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Suggeste	<sup>d</sup> Ceftazidime 100 mg/mL Intravenous Injection (Solution, 10 mL)	FIN	F 008 724
Formu	a contactante roo mg me maavenous mjeetion (solution, ro me)		1 000 /21

## SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Ceftazidime with Sodium Carbonate	TBD					
Sterile Water for Injection, USP	8.0	mL				
Sterile Water for Injection, USP	q.s. to 10.0	mL				
Sodium Hydroxide 10% Solution	As required					
Hydrochloric Acid 10% Solution	As required					
			Q			

# SPECIAL PREPARATORY CONSIDERATIONS

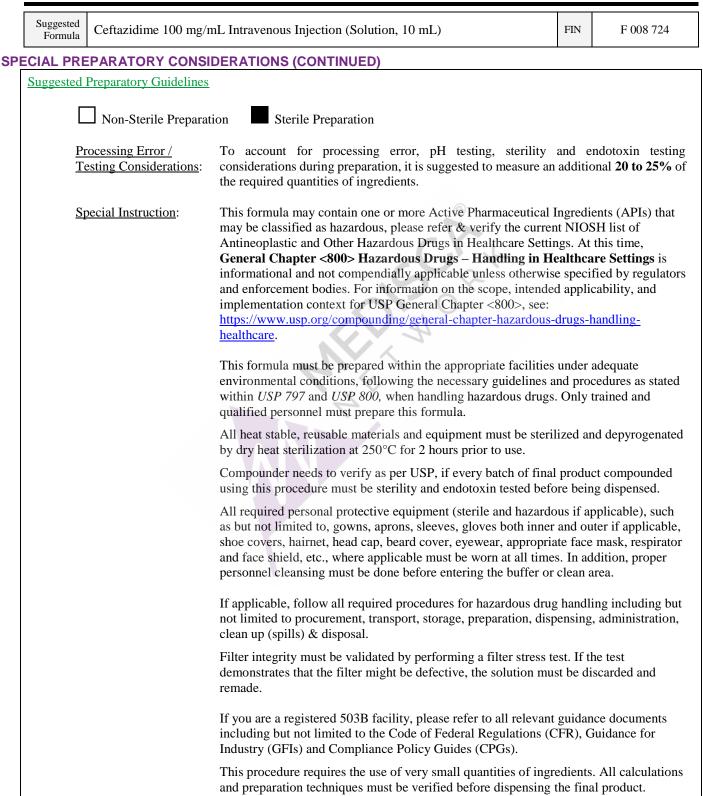
Ingredient-Specific Information

*Light Sensitive* (protect from light whenever possible):

Ceftazidime with Sodium Carbonate



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### SUGGESTED PREPARATION (for 10 mL)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor <sup>(*)</sup> :	Processing Error	Qty. to measure
Ceftazidime with Sodium Carbonate §	TBD				
Sterile Water for Injection, USP §	8.0	mL			
Sterile Water for Injection, USP §	q.s. to 10.0	mL			
Sodium Hydroxide 10% Solution §	As required		Š		
Hydrochloric Acid 10% Solution §	As required	C	XL		

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

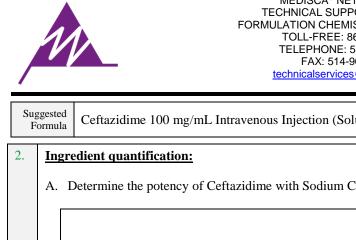
§ Weigh / measure just prior to use.

Preparatory Instruction

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

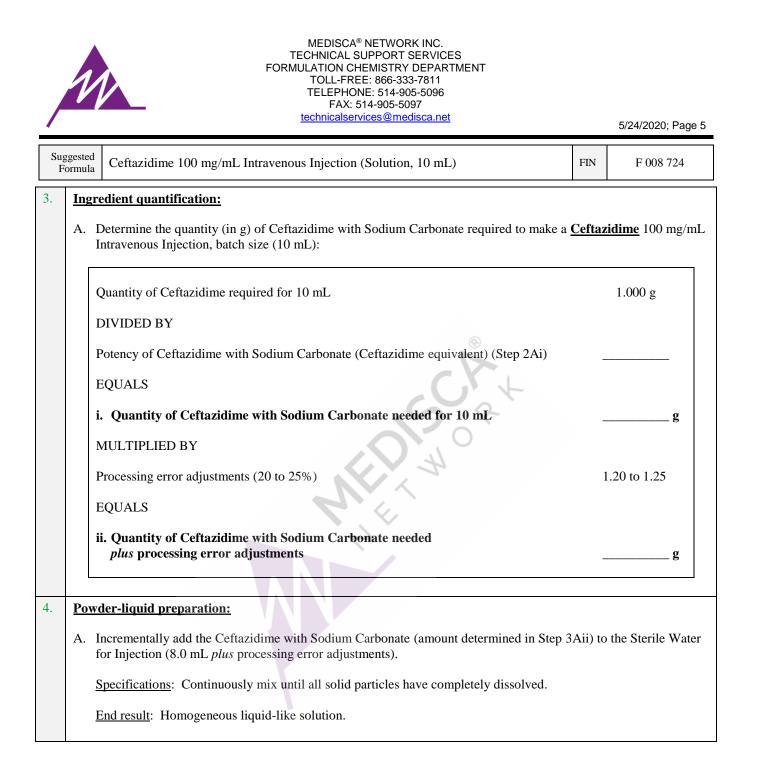
# 1. Equipment sterilization:

