



Suggested Formula	Vitamin D ₃ 10 000 Units/mL Oral Liquid (Oil Suspension, 30 mL)	FIN	F 007 150
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SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Vitamin D ₃ (100 000 – 110 000 IU/g)	TBD					
Silica Gel (Micronized)	0.60	g				
Saccharin Sodium, USP	0.03	g				
Butylated Hydroxytoluene (BHT), NF	0.03	g				
Peppermint Oil (Natural), NF	0.06	g				
Almond Oil (Sweet) (Natural), NF	1.5	mL				
Almond Oil (Sweet) (Natural), NF	13.5	mL				
Almond Oil (Sweet) (Natural), NF	q.s. to 30.0	mL				

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Hygroscopic (protect from moisture whenever possible):	Silica Gel
Light sensitive (protect from light whenever possible):	Vitamin D ₃ , Almond Oil, Peppermint Oil, Butylated Hydroxytoluene
Moisture sensitive (protect from humidity whenever possible):	Vitamin D ₃ , Butylated Hydroxytoluene
Heat Sensitive (protect from heat whenever possible):	Vitamin D ₃ , Butylated Hydroxytoluene
Oxygen sensitive (protect from air whenever possible):	Vitamin D ₃

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 **12 to 15%** 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.

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 (30 mL)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): _____	Processing Error	Qty. to measure
Vitamin D ₃ (100 000 – 110 000 IU/g) §	TBD				
Silica Gel (Micronized) §	0.60	g			
Saccharin Sodium, USP	0.03	g			
Butylated Hydroxytoluene (BHT), NF §	0.03	g			
Peppermint Oil (Natural), NF §	0.06	g			
Almond Oil (Sweet) (Natural), NF §	1.5	mL			
Almond Oil (Sweet) (Natural), NF §	13.5	mL			
Almond Oil (Sweet) (Natural), NF §	q.s. to 30.0	mL			

§ Weigh / measure just prior to use.

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

Preparatory Instruction

1. Ingredient quantification:

- A. Determine the quantity (in g) of Vitamin D₃ (100 000 – 110 000 IU/g) required to make a 30 mL batch of Vitamin D₃ 10 000 IU/mL:

Quantity of Vitamin D ₃ required for a 30 mL Oral Liquid	300 000 IU
DIVIDED BY	
Assay result (from certificate of analysis: IU/g)	_____ IU/g
EQUALS	
i. Quantity of Vitamin D₃ needed for a 30 mL Oral Liquid	_____ g
MULTIPLIED BY	
Processing error adjustments (12 to 15%)	1.12 to 1.15
EQUALS	
ii. Quantity of Vitamin D₃ needed <i>plus</i> processing error adjustments	_____ g



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2.	<p><u>Powder-liquid preparation:</u></p> <p>A. Combine and triturate the following ingredients together to form a fine, homogeneous powder blend:</p> <ul style="list-style-type: none">-Vitamin D₃ (amount determined in Step 1Aii)-Saccharin Sodium-Butylated Hydroxytoluene (BHT) <p>B. Combine and mix the following ingredients together to form a homogeneous liquid-like solution:</p> <ul style="list-style-type: none">-Peppermint Oil (Natural)-Almond Oil (Sweet) (Natural) (1.5 mL <i>plus</i> processing error adjustments) <p>C. Levigate the fine, homogeneous powder blend (Step 2A) with the homogeneous liquid-like solution (Step 2B).</p> <p><u>End result:</u> Homogeneous paste-like dispersion.</p>
3.	<p><u>Medium integration</u></p> <p>A. In the given order, sequentially and slowly add the following ingredients to the Almond Oil (Sweet) (Natural) (13.5 mL <i>plus</i> processing error adjustments):</p> <ul style="list-style-type: none">-Silica Gel (Micronized)-Homogeneous paste-like dispersion (Step 2C) <p><u>Specifications:</u> Continuously mix, using high-shear mixing techniques.</p> <p><u>End result:</u> Homogeneous liquid-like dispersion.</p> <p><u>Note:</u> Add the next ingredient, once the previous one has been completely added and dispersed.</p>
4.	<p><u>Filling to volume:</u></p> <p>A. Add additional Almond Oil (Sweet) (Natural) to the mixture (Step 3A) to fill to the required batch size (30.0 mL <i>plus</i> processing error adjustments).</p> <p><u>Specifications:</u> Continuously mix, using high-shear mixing techniques.</p> <p><u>End result:</u> Homogeneous liquid-like dispersion.</p>
5.	<p><u>Product transfer:</u></p> <p>Transfer the final product into the specified dispensing container (see “Packaging requirements”).</p> <p><u>Note:</u> Continuously mix the final product during the transfer process into the recommended dispensing containers in order to maintain homogeneity.</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.	5	Cap tightly after use.
	2	Keep out of reach of children.	6	Protect from light.
	3	Consult your health care practitioner if any other prescription or over-the-counter medications are currently being used or are prescribed for future use.	7	Shake well before use.
	4	Keep at room temperature (20°C – 23°C).	8	Keep in a dry place.
Pharmacist Instructions	Add any auxiliary labels specific to the active 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.

REFERENCES

1.	Suspensions. In: Allen, LV, Jr. <i>The Art, Science, and Technology of Pharmaceutical Compounding Fifth Edition</i> . American Pharmacists Association; 2016: 279.
2.	Centrum ProNutrient Vitamin D ₃ . In: Canadian Pharmacists Association. <i>Compendium of Pharmacists and Specialties, 2015</i> : 652.
3.	Almond Oil. In: Rowe RC. <i>Handbook of Pharmaceutical Excipients, 7th Edition</i> . American Pharmaceutical Association; 2012: 32.
4.	Butylated Hydroxytoluene. In: Rowe RC. <i>Handbook of Pharmaceutical Excipients, 7th Edition</i> . American Pharmaceutical Association; 2012: 80.
5.	Colloidal Silicon Dioxide. In: Rowe RC. <i>Handbook of Pharmaceutical Excipients, 7th Edition</i> . American Pharmaceutical Association; 2012: 198.
6.	Saccharin Sodium. In: Rowe RC. <i>Handbook of Pharmaceutical Excipients, 7th Edition</i> . American Pharmaceutical Association; 2012: 696.
7.	Colecalciferol. In: Sweetman SC, ed. <i>Martindale: The Complete Drug Reference, 36th Edition</i> . London, England: The Pharmaceutical Press; 2009: 1986.
8.	Vitamin D ₃ (Monograph). In: O'Neil MJ. <i>The Merck Index 15th Edition</i> . Whitehouse Station, NJ: Merck & Co, Inc.; 2013: Monograph #10 216.



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9.	Cholecalciferol (Vitamin D ₃). In: Trissel LA. <i>Trissel's Stability of Compounded Formulations, 5th Edition</i> . American Pharmaceutical Association; 2012: 118.
10.	Cholecalciferol (Monograph). <i>United States Pharmacopeia XXXIX / National Formulary 34</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2016: 3137.
11.	Vitamin D and Analogs Systemic. Thomson Micromedex. <i>USP DI – Drug Information for the Health Care Professional, 26th Edition</i> . Taunton, MA: US Pharmacopeial Convention, Inc; 2006: 2965.
12.	USP <795>. <i>United States Pharmacopeia XXXIX / National Formulary 34</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2016: 617.



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