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	Benzocaine 20%, Lidocaine Hydrochloride 7%, Tetracaine Hydrochloride 7% Topical Gel (Suspension, 30 g)	FIN	F 009 035

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Benzocaine, USP	6.000	g				
Lidocaine Hydrochloride, USP	TBD					
Tetracaine Hydrochloride, USP	2.100	g				
Polysorbate 80, NF	0.5	mL				
Ethoxy Diglycol, NF	0.5	mL				
Medisca VersaPro™ Anhydrous Base	1.50	g				
Medisca VersaPro™ Anhydrous Base	TBD					

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	Benzocaine 20%, Lidocaine Hydrochloride 7%, Tetracaine Hydrochloride 7% Topical Gel (Suspension, 30 g)	FIN	F 009 035

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Light Sensitive *(protect from light whenever possible):*	*Benzocaine, Tetracaine Hydrochloride, Polysorbate 80*
Hygroscopic *(protect from moisture whenever possible):*	*Tetracaine Hydrochloride, Polysorbate 80, Ethoxy Diglycol*
Oxygen Sensitive *(protect from air whenever possible):*	*Polysorbate 80*
Narrow Therapeutic Index	*Lidocaine Hydrochloride*

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: 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.

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	Benzocaine 20%, Lidocaine Hydrochloride 7%, Tetracaine Hydrochloride 7% Topical Gel (Suspension, 30 g)	FIN	F 009 035

SUGGESTED PREPARATION (for 30 g)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Benzocaine, USP §	6.000	g			
Lidocaine Hydrochloride, USP	TBD				
Tetracaine Hydrochloride, USP §	2.100	g			
Polysorbate 80, NF §	0.5	mL			
Ethoxy Diglycol, NF §	0.5	mL			
Medisca VersaPro™ Anhydrous Base	1.50	g			
Medisca VersaPro™ Anhydrous Base	TBD				

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

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	Benzocaine 20%, Lidocaine Hydrochloride 7%, Tetracaine Hydrochloride 7% Topical Gel (Suspension, 30 g)	FIN	F 009 035

Preparatory Instruction

1. **Ingredient quantification:**

A. Determine the potency of Lidocaine Hydrochloride based on the certificate of analysis:

	100%
MINUS	
Water Content (from certificate of analysis)	_____ %
DIVIDED BY	100
EQUALS	
Quantity of water free Lidocaine Hydrochloride, in decimal	_____
MULTIPLIED BY	
Assay on anhydrous basis result (from certificate of analysis)	_____ %
DIVIDED BY	100
EQUALS	
i. Potency of Lidocaine Hydrochloride, in decimal	_____

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	Benzocaine 20%, Lidocaine Hydrochloride 7%, Tetracaine Hydrochloride 7% Topical Gel (Suspension, 30 g)	FIN	F 009 035

2. **Ingredient quantification:**

A. Determine the quantity (in g) of Lidocaine Hydrochloride required to make a Lidocaine Hydrochloride 7% Topical Gel, batch size (30 g):

Quantity of Lidocaine Hydrochloride required for 30 g	2.100 g
DIVIDED BY	
Potency of Lidocaine Hydrochloride, in decimal (Step 1Ai)	_____
EQUALS	
i. Quantity of Lidocaine Hydrochloride needed for 30 g	_____ **g**
MULTIPLIED BY	
Processing error adjustments (12 to 15%):	1.12 to 1.15
EQUALS	
ii. Quantity of Lidocaine Hydrochloride needed *plus* processing error adjustments:	_____ **g**

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	Benzocaine 20%, Lidocaine Hydrochloride 7%, Tetracaine Hydrochloride 7% Topical Gel (Suspension, 30 g)	FIN	F 009 035

3. **Ingredient quantification:**

A. Determine the actual quantity of VersaPro™ Anhydrous Base to weigh for the required batch size (30 g):

Total Weight of the batch	30.00 g
MINUS	
Total amount of other ingredients except Lidocaine Hydrochloride	10.634 g
MINUS	
The weight of Lidocaine Hydrochloride (Step 2Ai)	_____ g
EQUALS	
i. Quantity of VersaPro™ Anhydrous Base needed for 30 g	_____ g
MULTIPLIED BY	
Processing error adjustments (12 to 15%)	1.12 to 1.15
EQUALS	
ii. Weight of VersaPro™ Anhydrous Base required *plus* processing error adjustments	_____ g

4. **Powder-liquid preparation:**

A. Combine and triturate the following ingredients together to form a fine, homogeneous powder blend:

-Benzocaine
-Lidocaine Hydrochloride (amount determined in Step 2Aii)
-Tetracaine Hydrochloride

B. Combine and mix the following ingedients together to from a homogeneous liquid-like dispersion:

-Polysorbate 80
-Ethoxy Diglycol
-VersaPro™ Anhydrous Base (1.50 g *plus* processing error adjustments).

C. Levigate the fine, homogeneous powder blend (Step 4A) with the homogeneous liquid-like dispersion (Step 4B)

End result: Homogeneous paste-like dispersion.

Suggested Formula	Benzocaine 20%, Lidocaine Hydrochloride 7%, Tetracaine Hydrochloride 7% Topical Gel (Suspension, 30 g)	FIN	F 009 035

5.	**Medium incorporation:** A. Incrementally add the homogeneous paste-like dispersion (Step 1B) to the VersaPro™ Anhydrous Base (amount determined in Step 3Aii). Specifications: Continuously mix, using high-shear mixing techniques. End result: Homogeneous gel-like dispersion. B. If the final result is gritty, pass it through the ointment mill until it becomes smooth and uniform.
6.	**Product transfer:** Transfer the final product into the specified dispensing container (see “Packaging requirements”).

