Furosemide 10 mg/mL Oral Suspension (Anhydrous SuspendIt®)

SUGGESTED FORMULA FOR
Furosemide 10 mg/mL Oral Suspension (Anhydrous SuspendIt®)
Version: 7.0
100 mL

FUROSEMIDE USP	1 g
PCCA ANHYDROUS SUSPENDIT® USP Verified Excipient Ingredient	q.s. 100 ml

SUGGESTED COMPOUNDING 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.

Note:

Anhydrous SuspendIt® carries the USP Verified Mark for Excipients, which helps ensure that current Good Manufacturing Practices (cGMP) and product quality standards have been met.

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 mortar and pestle, triturate Furosemide to reduce particle size.
2. Add PCCA Anhydrous SuspendIt to Step 1 and mix well to make a smooth paste. Use an amount of PCCA Anhydrous SuspendIt that is approximately 5% of the final volume. For example, if the final volume is 100 mL, use 5 mL of PCCA Anhydrous SuspendIt.
3. Slowly, add PCCA Anhydrous SuspendIt to Step 2 in portions while mixing, then transfer to an appropriate size pre-calibrated beaker. Use an amount of PCCA Anhydrous SuspendIt that is approximately 30% of the final volume. For example, if the final volume is 100 mL, use 30 mL of PCCA Anhydrous SuspendIt. Use a rubber spatula to thoroughly scrape the sides of the mortar during this process.
4. Rinse the Step 3 mortar with PCCA Anhydrous SuspendIt. Use an amount of PCCA Anhydrous SuspendIt that is approximately 10% of the final volume. For example, if the final volume is 100 mL, use 10 mL of PCCA Anhydrous SuspendIt. Combine the rinsing into the Step 3 beaker, using the rubber spatula to thoroughly scrape the sides of the mortar during this process. Do this step a total of two (2) times to completely rinse the mortar.
5. Bring Step 4 to the final volume with PCCA Anhydrous SuspendIt.
6. Transfer the Step 5 preparation to an appropriate size Electronic Mortar & Pestle (EMP) Jar. Use the rubber spatula to thoroughly scrape the sides of the beaker during this process.
7. Mix Step 6 with the EMP for two (2) minutes on a medium setting, then transfer to an appropriate size dispensing container. Due to the viscosity of the preparation, using the EMP mixing method is advised to obtain optimal content uniformity.
8. Physical description of this preparation: off-white to faint beige suspension.

Note: Protect from light.

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

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

Note: Shake Well Before Using.

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 oral liquid dosage form with a water activity (Aw) of <0.6 is 90 days.

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

Note: The maximum Beyond-Use Date (BUD) after compounding is estimated to be 90 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.**

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