VELETRI® (epoprostenol)
Stability of VELETRI

SUMMARY

- The stability and preservation of reconstituted and fully diluted solutions of VELETRI for injection was evaluated under a range of storage conditions and is summarized below.[1]
- No information is available regarding the stability of VELETRI for injection when placed in a pneumatic tube or shaken.

CLINICAL DATA

The stability and preservation of reconstituted and fully diluted solutions of VELETRI for injection was evaluated under a range of storage conditions.[1] Reconstituted VELETRI for injection was stable up to one day when stored at 77°F (25°C) or 7 days when stored at 41°F (5°C). Depending on the concentration and conditions studied, the authors describe the following results summarized in Table: Stability of Reconstituted and Fully Diluted VELETRI for Injection Solutions, Expressed in Terms of Potency (Relative to Initial Potency at Time Zero), When Exposed to Temperatures Between 77°F (25°C) and 104°F (40°C), Table: Stability of Diluted Solutions of VELETRI for Injection Stored for 24 or 48 Hours at 77°F (25°C) or 86°F (30°C), After Reconstitution and Storage at 41°F (5°C) for 8 Days, Table: Shelf-lives and Storage Conditions for VELETRI for Injection for Clinical Administration After Several Days of Storage of the Reconstituted Solution, and Table: Shelf-lives and Storage Conditions for VELETRI for Injection for Clinical Administration After Several Days of Storage of the Diluted Solution below.[1]

Stability of Reconstituted and Fully Diluted VELETRI for Injection Solutions, Expressed in Terms of Potency (Relative to Initial Potency at Time Zero), When Exposed to Temperatures Between 77°F (25°C) and 104°F (40°C)[1]

Concentration	Time Exposed	Temperature	Potency
3000 ng/mL	48 hours	77°F (25°C)	>90%
	24 hours	86°F (30°C)	>90%
	8 hours	104°F (40°C)	>90%
15,000 ng/mL	72 hours	77°F (25°C)	>90%
	24 hours	86°F (30°C)	>90%
	12 hours	104°F (40°C)	>90%
60,000 ng/mL	72 hours	77°F (25°C)	>90%
	48 hours	86°F (30°C)	>90%
	24 hours	104°F (40°C)	>90%

Stability of Diluted Solutions of VELETRI for Injection Stored for 24 or 48 Hours at 77°F (25°C) or 86°F (30°C), After Reconstitution and Storage at 41°F (5°C) for 8 Days[1]

Concentration	Time Exposed at 77°F (25°C) or 86°F (30°C)	Potency
3000 ng/mL	24 hours	>90%
15,000 ng/mL	24 hours	>92%
60,000 ng/mL	24 hours	>95%
	48 hours	>93%

Shelf-lives and Storage Conditions for VELETRI for Injection for Clinical Administration After Several Days of Storage of the Reconstituted Solution[1]

Concentration	Condition of Storage of Reconstituted Solution	Maximum Shelf-life of Diluted Solution
≥ 3000 ng/mL and < 15,000 ng/mL	7 days at 41°F (5°C) OR 1 day at 77°F (25°C)	24 hours at 77°F (25°C)[a]
		12 hours at 86°F (30°C)[a]
		8 hours at 104°F (40°C)
≥ 15,000 ng/mL and < 60,000 ng/mL	7 days at 41°F (5°C) OR 1 day at 77°F (25°C)	48 hours at 77°F (25°C)[a]
		24 hours at 86°F (30°C)[a]
		8 hours at 104°F (40°C)
≥ 60,000 ng/mL	7 days at 41°F (5°C) OR 1 day at 77°F (25°C)	72 hours at 77°F (25°C)[a]
		48 hours at 86°F (30°C)[a]
		24 hours at 104°F (40°C)
[a]Each recommendation includes a short excursion at 40°C for up to 2 hours for concentration below 15,000 ng/mL, up to 4 hours for a concentration between 15,000 ng/mL and 60,000 ng/mL and up to 8 hours for concentration above 60,000 ng/mL.		

Shelf-lives and Storage Conditions for VELETRI for Injection for Clinical Administration After Several Days of Storage of the Diluted Solution[1]

Concentration	Condition of Storage of Diluted Solution	Maximum Shelf-life of Diluted Solution
≥ 3000 ng/mL and < 15,000 ng/mL	≤ 8 days at 41°F (5°C)	24 hours at 77°F (25°C)[a]
		24 hours at 86°F (30°C)[a]
≥ 15,000 ng/mL and < 60,000 ng/mL	≤ 8 days at 41°F (5°C)	48 hours at 77°F (25°C)[a]
		24 hours at 86°F (30°C)[a]
≥ 60,000 ng/mL	≤ 8 days at 41°F (5°C)	48 hours at 77°F (25°C)[a]
		48 hours at 86°F (30°C)[a]
[a]Each recommendation includes a short excursion at 40°C for up to 2 hours for concentration below 15,000 ng/mL, up to 4 hours for a concentration between 15,000 ng/mL and 60,000 ng/mL and up to 8 hours for concentration above 60,000 ng/mL.		

LITERATURE SEARCH

A literature search of MEDLINE®, EMBASE®, BIOSIS Previews®, Derwent® (and/or other resources, including internal/external databases) was conducted on 4 March 2024.

REFERENCES

1. Lambert O, Bandilla D. Stability and preservation of a new formulation of epoprostenol sodium for treatment of pulmonary arterial hypertension. *Drug Des Devel Ther*. 2012;6:235-244.