Cambridge Polymer Group

Root Cause Analysis of Cracked PC Syringes

Summary

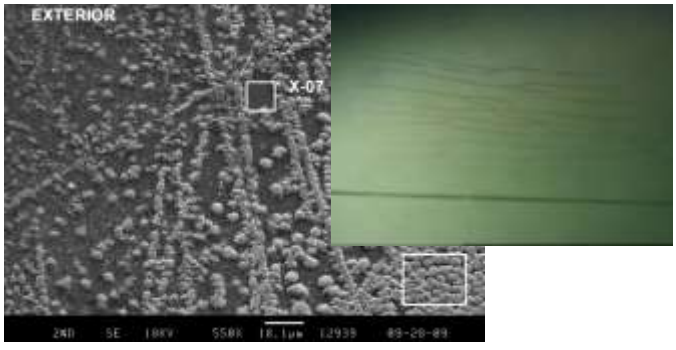
A client requested a root cause analysis of cracks and haziness that appeared in polycarbonate (PC) syringes during accelerated aging as part of a shelf-storage study. The results of the study were unexpected and revealed a few issues with the manufacturing line.

Description

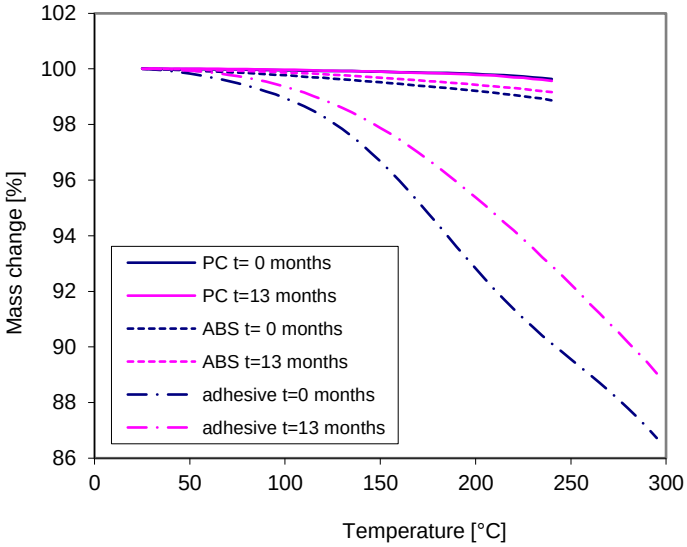
The PC syringes had a secondary component adhered to the luer lock of the syringe with a UV-curable epoxy adhesive. The plunger was comprised of acrylonitrile-butadiene-styrene. The syringes were ethylene oxide (EtO) sterilized, and aging was conducted in a humid environment at elevated temperature. The client had never detected cracking in unaged samples but observed that an optional IPA wash appeared to prevent the issue. Environmental stress cracking (ESC) was suspected.

Analysis

Scanning electron microscopy with energy dispersive spectroscopy showed that the hazy regions had curvilinear patterns of raised droplets comprised of carbon and oxygen. FTIR analysis of these regions showed that the oxygen was in the form of hydroxyls and possible carbonyls (challenging to differentiate from the polycarbonate). Fingerprints were found on some samples, and an investigation of the manufacturing facility showed that some assemblers were not wearing gloves, and potentially transferring skin oil to the syringes.



Cracks in syringe (right), SEM of hazy region (left)



TGA of unaged and aged components of syringe.

Thermogravimetric analysis (TGA) showed that uncured epoxy adhesive may be off-gassing, but that the ABS plunger and polycarbonate barrel were not off-gassing, even after 13 months of aging. A design of experiment study with 6 variables (hand oil, humidity, EtO sterilization, unreacted epoxy monomer, ABS plunger, and an isopropyl alcohol wipe) was conducted with accelerated aging to see which conditions led to cracking and haziness. No single parameter led to cracking or haziness, but rather a combination of hand oil or monomer coupled with EtO sterilization or humidity resulted in cracking and haziness. IPA wiping reduced haziness and cracking, even with these materials present.

The client instituted retraining on wearing gloves during assembly, increased the UV cure time for the epoxy, and included an IPA wipe during cleaning to remove items that could result in the environmental stress cracking observed.

This study demonstrates the importance of a structured strategy in a root-cause investigation, but also the importance of experience when reviewing data and images.

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