SiO2 MATERIALS SCIENCE℠

Oxygen Barrier Stability of Coated Vial after Mechanical Load

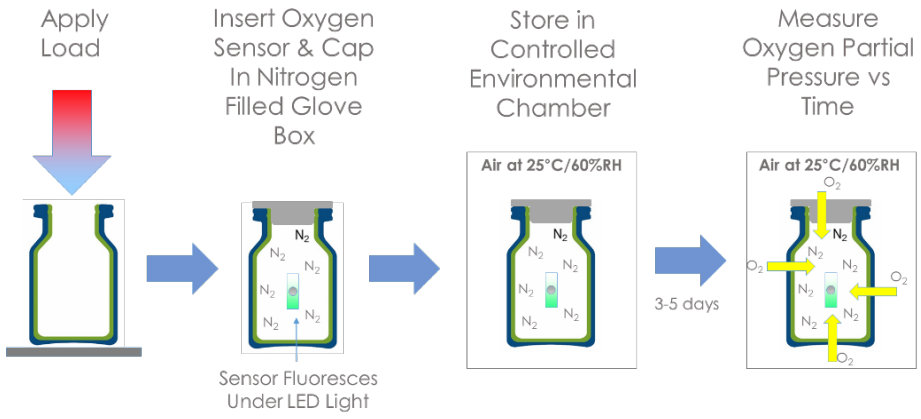
Technical Bulletin Series 2020-003

INTRODUCTION

Polymeric materials such as cyclic olefin polymers (COP) are used for parenteral drug packaging because they possess the best combination properties including glass-like optical clarity, mechanical & impact strength, low extractables, dimensional consistency, heat resistance and a moisture vapor barrier. The robust mechanical properties of COP enable a shatter resistant container under severe handling conditions. The high heat deflection facilitates steam sterilization of COP containers. While the polymer matrix is clearly robust it was necessary to demonstrate that the thin (< 0.5 micron) oxygen barrier coating on the inside wall of the vial will remain in-tact without adhesion or mechanical failure. One way to demonstrate this is to show that the barrier coated COP container maintains oxygen barrier even after extreme mechanical load and strain.

METHODS & MATERIALS

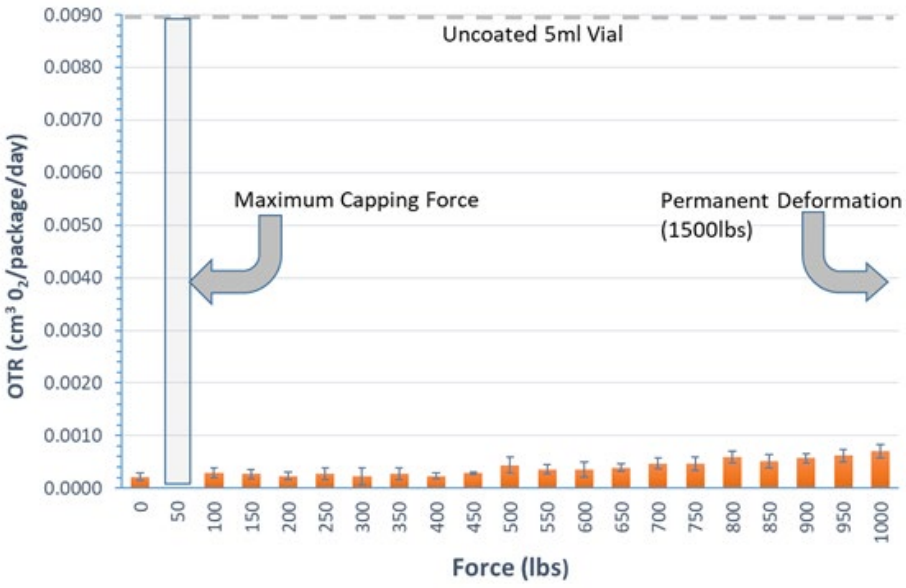
A study was conducted to understand the effect of increasing load on the barrier coating by analysis of the oxygen transmission rate (OTR) into a vial. An Instron was used to apply various compressive top-down loads to 6 mL vials. Oxygen transmission rate (OTR) measurement was then conducted by optical fluorescence method using a Mocon OpTech – O2 Platinum System. The OTR test method sequence after applying load to the vial is illustrated below.



RESULTS & DISCUSSION

Coated COP vials were shown to withstand up to 1,500 lbs (680 kg) of top-down load before evidence of permanent deformation was observed. This load is an order of magnitude large than normal capping line operations would impart on vials. Testing results below show that OTR was maintained below 0.0005 cm3 O2/package/day up to 1,000 lbs (i.e., 456 kg) of top-down force. This is about 20 times lower OTR compared to an uncoated COP vial. Permanent deformation of the vial was observed beyond 1500 lbs of force.

This work proves that even after the application of extreme load causing reversible flexing of the vial, the oxygen barrier coating remains in-tact, bonded and maintains barrier to oxygen. The data in the bar graph below indicates that there is at least 10 times reduction in OTR after 1000lbs of top-down force is applied. This suggests that the coating can tolerate capping forces in excess of normal capping operations without cracking, deformation and loss of barrier. This also indicates that external forces subjected to drug product filled vials during manufacturing and normal use will not affect the oxygen barrier properties.



CONCLUSION

Generally, glass is inherently thought of as a brittle material prone to cracking and fatigue. However, a submicron thick glass-like barrier coating on the inside of a COP vial can withstand mechanical stress without adhesion or mechanical failure. Maintaining OTR after mechanical load was an indirect means of demonstrating this performance. Ordinary borosilicate glass would shatter or fracture under similar mechanical loads.