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| | | | |
|---|---|---|---|
| Suggested Formula | Clindamycin Hydrochloride 40.72 mg Oral Capsules<br>(Powder Blend, 100 x Size # 1 Capsule) | FIN | F 001 928v2 |

NOTE: Clindamycin Hydrochloride 40.72 mg is equivalent to Clindamycin 37.5 mg.

## SUGGESTED FORMULATION

| Ingredient Listing | Qty. | Unit | NDC # | Supplier | Lot Number | Expiry Date |
|---|---|---|---|---|---|---|
| Clindamycin Hydrochloride (Dehydrated), USP | 4.072 | g | | | | |
| Lactose (Monohydrate), NF | TBD | | | | | |
| Sodium Chloride, USP | As required | | | | | |

## SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

***Narrow Therapeutic Index:*** *Clindamycin Hydrochloride (Dehydrated)*

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: Protective apparel, such as a lab coat, disposable gloves, eyewear and face-masks should always be worn.

**Clindamycin Hydrochloride (Dehydrated) has a Narrow Therapeutic Index. 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 Size #1 Capsules)

Weigh and / or measure the following ingredients when appropriate:

| Ingredient Listing | Qty. | Unit | Multiplication factor (*): ____ | Processing Error | Qty. to measure |
|---|---|---|---|---|---|
| Clindamycin Hydrochloride (Dehydrated), USP | 4.072 | g | | | |
| Lactose (Monohydrate), NF | TBD | | | | |
| Sodium Chloride, USP | As required | | | | |

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

| Preparatory Instruction | |
|---|---|
| 1. | **Lactose (Monohydrate) requirements for 100 x size #1 capsules**<br>A. Calculate the amount of Lactose (Monohydrate) required for the batch. Refer to attached appendix for details. |
| 2. | **Powder preparation:**<br>A. Triturate the Clindamycin Hydrochloride to form a fine, homogeneous powder.<br>B. By geometric addition, combine and mix the following ingredients together:<br>-Fine, homogeneous powder (Step 2A)<br>-Lactose (Monohydrate) (Quantity determined in appendix **(I)**) |
| 3. | **Product transfer:**<br>Fill each of 100 Size #1 capsules with the powder blend (Step 2B). Close each capsule tightly.<br>Clean each capsule by placing the capsules in a container filled with Sodium chloride, and then gently rolling the container. Pour the container contents into a 10-mesh sieve, and allow the Sodium chloride to pass through. Finally, roll the capsules on a cloth-covered surface. |
| 4. | **Validation technique (average capsule weight):**<br>The final weight of each capsule (not including capsule shell) should fall between 90 and 110% of the theoretically calculated weight, in accordance to USP 795 guidelines. The theoretically calculated weight can be determined by adding the amount in appendix **(G)** + 0.04072 g together. |
| 5. | **Product transfer:**<br>Transfer the final product into the specified dispensing container (see “Packaging Requirements”). |

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|---|---|---|---|

## SUGGESTED PRESENTATION

| | | | | | |
|---|---|---|---|---|---|
| Estimated Beyond-Use Date | | 6 months, as per USP. | Packaging Requirements | | Tightly closed vials. |
| Auxiliary Labels | 1 | Use as directed. Do not exceed prescribed dose. | 4 | | Keep in a dry place. |
| | 2 | Keep out of reach of children. | 5 | | Cap tightly after use. |
| | 3 | Keep at room temperature (20°C – 23°C). | 6 | | **Consult your health care practitioner if any other prescription or over-the-counter medications are currently being used or are prescribed for future 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. | | | |

## REFERENCES


1. Capsules. In: Allen, LV, Jr. *The Art, Science and Technology of Pharmaceutical Compounding.* American Pharmaceutical Association; 1998: 91.
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9. USP <795>. *United States Pharmacopeia XXVIII / National Formulary 23.* Rockville, MD. US Pharmacopeial Convention, Inc. 2004: 2457.
10. Clindamycin Systemic. Thomson Micromedex. *USP DI – Drug Information for the Health Care Professional, 26th Edition.* Taunton, MA: US Pharmacopeial Convention, Inc; 2006: 904.

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| Appendix | Calculating the quantity of excipient required for the batch | | |
|---|---|---|---|

## Procedure

1. **Capsule filling:**

   a. For each ingredient powder below, determine the average capsule fill weight by filling and weighing five TARED CAPSULES. Do not forget to divide the total weight by 5 to obtain an average capsule fill weight. Also, triturate the ingredient powder first if required in formulation

   Plug each amount into Step 2, column B.

2. **Volume Percent Occupied:**

| Ingredients | **Column A** Quantity Required per capsule | **Column B** Average capsule fill weight | **Column C** A/B x 100 equals percent filled |
|---|---|---|---|
| a. Clindamycin Hydrochloride | 0.04072 **g** | _____ **g** | _____ % |
| b. Lactose (Monohydrate) | | _____ **g** | |
| c. Total (add column C together) | | | _____ % **(D)** |

3. **Calculate the quantity of Lactose (Monohydrate) required for the batch:**

   a. Percent of Lactose (Monohydrate) required = 100% – (D) _____ % **(E)**

   b. Average capsule fill weight of Lactose (Monohydrate) (from column B, Step 2b): _____ g **(F)**

   c. Quantity of Lactose (Monohydrate) required per capsule = [(E) ÷ 100 × (F)] _____ g **(G)**

   d. Total quantity of Lactose (Monohydrate) required for the batch = 100 capsules × (G) _____ g **(H)**

   e. Total quantity of Lactose (Monohydrate) *plus* processing error = (H) x 1.05-1.09 _____ g **(I)**