ONCOERA SF 401 CLOSED MALE LUER CONNECTOR

DRUG AND LIPID COMPATIBILITY

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The Importance of Drug Compatibility

Antineoplastic drugs are toxic. Therefore, a number of devices have become available to enhance healthcare staff safety in handling such drugs. These devices not only need to minimize hazardous drugs exposure, but also must maintain their integrity and functionality when exposed to such drugs in a clinical environment. However, it is well known that some of these drugs are also incompatible with many polymers used to manufacture disposable medical devices for drug administration. Such incompatibility may lead to the degradation of the polymer material leading to crazes, cracks, breakages and ultimately to the dysfunction of the device. Another important aspect is that the incompatibility of the polymer may lead to a phenomena called Environmental Stress Cracking when subjected to stress. Such stresses are common and relevant phenomena in medical devices, especially when female-male luer connection is used. The following study will show that ONCOERA SF 401 Closed Male Luer Connector device is compatible to a selection of hazardous drugs that represent extreme scenarios.

Drug Selection

In this study, the device was exposed to a representative selection of hazardous drugs in accordance with NIOSH alert and American Cancer Society guidance. Drugs were selected according to the following consideration and rationale:

1. Cancer treatment drugs were divided into known family groups according to their operation mechanism: Anti-metabolites, Alkylating Agents, Anti-tumor antibiotics, Mitotic inhibitors, Topoisomerase inhibitors and Immunotherapy.
2. From each group a representative drug was selected according to: Frequency of use, Toxicity (hazardous to the medical staff), Ability to attack ONCOERA SF 401 flow path raw materials (Polysulfone, Polycarbonate)
3. Drug Selection Rational was reviewed and approved by the Director of Pharmacy to be in accordance with "NIOSH Alert" drugs list
4. Additional considerations such as molecular size, pH, organic/inorganic etc.

TESTED DRUGS	
Drug Name	**Group Family**
Cisplatin	Alkylating Agents
Cyclophosphamide	Alkylating Agents
Fluorouracil (5-FU)	Anti-metabolites
Doxorubicin (Adriamycin)	Anti-tumor antibiotics
Pactitaxel	Mitotic inhibitors
Etoposide (VP-16, Etopophos®, Vepesid®)	Topoisomerase Inhibitors
Bevacizumab (Avastin)	Immunotherapy
Intralipid 20% (A 20% I.V. Fat Emulsion)	

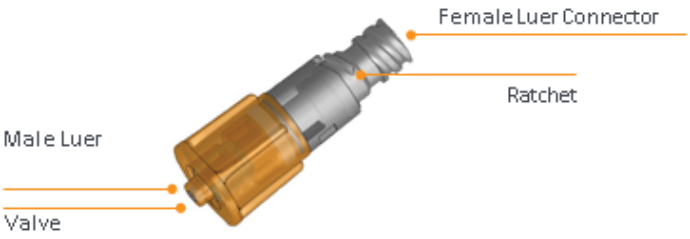
ONCOERA SF 401, a Closed Male Luer Connector, is designed to minimize dripping of liquids and drugs from a male Luer connector that is commonly used in hazardous drugs administration. The device is composed of a normally closed male luer valve from its proximal end that opens upon the connection of the male luer connector to a female luer connector and closes automatically upon disconnection of the two.

Method

Samples of ONCOERA SF 401 Closed Male Luer Connector were aged to simulate 5 years shelf life, according to Arrhenius equation Q10=2 method, sterilized and exposed to different worst case scenarios of shelf life simulations. Following to the shelf life simulation, the components were exposed to the above drugs for 24 and 96 hours according to actual use simulation protocol. Then the exposed components were tested for leakages according to ISO 594-27 standard and for flow rate passing through the parts. Leakage was tested when components were in the closed as well as in the open positions. Flow rates were measured when the device was connected to both open female luer and most common needle free connectors in the market and were in accordance with ISO 594 standard.

Conclusion

All tested components and groups passed the tests. Furthermore, no degradation in product performances was observed, neither after 24 hours of exposure nor after 96 hours. The ONCOERA SF 401 Closed Male Luer Connector device maintains its performance and integrity when exposed to hazardous drugs and is effectively compatible to a variety of hazardous drugs commonly used in oncology therapy and with correlation to NIOSH Alert drugs list.



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