Fetroja® – Y-Site Compatibility

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Summary

- **Lu et al (2021)** evaluated the physical compatibility of cefiderocol (prepared as a 2% cefiderocol solution) with 91 injectable drug products in a simulated Y-site co-administration[1,2]
  - The diluents used included Sterile Water for Injection USP (SWFI), 0.9% Sodium Chloride Injection USP (NS), or 5% Dextrose Injection USP (D5W)
  - Compatibility was established by visual observations, turbidity, and particle matter measurements

- The 2% cefiderocol solution was found to be physically compatible with 63 of the 91 drugs tested in both NS and D5W for at least 4 hours[1,2]
  - Of the NS admixtures, cefiderocol was physically compatible with all but 22 tested drug products
  - Of the D5W admixtures, cefiderocol was physically compatible with all but 23 tested drug products

- Please find the compatibility results for all tested drug products in the **Appendix (Table 1)** and the summary results for incompatible mixtures in the **Appendix (Table 2)**

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Y-Site Compatibility Study

Lu et al (2021) evaluated the physical compatibility of cefiderocol (prepared as a 2% cefiderocol solution) with 91 injectable drug products in a simulated Y-site co-administration[1,2]

Methods

- The co-administered drug products were tested undiluted or prepared and diluted to the target concentration for testing
- The diluents used included SWFI, 0.9% NS, or 5% D5W
- Reconstituted cefiderocol was further diluted in NS or D5W to the test concentration of 2% cefiderocol
  - The diluted cefiderocol was combined with a test drug product at a 1:1 volume ratio. Each mixture was prepared twice, reversing the order of addition between the 2 samples
- The physical compatibility of the mixtures was based on visual observation, turbidity, and particulate matter and measured immediately after mixing, and then at 1 and 4 h after at room temperature

Results

- Of the NS admixtures, cefiderocol was physically compatible with all but 22 tested drug products
- A total of 19/22 drugs were found to cause significant cloudiness immediately upon mixing with the diluted solution of cefiderocol in NS
  - In addition to the 22 drug products that were incompatible with cefiderocol, amikacin sulfate and polymyxin B sulfate compatibility data were inconclusive
- Of the D5W admixtures, cefiderocol was physically compatible with all but 23 tested drug products
  - A total of 19/23 drug products showed clear signs of incompatibility through visual inspection when mixed with the diluted solution of cefiderocol in D5W
- Please find the compatibility results for all tested drug products in the **Appendix (Table 1)** and the summary results for incompatible mixtures in the **Appendix (Table 2)**

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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*, and *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, *E coli*, *Enterobacter cloacae* complex, *K pneumoniae*, *P aeruginosa*, and *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 2.4 Drug Compatibility** of the Full **Fetroja Prescribing Information**[3]:

> Fetroja solution for administration is compatible with:
>
> - 0.9% sodium chloride injection, USP
> - 5% dextrose injection, USP
>
> The compatibility of Fetroja solution for administration with solutions containing other drugs or other diluents has not been established.

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

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Literature Search

As of May 2026, 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 drug compatibility with cefiderocol. 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

C/C	clear/colorless
cUTI	complicated urinary tract infection
D5W	5% dextrose injection USP
FDA	Food and Drug Administration
HABP	hospital-acquired bacterial pneumonia
NS	normal saline or 0.9% sodium chloride injection USP
NT	not tested
NTU	nephelometric turbidity units
SWFI	sterile water for injection USP
T0	sampling time at 0 hours post mixing
T1	sampling time at 1 hour post mixing
T4	sampling time at 4 hours post mixing
USP	United States Pharmacopeia
VABP	ventilator-associated bacterial pneumonia

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References

1. Lu J, Liu Q, Kupiec TC, et al. Physical compatibility of cefiderocol with selected intravenous drugs during simulated Y-site administration. *Int J Pharm Compd*. 2021;25(1):52-61.
2. Lu J, Liu Q, Kupiec TC, et al. Physical compatibility of cefiderocol with selected intravenous drugs during simulated Y-site administration. Erratum in: *Int J Pharm Compd*. 2021;25(1):52-61.
3. Fetroja® (cefiderocol) for injection, for intravenous use [Prescribing Information]. Shionogi Inc.

