

ONCOERA® SF401 CLOSED MALE LUER CONNECTOR

GRAVITY FLOW TEST

CLINICAL STUDY

MAY, 2023



ONCOERA® SAFE SF401

ONCOERA® SAFE Needle-Free Syringe Adapters are connectors used for the safe preparation and transport of hazardous drugs. Syringe Adapters creates a closed system between syringe and vial adapters, as well as infusion sets and needle-free connectors. In this way, it reduces the risk of exposure to hazardous drugs and protects the drug from microbiological contamination.

- Supports closed system.
- Protects compounded drug, personnel, and compounding environment.
- Reduces surface contamination and prevents leakage.
- Quickly and easily connects to a needle-free vein valve.
- Prevents needle stick accidents.
- Provides safe preparation, handling and administration.
- Compatible with all standard luer connectors.
- Chemical compatibility has been proven.
- Suitable for use with IV administration sets.
- Provides high flow rate.



Acceptance Criteria: Gravity flow rates above 1000 mL in 10 minutes are accepted. Flow rates that do not reach 1000 mL in 10 minutes are rejected.

METHOD

An 80 cm extension line with spike is connected to the end of the product with a needle-free connector. The spike tip is immersed in the infusion bag containing 500 ml of water (Density=1). By opening the clamp of the extension line, liquid is passed through the set and the male luer connector (Priming). The clamp is closed. The tared container is placed on the precision scale. By opening the clamp of the set, the liquid passing through the closed male luer connector in free flow is collected in the container on the precision scale. The flow rate in 1 minute is calculated with the formula weight of the liquid in the container = mL (density=1).

CONCLUSION

In the gravity flow test performed, ONCOERA® SAFE SF401 Closed Male Luer Connectors met the acceptance criteria with an average flow rate of 160.2 mL/min.

GRAVITY FLOW TEST				
Sample No	Density (g/mL)	Gravity Flow (g/min)	Gravity Flow (mL/min)	Accepted
1	1	160,0	160,0	✓
2	1	157,9	157,9	✓
3	1	159,0	159,0	✓
4	1	161,0	161,0	✓
5	1	157,0	157,0	✓
6	1	166,5	166,5	✓



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