Suggested Formula	Benzocaine 20%, Lidocaine Hydrochloride 7%, Tetracaine Hydrochloride 7% Topical Gel (Suspension, 30 g)	FIN	F 009 035

SUGGESTED PRESENTATION

Estimated Beyond-Use Date	6 months, as per USP 795*.		Packaging Requirements	- Tightly closed, light-resistant ointment tube/jar. - To be administered with a metered-dose measuring device.	
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.		6	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.
	2	Keep out of reach of children.		7	Protect from light.
	3	May impair mental and/or physical ability. Use care when operating a car or machinery.		8	Consult your health care practitioner if any other prescription or over-the-counter medications are currently being used or are prescribed for future use.
	4	Cap tightly after use.		9	Keep at controlled room temperature (20°C – 25°C).
	5	Keep in a dry place.		10	For external use only.
Pharmacist Instructions	Add any auxiliary labels specific to the API to the dispensing container as deemed necessary. **IMPORTANT:** - Small batch is prepared due to inherent potential of systemic toxicity. - Limits as to the total amount of product used should be established by a physician. - You should not apply this product to open wounds, areas of skin that are damaged or blistered, deep wounds, or large areas. - Continued application of this product might produce systemic side effects. Advise patient accordingly.				
Patient Instructions	Contact your pharmacist in the event of adverse reactions. **IMPORTANT:** - Do not cover the site of application. - The quantity of API administered is directly dependent on the quantity of product applied.				

*** 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.	Gels. In: Allen, LV, Jr. *The Art, Science, and Technology of Pharmaceutical Compounding Fifth Edition.* American Pharmacists Association; 2016: 339.
2.	Xylocaine Jelly 2%. In: Canadian Pharmacists Association. *Compendium of Pharmacists and Specialties, 2017*: 3947.
3.	Diethylene Glycol Monoethyl Ether. In: Sheskey, P.J., ed. *Handbook of Pharmaceutical Excipients, 8th Edition.* Pharmaceutical Press and American Pharmacists Association; 2017: 321.
4.	Polyoxyethylene Sorbitan Fatty Acid Esters. In: Sheskey, P.J., ed. *Handbook of Pharmaceutical Excipients, 8th Edition.* Pharmaceutical Press and American Pharmacists Association; 2017: 736.

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	Benzocaine 20%, Lidocaine Hydrochloride 7%, Tetracaine Hydrochloride 7% Topical Gel (Suspension, 30 g)	FIN	F 009 035

5.	Benzocaine. In: Brayfield, A., ed. *Martindale: The Complete Drug Reference, 38th Edition.* London, England: The Pharmaceutical Press; 2014: 1980.
6.	Lidocaine Hydrochloride. In: Brayfield, A., ed. *Martindale: The Complete Drug Reference, 38th Edition.* London, England: The Pharmaceutical Press; 2014: 1988.
7.	Tetracaine Hydrochloride. In: Brayfield, A., ed. *Martindale: The Complete Drug Reference, 38th Edition.* London, England: The Pharmaceutical Press; 2014: 1996.
8.	Benzocaine (Monograph). In: O'Neil MJ. *The Merck Index 15th Edition*. Whitehouse Station, NJ: Merck & Co, Inc.; 2013: Monograph #1088.
9.	Lidocaine (Monograph). In: O'Neil MJ. *The Merck Index 15th Edition*. Whitehouse Station, NJ: Merck & Co, Inc.; 2013: Monograph #5535.
10.	Tetracaine Hydrochloride (Monograph). In: O'Neil MJ. *The Merck Index 15th Edition*. Whitehouse Station, NJ: Merck & Co, Inc.; 2013: Monograph #9333.
11.	Benzocaine. In: Trissel LA. *Trissel's Stability of Compounded Formulations, 5th Edition.* American Pharmaceutical Association; 2012: 62.
12.	Lidocaine Hydrochloride. In: Trissel LA. *Trissel's Stability of Compounded Formulations, 5th Edition.* American Pharmaceutical Association; 2012: 288.
13.	Tetracaine. In: Trissel LA. *Trissel's Stability of Compounded Formulations, 5th Edition.* American Pharmaceutical Association; 2012: 463.
14.	Benzocaine (Monograph). *United States Pharmacopeia XLIII / National Formulary 38.* Rockville, MD. US Pharmacopeial Convention, Inc. 2020: 502.
15.	Lidocaine Hydrochloride (Monograph). *United States Pharmacopeia XLIII / National Formulary 38.* Rockville, MD. US Pharmacopeial Convention, Inc. 2020: 2623.
16.	Tetracaine Hydrochloride (Monograph). *United States Pharmacopeia XLIII / National Formulary 38.* Rockville, MD. US Pharmacopeial Convention, Inc. 2020: 4295.
17.	Benzocaine. Thomson Micromedex. *USP DI – Drug Information for the Health Care Professional, 26th Edition.* Taunton, MA: US Pharmacopeial Convention, Inc; 2006: 194.
18.	Lidocaine. Thomson Micromedex. *USP DI – Drug Information for the Health Care Professional, 26th Edition.* Taunton, MA: US Pharmacopeial Convention, Inc; 2006: 196.
19.	Tetracaine. Thomson Micromedex. *USP DI – Drug Information for the Health Care Professional, 26th Edition.* Taunton, MA: US Pharmacopeial Convention, Inc; 2006: 197.
20.	USP <795>. *United States Pharmacopeia XLIII / National Formulary 38.* Rockville, MD. US Pharmacopeial Convention, Inc. 2020: 7025.