



Suggested Formula	Cabergoline 500 µg/mL Oral Liquid (Solution, 20 mL)	FIN	F 006 902
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SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Cabergoline 1% Stock Solution †	1.00	mL				
Propylene Glycol, USP	10.0	mL				
Tutti Frutti Flavor	0.2	mL				
Propylene Glycol, USP	q.s. to 20.0	mL				
† Cabergoline 1 % Stock Solution						
Cabergoline, USP	0.100	g				
Propylene Glycol, USP	9.0	mL				
Propylene Glycol, USP	q.s. to 10.0	mL				

SPECIAL PREPARATORY CONSIDERATIONS

<u>Ingredient-Specific Information</u>	
<i>Light sensitive (protect from light whenever possible):</i>	<i>Cabergoline, Propylene Glycol</i>
<i>Hygroscopic (protect from moisture whenever possible):</i>	<i>Propylene Glycol</i>
<u>Suggested Preparatory Guidelines</u>	
<input checked="" type="checkbox"/> Non-Sterile Preparation	<input type="checkbox"/> Sterile Preparation
<u>Processing Error / Testing Considerations:</u>	To account for processing error considerations during preparation, it is suggested to measure an additional 15 to 20% of the required quantities of ingredients.
<u>Special Instruction:</u>	Protective apparel, such as a lab coat, disposable gloves, eyewear and face-masks should always be worn. 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 20 mL)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Cabergoline 1% Stock Solution † §	1.00	mL			
Propylene Glycol, USP §	10.0	mL			
Tutti Frutti Flavor	0.2	mL			
Propylene Glycol, USP §	q.s. to 20.0	mL			
† Cabergoline 1 % Stock Solution					
Cabergoline, USP §	0.100	g	---	---	
Propylene Glycol, USP §	9.0	mL	---	---	
Propylene Glycol, USP §	q.s. to 10.0	mL	---	---	

* Takes into account increased batch size conversions and density conversions, if required.

§ Weigh / measure just prior to use.

Preparatory Instruction

1. † Cabergoline 1% Stock Solution preparation:

- A. Triturate the Cabergoline (0.100 g) to form a fine, homogeneous powder.
- B. Incrementally add the fine, homogeneous powder (Step 1A) to the Propylene Glycol (9.0 mL).

Specifications: Continuously mix until all solid particles have completely dissolved.

End result: Homogeneous liquid-like solution.

- C. Add additional Propylene Glycol to the mixture to fill to the required batch size (10.0 mL).

Specifications: Continuously mix.

End result: Homogeneous liquid-like solution.



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2.	<p><u>Liquid preparation:</u></p> <p>A. In the given order, sequentially add the following ingredients to the Propylene Glycol (10.0 mL <i>plus</i> processing error adjustments):</p> <ul style="list-style-type: none">-Tutti Frutti Flavor-Cabergoline 1% Stock Solution (1.00 mL <i>plus</i> processing error adjustments). <p><u>Specifications:</u> Continuously mix.</p> <p><u>End result:</u> Homogeneous liquid-like solution.</p> <p><u>Note:</u> Add the next ingredient, once the previous one has been completely added and dissolved.</p>
3.	<p><u>Filling to volume:</u></p> <p>A. Add additional Propylene Glycol to the mixture (Step 2A) to fill to the required batch size (20.0 mL <i>plus</i> processing error adjustments).</p> <p><u>Specifications:</u> Continuously mix.</p> <p><u>End result:</u> Homogeneous liquid-like solution.</p>
4.	<p><u>Product transfer:</u></p> <p>A. 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, as per USP*.	Packaging Requirements	- Tightly closed, light-resistant dispensing bottle. - To be administered with a metered-dose measuring device.	
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	6	Keep at room temperature (20°C – 23°C).
	2	Keep out of reach of children.	7	Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use.
	3	Protect from light.	8	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.
	4	May impair mental and/or physical ability.	9	Cap tightly after use.
	5	Keep in a dry place.	10	For rat use only.
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.			

* The BUD is not later than the time remaining until the earliest expiration date of any API or 6 months, whichever is earlier.



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REFERENCES

1.	Solutions. In: Allen, LV, Jr. <i>The Art, Science and Technology of Pharmaceutical Compounding Fourth Edition</i> . American Pharmaceutical Association; 2012: 225.
2.	Dostinex. In: Canadian Pharmacists Association. <i>Compendium of Pharmacists and Specialties, 2015</i> : 988.
3.	Propylene Glycol. In: Rowe RC. <i>Handbook of Pharmaceutical Excipients, 7th Edition</i> . American Pharmaceutical Association; 2012: 672.
4.	Cabergoline. In: Sweetman SC, ed. <i>Martindale: The Complete Drug Reference, 36th Edition</i> . London, England: The Pharmaceutical Press; 2009: 802.
5.	Cabergoline (Monograph). In: O'Neil MJ. <i>The Merck Index 15th Edition</i> . Whitehouse Station, NJ: Merck & Co, Inc.; 2013: Monograph #1606.
6.	Cabergoline. <i>United States Pharmacopeia XXXIX / National Formulary 34</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2016: 2842.
7.	Cabergoline Systemic. Thomson Micromedex. <i>USP DI – Drug Information for the Health Care Professional, 26th Edition</i> . Taunton, MA: US Pharmacopeial Convention, Inc; 2006: 708.
8.	USP <795>. <i>United States Pharmacopeia XXXIX / National Formulary 34</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2016: 617.

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