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SCIENCE INSIDE™

Mechanical Stability of the Oxygen Barrier Coating

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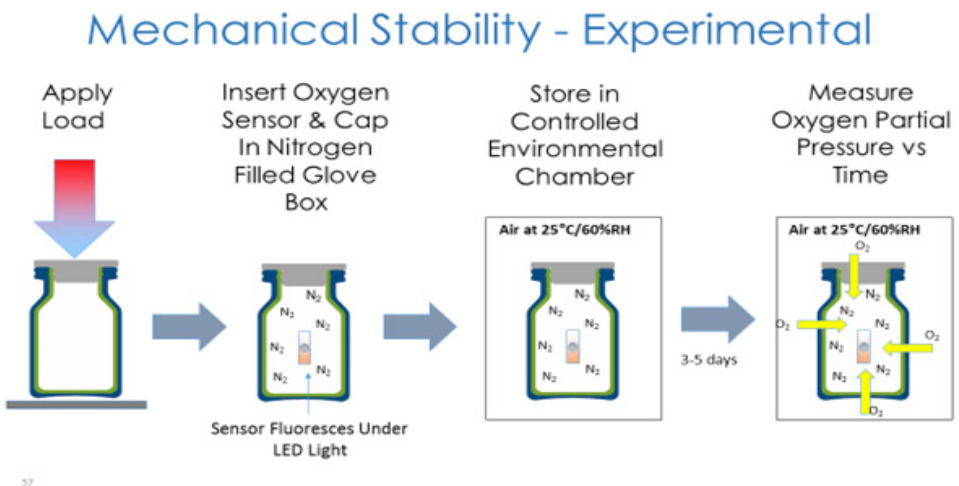
Introduction

Polymeric materials such as cyclic olefin polymers (COP) may be used for parenteral drug packaging because they possess high optical clarity, high strength and impact resistance, low extractables, dimensional consistency and a moisture vapor barrier. The robust mechanical properties of COP provide an impact and shatter resistant container that can tolerate severe handling without failure. While the polymer matrix is robust there is concern that the thin oxygen barrier film will yield and not protect the interior of the vial from oxygen ingress.

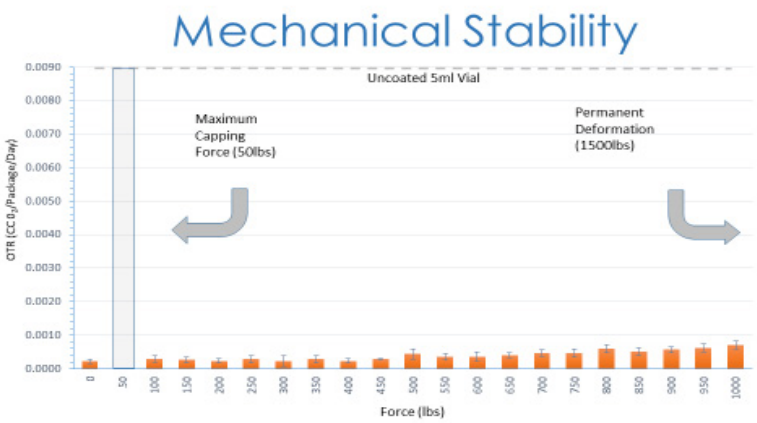
Method

Vials composed of COP were shown to withstand up to 1,500 pounds (680 kgs) of top down load before evidence of permanent deformation was observed. This load is an order of magnitude greater than normal capping operations would impart to the vial. A study was conducted to understand the effect of increasing load on the barrier film coating by analysis of the oxygen transmission rate (OTR) into a vial. An Instron was used to apply various compressive loads to 6 mL vials. Oxygen transmission rate (OTR) was then analyzed by optical fluorescence with a Mocon OpTech – O2 Platinum System.



Results

Testing results show that OTR did not exceed 0.0005 cc O2/Package/Day up to 1,000 pounds (456 kgs) of top down force.



Barrier coating performance maintained well above normal capping force.

Conclusion

Generally, glass is thought of as a brittle material. However, when glass is thin, it is flexible. For example, fiber optic cables and fiberglass have robust qualities that make them ideal for their applications. It is for this reason the coating integrity is maintained when the container walls are deflected. The silicon-oxide barrier coating used is very thin, at about 0.5 microns. The thin coating provides robustness and coating stability to mechanical stress.

This work proves that, even after the application of force that causes temporary flexing and movement, the glass lining moves with the polymer matrix and remains intact. This work indicates that there is at least a 10X improvement in oxygen barrier performance maintained after significant force is applied. This implies that the coating can tolerate capping forces in excess of normal operations without cracking, deformation and loss of OTR. This also indicates that the external forces the drug product may encounter in the field and during administration will not affect the oxygen transmission properties of the vial.