Minimise delamination risk

SCHOTT Pharmaceutical Systems is at the forefront of pharmaceutical primary packaging solutions. Dr Bernhard Hladik, head of product management, explains how the new SCHOTT Vials DC has tackled the delamination conundrum.

SCHOTT Vials DC offer pharmaceutical companies a new way to lower the risk of delamination by providing an improved packaging product.

Finding a solution to the problem of delamination, which is the peeling of inorganic flakes from the inner glass surface of a pharmaceutical vial as a result of interaction with its contents, remains a top priority for the pharmaceutical industry. This phenomenon has already caused numerous recalls costing several million dollars. The US drug authority the FDA thus explicitly requires that pharmaceutical companies manage their risks closely. But there is good news: SCHOTT Vials DC (which stands for 'delamination controlled') offer pharmaceutical companies a new way to lower the risk of delamination by providing an improved packaging product.

These vials offer a more homogeneous surface thanks to an improved production process, not only for new products that have yet to undergo stability tests, but also for those that are already well established in the marketplace.

> "SCHOTT is the first packaging manufacturer capable of determining the risk of delamination based on threshold values."

Dr Bernhard Hladik, head of product management, SCHOTT Pharmaceutical Systems, says that the mechanism behind delamination has been researched thoroughly and is well understood.

"When the bottom of the vial is formed, volatile components such as boron and sodium evaporate," he explains. "They then go on to form inhomogeneous spots on the glass surface near the bottom of the vial that show a higher tendency to delaminate. With our new SCHOTT Vials DC, we have improved the production process even further to ensure that the glass surface is more homogeneous and thus less susceptible to delamination."

To confirm this effect, SCHOTT conducted storage studies with systems that showed a high tendency towards delamination while using standard type 1 vials. The results showed that SCHOTT Vials DC remained stable even after eight weeks of storage involving a 15% potassium chloride solution and a 10% sodium thiosulfate solution at a temperature of 60°C, while conventionally manufactured vials showed clear initial signs of delamination.

Quick testing – how it works

SCHOTT is also the first packaging manufacturer capable of determining the risk of delamination based on threshold values, and then monitoring these values over the course of manufacturing. To achieve this, the company developed a patented Quicktest.

"In the past, the vials had to be examined very carefully with a stereo microscope during testing in order to be able to comment on delamination. For this reason, it was impossible to control the production process in a timely manner," Hladik adds. "In the SCHOTT Delamination Quicktest, a certain number of vials are removed from every batch. The random samples are then subjected to stress for four hours inside an autoclave to identify the delamination critical zone.

"In a second step, the vials are filled with high-purity water for injection (WFI) and sodium is extracted inside an autoclave. The volume of sodium extracted correlates with the probability that the vials will experience delamination at a later point in time."

By monitoring these values and adhering to certain thresholds, SCHOTT is now able to control the risk of delamination for the first time.

SCHOTT Vials DC will be available in the ISO formats 2R–10R from early 2014. ■

Further information
SCHOTT Pharmaceutical Systems
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