ENCLOSURE

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

Fetroja® – Y-Site Compatibility

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Summary | Y-Site Compatibility Study | Relevant Prescribing Information | Literature Search, Abbreviations, & References | Appendix
Appendix Table 1 | Appendix Table 2

Appendix

Appendix Table 1. Cefiderocol Y-Site Compatibility Report[2]

Drug Product[a]	Test Concentration	Cefiderocol 2% (Normal saline)	Cefiderocol 2% (D5W)
Acyclovir sodium	7 mg/mL	Not compatible	Not compatible
Albumin	250 mg/mL	Not compatible	Not compatible
Amikacin sulfate	5 mg/mL	Inconclusive	Compatible
Aminophylline	1 mg/mL	Not compatible	Compatible
Amiodarone hydrochloride	4 mg/mL	Not compatible	Not compatible
Amphotericin B	1 mg/mL	Not compatible	Not compatible
Anidulafungin	0.77 mg/mL	Compatible	Compatible
Azithromycin	2 mg/mL	Compatible	Compatible
Aztreonam	20 mg/mL	Compatible	Compatible
Bumetanide	0.25 mg/mL	Compatible	Compatible
Calcium gluconate	20 mg/mL	Compatible	Compatible
Caspofungin acetate	0.5 mg/mL	Not compatible	Not compatible
Cefazolin	20 mg/mL	Compatible	Compatible
Cefepime hydrochloride	40 mg/mL	Compatible	Compatible
Ceftaroline fosamil	12 mg/mL	Compatible	Compatible
Ceftazidime-Avibactam sodium	40 mg/mL	Compatible	Compatible
Ceftolozane sulfate-Tazobactam sodium	15 mg/mL	Compatible	Compatible
Ciprofloxacin	2 mg/mL	Compatible	Not compatible
Cisatracurium besylate	0.4 mg/mL	Compatible	Compatible
Clindamycin phosphate	10 mg/mL	Compatible	Compatible
Colistimethate sodium	4.5 mg/mL	Compatible	Compatible
Daptomycin	20 mg/mL	Compatible	Compatible
Dexamethasone sodium phosphate	1 mg/mL	Compatible	Compatible
Dexmedetomidine hydrochloride	0.004 mg/mL	Compatible	Compatible
Digoxin	0.25 mg/mL	Compatible	Compatible
Diltiazem hydrochloride	5 mg/mL	Compatible	Compatible
Diphenhydramine hydrochloride	50 mg/mL	Not compatible	Not compatible
Dobutamine hydrochloride	4 mg/mL	Not compatible	Not compatible
Doxycycline	1 mg/mL	Not compatible	Not compatible
Epinephrine	0.016 mg/mL	Compatible	Compatible
Ertapenem sodium	20 mg/mL	Compatible	Compatible
Esomeprazole sodium	0.8 mg/mL	Not compatible	Not compatible

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Appendix (Cont'd)

Appendix Table 1. Cefiderocol Y-Site Compatibility Report[2]

