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	Ketamine Hydrochloride 11.5 mg/mL Intravenous Injection (Solution, 100 mL)	FIN	F 002 682v2

Note: Ketamine Hydrochloride 11.5 mg/mL is equivalent to Ketamine 10 mg/mL.

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Ketamine Hydrochloride, USP	1.150	g				
Sodium Chloride, USP	0.31	g				
Benzyl Alcohol, NF	2.0	mL				
Sterile Water For Injection, USP	80.0	mL				
Sterile Water For Injection, USP	q.s. to 100.0	mL				

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

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

Light sensitive *(protect from light whenever possible):* — *Ketamine Hydrochloride, Benzyl Alcohol*

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 **5 to 9%** 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	Ketamine Hydrochloride 11.5 mg/mL Intravenous Injection (Solution, 100 mL)	FIN	F 002 682v2

SUGGESTED PREPARATION (for 100 mL)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Ketamine Hydrochloride, USP §	1.150	g			
Sodium Chloride, USP §	0.31	g			
Benzyl Alcohol, NF §	2.0	mL			
Sterile Water For Injection, USP §	80.0	mL			
Sterile Water For Injection, USP §	q.s. to 100.0	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.	**Powder preparation:** A. Combine and triturate the following ingredients together to form a fine, homogeneous powder blend: -Ketamine Hydrochloride -Sodium Chloride
3.	**Medium preparation:** A. Combine and mix the following ingredients together: -Benzyl Alcohol -Sterile Water For Injection (80.0 mL *plus* processing error adjustments) Specifications: Mix until homogeneous. End result: Homogeneous liquid-like solution.

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	Ketamine Hydrochloride 11.5 mg/mL Intravenous Injection (Solution, 100 mL)	FIN	F 002 682v2

4.	**Powder to medium integration:** A. Incrementally add the fine homogeneous powder blend (Step 2A) to the following mixture: -Homogeneous liquid-like solution (Step 3A) Specifications: Continuously mix until all solid particles have completely dissolved. End result: Homogeneous liquid-like solution.
5.	**Filling to volume:** A. Add additional Sterile Water For Injection to the mixture (Step 4A) to fill to the required batch size (100.0 mL *plus* processing error adjustments). Specifications: Continuously mix. End result: Homogeneous liquid-like solution.
6.	**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.
7.	**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.
8.	**Sterility testing:** Validate the Test sample for sterility and endotoxins, in accordance to current USP 797 regulatory guidelines.

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	Ketamine Hydrochloride 11.5 mg/mL Intravenous Injection (Solution, 100 mL)	FIN	F 002 682v2

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.	8		Protect from light.
	2	Keep out of reach of children.	9		Discard container after use.
	3	Consult your health care practitioner if any other prescription or over-the-counter medications are currently being used or are prescribed for future use.	10		**Controlled substance. Dangerous unless used as directed.**
	4	Do not use if discolored.	11		Discard in the presence of particulate matter.
	5	Keep refrigerated. Do not freeze.	12		**Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.**
	6	**May impair mental and/or physical ability. Use care when operating a car or machinery.**	13		**May produce psychological and/or physical dependence.**
	7	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.			

Suggested Formula	Ketamine Hydrochloride 11.5 mg/mL Intravenous Injection (Solution, 100 mL)	FIN	F 002 682v2

REFERENCES

1.	USP <797> Pharmaceutical Compounding – Sterile Preparations. US Pharmacopeial Convention, Inc. *United States Pharmacopeia XXVIII / National Formulary 23.* Rockville, MD. 2004: 2461.
2.	Parenteral Preparations. In: Allen, LV, Jr. *The Art, Science and Technology of Pharmaceutical Compounding.* American Pharmaceutical Association; 1998: 251.
3.	Benzyl Alcohol. In: Rowe RC. *Handbook of Pharmaceutical Excipients, 4th Edition*. American Pharmaceutical Association; 2003: 53.
4.	Ketamine (Monograph). In: O'Neil MJ. *The Merck Index 14th Edition*. Whitehouse Station, NJ: Merck & Co, Inc.; 2006: Monograph #5295.
5.	Benzyl Alcohol (Monograph). In: O'Neil MJ. *The Merck Index 13th Edition*. Whitehouse Station, NJ: Merck & Co, Inc.; 2001: 193.
6.	Benzyl Alcohol (Monograph). *United States Pharmacopeia XXVIII / National Formulary 23.* Rockville, MD. US Pharmacopeial Convention, Inc. 2004: 2965.
7.	Ketamine Hydrochloride. In: Trissel LA. *Trissel's Stability of Compounded Formulations, 2nd Edition.* American Pharmaceutical Association; 2000: 205.
8.	Ketamine Hydrochloride (Monograph). *United States Pharmacopeia XXVIII / National Formulary 23.* Rockville, MD. US Pharmacopeial Convention, Inc. 2004: 1096.