™ 30 (Pre-Mixed)	q.s. to 100.0	mL			

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

	Preparatory Instruction
1.	**Powder-liquid preparation:** A. Triturate the Amitriptyline Hydrochloride to form a fine, homogeneous powder. B. Levigate the fine homogeneous powder (Step 1A) with the Ethoxy Diglycol. End result: Homogeneous paste-like dispersion.
2.	**Filling to volume:** A. Geometrically add PLO Gel Mediflo™ 30 (Pre-Mixed) to the homogeneous paste-like dispersion (Step 1B) to fill to the required batch size (100.0 mL *plus* processing error adjustments). Specifications: Continuously mix, using high-shear mixing techniques. End result: Homogeneous gel-like dispersion.
3.	**Product transfer:** Transfer the final product into the specified dispensing container (see “Packaging requirements”).

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SUGGESTED PRESENTATION

Estimated Beyond-Use Date	90 days at 25°C or 4°C, based on available stability studies through Medisca*		Packaging Requirements	- Tightly closed, light-resistant ointment tube/jar. - To be administered with a metered-dose measuring device.
	*Suggested BUD is based on the **exact** execution of the indicated ingredient list, quantities and procedures listed within this formulation. ***Note:*** ***This data is provided for informational purposes only, representing the results of a study of the product stability with various active pharmaceutical ingredients. It does not serve, and may not be construed, as a representation or guarantee of product performance. In all cases the practitioner is advised to consult recognized pharmaceutical compendia and other recognized sources for product formulation and other product characteristics, including stability. MEDISCA Network Inc. makes no warranties or representations with regard to the functioning or appropriateness of this product in any compounded formulation, which use is solely at the discretion and liability of the practitioner.***			
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	6	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.
	2	Keep out of reach of children.	7	Cap tightly after use.
	3	Consult your health care practitioner if any other prescription or over-the-counter medications are currently being used or are prescribed for future use.	8	For external use only.
	4	Keep at room temperature or, Keep refrigerated. Do not freeze.	9	May impair mental and/or physical ability. Use care when operating a car or machinery.
	5	Keep in a dry place.	10	Protect from light.
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. **IMPORTANT:** The quantity of API administered is directly dependent on the quantity of product applied.			

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REFERENCES

1.	Ointments, Creams, and Pastes. In: Allen, LV, Jr. *The Art, Science, and Technology of Pharmaceutical Compounding Fifth Edition.* American Pharmacists Association; 2016: 317.
2.	Amitriptyline Hydrochloride. In: Sweetman SC, ed. *Martindale: The Complete Drug Reference, 36th Edition.* London, England: The Pharmaceutical Press; 2009: 376.
3.	Amitriptyline (Monograph). In: O'Neil MJ. *The Merck Index 15th Edition*. Whitehouse Station, NJ: Merck & Co, Inc.; 2013: Monograph #483.
4.	Amitriptyline Hydrochloride. In: Trissel LA. *Trissel's Stability of Compounded Formulations, 5th Edition.* American Pharmaceutical Association; 2012: 33.
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6.	Amitriptyline. Thomson Micromedex. *USP DI – Drug Information for the Health Care Professional, 26th Edition.* Taunton, MA: US Pharmacopeial Convention, Inc; 2006: 308.
7.	USP <795>. *United States Pharmacopeia XLI / National Formulary 36.* Rockville, MD. US Pharmacopeial Convention, Inc. 2018: 6546.