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Compatibility with All Known Hazardous Drugs

Background

The Chemfort™ system is used to ensure safety and sterility during preparation and handling of hazardous drugs. The plastics that comprise the Chemfort™ system provide effective chemical and mechanical resistance to all drug ingredients.

Generally, the ingredients of drug products can be divided into two groups:

- **Active pharmaceutical ingredients (API)** - any component that provides pharmacological activity or has other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or animals.[1]
- **Inactive ingredients** - drug components that do not increase or affect the therapeutic action of the active ingredient. However, not all inactive ingredients are chemically inert. [2]

The inactive ingredients' roles in a drug solution formulation can include pH buffer, stabilizer or drug solvent. Typically, drugs use saline or pure water as a solvent, but there are several drugs which cannot be dissolved in water. Therefore, they include organic solvents as part of the inactive ingredients.

It is known that drug solvents can chemically affect materials thus causing breakages or other structure fractures following prolonged contact between raw material and a drug solution. The most aggressive solvents are Polysorbate 80, Cremophor® EL and N'N' Dimethylacetamide, which are solvents that can be found in several cytotoxic drugs. The following drugs contain the largest solvent concentrations:

Toposar™ (Etoposide) - Polysorbate 80 (Tween 80) 8% w/w, Ethyl alcohol 27% w/w, Polyethylene glycol 62% w/w, Citric acid 0.2% w/w, Benzyl ethanol 3% w/w. Other drugs also consist of the Polysorbate 80, but at a lower percentage.

Paclitaxel - 527 mg of purified Cremophor® EL (polyoxyethylated castor oil) and 49.7% (v/v) dehydrated alcohol. Other drugs can also include Cremophor® EL, but at a lower percentage.

Treanda® (Bendamustine hydrochloride) - N,N-dimethylacetamide (DMA) 59% w/w, and Propylene Glycol 32% w/w. Other drugs also consist of DMA, but at a lower percentage.

Goal of Study

This study was conducted in order to verify the Chemfort™ Syringe Adaptor and Vial Adaptor resistance to the most extreme drug solvents (Etoposide, Paclitaxel and Treanda) during the course of an exposure period of 7 days.
Based on this study, the compatibility of all the Chemfort™ components with cytotoxic drugs can be determined, since their raw materials are used in vial and syringe adaptors.

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Test Parameters

The study consisted of the procedure for delivering a drug from a vial to a syringe, and examined the following:

- Leakage from the Syringe Adaptor
- Sign of breakage and other mechanical damage occurring on the Hub.
- Sign of breakage and other mechanical damage occurring on the Vial Adaptor.
- Functionality - the ability to deliver a drug from the syringe to the vial through the Chemfort™ system.

Tested Components

Chemfort™ Vial Adaptor and Syringe Adaptors

- Fresh after sterilization
- Aged - One-year simulated aging - following 6.5 weeks of accelerated aging in 55°C simulating 1 year of natural aging.
- Aged - Three years simulated aging - following 19.5 weeks of accelerated aging in 55°C simulating 3 years of natural aging.

Solutions

- Etoposide drug solution
- Paclitaxel drug solution
- Treanda solvent (35% w/w Propylene Glycol 65% w/w of N'N'-Dimethylacetamide)

Procedure

50 pairs of Vial Adaptor/Vial and Syringe Adaptor/Syringe were tested with each solvent/drug.

Each pair was connected. 5 mL of solvent/drug was transferred from the vial to the syringe, and then 3 mL were returned to the vial. This procedure was performed on days 0, 1, 3, 5, 7. In each of these time points the functionality of the Chemfort™ system and the mechanical integrity of the structural elements were assessed.

Figure 1: Assembly of a Vial Adaptor to vial

Figure 2: Assembly of a Syringe Adaptor to syringe

Figure 3: Connection of Syringe Adaptor to Vial Adaptor

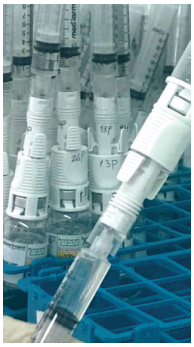

Figure 4: Withdrawal of solvent to and from the vial to the syringe

Figure 5: Injection of solvent to the vial using a Syringe Adaptor to Vial Adaptor system

Acceptance Criteria

1. **Functionality -** Proper functionality which allows regular delivery of the tested liquid through the testing assembly. This includes no leakages that were detected while operating the devices.
2. **Mechanical integrity -** No breakage or structural deformation in the Syringe Adaptor Hub and Vial Adaptor spike which are in contact with the testing solvent.

Results and Conclusion

The functionality and mechanical integrity of the Vial and Syringe Adaptors were found to be in compliance with the requirements for 7 days: the solvents were easily delivered from the syringe to the vial and vice versa. There were no signs of breakage or structure damages. The overall shape of the products has not been affected. This was true for the fresh products as well as for products following accelerated aging simulating one or three years.

The drugs/solvents chosen for this study are considered to be the most aggressive solvent types among all hazardous drugs. Thus, it can be concluded that the Chemfort™ products can be used with all hazardous drugs for 7 days.

References

1. (http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm)
2. (http://www.drugs.com/inactive/)