



QUESTION

How can I use Humco Cherry Syrup as a vehicle of delivery for Oral Liquid formulations?

RESPONSE

Details

Humco Cherry Syrup can be used as an alternative vehicle of delivery for Active Pharmaceutical Ingredients (API(s)) via the oral route that are water soluble and will go into solution.

The water content of Humco Cherry is between 13.0 – 15.0% (refer to CofA for specific lot).

We recommend verifying the aqueous solubility of the API(s) at the prescribed concentration in order to determine its solubility in Humco Cherry Syrup. Also important, always verify the compatibility of the API(s) within the vehicle along with any other excipients utilized within the final compounded preparation.

Below are examples of some APIs that are water soluble and suitable for use with the vehicle:

- Atenolol
- Baclofen
- Cimetidine Hydrochloride
- Diphenhydramine Hydrochloride
- Naltrexone
- Neomycin Sulfate
- Ranitidine Hydrochloride

For your convenience, please refer to the attached “blank” formula as a basic template that can be used when compounding an Oral Liquid Solution using Humco Cherry Syrup.

REFERENCES

1. USP <795>. *United States Pharmacopeia XXXII / National Formulary 27*. Rockville, MD. US Pharmacopeial Convention, Inc. 2009: 314.



Suggested Formula	API(s) (xx.x) mg/mL Oral Liquid (Solution, 100 mL)	FIN	F 000 HCS
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SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
API(s)	As prescribed					
Flavor	q.s.					
Glycerin, USP	6.0	mL				
Humco Cherry Syrup	70.0	mL				
Humco Cherry Syrup	q.s. to 100.0	mL				

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Light sensitive (protect from light whenever possible): *TBD*

Hygroscopic (protect from moisture whenever possible): *TBD, Glycerin*

Moisture sensitive (protect from humidity whenever possible): *TBD*

Oxygen sensitive (protect from air whenever possible): *TBD*

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.

This procedure requires the use of very small quantities of ingredients. All calculations and preparation techniques must be verified before dispensing the final product.



Suggested Formula	API(s) (xx.x) mg/mL Oral Liquid (Solution, 100 mL)	FIN	F 000 HCS
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SUGGESTED PREPARATION (for 100 mL)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
API(s)	As prescribed				
Flavor	q.s.				
Glycerin, USP §	6.0	mL			
Humco Cherry Syrup	70.0	mL			
Humco Cherry Syrup	q.s. to 100.0	mL			

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

§ Weigh / measure just prior to use.

Preparatory Instruction	
1.	<p><u>Powder preparation:</u></p> <p>A. Combine and triturate the API(s) (together) to form a fine, homogeneous powder (blend).</p>
2.	<p><u>Powder-liquid preparation:</u></p> <p>A. Combine and mix the following ingredients together to form a homogenous liquid like solution:</p> <ul style="list-style-type: none"> - Flavor - Glycerin <p>B. Levigate the fine, homogeneous powder (blend) (Step 1A) with the homogenous liquid like solution (Step 2A).</p> <p><u>Specifications:</u> Continuously mix.</p> <p><u>End result:</u> Homogeneous liquid-like dispersion.</p>
3.	<p><u>Medium integration:</u></p> <p>A. Incrementally add the homogeneous liquid-like dispersion (Step 2B) to the Humco Cherry Syrup (70.0 mL <i>plus</i> processing error adjustments).</p> <p><u>Specifications:</u> Continuously mix until all solid particles have completely dissolved.</p> <p><u>End result:</u> Homogeneous liquid-like solution.</p>
4.	<p><u>Filling to volume:</u></p> <p>A. Add additional Humco Cherry Syrup to the mixture (Step 3A) to fill to the required batch size (100.0 mL <i>plus</i> processing error adjustments).</p> <p><u>End result:</u> Homogeneous liquid-like solution.</p>



Suggested Formula	API(s) (xx.x) mg/mL Oral Liquid (Solution, 100 mL)	FIN	F 000 HCS
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5.	Product transfer: Transfer the final product into the specified dispensing container (see “Packaging requirements”).
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SUGGESTED PRESENTATION

Estimated Beyond-Use Date	14 days, refrigerated.	Packaging Requirements	- Tight, amber glass bottle. - To be administered with a metered dose-measuring device	
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	6	Keep refrigerated. Do not freeze.
	2	May impair mental and/or physical ability. Use care when operating a car or machinery.	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	Shake well before use.	8	Keep out of reach of children.
	4	Cap tightly after use.	9	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.
	5	Protect from light.	10	May produce psychological and/or physical dependence.
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.	Solutions. In: Allen, LV, Jr. <i>The Art, Science and Technology of Pharmaceutical Compounding Third Edition</i> . American Pharmaceutical Association; 2008: 195.
2.	USP <795>. <i>United States Pharmacopeia XXXII / National Formulary 27</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2009: 314.

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