



Suggested Formula	Rifampin 75 mg Oral Capsules (Powder Blend, 100 x Size #0 Capsules)	FIN	F 003 091
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SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Rifampin (Rifampicin), USP	7.500	g				
Lactose (Monohydrate), NF	TBD					
Sodium Chloride, USP	As required					

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Air sensitive (protect from air whenever possible):

Rifampin

Moisture Sensitive (protect from humidity whenever possible):

Rifampin

Light sensitive (protect from light whenever possible):

Rifampin

Suggested Preparatory Guidelines

Non-Sterile Preparation Sterile Preparation

Processing Error /

Testing Considerations:

Special Instruction:

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

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

All calculations and preparation techniques must be verified before dispensing the final product.



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SUGGESTED PREPARATION (for 100 Size #0 Capsules)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Rifampin (Rifampicin), USP §	7.500	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. **Ingredient quantification (API requirements per capsule):**

Calculate the quantity (in mL) of Rifampin required for one, size #0 capsule:

- A. Calculate the Rifampin tapped density. Refer to the attached Appendix for details:
- B. Determine the quantity (in mL) of the Rifampin required for each capsule:

Required quantity (in g) of Rifampin per capsule:	0.075 g
DIVIDED BY	
Rifampin tapped density (from Appendix):	_____ g / mL
EQUALS	
Quantity of Rifampin (in mL) required for 1 capsule	_____ mL



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2. **Ingredient quantification (excipient requirements for 100 x size #0 capsules):**

- A. Calculate the tapped density of Lactose (Monohydrate). Refer to the Appendix for details.
B. Calculate the quantity (in mL) of Lactose (Monohydrate) required for each capsule:

Volume of Size #0 capsule:	0.68 mL
MINUS	
Quantity (in mL) of Rifampin powder required for 1 capsule (Step 1B):	_____ mL
EQUALS	
Quantity (in mL) of Lactose (Monohydrate) required for 1 capsule	_____ mL

- C. Calculate the total quantity (g) of Lactose (Monohydrate) required:

Tapped Density of Lactose (Monohydrate) (from Appendix)	_____ g/mL
MULTIPLIED BY	
Quantity (in mL) of Lactose (Monohydrate) required for 1 capsule (Step 2B)	_____ mL
EQUALS	
i. Quantity (in g) of Lactose (Monohydrate) required for 1 capsule	_____ g
MULTIPLIED BY	
Conversion factor – 1 to 100 capsules	100
EQUALS	
ii. Quantity (in g) of Lactose (Monohydrate) required for 100 capsules	_____ g
MULTIPLIED BY	
Conversion factor for processing error (5 to 9%)	1.05 to 1.09
EQUALS	
iii. Quantity (in g) of Lactose (Monohydrate) required plus processing error	_____ g



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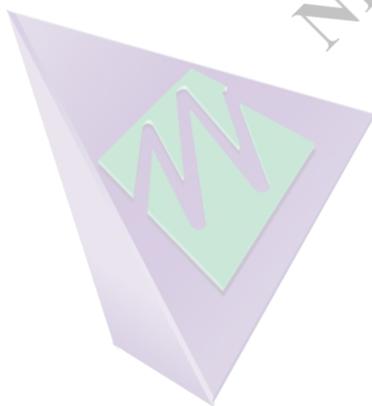
2.	<p>D. Calculate the theoretical weight of powder per capsule:</p> <table border="1" style="margin-left: 40px;"> <tr> <td>Required quantity (in g) of Rifampin per capsule:</td> <td style="text-align: right;">0.075 g</td> </tr> <tr> <td>PLUS</td> <td></td> </tr> <tr> <td>Quantity (in g) of Lactose (Monohydrate) required for 1 capsule (Step 2Ci)</td> <td style="text-align: right;">_____ g</td> </tr> <tr> <td>EQUALS</td> <td></td> </tr> <tr> <td>Theoretical weight of powder (in g) per capsule</td> <td style="text-align: right;">_____ g</td> </tr> </table>	Required quantity (in g) of Rifampin per capsule:	0.075 g	PLUS		Quantity (in g) of Lactose (Monohydrate) required for 1 capsule (Step 2Ci)	_____ g	EQUALS		Theoretical weight of powder (in g) per capsule	_____ g
Required quantity (in g) of Rifampin per capsule:	0.075 g										
PLUS											
Quantity (in g) of Lactose (Monohydrate) required for 1 capsule (Step 2Ci)	_____ g										
EQUALS											
Theoretical weight of powder (in g) per capsule	_____ g										
3.	<p><u>Powder preparation:</u></p> <p>A. Triturate the Rifampin to form a fine, homogeneous powder.</p> <p>B. By geometric addition, combine and mix the following ingredients together:</p> <ul style="list-style-type: none"> -Fine, homogeneous powder (Step 3A) -Lactose (Monohydrate) – (quantity determined in Step 2Ciii) <p><u>End result:</u> Homogeneous powder blend.</p>										
4.	<p><u>Product transfer (powder-to-capsule filling):</u></p> <p>Fill each of 100 Size #0 capsules with the homogeneous powder blend (Step 3B). Close each capsule tightly.</p> <p>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.</p>										
5.	<p><u>Validation technique (average capsule weight):</u></p> <p>The final weight of each capsule (not including capsule shell) should fall between 90 and 110% of the theoretically calculated weight (Step 2D), in accordance to USP 795 guidelines.</p>										
6.	<p><u>Product transfer (solid-to-dispensing container filling):</u></p> <p>Transfer the final product into the specified dispensing container (see “Packaging Requirements”).</p>										