Drug Product[a]	Test Concentration	Cefiderocol 2% (Normal saline)	Cefiderocol 2% (D5W)
Famotidine	4 mg/mL	Not compatible	Not compatible
Fentanyl citrate	0.05 mg/mL	Compatible	Compatible
Fluconazole (in NS)[b]	2 mg/mL	Compatible	Compatible
Furosemide	3 mg/mL	Compatible	Compatible
Gentamicin sulfate	5 mg/mL	Compatible	Compatible
Heparin sodium	1000 U/mL	Compatible	Compatible
Hydrocortisone sodium succinate	1 mg/mL	Compatible	Compatible
Hydromorphone hydrochloride	1 mg/mL	Compatible	Compatible
Imipenem-cilastatin sodium	10 mg/mL	Compatible	Compatible
Insulin human regular	1 U/mL	Compatible	Compatible
Iron Dextran	25 mg/mL	Compatible	Compatible
Iron Sucrose	20 mg/mL	Not compatible	Not compatible
Labetalol hydrochloride	5 mg/mL	Not compatible	Not compatible
Levofloxacin	5 mg/mL	Compatible	Compatible
Lidocaine hydrochloride	8 mg/mL	Compatible	Compatible
Linezolid	2 mg/mL	Compatible	Compatible
Lorazepam	1 mg/mL	Not compatible	Not compatible
Magnesium sulfate	100 mg/mL	Compatible	Compatible
Mannitol	20%	Compatible	Compatible
Meropenem	10 mg/mL	Compatible	Compatible
Meropenem-Vaborbactam	8 mg/mL	Compatible	Compatible
Methylprednisolone acetate	20 mg/mL	Not compatible	Not compatible
Metoclopramide hydrochloride	0.2 mg/mL	Compatible	Compatible
Metronidazole	5 mg/mL	Compatible	Compatible
Micafungin sodium	4 mg/mL	Compatible	Compatible
Milrinone lactate	0.2 mg/mL	Compatible	Compatible
Midazolam hydrochloride	2 mg/mL	Compatible	Compatible
Morphine sulfate	15 mg/mL	Compatible	Inconclusive
Mycophenolate mofetil	6 mg/mL	Not compatible	Not compatible
Naloxone hydrochloride	0.04 mg/mL	Compatible	Compatible
Nicardipine hydrochloride	0.1 mg/mL	Compatible	Compatible
Nitroglycerin	0.4 mg/mL	Compatible	Compatible

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Summary | Y-Site Compatibility Study | Relevant Prescribing Information | Literature Search, Abbreviations, & References | Appendix
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Appendix (Cont'd)

Appendix Table 1. Cefiderocol Y-Site Compatibility Report[2]

Drug Product[a]	Test Concentration	Cefiderocol 2% (Normal saline)	Cefiderocol 2% (D5W)
Multivitamins	0.02 mL/mL	Compatible	Compatible
Norepinephrine bitartrate	0.128 mg/mL	Compatible	Compatible
Octreotide acetate	0.004 mg/mL	Compatible	Compatible
Ondansetron	0.16 mg/mL	Compatible	Compatible
Pantoprazole sodium	0.4 mg/mL	Compatible	Compatible
Phenytoin sodium	10 mg/mL	Not compatible	Not compatible
Phenylephrine hydrochloride	1 mg/mL	Compatible	Inconclusive
Polymyxin B sulfate (in D5W)[c]	1250 U/mL	Inconclusive	Not compatible
Posaconazole	2 mg/mL	Not compatible	Not compatible
Propofol	10 mg/mL	Not compatible	Not compatible
Potassium chloride	0.1 mg/mL	Compatible	Compatible
Potassium phosphate	0.3 mmol/mL	Compatible	Compatible
Ranitidine hydrochloride	2.5 mg/mL	Compatible	Compatible
Rocuronium bromide	5 mg/mL	Not compatible	Not compatible
Sodium bicarbonate	1 mEq/mL	Compatible	Inconclusive
Sodium phosphate	0.5 mmol/mL	Compatible	Compatible
Succinylcholine chloride	2 mg/mL	Compatible	Compatible
Sulfamethoxazole–Trimethoprim	5 mg/mL	Compatible	Compatible
Tedizolid phosphate	0.8 mg/mL	Compatible	Compatible
Tigecycline	1 mg/mL	Compatible	Compatible
Tobramycin sulfate	10 mg/mL	Not compatible	Not compatible
Total Parenteral Nutrition Electrolytes	6.2 mOsmol/mL	Compatible	Compatible
Vancomycin hydrochloride	5 mg/mL	Not compatible	Not compatible
Vasopressin	1 U/mL	Compatible	Compatible
Vecuronium bromide[c]	1 mg/mL	Compatible	Compatible
Voriconazole	2 mg/mL	Compatible	Compatible

