MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
TOLL-FREE: 866-333-7811
TELEPHONE: 514-905-5096
FAX: 514-905-5097
technicalservices@medisca.net

Suggested Formula	Diazepam 0.5% Rectal Gel (Suspension, 10 mL)	FIN	F 005 175v2

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Diazepam, USP	0.050	g				
Hypromellose (4000 CPS) Methocel E4M, USP	0.40	g				
Benzyl Alcohol, NF	0.2	mL				
Propylene Glycol, USP	5.0	mL				
Purified Water, USP	q.s. to 10.0	mL				

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Controlled substance *(adhere to proper handling and documentation procedures)* — *Diazepam*

Hygroscopic *(protect from moisture whenever possible):* — *Hypromellose, Propylene Glycol*

Light sensitive *(protect from light whenever possible):* — *Diazepam, Benzyl Alcohol, Propylene Glycol*

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 **20 to 25%** 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.

MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
TOLL-FREE: 866-333-7811
TELEPHONE: 514-905-5096
FAX: 514-905-5097
technicalservices@medisca.net

Suggested Formula	Diazepam 0.5% Rectal Gel (Suspension, 10 mL)	FIN	F 005 175v2

SUGGESTED PREPARATION (for 10 mL)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Diazepam, USP §	0.050	g			
Hypromellose (4000 CPS) Methocel E4M, USP §	0.40	g			
Benzyl Alcohol, NF §	0.2	mL			
Propylene Glycol, USP §	5.0	mL			
Purified Water, 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.	**Powder-liquid preparation:** A. Triturate the Diazepam to form a fine, homogeneous powder. B. Levigate the fine, homogeneous powder (Step 1A) with Propylene Glycol. End result: Homogeneous liquid-like solution.
2.	**Powder-liquid to Medium Incorporation:** A. In the given order, sequentially add the following ingredients to the homogenous liquid-like solution (Step 1B): -Benzyl Alcohol -Hypromellose (4000 CPS) Methocel E4M Specifications: Continuously mix. End result: Homogeneous liquid-like dispersion.
3.	**Filling to volume:** A. Add Purified Water to the mixture (Step 2A) to fill to the required batch size (10.0 mL *plus* processing error adjustments). Specification: Continuously mix, using high-shear mixing techniques. End result: Homogeneous gel-like dispersion.

Suggested Formula	Diazepam 0.5% Rectal Gel (Suspension, 10 mL)	FIN	F 005 175v2

4.	**Gelification:** A. Set the mixture aside for at least 2 hours for gelification to occur. Stir occasionally. End result: Homogeneous gel-like dispersion.
5.	**Product transfer:** Transfer the final product into the specified dispensing container (see "Packaging requirements").

SUGGESTED PRESENTATION

Estimated Beyond-Use Date		30 days, as per USP.	Packaging Requirements	Tightly closed, light-resistant metal ointment tube with metered rectal applicator.
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	8	Protect from light.
	2	Keep out of reach of children.	9	Keep in a dry place.
	3	For rectal use only.	10	Controlled substance. Dangerous unless used as directed.
	4	Keep at room temperature (20°C – 23°C).	11	Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use.
	5	Cap tightly after use.	12	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.
	6	May impair mental and/or physical ability.	13	May produce psychological and/or physical dependence.
	7	For veterinary 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. **IMPORTANT:** The quantity of API administered is directly dependent on the quantity of product applied.			

Suggested Formula	Diazepam 0.5% Rectal Gel (Suspension, 10 mL)	FIN	F 005 175v2

REFERENCES

1.	Gels. In: Allen, LV, Jr. *The Art, Science and Technology of Pharmaceutical Compounding Third Edition.* American Pharmaceutical Association; 2008: 255.
2.	Hypromellose. In: Rowe RC. *Handbook of Pharmaceutical Excipients, 6th Edition*. American Pharmaceutical Association; 2009: 326.
3.	Benzyl Alcohol. In: Rowe RC. *Handbook of Pharmaceutical Excipients, 6th Edition*. American Pharmaceutical Association; 2009: 64.
4.	Diazepam. In: Sweetman SC, ed. *Martindale: The Complete Drug Reference, 36th Edition*. London, England: The Pharmaceutical Press; 2009: 986.
5.	Diazepam (Monograph). In: O'Neil MJ. *The Merck Index 14th Edition*. Whitehouse Station, NJ: Merck & Co, Inc.; 2006: Monograph #2994.
6.	Diazepam. In: Trissel LA. *Trissel's Stability of Compounded Formulations, 3rd Edition.* American Pharmaceutical Association; 2005: 138.
7.	Diazepam (Monograph). *United States Pharmacopeia XXXV / National Formulary 30.* Rockville, MD. US Pharmacopeial Convention, Inc. 2012: 2868.
8.	USP <797>. *United States Pharmacopeia XXXV / National Formulary 30.* Rockville, MD. US Pharmacopeial Convention, Inc. 2012: 350.