

6/15/2009; page 1

Suggested Formula	Ascorbic Acid 1500 mg/30 mL, Calcium Gluconate 300 mg/30 mL, Dexpanthenol 750 mg/30 mL, Magnesium Sulfate 1500 mg/30 mL, Methylcobalamin 10 000 µg/30 mL, Niacinamide 50 mg/30 mL, Pyridoxine Hydrochloride 200 mg/30 mL, Riboflavin-5-Phosphate Sodium 15 mg/30 mL, Thiamine Hydrochloride 50 mg/30 mL Intravenous Injection (Solution, 30 mL)	FIN	F 003 858
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SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Ascorbic Acid 500 mg/mL Injection	3.00	mL				
Calcium Gluconate 10% Injection	3.00	mL				
Dexpanthenol 250 mg/mL Injection	3.00	mL				
Magnesium Sulfate 500 mg/mL Injection	3.00	mL				
Methylcobalamin 0.667% Stock Solution †	1.50	mL				
Niacinamide, USP	0.050	g				
Pyridoxine Hydrochloride 100 mg/mL Injection	2.00	mL				
Riboflavin-5-phosphate sodium 1% Stock Solution ††	1.50	mL				
Thiamine Hydrochloride 100 mg/mL Injection	0.50	mL				
Sterile Water for Injection, USP	q.s. to 30.0	mL				
The second state of t						
Methylcobalamin	0.100	g				
Sterile Water for Injection, USP	12.0	mL				
Sterile Water for Injection, USP	q.s. to 15.0	mL				
†† Riboflavin-5-phosphate sodium 1% Stock Solution						
Riboflavin-5-phosphate sodium, USP	0.100	g				
Sterile Water for Injection, USP	9.0	mL				
Sterile Water for Injection, USP	q.s. to 10.0	mL				



6/15/2009; page 2 TMP 045

Suggested Formula		Aethylcobalamin 10 000 µg/30 mL, Niaci mL, Riboflavin-5-Phosphate Sodium 15 ection (Solution, 30 mL)		FIN	F 003 85
	PARATORY CONSI	DERATIONS			
Ingredient-	Specific Information				
Light se	e nsitive (protect from li	ght whenever possible):	Ascorbic Acid, Methylcobalamin, Hydrochloride, Riboflavin-5-phos		
Oxygen	Sensitive (protect from	n oxygen whenever possible):	Ascorbic Acid		
Hygroso	copic (protect from mot	isture whenever possible):	Dexpanthenol, Riboflavin-5-phos	phate so	odium
Suggested I	Preparatory Guidelines				
C	Non-Sterile Preparat	tion Sterile Preparation			
Pr	ocessing Error /	To account for processing error	or sterility and endotoxin testing cor	nsiderat	ions during
	esting Considerations:		o measure an additional 12 to 15%		
Te		preparation, it is suggested to quantities of ingredients. This formula must be prepared environmental conditions, follo		% of the second	he required ate es as stated
Te	esting Considerations:	preparation, it is suggested to quantities of ingredients. This formula must be prepared environmental conditions, follo within <i>USP 797</i> . Only trained a	within the appropriate facilities under wing the necessary guidelines and pro- and qualified personnel must prepare to als and equipment must be sterilized a	% of the second	he required ate es as stated nula.
Te	esting Considerations:	preparation, it is suggested to quantities of ingredients. This formula must be prepared environmental conditions, follo within <i>USP 797</i> . Only trained a All heat stable, reusable materi- by dry heat sterilization at 250°	within the appropriate facilities under within the appropriate facilities under owing the necessary guidelines and pro- and qualified personnel must prepare to als and equipment must be sterilized a PC for 2 hours prior to use. mpounded using this procedure must	% of the second	he required ate es as stated nula. yrogenated
Te	esting Considerations:	 preparation, it is suggested to quantities of ingredients. This formula must be prepared environmental conditions, followithin USP 797. Only trained a All heat stable, reusable materiable dry heat sterilization at 250° Every batch of final product co endotoxin tested before being de Protective apparel, such as a sterilization at face-masks should 	within the appropriate facilities under within the appropriate facilities under owing the necessary guidelines and pro- and qualified personnel must prepare to als and equipment must be sterilized a PC for 2 hours prior to use. mpounded using this procedure must	% of the radeque occedure this form and dep be steri	he required ate es as stated nula. yrogenated lity and cap,
Te	esting Considerations:	 preparation, it is suggested to quantities of ingredients. This formula must be prepared environmental conditions, followithin USP 797. Only trained at All heat stable, reusable materiate by dry heat sterilization at 250° Every batch of final product co endotoxin tested before being de Protective apparel, such as a steril eyewear and face-masks should cleansing must be done before to Filter integrity must be validated 	within the appropriate facilities under owing the necessary guidelines and pro- and qualified personnel must prepare to als and equipment must be sterilized a 'C for 2 hours prior to use. mpounded using this procedure must lispensed. erile gown, sterile gloves, shoe covers d always be worn. In addition, proper	% of the radeque ocedure this form and dep be steri	he required ate es as stated nula. yrogenated lity and cap, nel



