Lorazepam 1 mg/mL/Diphenhydramine HCl 12.5 mg/mL/ Haloperidol 2 mg/mL/Metoclopramide 20 mg/mL Topical Gel (PermE8® Anhydrous)

SUGGESTED FORVULA FOR
Lorazepam 1 mg/mL/Diphenhydramine HCI 12.5 mg/mL/Haloperidol 2 mg/mL/ Metoclopramide 20 mg/mL Topical Gel (PermE8® Anhydrous)
Version: 6.0
10 mL

LORazepam USP CIV	0.01 g
diphenhydrAMINE HYDROCHLORIDE USP	0.125 g
HALOPERIDOL USP	0.02 g
METOCLOPRAMIDE HYDROCHLORIDE USP MONOHYDRATE	0.236 g
PROPYLENE GLYCOL USP	0.5 ml
BASE, PCCA PERME8® ANHYDROUS GEL	q.s. 10 ml

SUGGESTED COMPOU\DING PROCEDURE

Note: For compounded preparations, USP standards dictate that the intended strength must be +/-10% of the labeled Active Pharmaceutical Ingredient (API) strength, unless the monograph of the preparation states otherwise. You should follow recommendations for potency testing using an appropriate analytical method for the specific API, Compounded Sterile Preparation (CSP), Compounded Nonsterile Preparation (CNSP), and container closure that will be used. If assistance is needed, please contact Eagle Analytical Services regarding the initiation of a testing program.

SPECIAL INSTRUCTIONS:

PCCA's Blue Box Warning:
ATTENTION: This formula has been tested in the PCCA Lab using only PCCA chemicals and proprietary bases (except when noted). Any variations to this formulation, including substitution with a non-PCCA chemical or non-PCCA base, may affect physical integrity, solubility, organoleptic properties or result in potency or content uniformity issues. This type of substitution will cause the assigned BUD to be invalid.

PCCA

Note: It will be necessary to use an Analytical Balance to accurately weigh any ingredient(s) used in this formula that have a weight of less than 40 mg (0.04 Gm).

Note: Metoclopramide 1 milligram is equivalent to Metoclopramide Hydrochloride Monohydrate 1.182 milligrams.

Note: This formulation should be mixed and dispensed in Baxter Exacta-Med Amber Oral/Topical syringes due to the silicones contained in the base. These syringes contain a thin black o-ring that allows for better movement between the plunger and barrel compared to other syringes available on the market.

Note: USP chapter <795> states guidelines regarding "component evaluation before use." *"Compounding personnel must visually re-inspect all components to detect any container breakage, looseness of the cap or closure, or deviation from the expected appearance or texture of the contents that might have occurred during storage."*

1. Using a glass mortar and pestle, triturate Lorazepam, Diphenhydramine Hydrochloride, Haloperidol and Metoclopramide Hydrochloride together. Add Propylene Glycol and mix well.
2. Add PCCA PermE8 Anhydrous Gel Base to Step 1 in portions and mix well. Use an amount of PCCA PermE8 Anhydrous Gel Base that is approximately 60% of the final volume. For example, if the final volume is 10 mL, use 6 mL of PCCA PermE8 Anhydrous Gel Base.
3. Remove the plunger from a Baxter Exacta-Med 10 mL Oral/Topical Syringe (PCCA #35-4481), then transfer the Step 2 mixture into the barrel. Replace the plunger into the barrel, and holding syringe upright, slowly push up the plunger, allowing the air to escape. Measure the volume in the syringe and calculate how much PCCA PermE8 Anhydrous Gel Base is needed to bring to the final volume.
4. In a separate Baxter Exacta-Med 10 mL Oral/Topical Syringe, add the required amount of PCCA PermE8 Anhydrous Gel Base.
5. Connect the syringe in Step 4 to the syringe in Step 3 using an Oral/Oral Adapter (PCCA #35-2228).
6. Mix Step 5 back and forth from syringe-to-syringe until a uniform mixture is formed.
7. Dispense the Step 6 final preparation in Baxter Exacta-Med Amber 1 mL Oral/Topical Syringes (PCCA #35-4483).
8. Physical description of this preparation: off-white to pale beige gel.

