MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
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Suggested Formula	Lidocaine Hydrochloride 1%, 2% Injection (Solution, 50 mL)	FIN	F 002 236v2

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Lidocaine Hydrochloride, USP	TBD					
Benzyl Alcohol, NF	1.0	mL				
Sodium Chloride, USP	TBD					
Sterile Water for Injection, USP	40.0	mL				
Sterile Water for Injection, USP	q.s. to 50.0	mL				
Sodium Hydroxide 1 N Solution	As required					

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Narrow Therapeutic Index *Lidocaine Hydrochloride*

Light sensitive *(protect from light whenever possible):* *Benzyl Alcohol*

Suggested Preparatory Guidelines

☐ Non-Sterile Preparation ■ Sterile Preparation

Processing Error / Testing Considerations: To account for processing error, sterility, pH and endotoxin testing considerations during preparation, it is suggested to measure an additional **10 to 12%** of the required quantities of ingredients.

Special Instruction: This formula must be prepared within the appropriate facilities under adequate environmental conditions, following the necessary guidelines and procedures as stated within *USP 797*. Only trained and qualified personnel must prepare this formula.

All heat stable, reusable materials and equipment must be sterilized and depyrogenated by dry heat sterilization at 250°C for 2 hours prior to use.

Every batch of final product compounded using this procedure must be sterility and endotoxin tested before being dispensed.

Protective apparel, such as a sterile gown, sterile gloves, shoe covers, head cap, eyewear and face-masks should always be worn. In addition, proper personnel cleansing must be done before entering the buffer or clean area.

Filter integrity must be validated by performing a filter stress test. If the test demonstrates that the filter might be defective, the solution must be discarded and remade.

Lidocaine Hydrochloride has a Narrow Therapeutic Index.

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 50 mL)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Lidocaine Hydrochloride, USP §	TBD				
Benzyl Alcohol, NF §	1.0	mL			
Sodium Chloride, USP §	TBD				
Sterile Water for Injection, USP §	40.0	mL			
Sterile Water for Injection, USP §	q.s. to 50.0	mL			
Sodium Hydroxide 1 N Solution §	As required				

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

Preparatory Instruction

IMPORTANT: All preparatory procedures must be performed using proper Aseptic Technique

1. **Equipment sterilization:**

   Following the manufacturer's specifications, sterilize and depyrogenate all heat stable, reusable materials and equipment, then return to ambient temperature.

2. **Ingredient quantification:**

   Based on the desired concentration of the injection, determine the required quantity of Lidocaine Hydrochloride to weigh for a 50 mL batch:

Required concentration of Lidocaine Hydrochloride	Lidocaine Hydrochloride to weigh		Processing Error adjustments		Lidocaine Hydrochloride to weigh (plus processing error adjustments)
1%	0.500 g	Multiply	1.10 to 1.12	Equals	_____ g
2%	1.000 g		1.10 to 1.12		_____ g

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3. **Ingredient quantification:**

Based on the desired concentration of the injection, determine the required quantity of Sodium Chloride to weigh for a 50 mL batch:

Required concentration of Lidocaine Hydrochloride	Sodium Chloride to weigh		Processing Error adjustments		Sodium Chloride to weigh (plus processing error adjustments)
1%	0.17 g	Multiply	1.10 to 1.12	Equals	_____ g
2%	0.06 g		1.10 to 1.12		_____ g

4. **Liquid preparation:**

A. Combine and mix the following ingredients together:

-Benzyl Alcohol
-Sterile Water for Injection (40.0 mL *plus* processing error adjustments)

End result: Homogeneous liquid-like solution.

5. **Powder to medium incorporation:**

A. In the given order, sequentially add the following ingredients to the homogeneous liquid-like solution (Step 4A):

-Lidocaine Hydrochloride (amount determined in Step 2)
-Sodium Chloride (amount determined in Step 3)

Specifications: Continuously mix until all solid particles have completely dissolved.

End result: Homogeneous liquid-like solution.

Note: Add the next ingredient, once the previous one has been completely added and dissolved.

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6. **pH testing:**

A. Draw an appropriate amount of the mixture (Step 5A).

B. Test the pH of the sample. It should lie between 5.5 and 6.5.

C. If the pH < 5.5, carefully add in a dropwise manner the Sodium Hydroxide 1 N Solution to the mixture:

1. Draw and transfer 1 or 2 drops of the Sodium Hydroxide 1 N Solution to the mixture.
2. Stir for at least 5 minutes to evenly disperse the Sodium Hydroxide 1 N Solution.
3. Re-test the pH.
4. Continue to add the Sodium Hydroxide 1 N until the pH of 5.5 to 6.5 is obtained.

IMPORTANT: Do not allow the pH to rise above 6.5.

7. **Filling to volume:**

A. Add additional Sterile Water for Injection to the above mixture to fill to the required batch size (50.0 mL *plus* processing error adjustments).

Specifications: Continuously mix.

End result: Homogeneous liquid-like solution.

8. **Filtering and transferring:**

Aseptically filter the solution through a 0.22-µm sterile filter into the recommended dispensing container (see Packaging requirements). Transfer the remainder into a separate dispensing container. This is to be used as the Test sample for sterility and endotoxin testing.

9. **Filter integrity test:**

Validate filter integrity by performing a filter stress test. If the test demonstrates that the filter might be defective, the solution must be discarded and remade.

10. **Sterility testing:**

Validate the Test sample for sterility and endotoxins, in accordance to current USP 797 regulatory guidelines.

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SUGGESTED PRESENTATION

Estimated Beyond-Use Date		14 days, refrigerated, as per USP. BUD based on a successful sterility and endotoxin test result.	Packaging Requirements		Sterile, tightly closed, light-resistant unit dose injection vials.
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	7		Discard container after use.
	2	Keep out of reach of children.	8		Protect from light.
	3	Keep refrigerated. Do not freeze.	9		Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use.
	4	**Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.**	10		**May impair mental and/or physical ability. Use care when operating a car or machinery.**
	5	Discard in the presence of particulate matter.	11		Do not used if product changes color.
	6	Equilibrate to room temperature before use.			
Pharmacist Instructions		Add any auxiliary labels specific to the API to the dispensing container as deemed necessary. **IMPORTANT: TO BE ADMINISTERED ONLY BY THE PRESCRIBING PHYSICIAN.**			
Patient Instructions		Contact your pharmacist in the event of adverse reactions.			

REFERENCES

1. USP <797> Pharmaceutical Compounding – Sterile Preparations. US Pharmacopeial Convention, Inc. *United States Pharmacopeia XXVIII / National Formulary 23.* Rockville, MD. 2004: 2461.
2. Benzyl Alcohol. In: Rowe RC. *Handbook of Pharmaceutical Excipients, 4th Edition*. American Pharmaceutical Association; 2003: 53.
3. Lidocaine (Monograph). In: O'Neil MJ. *The Merck Index 13th Edition*. Whitehouse Station, NJ: Merck & Co, Inc.; 2001: 982.
4. Lidocaine Hydrochloride (Monograph). US Pharmacopeial Convention, Inc. *United States Pharmacopeia XXVIII / National Formulary 23.* Rockville, MD. 2004: 1003.
5. Lidocaine Hydrochloride. Thomson Micromedex. *USP DI – Drug Information for the Health Care Professional, 26th Edition.* Taunton, MA: US Pharmacopeial Convention, Inc; 2006: 1930.