OLAV™ Closed Male Luer Connector
Drug and lipid compatibility

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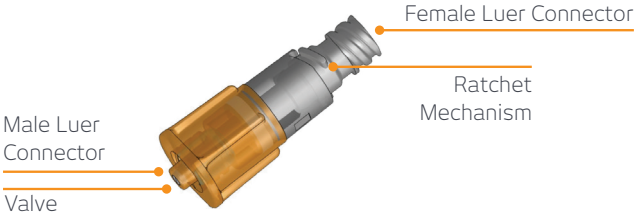
Introduction

Antineoplastic drugs are toxic not only to cancerous tissue, but to healthy organs as well. Long-term contact with such drugs was shown to have mutagenic and even cancer-promoting effects[1,2]; 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[3]. The following summary will show that OLAV™ Closed Male luer Connector device is compatible to a selection of hazardous drugs that represent extreme scenarios.

System, Description and Performance

OLAV™ is a Closed Male Luer Connector designed to minimize dripping of liquids and drugs from a male luer connector, commonly used in hazardous drugs administration. The device is composed of a normally closed male luer valve at the proximal end that opens when attached to a female luer connector to allow infusion. Upon disconnection, the valve closes automatically preventing leakage of fluid or medication. The male luer tip is level with the valve mechanism, ensuring minimal drug residues remaining on the tip. From its distal end the device includes a female luer connector, allowing it to be connected to many medical devices for fluid administration, e.g. a syringe or infusion set. The female luer connector is designed with a ratchet mechanism, preventing the risk of hazardous drug spillage, following inadvertent detachment of the OLAV™ from the syringe or infusion set.



Compatibility with Hazardous Drugs

The compatibility of the OLAV™ device with hazardous drugs was demonstrated in a study[4] performed by Elcam Medical, in cooperation with Western Galilee Medical Center's pharmacy (Nahariya, Israel). In this study, the device was exposed to a representative selection of hazardous drugs in accordance with NIOSH alert[5] and American Cancer Society guidance[6]. 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.

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2. From each group a representative drug was selected according to:
- Frequency of use
- Toxicity (hazardous to the medical staff)
- Ability to attack OLAV™ 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 or f5U)	Anti-metabolites
Doxorubicin (Adriamycin)	Anti-tumor antibiotics
Paclitaxol (Taxol)	Mitotic inhibitors
Etoposide (VP-16, Etopophos®, Vepesid®)	Topoisomerase Inhibitors
Bevacizumab (Avastin)	Immunotherapy
Intralipid 20% (A 20% I.V. Fat Emulsion)	known to be incompatible with many amorphous plastic materials

Samples of OLAV™ 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 594-2[7] 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. All tested components and groups passed the tests and products performed according to their specifications. Furthermore, no degradation in product performances was observed, neither after 24 hours of exposure nor after 96 hours.

Conclusions

The OLAV™ 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[5] drugs list.

References

1. S. Burgaz et al., Human Toxicol., 1988, 7, 557
2. T. Skov et al., Br. J. Ind. Med., 1992, 49, 855
3. Evaluating Environmental Stress Cracking of Medical Plastics,: E. J. Moskala ,M. Jones, May 1, 1998, MDDI website
4. Closed Male Connector - CMC V&V Test Report for Compatibility with Hazardous Drugs. Elcam Medical, July 24 2011
5. NIOSH list, publication number 2004-165, September 2004
6. American Cancer Society guidance", 17-Jul-09
7. ISO 594-2:1998 - Conical fittings with 6 % (luer) taper for syringes, needles and certain other medical equipment -- Part 2: Lock fittings

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