Note: Protect from light.

Note: Store in an air-tight, light-resistant container.

Note: Store at controlled room temperature of 20°-25°C.

Note: Lorazepam is incompatible with certain types of plastics such as PVC.

Note: Keep Proper Controlled Substance Records.

Note: USP chapter <795> states guidelines regarding "visual inspection." After the completion of compounding, the preparation must be visually inspected to determine whether the physical appearance is as expected. The inspection also must include visual inspection of container closure integrity.

Note: No claims are made as to the safety or efficacy of this preparation. This formulation is provided solely at the unsolicited request of the pharmacist.

Note: USP chapter <795> sets forth parameters to consider when establishing a Beyond-Use Date (BUD) and states, *"BUDs for CNSPs should be established conservatively to ensure that the preparation maintains its required characteristics to minimize the risk of contamination or degradation."* Stability testing may be performed by an FDA-registered laboratory using a stability-indicating assay to extend the BUD. An antimicrobial effectiveness test (see USP chapter <51>) must also be performed by an FDA-registered laboratory when extending the BUD of an aqueous compounded nonsterile preparation (CNSP).

Note: According to USP guidelines, "in the absence of a *USP-NF* Compounded Preparation Monograph or CNSP-Specific Stability Information," the maximum Beyond-Use Date (BUD) for a compounded nonsterile preparation (CNSP) that is a nonaqueous dosage form (excluding nonaqueous oral liquids) with a water activity (Aw) of <0.6 is 180 days.

For more information, refer to current USP chapter <795>.

Note: The maximum Beyond-Use Date (BUD) after compounding is estimated to be 180 days .

SAFETY WHEN COMPOUNDING! Serious injury to patients, including death, can result from preparations made using improper compounding procedures and/or equipment, preparations made under insanitary conditions, calculation errors and other errors made by pharmacy personnel. Follow the Warnings given on **all** formulas, their components and any associated documentation. Use appropriate precautions to protect yourself, your patients and others in your lab during compounding. Always make sure you have checked the PCCA Formula Database and are following the most up-to-date version of a formula as changes are continuously made to existing formulations to provide the most up-to-date guidance.

Compounders should know and **keep current on all relevant USP chapters** that relate to sterile or nonsterile compounding. Do not compound unless you have had the appropriate compounding training and are committed to stay current in this field.

Appropriate use of this formula should be determined by the prescriber, in consultation with the pharmacist and patient. Any questions about the prescription written by the prescriber should always be resolved before compounding. Know exactly what the prescriber is ordering for the patient. It is the pharmacist's responsibility to also ensure the formulation they are dispensing meets regulatory requirements in their home jurisdiction and any alternative jurisdiction that the medication may be sent to. **Remember, you the pharmacist, are responsible for the final compounded preparation, and the safety of your patients.**

Literature:

Literature: Samanta, M.K., Dube, R., & Suresh, B. (2003). Transdermal drug delivery system of haloperidol to overcome self-induced extrapyramidal syndrome. *Drug Development and Industrial Pharmacy,* 29(4), 405-415. doi: 10.1081/DDC-120018376

Literature: Bleicher, J., Bhaskara, A., Huyck, T., Constantino, S., Bardia, A., Loprinzi, C.L., & Silberstein, P.T. (2008). Lorazepam, diphenhydramine, and haloperidol transdermal gel for rescue from chemotherapy-induced nausea/ vomiting: results of two pilot trials. *The Journal of Supportive Oncology,* 6(1), 27-32.

Literature: Moon, R. B. (2006). ABHR gel in the treatment of nausea and vomiting in the hospice patient. International Journal of Pharmaceutical Compounding, 10(2), 95.

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