6/15/2009; page 3 TMP 045

Suggested Formula	Ascorbic Acid 1500 mg/30 mL, Calcium Gluconate 300 mg/30 mL, Dexpanthenol 750 mg/30 mL, Magnesium Sulfate 1500 mg/30 mL, Methylcobalamin 10 000 µg/30 mL, Niacinamide 50 mg/30 mL, Pyridoxine Hydrochloride 200 mg/30 mL, Riboflavin-5-Phosphate Sodium 15 mg/30 mL, Thiamine Hydrochloride 50 mg/30 mL Intravenous Injection (Solution, 30 mL)	FIN	F 003 858	
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SUGGESTED PREPARATION (for 30 mL)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor ^(*) :	Processing Error	Qty. to measure
Ascorbic Acid 500 mg/mL Injection §	3.00	mL			
Calcium Gluconate 10% Injection §	3.00	mL			
Dexpanthenol 250 mg/mL Injection §	3.00	mL			
Magnesium Sulfate 500 mg/mL Injection §	3.00	mL			
Methylcobalamin 0.667% Stock Solution † §	1.50	mL			
Niacinamide, USP §	0.050	g			
Pyridoxine Hydrochloride 100 mg/mL Injection §	2.00	mL			
Riboflavin-5-phosphate sodium 1% Stock Solution †† §	1.50	mL			
Thiamine Hydrochloride 100 mg/mL Injection §	0.50	mL			
Sterile Water for Injection, USP §	q.s. to 30.0	mL			
the state of					
Methylcobalamin §	0.100	g			
Sterile Water for Injection, USP §	12.0	mL			
Sterile Water for Injection, USP §	q.s. to 15.0	mL			
†† Riboflavin-5-phosphate sodium 1% Stock Solution					
Riboflavin-5-phosphate sodium, USP §	0.100	g			
Sterile Water for Injection, USP §	9.0	mL			
Sterile Water for Injection, USP §	q.s. to 10.0	mL			

* Takes into account increased batch size conversions and density conversions, if required.

§ Weigh / measure just prior to use.



