



Suggested Formula	Ursodiol 150 mg Oral Capsules (Powder blend, 100 x Size # 3 Capsules)	FIN	F 000 414v2
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**SUGGESTED FORMULATION**

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Ursodiol	15.000	g				
Cellulose (Microcrystalline), NF	to be calculated					
Sodium Chloride, USP	As required					

**SPECIAL PREPARATORY CONSIDERATIONS**

Ingredient-Specific Information

*Hygroscopic (protect from moisture whenever possible):* Cellulose (Microcrystalline)

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 **10 to 12%** 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.

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

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**SUGGESTED PREPARATION (for 100 Size #3 Capsules)**

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Ursodiol	15.000	g			
Cellulose (Microcrystalline), NF (§)	to be calculated				
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 Ursodiol required for one, size #3 capsule:

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

Required quantity (in g) of Ursodiol per capsule:	0.150 g
DIVIDED BY	
Ursodiol bulk density (from Appendix):	_____ g / mL
EQUALS	
<b>Quantity of Ursodiol (in mL) required for 1 capsule</b>	<b>_____ mL</b>

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2. **Ingredient quantification (excipient requirements for 100 x size #3 capsules):**

A. Calculate the bulk density of Cellulose (Microcrystalline). Refer to the attached Appendix for details.

B. Calculate the quantity (in mL) of Cellulose (Microcrystalline) required for each capsule:

Volume of Size #3 capsule:	0.30 mL
MINUS	
Quantity (in mL) of Ursodiol powder required for 1 capsule (Step 1B):	_____ mL
EQUALS	
<b>Quantity (in mL) of Cellulose (Microcrystalline) required for 1 capsule</b>	<b>_____ mL</b>

C. Calculate the total quantity (g) of Cellulose (Microcrystalline) required:

Bulk Density of Cellulose (Microcrystalline) (from Appendix)	_____ g/mL
MULTIPLIED BY	
Quantity (in mL) of Cellulose (Microcrystalline) required for 1 capsule (Step 2B)	_____ mL
EQUALS	
<b>i. Quantity (in g) of Cellulose (Microcrystalline) required for 1 capsule</b>	<b>_____ g</b>
MULTIPLIED BY	
Conversion factor – 1 to 100 capsules	100
EQUALS	
<b>ii. Quantity of Cellulose (Microcrystalline) required for 100 capsules</b>	<b>_____ g</b>
MULTIPLIED BY	
Conversion factor for processing error (10 to 12%)	1.10 to 1.12
EQUALS	
<b>iii. Quantity of Cellulose (Microcrystalline) required plus processing error</b>	<b>_____ g</b>

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2.	D. Calculate the theoretical weight of powder per capsule: <table border="1" data-bbox="305 489 1333 743"><tr><td>Required quantity (in g) of Ursodiol per capsule:</td><td>0.150 g</td></tr><tr><td>PLUS</td><td></td></tr><tr><td>Quantity (in g) of Cellulose (Microcrystalline) required for 1 capsule (Step 2Ci) _____</td><td>g</td></tr><tr><td>EQUALS</td><td></td></tr><tr><td><b>Theoretical weight of powder (in g) per capsule</b></td><td><b>_____ g</b></td></tr></table>	Required quantity (in g) of Ursodiol per capsule:	0.150 g	PLUS		Quantity (in g) of Cellulose (Microcrystalline) required for 1 capsule (Step 2Ci) _____	g	EQUALS		<b>Theoretical weight of powder (in g) per capsule</b>	<b>_____ g</b>
Required quantity (in g) of Ursodiol per capsule:	0.150 g										
PLUS											
Quantity (in g) of Cellulose (Microcrystalline) required for 1 capsule (Step 2Ci) _____	g										
EQUALS											
<b>Theoretical weight of powder (in g) per capsule</b>	<b>_____ g</b>										
3.	<b><u>Powder preparation:</u></b> A. By geometric addition, combine and mix the following ingredients together: - Cellulose (Microcrystalline) – (quantity determined from Step 2Ciii) - Ursodiol – (15.000 g <i>plus</i> processing error adjustments)  <u>End result:</u> Homogeneous powder blend.										
4.	<b><u>Product transfer (powder-to-capsule filling):</u></b> Fill each of 100 Size #3 capsules with the homogeneous powder blend (Step 3A). Close each capsule tightly. 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.										
5.	<b><u>Validation technique (average capsule weight):</u></b> 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.										
6.	<b><u>Product transfer (solid-to-dispensing container filling):</u></b> Transfer the final product into the specified dispensing container (see “Packaging Requirements”).										

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### SUGGESTED PRESENTATION

Estimated Beyond-Use Date	6 months	Packaging Requirements	Pill bottle or wide-mouth container	
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	4	Cap tightly after use.
	2	Keep out of reach of children.	5	<b>Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use.</b>
	3	Keep in a dry place.	6	
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.	USP <795>. <i>United States Pharmacopeia XXVIII / National Formulary 23</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2004: 2457.
3.	Urso. In: Canadian Pharmacists Association. <i>Compendium of Pharmacists and Specialties, 2003</i> . p. 1797.
4.	Cellulose, Microcrystalline. In: Rowe RC. <i>Handbook of Pharmaceutical Excipients, 4<sup>th</sup> Edition</i> . American Pharmaceutical Association; 2003:108.
5.	Ursodiol (Monograph). In: O'Neil MJ. <i>The Merck Index 13<sup>th</sup> Edition</i> . Whitehouse Station, NJ: Merck & Co, Inc.; 2001: 1761.
6.	Gennaro AR, ed. <i>Remington: The Science and Practice of Pharmacy, 20<sup>th</sup> Edition</i> . Baltimore, MD: Lippincott Williams & Wilkins; 2000.

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Appendix	Bulk Density Calculation for Capsules		
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Bulk Density Calculation											
1.	<p><b><u>Powder preparation:</u></b></p> <p>a. Measure a sufficient quantity of the specified ingredient.</p>										
2.	<p><b><u>Bulk density calculation:</u></b></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 bulk density:</p> <table border="1" style="margin-left: 40px;"> <tr> <td>Weight of the ingredient (Step b – Step a)</td> <td>_____ g</td> </tr> <tr> <td>DIVIDED BY</td> <td></td> </tr> <tr> <td>Fill volume of five, Size #3 capsules (5 x 0.3 mL)</td> <td>1.5 mL</td> </tr> <tr> <td>EQUALS</td> <td></td> </tr> <tr> <td><b>Ingredient bulk density</b></td> <td>_____ g/mL</td> </tr> </table>	Weight of the ingredient (Step b – Step a)	_____ g	DIVIDED BY		Fill volume of five, Size #3 capsules (5 x 0.3 mL)	1.5 mL	EQUALS		<b>Ingredient bulk density</b>	_____ g/mL
Weight of the ingredient (Step b – Step a)	_____ g										
DIVIDED BY											
Fill volume of five, Size #3 capsules (5 x 0.3 mL)	1.5 mL										
EQUALS											
<b>Ingredient bulk density</b>	_____ g/mL										
3.	Discard the capsules and any remaining powder.										

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