[a]Unless otherwise specified, the challenge drugs were reconstituted according to their package inserts, and then diluted to the test concentrations in NS or D5W for mixing with 2% Cefiderocol in the same final diluent used to dilute the challenge drugs.
[b]Fluconazole was diluted in NS to test concentration for preparation of both NS- and D5W-mixtures.
[c]Polymyxin B sulfate was diluted in D5W to the test concentration for preparation of both NS- and D5W-mixtures.

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Appendix Table 2. Summary Results for Incompatible Mixtures of Diluted Cefiderocol and Challenge Drugs in NS and D5W Diluents[2]

Challenge Drug	Diluent[a]	Evaluation Parameters			
		Visual	Tyndall	Turbidity	Particulate Matter
Acyclovir sodium	NS	Colorless w/large white particles	Colorless w/large white particles	NT	NT
	D5W	Colorless w/large white particles	Colorless w/large white particles	NT	NT
Albumin	NS	Clear, slightly yellow	Hazy, slightly yellow	Increased ~ 8 NTU (T0, T1, T4)	Prep B: high particles ≥ 10 & 25 µm
	D5W	Clear yellow	Hazy, yellow	Increased ~ 6 NTU (T0, T1, T4)	Within limits
Amikacin sulfate	NS	C/C	C/C	No significant change	Prep B: high particles ≥ 2 & 10 µm
	D5W	C/C	C/C	No significant change	Within limits
Aminophylline	NS	C/C	C/C	No significant change	High particles ≥ 2 & 10 µm
	D5W	C/C	C/C	No significant change	Within limits
Amiodarone hydrochloride	NS	Foamy & hazy	Foamy, cloudy white particles	NT	NT
	D5W	Foamy, hazy w/white particles	Foamy, hazy w/white particles	NT	NT
Amphotericin B	NS	Foamy, yellow w/white particles	Foamy, yellow w/white particles	NT	NT
	D5W	Foamy, hazy yellow	Foamy, hazy yellow w/white particles	NT	NT
Caspofungin acetate	NS	Cloudy white	Cloudy, very pale yellow w/white particles	NT	NT
	D5W	Cloudy w/white particles	Cloudy, very pale yellow w/white particles	NT	NT
Ciprofloxacin	NS	C/C	C/C	No significant change	Within limits
	D5W	C/C	C/C- slight haze	Increased > 0.5 NTU (T4)	NT
Diphenhydramine hydrochloride	NS	Cloudy w/white precipitants	Pale yellow w/white precipitants	NT	NT
	D5W	Cloudy w/white precipitants	Pale yellow w/white precipitants	NT	NT
Dobutamine hydrochloride	NS	Cloudy w/white particles	Cloudy w/white particles	NT	NT
	D5W	Cloudy w/white particles	Cloudy w/white particles	NT	NT
Doxycycline	NS	Cloudy white	Foamy, cloudy w/fine white particles	NT	NT
	D5W	Cloudy white	Foamy, cloudy w/fine white particles	NT	NT

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Appendix (Cont'd)

Appendix Table 2. Summary Results for Incompatible Mixtures of Diluted Cefiderocol and Challenge Drugs in NS and D5W Diluents[2]