6/15/2009; page 4

Suggested Formula	Ascorbic Acid 1500 mg/30 mL, Calcium Gluconate 300 mg/30 mL, Dexpanthenol 750 mg/30 mL, Magnesium Sulfate 1500 mg/30 mL, Methylcobalamin 10 000 µg/30 mL, Niacinamide 50 mg/30 mL, Pyridoxine Hydrochloride 200 mg/30 mL, Riboflavin-5-Phosphate Sodium 15 mg/30 mL, Thiamine Hydrochloride 50 mg/30 mL Intravenous Injection (Solution, 30 mL)	FIN	F 003 858
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	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.	† Methylcobalamin 0.667% Stock Solution preparation:
	A. Triturate the Methylcobalamin to form a fine, homogeneous powder.
	B. Incrementally add the fine, homogeneous powder (Step 2A) to the Sterile Water for Injection (12.0 mL)
	Specifications: Continuously mix until all solid particles have completely dissolved.
	End result: Homogeneous liquid-like solution.
	C. Add additional Sterile Water for Injection to the mixture (Step 2B) to fill to the required batch size (15.0 mL).
	Specifications: Continuously mix.
	End result: Homogeneous liquid-like solution.
3.	†† Riboflavin-5-phosphate sodium 1% Stock Solution preparation:
	A. Triturate the Riboflavin-5-phosphate sodium to form a fine, homogeneous powder.
	B. Incrementally add the fine, homogeneous powder (Step 3A) to the Sterile Water for Injection (9.0 mL)
	Specifications: Continuously mix until all solid particles have completely dissolved.
	End result: Homogeneous liquid-like solution.
	C. Add additional Sterile Water for Injection to the mixture (Step 3B) to fill to the required batch size (10.0 mL).
	Specifications: Continuously mix.
	End result: Homogeneous liquid-like solution.



6/15/2009; page 5 TMP 045

	Ascorbic Acid 1500 mg/30 mL, Calcium Gluconate 300 mg/30 mL, Dexpanthenol 750 mg/30 mL, Magnesium Sulfate 1500 mg/30 mL, Methylcobalamin 10 000 µg/30 mL, Niacinamide 50 mg/30 mL, Pyridoxine Hydrochloride 200 mg/30 mL, Riboflavin-5-Phosphate Sodium 15 mg/30 mL, Thiamine Hydrochloride 50 mg/30 mL Intravenous Injection (Solution, 30 mL)						
4.	Medium Integration:						
	 A. In the given order, sequentially add the following ingredients to the Ascorbic Acid 500 mg/mL Injection: -Calcium Gluconate 10% Injection -Dexpanthenol 250 mg/mL Injection -Magnesium Sulfate 500 mg/mL Injection -Methylcobalamin 0.667% Stock Solution (1.50 mL <i>plus</i> processing error adjustments) -Pyridoxine Hydrochloride 100 mg/mL Injection -Riboflavin-5-phosphate sodium 1% Stock Solution (1.50 mL <i>plus</i> processing error adjustments) -Thiamine Hydrochloride 100 mg/mL Injection -Niacinamide 						
	<u>Specifications</u> : Continuously mix until all solid particles have completely dissolved. <u>End result</u> : Homogeneous liquid-like solution.						
	<u>Note:</u> Add the next ingredient, once the previous one has been completely added and dissolved.						
5.	Filling to volume:						
	A. Add Sterile Water for Injection to the mixture (Step 4A) to fill to the required batch size (30.0 mL <i>plus</i> processing error adjustments).						
	Specifications: Continuously mix.						
	End result: Homogeneous liquid-like solution.						
6.	Filtering and transferring:						
	Aseptically filter the solution through a 0.22 - μ m 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.						



6/15/2009; page 6 TMP 045

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SUGGESTED PRESENTATION

	Estimated Beyond-Use Date		35 days, refrigerated. BUD based on a successful sterility and endotoxin test result.	Packag Requireme		Sterile, tight, light-resistant unit dose injection vials.		
		1	Use as directed. Do not exceed p dose.	prescribed	8	Discard in the presence of particulate matter.		
		2	Keep out of reach of children.		9	Discard container after use.		
		3	Keep refrigerated. Do not freeze.		10	Do not use if product changes color.		
	Auxiliary	4	4 Protect from light.			Keep in a dry place.		
	Labels	5	Equilibrate to room temperature before use.			Hypertonic solution. Inject slowly.		
		6	Do not take with alcohol, sle tranquilizers or other CNS depressa		13	May impair mental and/or physical ability. Use care when operating a car or machinery.		
		7	Consult your health care practition other prescription or over-the medications are currently being us prescribed for future use.	ne-counter				
Pharmacist Instructions Add any auxiliary labels specific to the API to the dispen				nsing container as deemed necessary.				
	Patient Instructions Contact your pharmacist in the event of adverse reactions.				15.			

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6/15/2009; page 7

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6/15/2009; page 8

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