

Arisure[®] Dry Spike Chemical Compatibility

Introduction

In addition to presenting health risks for healthcare workers, many common infusion drugs contain chemicals which can cause damage to infusion and compounding devices.

Damage to devices has the potential to expose healthcare workers to spills and compromise their safety. One or more elements in common drug formulations increase the risk of damage to plastic devices. These elements include: drug preservatives (Benzyl Alcohol), excipients (Cremophor EL), infusate chemistries (low pH), or other formulation chemistries known to cause damage to plastics.

The Arisure Dry Spike is a single use, non-pyrogenic device intended for use as an accessory to an IV set. To demonstrate that the Arisure Dry Spike is compatible with drugs that contain risk of damage to such polymeric devices, several tests were conducted to challenge the devices with prolonged, continuous, fluid path exposure to drugs which present a range of these formulation elements. The two chemicals used to test compatibility include Taxol and Etoposide analogues. The ANV valve portion of the Dry Spike was also tested with isopropanol per TSD 005.01.

Procedure

A chemical compatibility test was administered on sterilized Arisure Dry Spike devices. To perform this test, master drug vials, each containing Taxol and Etoposide analogues, were prepared. Drug was withdrawn into syringes. Test devices were attached to IV bags and drug injected into both lumens of the Dry Spike to test complete compatibility.

Devices were observed for leaks. After 24 hours of exposure, the performance of the devices were tested according to Table 1.

Results

Table 1. Arisure Dry Spike (24 hours).

Drug	Requirement	Arisure Dry Spike
Taxol analogue	Security of Attachment	35/35 Pass
Etoposide analogue	Security of Attachment	35/35 Pass

Each test device passed security of attachment and satisfied the requirements (i.e. no leaks nor failures occurred).

Conclusions

The Arisure Dry Spike passed testing. The results demonstrate that the Arisure Dry Spike is chemically compatible with common infusion drugs.

Data on file at Yukon Medical. Arisure Dry Spike Chemical Compatibility Whitepaper TSD 006.01.