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



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2. <u>Ingr</u>	Ingredient quantification:						
A. I	Determine the potency of Ceftazidime with Sodium Carbonate based on the certificate of	analys	sis:				
			100%				
n	MINUS						
Ι	Loss on drying (from certificate of analysis)	_	%				
Ν	MINUS						
S	Sodium Carbonate concentration (from certificate of analysis)	-	%				
I	DIVIDED BY		100				
I	EQUALS						
	Quantity of dried and Sodium Carbonate free of Ceftazidime vith Sodium Carbonate, in decimal	-					
N	MULTIPLIED BY						
I	Assay on dried and Sodium Carbonate free basis result (from certificate of analysis)	-	%				
I	DIVIDED BY		100				
H	EQUALS						
i	. Potency of Ceftazidime with Sodium Carbonate (Ceftazidime equivalent), in decin	nal _					





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5.	pH testing:					
	A. Draw an appropriate amount of the mixture (Step 4A).					
	B. Test the pH of the sample. It should lie between 5.0 and 7.5.					
	C. <u>I</u>	f the pH < 5.0 carefully add, in a dropwise fashion, the Sodium Hydroxide 10% Solution	to the	mixture:		
	2 3	<ul> <li>Draw and transfer 1 or 2 drops of the Sodium Hydroxide 10% Solution to the mixture.</li> <li>Stir for at least 5 minutes to evenly disperse the Sodium Hydroxide 10% Solution.</li> <li>Re-test the pH.</li> <li>Continue to add the Sodium Hydroxide 10% Solution until the pH of 5.0 to 7.5 is obt</li> <li>IMPORTANT: Do not allow the pH to rise above 7.5.</li> </ul>				
	D. <u>I</u>	f the pH > 7.5, carefully add, in a dropwise fashion, the Hydrochloric Acid 10% Solution	to the	mixture:		
	2 3	<ul> <li>Draw and transfer 1 or 2 drops of the Hydrochloric Acid 10% Solution to the mixture.</li> <li>Stir for at least 5 minutes to evenly disperse the Hydrochloric Acid 10% Solution.</li> <li>Re-test the pH.</li> <li>Continue to add the Hydrochloric Acid 10% Solution until the pH of 5.0 to 7.5 is obtice.</li> </ul>				
		IMPORTANT: Do not allow the pH to fall below 5.0.				
6.	Filling to volume:					
	A. Add additional Sterile Water for Injection to the above mixture to fill to the required batch size (10.0 mL <i>plus</i> processing error adjustments).					
	Specifications: Continuously mix.					
	End result: Homogeneous liquid-like solution.					
7.	Filter	ing 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.					
8.	Filte	r integrity test:				
		ate filter integrity by performing a filter stress test. If the test demonstrates that the filter on must be discarded and remade.	might	be defective, the		



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	9.	Terminal Sterilization:						
		In relation to the chemical composition of the formulation, final packaging, etc., select and validate an end-stage sterilization method and follow the manufacturer's specification.						
	10.	Sterility a	and ]	Endotoxin testing:				
		Validate t	he T	est sample for sterility and endotoxins, in accor	dance	e to current USP 797 regula	atory g	uidelines.
SU	GGE	STED PRI	ESE	NTATION		œ		
	24 hours controlled room       temperature, 3 days       refrigerated or 45 days frozen				Sterile, light-resistant un	it-dose	injection vials.	
			1	Use as directed. Do not exceed prescribed dose.	7	Equilibrate to room temp	oeratur	e before use.
		Auxiliary Labels	2	Keep out of reach of children.	8	Preservative free solu Discard any unused por		single use only.
			3	Do not use if product changes color.	9	Consult your health of prescription or over-the currently being used or use.	-count	er medications are
			4	Discard in the presence of particulate matter.	10	Discard container after u	se.	
			5	Keep at controlled room temperature, $(20^{\circ}C - 25^{\circ}C)$ , refrigerated $(2^{\circ}C - 8^{\circ}C)$ or frozen $(-25^{\circ}C \text{ to } -10^{\circ}C)$ .	11	Hypertonic solution. In	nject sl	lowly.
			6	Protect from light.				
	F	Pharmacist Add any auxiliary labels specific to the API to the dispensing container as deemed necessary.						

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.



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### REFERENCES

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