MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
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technicalservices@medisca.net

Suggested Formula	Zolpidem Tartrate 5 mg/5 mL Oral Liquid (Suspension, 100 mL)	FIN	F 003 282v5

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Zolpidem Tartrate (10 mg) Tablets	10	Units				
Glycerin, USP	5.0	mL				
Raspberry Flavor (Concentrate)	0.1	mL				
Medisca Oral Suspend (Suspending Vehicle)	50.0	mL				
Medisca Oral Syrup (Flavored Syrup Vehicle)	q.s. to 100.0	mL				

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SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Controlled Substance *(adhere to proper handling and documentation procedures)* — *Zolpidem Tartrate*

Hygroscopic *(protect from moisture whenever possible):* — *Glycerin*

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: This formula may contain one or more Active Pharmaceutical Ingredients (APIs) that may be classified as hazardous, please refer & verify the current NIOSH list of Antineoplastic and Other Hazardous Drugs in Healthcare Settings. At this time, **General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings** is informational and not compendially applicable unless otherwise specified by regulators and enforcement bodies. For information on the scope, intended applicability, and implementation context for USP General Chapter <800>, see: https://www.usp.org/compounding/general-chapter-hazardous-drugs-handling-healthcare.

This formula must be prepared within the appropriate facilities under adequate environmental conditions, following the necessary guidelines and procedures as stated within *USP 795* and *USP 800*, when handling hazardous drugs. Only trained and qualified personnel must prepare this formula.

All required personal protective equipment (hazardous if applicable), such as but not limited to, lab coat, protective sleeves, gloves both inner and outer if applicable, dedicated shoe covers, hairnet, beard cover, eyewear, appropriate face mask, respirator and face shield, etc., where applicable must be worn at all times.

If applicable, follow all required procedures for hazardous drug handling including but not limited to procurement, transport, storage, preparation, dispensing, administration, clean up (spills) & disposal.

If you are a registered 503B facility, please refer to all relevant guidance documents including but not limited to the Code of Federal Regulations (CFR), Guidance for Industry (GFIs) and Compliance Policy Guides (CPGs).

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 100 mL)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Zolpidem Tartrate (10 mg) Tablets	10	Units			
Glycerin, USP §	5.0	mL			
Raspberry Flavor (Concentrate)	0.1	mL			
Medisca Oral Suspend (Suspending Vehicle)	50.0	mL			
Medisca Oral Syrup (Flavored Syrup Vehicle)	q.s. to 100.0	mL			

§ Weigh / measure just prior to use.
* Takes into account increased batch size conversions and density conversions, if required.

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Preparatory Instruction

1. **Ingredient quantification (determine the actual quantity of Zolpidem Tartrate (10 mg) tablet powder mix to weigh):**

A. Weigh 11 Zolpidem Tartrate (10 mg) Tablets. Record the total weight here: _____ g

B. Calculate the average weight of powder in each tablet:

Weight of 11 tablets (from Step 1A):	_____ g
DIVIDED BY	
Number of tablets:	11
EQUALS	
Average weight of a single Zolpidem Tartrate (10 mg) Tablet:	_____ g

C. Calculate the weight of powder equivalent to 10 tablets:

Average weight of a single Zolpidem Tartrate (10 mg) Tablet (from Step 1B):	_____ g
MULTIPLIED BY	
Number of tablets required:	10
EQUALS	
Weight of powder equivalent to 10 tablets:	_____ g

D. Calculate the weight of powder required *plus* processing error adjustments:

Weight of powder equivalent to 10 tablets (from Step 1C):	_____ g
MULTIPLIED BY	
Processing error adjustments (5 to 9%):	1.05 to 1.09
EQUALS	
Weight of powder required *plus* processing error adjustments:	_____ **g**

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2. **Powder preparation:**

A. Crush and triturate the 11 Zolpidem Tartrate (10 mg) Tablets into a fine homogeneous powder.

B. Sieve and weigh the quantity of Zolpidem Tartrate (10 mg) tablet powder mix required for the batch (refer to Step 1D) and discard the remaining powder.

3. **Powder-liquid preparation:**

A. Levigate the Zolpidem Tartrate (10 mg) tablet powder mix (amount weighed in Step 2B) with the Glycerin.

End result: Homogeneous paste-like dispersion.

4. **Medium preparation:**

A. Combine and mix the following ingredients together:

-Oral Suspend (Suspending Vehicle)
-Raspberry Flavor (Concentrate)

End result: Homogeneous liquid-like dispersion.

5. **Powder-liquid to medium integration:**

A. Incrementally add the homogeneous paste-like dispersion (Step 3A) to the homogeneous liquid-like dispersion (Step 4A).

Specifications: Continuously mix, using high-shear mixing techniques.

End result: Homogeneous liquid-like dispersion.

6. **Filling to volume:**

A. Add Oral Syrup (Flavored Syrup Vehicle) to the mixture (Step 5A) to fill to the required batch size (100.0 mL *plus* processing error adjustments).

Specifications: Continuously mix.

End result: Homogeneous liquid-like dispersion.

7. **Product transfer:**

A. Transfer the final product into the specified dispensing container (see "Packaging requirements").

Note: Continuously mix the final product during the transfer process into the recommended dispensing containers in order to maintain homogeneity.

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SUGGESTED PRESENTATION

Estimated Beyond-Use Date		14 days, refrigerated, as per USP 795.	Packaging Requirements		- Tightly closed dispensing bottle. - To be administered with a metered-dose measuring device.
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.		6	Consult your health care practitioner if any other prescription or over-the-counter medications are currently being used or are prescribed for future use.
	2	Keep out of reach of children.		7	Keep refrigerated (2°C – 8°C). Do not freeze.
	3	**Shake well before use.**		8	Cap tightly after use.
	4	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.		9	Controlled substance. Dangerous unless used as directed.
	5	May impair mental and/or physical ability. Use care when operating a car or machinery.		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. Flavors, Sweeteners, and Colors. In: Allen, LV, Jr. *The Art, Science and Technology of Pharmaceutical Compounding Third Edition.* American Pharmaceutical Association; 2008: 89.
2. Glycerin. In: Rowe RC. *Handbook of Pharmaceutical Excipients, 4th Edition*. American Pharmaceutical Association; 2003: 257.
3. Zolpidem (Monograph). In: O'Neil MJ. *The Merck Index 14th Edition*. Whitehouse Station, NJ: Merck & Co, Inc.; 2006: Monograph #10190.
4. Zolpidem. Thomson Micromedex. *USP DI – Drug Information for the Health Care Professional, 26th Edition.* Taunton, MA: US Pharmacopeial Convention, Inc; 2006: 3014.
5. USP <795>. *United States Pharmacopeia XXXI / National Formulary 26.* Rockville, MD. US Pharmacopeial Convention, Inc. 2008.