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	Dexmedetomidine 4 mcg/mL Intravenous Injection (Solution, 50 mL)	FIN	F 004 774

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Dexmedetomidine Hydrochloride 100 mcg base/mL (Sterile) *	2.00	mL				
Sodium Chloride 0.9% for Injection (Sterile), USP	48.00	mL				

*** Delivered as Dexmedetomidine Hydrochloride**

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information
Suggested Preparatory Guidelines

☐ Non-Sterile Preparation ■ Sterile Preparation

Processing Error / Testing Considerations: To account for processing error, sterility 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.

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	Dexmedetomidine 4 mcg/mL Intravenous Injection (Solution, 50 mL)	FIN	F 004 774

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
Dexmedetomidine Hydrochloride 100 mcg base/mL (Sterile) §	2.00	mL			
Sodium Chloride 0.9% for Injection (Sterile), USP §	48.00	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:** A. Incrementally add the Dexmedetomidine Hydrochloride 100 mcg/mL Injection to the Sodium Chloride 0.9% for injection (48.00 mL). Specifications: Continuously mix. End result: Homogenous 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). Transfer the remainder into a separate dispensing container. This is to be used as the Test sample for sterility and endotoxin testing.
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.
5.	**Sterility testing:** Validate the Test sample for sterility and endotoxins, in accordance to current USP 797 regulatory guidelines.

Suggested Formula	Dexmedetomidine 4 mcg/mL Intravenous Injection (Solution, 50 mL)	FIN	F 004 774

SUGGESTED PRESENTATION

Estimated Beyond-Use Date	14 days, refrigerated, USP <797> BUD based on a successful sterility and endotoxin test result.		Packaging Requirements	Sterile, tightly closed, unit dose injection vials.
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	5	Do not use if discolored.
	2	Keep out of reach of children.	6	May produce psychological and/or physical dependence.
	3	Keep refrigerated. Do not freeze.	7	Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use.
	4	Equilibrate to room temperature before use	8	Discard container after use.
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.	Parenteral Preparations. In: Allen, LV, Jr. *The Art, Science and Technology of Pharmaceutical Compounding Third Edition.* American Pharmaceutical Association; 2008: 313.
2.	Precedex. In: Canadian Pharmacists Association. *Compendium of Pharmacists and Specialties, 2011.* 1909.
3.	Dexmedetomidine Hydrochloride. In: Sweetman SC, ed. *Martindale: The Complete Drug Reference, 36th Edition.* London, England: The Pharmaceutical Press; 2009: 986.
4.	Dexmedetomidine (Monograph). In: O'Neil MJ. *The Merck Index 14th Edition*. Whitehouse Station, NJ: Merck & Co, Inc.; 2006: #2946.
5.	USP <797>. United States Pharmacopeia *XXXII* / National Formulary 27. Rockville, MD. US Pharmacopeial Convention, Inc. 2009: 318.