Fetroja® – Compatibility with MINI-BAG Plus and VIAL-MATE Adaptors

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 | Clinical Studies | Compatibility Study | Relevant Prescribing Information | Literature Search | Abbreviations & References

Summary

- MINI-BAG Plus and VIAL-MATE Adaptors were not used during the administration of cefiderocol in the clinical development program. There is no clinical data to describe the use of these systems with cefiderocol in patients
- **Rathod D et al** evaluated the physical compatibility of the commercially available Baxter MINI-BAG Plus Container System and the Baxter VIAL-MATE Adaptor with cefiderocol vials[1]
  - The results showed that cefiderocol vials were compatible with both the MINI-BAG Plus Container System and the VIAL-MATE Adaptor
  - It was noted that some force was needed to attach the VIAL-MATE Adaptor to the cefiderocol vial
- The in-use stability data for the diluted cefiderocol infusion solution supports a concentration of 7.5 mg/mL up to 20 mg/mL[2]

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Clinical Studies

MINI-BAG Plus and VIAL-MATE Adaptors were not used during the administration of cefiderocol in the clinical development program.

There are no clinical data to describe the use of these systems with cefiderocol in patients.

The in-use stability data for the diluted cefiderocol infusion solution supports a concentration of 7.5 mg/mL up to 20 mg/mL.[2]

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Compatibility Study

Methods

MINI-BAG Plus Container System

- The physical compatibility of the commercially available Baxter MINI-BAG Plus Container System and the Baxter VIAL-MATE Adaptor with cefiderocol vials was tested at room temperature using predefined criteria (Table 1)[1]
- The compatibility of the MINI-BAG Plus Container System was tested with both cefiderocol vials that contained lyophilized cefiderocol and vials that were empty[1]
- Both 50 mL and 100 mL MINI-BAGS of 0.9% sodium chloride and 5% dextrose were tested in triplicate for qualitative physical compatibility and were connected based on the manufacturer's instructions[1]
- The connected cefiderocol vials and the MINI-BAGS were observed for 3 h for particulate matter, precipitation or discoloration[1]
  - Additionally, leaks from the connections were checked

VIAL-MATE Adaptor

- The physical compatibility of VIAL-MATE Adaptors was tested in triplicate with only empty cefiderocol vials at room temperature. A secure connection was tested via an audible click[1]

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Compatibility Study

Results

- The results demonstrated that the cefiderocol vial is compatible with both the MINI-BAG Plus Container System and the VIAL-MATE Adaptor. All results for both device systems met the predefined acceptance criteria and are summarized in **Table 1**[1]

MINI-BAG Plus Container System

- Cefiderocol was successfully reconstituted in 5% dextrose and 0.9% sodium chloride with both 50 mL and 100 mL MINI-BAGs[1]
- All reconstituted cefiderocol was transferred into the MINI-BAGS without backward leaks and no leaking from the connections detected over a 3 h observation period[1]
- No particulate matter, discoloration, or precipitation was detected[1]

VIAL-MATE Adaptor

- A secure connection between the empty cefiderocol vial and the VIAL-MATE Adaptor was demonstrated[1]
- It was also noted that some, but not excessive, force was needed to attach the VIAL-MATE Adaptor to the cefiderocol vial[1]

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Compatibility Study

Table 1. Predefined Physical Compatibility Criteria for Cefiderocol Vials with the MINI-BAG Plus Container System and the VIAL-MATE Adaptor[1]

Criteria	MINI-BAG Plus Container System[a]	VIAL-MATE Adaptor[b]
A secure connection is made between the system/adaptor and the cefiderocol vial	Yes	Yes
Successful multiple transfers of solution from the MINI-BAG into the cefiderocol vial are completed	Yes	Not applicable
Successful multiple transfers of solution from the cefiderocol vial back into the MINI-BAG are completed	Yes	Not applicable
No leaks are observed at the connection to the cefiderocol vial (observed over 3 h)	Yes	Not applicable
Cefiderocol vial remains empty (observed over 3 h)	Yes	Not applicable
No visible particulate matter, precipitation or discoloration was observed	Yes	Not applicable

[a]Conducted using empty vials and vials containing lyophilized cefiderocol; assessed in triplicate for each of 50 mL and 100 mL MINI-BAGS of 5% dextrose injection and 0.9% sodium chloride injection.
[b]Conducted using empty vials only; assessed in triplicate.

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Relevant Prescribing Information

Fetroja® is indicated in patients 18 years of age or older for the treatment of[3]:

- 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 patients with a known history of severe hypersensitivity to cefiderocol or other beta-lactam antibacterial drugs, or any other component of Fetroja.[3]

As stated in **Section 16.2 Storage and Handling** of the Fetroja **Full Prescribing Information**:

> Fetroja vials should be stored refrigerated at 2°C to 8°C (36°F to 46°F). Protect from light. Store in the carton until time of use.[3]

Please read the attached Fetroja **Full Prescribing Information**.

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Literature Search

As of December 2025, a computerized search of the published medical literature using internal and external databases (ie, Medline® and Embase®) has failed to identify relevant references regarding the compatibility of cefiderocol with MINI-BAG Plus and/or VIAL-MATE Adaptors. 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 it should not be considered all-inclusive.

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Abbreviations

cUTI	complicated urinary tract infection
FDA	Food and Drug Administration
h	hours
VABP	ventilator-associated bacterial pneumonia

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References

1. Rathod D, Chen Z, Slover CM, et al. Cefiderocol for injection: compatibility testing using the MINI-BAG Plus Container System and the VIAL-MATE Adaptor. *J Pharm Technol.* 2023;39(4):159-163. doi:10.1177/87551225231179585
2. Data on File 78. Shionogi Inc.
3. Fetroja® (cefiderocol) for injection, for intravenous use [Prescribing Information]. Shionogi Inc.

ENCLOSURE

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