Challenge Drug	Diluent[a]	Evaluation Parameters			
		Visual	Tyndall	Turbidity	Particulate Matter
Esomeprazole sodium	NS	C/C-brown w/fine white precipitants	C/C - brown w/fine white precipitants	NT	NT
	D5W	Light brown-hazy brown	Cloudy brown	NT	NT
Famotidine	NS	Slightly cloudy	Cloudy white particles	NT	NT
	D5W	Slightly cloudy white	Slightly cloudy-cloudy	NT	NT
Iron sucrose	NS	Opaque, dark red	Opaque, dark red	Increased ~ 3-36 NTU (T4)	NT
	D5W	Opaque, reddish brown	Opaque, reddish brown	Increased ~ 1-13 NTU (T0, T1)	NT
Labetalol hydrochloride	NS	Cloudy white	Cloudy w/large white particles	NT	NT
	D5W	Cloudy w/white particles	Cloudy w/large white particles	NT	NT
Lorazepam	NS	C/C	Lightly hazy w/white particles	NT	NT
	D5W	C/C	Lightly haze-hazy w/white particles	Increased ~ 1-3 NTU (T0, T1,T4)	High particles ≥ 2 µm
Methylprednisolone acetate	NS	Hazy	Hazy-cloudy w/white particles	NT	NT
	D5W	Slight haze-hazy	Slightly hazy-hazy w/white particles	NT	NT
Morphine sulfate	NS	C/C	C/C	No significant change	Within limits
	D5W	C/C	C/C	No significant change	Prep B: high particles ≥ 25 & 50 µm
Mycophenolate mofetil	NS	Foamy w/cloudy white particles	Foamy, cloudy w/fine white particles	NT	NT
	D5W	Foamy w/cloudy white particles	Foamy, cloudy w/fine white particles	NT	NT
Phenylephrine hydrochloride	NS	C/C	C/C	No significant change	Within limits
	D5W	C/C	C/C	No significant change	Prep A: high particles ≥ 2, 10, 25 & 50 µm
Phenytoin sodium	NS	Cloudy, yellow w/white precipitants	Yellow w/white precipitants	NT	NT
	D5W	Yellowish w/white precipitants	Light yellow w/white precipitants	NT	NT
Polymyxin B sulfate (D5W)[b]	NS	C/C	C/C w/slight haze & air bubbles	No significant change	Within limits
	D5W	C/C	C/C w/bubbles	Increased > 0.5 NTU (T4)	NT

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Appendix Table 2. Summary Results for Incompatible Mixtures of Diluted Cefiderocol and Challenge Drugs in NS and D5W Diluents[2]

Challenge Drug	Diluent[a]	Evaluation Parameters			
		Visual	Tyndall	Turbidity	Particulate Matter
Posaconazole	NS	Cloudy white	Cloudy w/white particles	NT	NT
	D5W	Cloudy w/white particles	Cloudy w/white particles	NT	NT
Propofol	NS	Opaque white	Opaque white	NT	NT
	D5W	Opaque white	Opaque white	NT	NT
Rocuronium bromide	NS	Cloudy, pale yellow w/white particles	Slightly yellow w/white particles	NT	NT
	D5W	Cloudy white particles	Cloudy w/white precipitants	NT	NT
Sodium bicarbonate	NS	C/C	C/C	No significant change	Within limits
	D5W	C/C	C/C	No significant change	Prep A: high particles ≥ 25 µm
Tobramycin sulfate	NS	C/C	Colorless w/white particles	NT	NT
	D5W	C/C	Colorless w/white particles	NT	NT
Vancomycin hydrochloride	NS	C/C	Cloudy w/white particles	NT	NT
	D5W	Cloudy w/white particles	Cloudy w/white particles	NT	NT

Abbreviations: C/C, clear/colorless, D5W, 5% dextrose injection USP; NS, normal saline or 0.9% sodium chloride injection USP; NT, not tested; NTU, nephelometric turbidity unit; T0, sampling time at 0 hours post mixing; T1, sampling time at 1 hour post mixing; T4, sampling time at 4 hours post mixing.

[a]Unless otherwise specified, the challenge drugs were reconstituted according to their package inserts, and then diluted to the test concentrations in NS or D5W for mixing with 2% cefiderocol in the same final diluent used to dilute the challenge drugs.

[b]Polymyxin B sulfate was diluted in D5W to the test concentration for preparation of both NS and D5W admixtures.