MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
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Suggested Formula	Sodium Bicarbonate 150 mEq/1000 mL Intravenous Injection (Solution, 1000 mL)	FIN	F 004 848

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Sodium Bicarbonate 4.2% Injection (Sterile, Preservative Free)	300.00	mL				
Dextrose 5% Injection, USP (Sterile, Preservative Free)	700.0	mL				

SPECIAL PREPARATORY CONSIDERATIONS

Suggested Preparatory Guidelines

☐ Non-Sterile Preparation ■ Sterile Preparation

Processing Error / Testing Considerations: To account for processing error during preparation, it is suggested to measure an additional **0 to 1%** 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.

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 1000 mL)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Sodium Bicarbonate 4.2% Injection (Sterile, Preservative Free) §	300.00	mL			
Dextrose 5% Injection, USP (Sterile, Preservative Free) §	700.0	mL			

* 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.	**Medium integration:** **Note**: All manipulations must be done under a laminar airflow hood. Disinfect the commercial vials with Alcohol 70% prior to withdrawing the required amount of liquid. A. Incrementally add the Sodium Bicarbonate 4.2% Injection to the Dextrose 5% Injection. Specifications: Continuously mix. End result: Homogeneous liquid-like solution.
3.	**Filtering and transferring:** Aseptically filter the solution through a 0.22-µm sterile filter into the recommended dispensing container (see Packaging requirements).
4.	**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.

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SUGGESTED PRESENTATION

Estimated Beyond-Use Date	14 days, refrigerated, as per USP.		Packaging Requirements	Sterile, tightly closed, unit-dose injection vials.
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	7	For medical office use only.
	2	Keep out of reach of children.	8	Discard container after use.
	3	Keep refrigerated. Do not freeze.	9	Equilibrate to room temperature before use.
	4	Do not used if product changes color.	10	Discard in the presence of particulate matter.
	5	Keep in a dry place.	11	**Preservative free solution, single use only. Discard any unused portion.**
	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.	12	**Hypertonic solution, inject slowly.**
Pharmacist Instructions	Add any auxiliary labels specific to the active ingredients 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

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5. Sodium Bicarbonate (Monograph). In: O'Neil MJ. *The Merck Index 14th Edition*. Whitehouse Station, NJ: Merck & Co, Inc.; 2006: Monograph #8583.
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7. Sodium Bicarbonate (Monograph). *United States Pharmacopeia XXXII / National Formulary 27.* Rockville, MD. US Pharmacopeial Convention, Inc. 2009: 3563.