

The CLC2000[®] Performance with High Risk Infusates

Introduction:

Some intravenous medications known as high risk infusates, and also referred to as anti-neoplastics, may come in contact with plastic devices or components through intravenous therapy. Such infusates are known to cause damage to plastic devices and may result in an interruption in IV therapy. The CLC2000 by **ICU Medical, Inc.**, is designed to be compatible with most clinical applications as well as those requiring the administration of anti-neoplastics. The following study was conducted to demonstrate the functional integrity of the CLC2000 when exposed to such infusates. The plastic components of CLC2000 are manufactured with polycarbonate, polyester and silicone. The following medications were used to conduct the study; Taxol, Cisplatin, Adriamycin, Oncovin and Lasix.

Procedure:

Sixty samples of the CLC2000 were assembled together to complete one test setup. The test infusate was prepared per the manufacturer's instructions and available in a 5cc luer lock syringe. Water was available in a 5cc syringe to be used as the study control. The syringe containing the test infusate was attached to the proximal end, or injection site of the of the CLC2000 test unit, by fully activating the CLC2000 and securing the luer lock connection. The contents of the syringe were infused through the entire test setup, until an excess of the drug was captured in a second syringe at the distal end, or male luer of the CLC2000. The test setup was a closed system and was monitored for leakage at all of the connection points.

At one hour intervals the samples were tested for patency by pushing at the proximal syringe, and then reversing the action by pushing at the distal syringe. This action was repeated twenty-four times per day, for seventy-two hours, or three days. At all times, each CLC2000 test unit was exposed to the infusate. Following the three days of exposure, the infusate was disposed of per the manufacturer's instructions and the samples were generously flushed to remove any drug residue.

The samples then underwent functional and visual inspection according to the CLC2000 performance specifications. Flow testing was used to identify any degradation of the internal polycarbonate poppet. Backpressure testing to 60 psig was used to identify any degradation of the silicone seal and polyester housing. All samples were visually inspected for degradation. The results of the study are reported in the following table.

Results:

| Test Infusate | Flow Rate: number of failures per 60 samples | Backpressure: number of failures per 60 samples | Overall Failure Rate for Test Infusate |
|----------------------|---|--|---|
| Taxol (2mg/mL): | 0/60 | 0/60 | 0% |
| Cisplatin (2mg/mL): | 0/60 | 0/60 | 0% |
| Adriamycin (3mg/mL): | 0/60 | 0/60 | 0% |
| Oncovin (1mg/mL): | 0/60 | 0/60 | 0% |
| Lasix (100mg/mL): | 0/60 | 0/60 | 0% |
| Control Water: | 0/60 | 0/60 | 0% |

Conclusions:

The CLC2000 met its functional specifications following exposure to the test infusate. According to this study the CLC2000 suffered no functional or visual degradation with Taxol, Cisplatin, Adriamycin, Oncovin and Lasix.