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| Suggeste | ^d 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

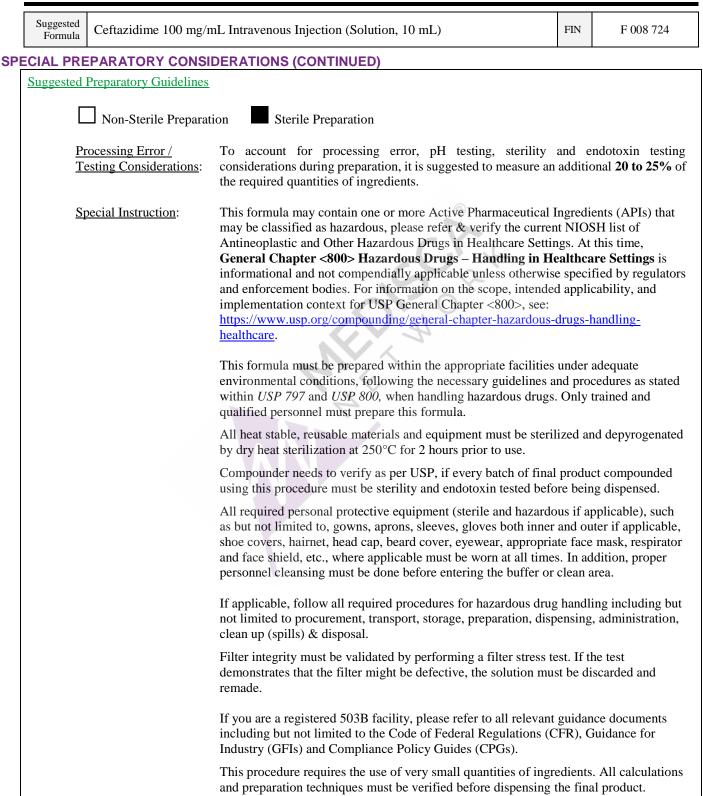
Ingredient-Specific Information

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 ^(*) : | 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.

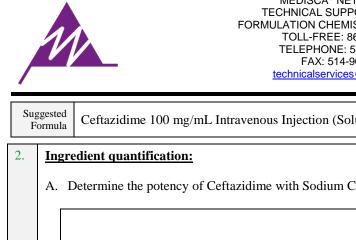
§ Weigh / measure just prior to use.

Preparatory Instruction

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

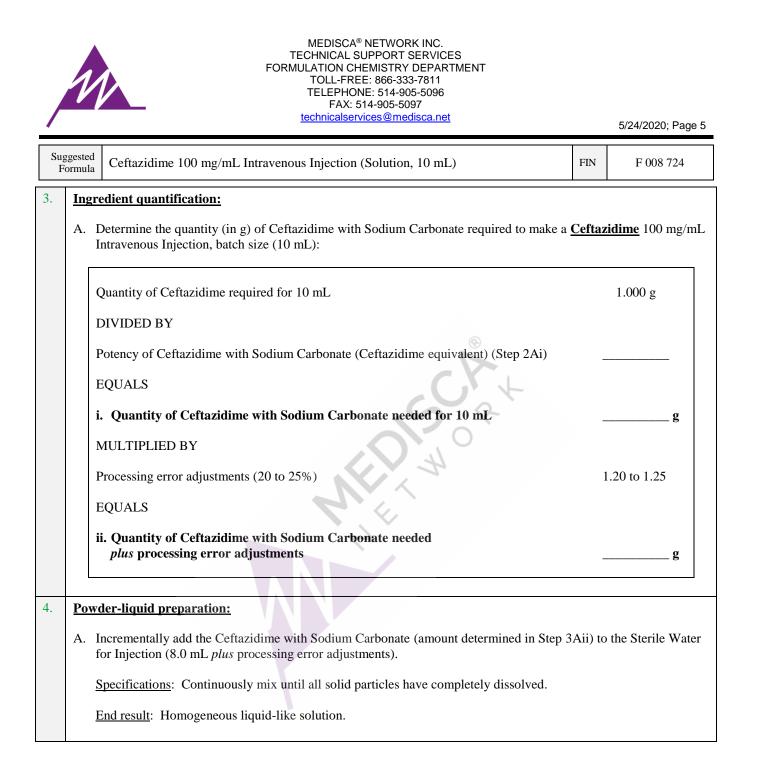
1. Equipment sterilization:

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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| Suggested Formula | | Ceftazidime 100 mg/mL Intravenous Injection (Solution, 10 mL) | FIN | F 008 724 | | |
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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 | Draw and transfer 1 or 2 drops of the Sodium Hydroxide 10% Solution to the mixture. Stir for at least 5 minutes to evenly disperse the Sodium Hydroxide 10% Solution. Re-test the pH. Continue to add the Sodium Hydroxide 10% Solution until the pH of 5.0 to 7.5 is obt IMPORTANT: Do not allow the pH to rise above 7.5. | | | | |
| | 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 | Draw and transfer 1 or 2 drops of the Hydrochloric Acid 10% Solution to the mixture. Stir for at least 5 minutes to evenly disperse the Hydrochloric Acid 10% Solution. Re-test the pH. Continue to add the Hydrochloric Acid 10% Solution until the pH of 5.0 to 7.5 is obtice. | | | | |
| | | 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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