Replace Dye Ingress with Mass Extraction to Mitigate Risks

A major pharmaceutical company in North America with manufacturing in the US, Canada and abroad had a problem, which was not unique to them. Their manufacturing process engineers could not reliably verify that their pouch packages were sealed properly and the product could potentially ship with questionable packaging which failed stability testing. They were using the dye ingress testing method, and found it was not only slow and operator dependent (not reliable), causing false accepts. The Dye Ingress test method was also very messy and involved destroying the packages tested, which become costly if done in few hundreds per day.

They contacted Advanced Test Concepts (ATC), Inc., Indianapolis, Indiana USA (www.atcinc.net) and presented us with their challenges. We implemented our patented Mass Extraction Technology and customized a solution focused around their needs in order to address all of their problems. Our Mass Extraction technology[1,2] for Container Closure Integrity Test (CCIT) for package such as pouches and blister packs is a non-destructive method and can achieve sensitivity of 3-5 micron defect size. It operates simply by putting the package into a small chamber, evacuating the air from the chamber and measuring the amount of air mass flow that is extracted from the container. In addition, the test system includes features to detect large leaks before the package is fully evacuated.

Samples were sent to ATC for evaluation and a proof of principle test was conducted. The pouch packages were shipped with laser drilled holes for validating the system. From this test, it was concluded that the mass extraction system far exceeded their expectations and their ROI for the system was achieved in a few months.

ATC conducted an IQ/OQ at our testing facility and the system was shipped to their facility for final IQOQ and implementation. After validation at their plant, the system has been running successfully, saving the pharmaceutical company time and money but most importantly giving them a better, safer method for CCIT testing.

ATC's simple solution met all of their criteria for CCIT testing.

- *Robustness*: Few hundreds pouches, some with laser drilled holes were tested over few days by operators, to provide consistent result of pass and fail. Failure of large, medium and small leak (5 micron and lower) was demonstrated. Each part was measured multiple times and the measurement was directly proportional to the defect size.

- *Nondestructive*: All tested packages that passed were good packages and could be shipped with the rest of the lot. This alone was a huge cost savings based on the samples tested and destroyed with their old method. Our automated material handling (such as Robotic sampling) eliminates potential human error and increase sampling rate.

- *Fast, Accurate, and Consistent*: With the ability to measure far better than the dye ingress test, our CCIT system performed faster with higher accuracy and consistency. Typical test times were 30 to 45 seconds for 5 micron defect size, enabling the pharmaceutical company to test more frequently, shortening their parts between tests.

- *Quantitative Data*: It also gave them a measured value of their seal integrity rather than the subjective result of their operator looking for blue dye penetration. This allowed them to compare various package materials, lots, vendors to quantify and improve their package performance. This added bonus was not expected when they first started looking for a suitable solution.

- *Traceability:* Our Leak Rx© program, FDA CDR21 Part 11 compliant, is used to collect daily production data and perform correlation to other stability tests over long period of time.

Chuck Davidson
Senior Application Engineer
Email: cdavidson@atcinc.net
Web: www.atcinc.net

References:

1) ATC's Mass Extraction Technology http://www.atcinc.net/how-it-works.asp
2) ATC's Mass Extraction Instruments Specifications http://www.atcinc.net/vacuum-leak.asp