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SUGGESTED PRESENTATION

Estimated Beyond-Use Date	6 months	Packaging Requirements	Tight, light-resistant vials.	
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	6	Cap tightly after use.
	2	Keep out of reach of children.	7	Keep in a dry place.
	3	May impair mental and/or physical ability. Use care when operating a car or machinery.	8	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.
	4	Keep at room temperature (20°C - 23°C)	9	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	Protect from light.	10	
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

1.	Capsules. In: Allen, LV, Jr. <i>The Art, Science and Technology of Pharmaceutical Compounding</i> . American Pharmaceutical Association; 1998: 91.
2.	Rifadin. In: Canadian Pharmacists Association. <i>Compendium of Pharmacists and Specialties, 2007</i> . 2081.
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4.	Sodium Chloride. In: Rowe RC. <i>Handbook of Pharmaceutical Excipients, 4th Edition</i> . American Pharmaceutical Association; 2003: 556.
5.	Rifampin. In: Sweetman SC, ed. <i>Martindale: The Complete Drug Reference, 34th Edition</i> . London, England: The Pharmaceutical Press; 2005: 250.
6.	Rifampin (Monograph). In: O'Neil MJ. <i>The Merck Index 14th Edition</i> . Whitehouse Station, NJ: Merck & Co, Inc.; 2006: Monograph #8216.
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8.	Rifampin (Monograph). <i>United States Pharmacopeia XXVIII / National Formulary 23</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2004: 1727.
9.	USP <795>. <i>United States Pharmacopeia XXVIII / National Formulary 23</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2004: 2457.
10.	Rifampin Systemic. Thomson Micromedex. <i>USP DI – Drug Information for the Health Care Professional, 26th Edition</i> . Taunton, MA: US Pharmacopeial Convention, Inc; 2006: 2595.

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Appendix	Tapped Density Calculation for Capsules		
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Tapped Density Calculation											
1.	<p><u>Powder preparation:</u></p> <p>a. Measure and triturate (if required in formulation) a sufficient quantity of the specified ingredient.</p>										
2.	<p><u>Tapped density calculation:</u></p> <p>a. Weigh five empty capsules. Record the total weight here: _____ g</p> <p>b. Fill the five capsules with the Ingredient powder and weigh. Record the total weight here: _____ g</p> <p>c. Calculate the tapped density:</p> <table border="1" style="margin-left: 40px;"> <tr> <td>Weight of the ingredient (Step b – Step a)</td> <td style="text-align: right;">_____ g</td> </tr> <tr> <td>DIVIDED BY</td> <td></td> </tr> <tr> <td>Fill volume of five, Size #0 capsules (5 x 0.680 mL)</td> <td style="text-align: right;">3.4 mL</td> </tr> <tr> <td>EQUALS</td> <td></td> </tr> <tr> <td>Ingredient tapped density</td> <td style="text-align: right;">_____ g/mL</td> </tr> </table>	Weight of the ingredient (Step b – Step a)	_____ g	DIVIDED BY		Fill volume of five, Size #0 capsules (5 x 0.680 mL)	3.4 mL	EQUALS		Ingredient tapped density	_____ g/mL
Weight of the ingredient (Step b – Step a)	_____ g										
DIVIDED BY											
Fill volume of five, Size #0 capsules (5 x 0.680 mL)	3.4 mL										
EQUALS											
Ingredient tapped density	_____ g/mL										
3.	Discard the capsules and any remaining powder.										

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