Fetroja® – Preparation of Doses Using Sterile Water for Injection

SHIONOGI

This medical response contains information in addition to that provided in the Fetroja® (cefiderocol) for injection, for intravenous use Full Prescribing Information approved by the U.S. Food and Drug Administration (FDA). Shionogi does not recommend the use of Fetroja in any manner other than as described in the Full Prescribing Information. **Please read the attached Fetroja Full Prescribing Information**.

Summary

- A stability study was conducted by external investigators that used sterile water for injection to reconstitute the cefiderocol vials and was subsequently diluted in normal saline (NS)[1]
  - Data on the stability or potency of the reconstituted solution was not reported
  - Please see the EXTERNAL STUDY section
- Data evaluating the stability or potency of cefiderocol reconstituted solution when subsequently diluted with sterile water for injection is not available

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External Study

This stability study was conducted by external investigators

Shionogi does not recommend the reconstitution of cefiderocol with sterile water based on the findings

Fernández-Rubio et al (2023) performed stability studies of broad Gram-negative beta-lactams for use in outpatient parenteral antimicrobial therapy (OPAT) programs. The purpose of this study was to evaluate the physicochemical stability of 9 antipseudomonal antibiotics, including cefiderocol, in elastomeric pumps and infusion bags at 4 different temperatures[1]

Methods[1]

- Cefiderocol was reconstituted with sterile water for injection to 100 mg/mL
- The total daily dose of 6 grams was diluted in 500 mL of NS to obtain the final concentration of 12 mg/mL
- All tested drugs were stored in polyisoprene elastomeric devices supplied from Leventon, and in polypropylene infusion bags supplied from Chirana T. Injecta
- Elastomeric devices and infusion bags were stored at 4 different temperatures protected from light: refrigerated (4±2°C), 25±2°C, 32±2°C, and 37±2°C
  - Samples were collected from both preparations at different timepoints over 72 hours (h) (0, 12, 24, 30, 48, and 72 h)
- Chemical stability was defined by the retention of >90% of the initial antibiotic concentration
- Physical stability was defined by visual inspection for clearness, color change, precipitation, or a pH change of ≤1 unit

Results[1]



72 h

- At 4°C and 25°C: Cefiderocol was **stable for up to 72 h**



24 h

- At 32°C and 37°C: Cefiderocol was **stable for up to 24 h**

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Relevant Prescribing Information

Fetroja® is indicated in patients 18 years of age or older for the treatment of:[2]

- Complicated urinary tract infections (cUTIs), including pyelonephritis caused by the following susceptible Gram-negative microorganisms:
  - *Escherichia coli*
  - *Klebsiella pneumoniae*
  - *Proteus mirabilis*
  - *Pseudomonas aeruginosa*
  - *Enterobacter cloacae* complex
- Hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP), caused by the following susceptible Gram-negative microorganisms:
  - *Acinetobacter baumannii* complex
  - *Escherichia coli*
  - *Enterobacter cloacae* complex
  - *Klebsiella pneumoniae*
  - *Pseudomonas aeruginosa*
  - *Serratia marcescens*

Fetroja is contraindicated in:[2]

- Patients with a known history of severe hypersensitivity to cefiderocol or other beta-lactam antibacterial drugs, or any other component of **Fetroja**

As stated in **Section 2.3 Preparation of Fetroja Solution for Administration** of the **Fetroja Full Prescribing Information**:[2]

- Reconstitute the powder for injection in the FETROJA vial with 10 mL of either 0.9% sodium chloride injection, USP or 5% dextrose injection, USP and gently shake to dissolve. Add the withdrawn volume to a 100 mL infusion bag containing 0.9% sodium chloride injection, USP or 5% dextrose injection, USP

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Literature Search

Oct 2025

As of October 2025, a computerized search of the published medical literature using internal and external databases (ie, Medline® and Embase®) has failed to identify any relevant references regarding the reconstitution of cefiderocol with sterile water for injection.

Please keep in mind that medical literature databases, while considered a major source of biomedical information, are selective in their sources, and the information derived from them should not be considered all-inclusive.

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Abbreviations

cUTIs	complicated urinary tract infections	NS	normal saline
FDA	US Food and Drug Administration	OPAT	outpatient parenteral antimicrobial therapy
h	hours	USP	United States Pharmacopeia
HABP	hospital-acquired bacterial pneumonia	VABP	ventilator-associated bacterial pneumonia

References

1. Fernández-Rubio B, Herrera-Hidalgo L, de Alarcón A, et al. Stability studies of antipseudomonal beta lactam agents for outpatient therapy. *Pharmaceutics*. 2023;15(12):2705. [Web Link]
2. Fetroja® (cefiderocol) for injection, for intravenous use [Prescribing Information]. Shionogi Inc.

Enclosure

Fetroja® (cefiderocol) for injection, for intravenous use [Prescribing Information]. Shionogi Inc.