PRESS INFORMATION

SCHOTT

SCHOTT introduces new pharmaceutical vials with minimized delamination risk

SCHOTT Vials DC: Innovation based on optimized manufacturing technique and patented SCHOTT Delamination Quicktest / Threshold values for delamination can be set for the first time ever

Mainz/Frankfurt, October 22, 2013 – SCHOTT will be presenting SCHOTT Vials DC – a pharmaceutical vial that, for the first time ever, allows for the risk of delamination to be determined based on threshold values. SCHOTT monitors these values over the course of the manufacturing process and is thus able to minimize the risk of delamination. The company succeeded in optimizing its manufacturing process to ensure that SCHOTT Vials DC have a more homogeneous surface, hence offering high chemical stability. Furthermore, SCHOTT is the first manufacturer to develop a patented test method that even allows for this lower tendency to delamination to be documented – known as SCHOTT Delamination Quicktest. SCHOTT Vials DC will be available as 2R to 10R ISO vials starting at the beginning of 2014.

The problem of delamination, in other words the peeling off of flakes from the inner glass surface of a pharmaceutical vial as a result of interaction with the formulation and / or medication, has become increasingly important to the pharmaceutical industry in recent years. Numerous recalls clearly confirm this, and the US drug authority in turn is explicitly requiring that pharmaceutical companies manage their risks more closely.

SCHOTT Vials DC thus represents an interesting solution for pharmaceutical companies interested in lowering the risk of delamination by selecting an improved packaging product. These vials are an interesting alternative not only for new products, but also for products that are already well established in the marketplace.

A more homogeneous surface thanks to a better production process

Dr. Bernhard Hladik, Head of Product Management, says that the mechanism behind delamination has been researched quite thoroughly and is well understood. “When the bottom of the vial is formed, volatile components like boron and sodium evaporate. 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 developed 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 to experience delamination while using standard Type I vials. The result: SCHOTT Vials DC remained stable even after six 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.

How the SCHOTT Delamination Quicktest works

SCHOTT is currently also the first 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 Quicktest and had it patented. “In the past, the vials had to be examined carefully with a stereomicroscope 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. He describes the way in which the SCHOTT Delamination Quicktest works as follows: “A certain number of vials are removed from every batch. The random samples are then subjected to stress for four hours inside an autoclave in order to tease out the delamination critical zone. In a second step, the vials are filled with high purity water (WFI – Water for Injection) 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 threshold values, SCHOTT is now able to control the risk of delamination for the first time ever.

Premiere at the trade exhibition CPhI

Visitors to booth 41D21 will be able to learn more about SCHOTT Vials DC from October 22 – 24, 2013. Furthermore, Dr. Bernhard Hladik will be introducing this innovation during a presentation he will be holding on the second day of the exhibition (CPhI Speakers' Corner, 10/23, 3:30 – 3:50 PM).

Picture ID: 215955

SCHOTT introduces SCHOTT Vials DC – a new pharmaceutical vial with minimized delamination risk.

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About SCHOTT

SCHOTT is an international technology group with more than 125 years of experience in the areas of specialty glasses and materials and advanced technologies. SCHOTT ranks number one in the world with many of its products. Its core markets are the household appliance, solar power, pharmaceuticals, electronics, optics, transportation and architecture industries. The company is strongly committed to contributing to its customers' success and making SCHOTT an important part of people's lives with high-quality products and intelligent solutions. SCHOTT is committed to managing its business in a sustainable manner and supporting its employees, society and the environment. The SCHOTT Group maintains close proximity to its customers with manufacturing and sales units in 35 countries. Its workforce of around 16,000 employees generated worldwide sales of approximately 2 billion euros for the 2011/2012 fiscal year. SCHOTT AG, with its headquarters in Mainz (Germany) is owned by the Carl Zeiss Foundation.

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PRESS INFORMATION

SCHOTT adaptiQ™: SCHOTT presents innovative system solution for ready-to-use pharmaceutical vials

Patented design allows for lyophilization and closing of pharmaceutical vials in the nest

Mainz/Frankfurt, October 22, 2013 – With adaptiQ, SCHOTT will be unveiling a new concept of ready-to-use pharmaceutical vials that has been modified in close cooperation with filling line manufacturers to meet the process requirements of the pharmaceutical industry. SCHOTT adaptiQ consists of a nest and tub configuration that allows for as many as 100 vials to be securely fixed inside a holder (nest) and delivered to the pharmaceutical company packaged in a sterile container. The company can then fill these vials on its filling line immediately without having to perform arduous processing steps like washing, drying and sterilization. What makes SCHOTT's innovation unique is its patented nest design; unlike all of the other solutions currently on the market, adaptiQ allows for vials to be subjected to all of the processing steps while inside the nest, even freeze-drying, weighing and closing for the first time ever. Besides simplifying the process, the main focus is on protecting the glass containers, which can no longer come into contact with each other or be scratched by coming into contact with machine components. Market introduction is scheduled for Q3/2014 and will start with the most popular ISO formats 2R and 4R. SCHOTT adaptiQ is expected to be gradually introduced in all of the most common ISO formats ranging from 2 to 30 ml. The company plans to make initial samples available starting at the end of October 2013.

Companies are showing much greater interest in flexible manufacturing concepts that allow for small batches or different ingredients/packaging configurations to be filled more efficiently. SCHOTT adaptiQ responds to this challenge by offering three special advantages, as Product Manager Gregor Deutschle explains: "If pharmaceutical companies can use the same production line for various lot sizes and different types of containers like syringes, vials and cartridges, this gives them much greater freedom to react to new market demands more quickly. Moreover, costs can be lowered by

shortening the process chain and reducing its complexity. It is then no longer necessary to invest in clean rooms, special washing machines and sterilization tunnels, or spend money to operate them."

Yet another advantage is the avoided glass-to-glass contact: securely fixed inside the nest, the containers are no longer able to tip over, fall out or collide with one another. This not only reduces the reject rate, but ensures the cosmetic quality of these packaging products.

Patented nest design

Pharmaceutical companies have already been benefiting from these advantages in other areas of packaging for years now. Roughly 80 percent of all pre-filled syringes that are sold in the world today are delivered to the filling lines in the form of a nest and tub configuration. Attempts to apply this successful syringe approach to other types of containers have failed in the past because vials still had to be individually removed from the nest for certain processing steps.

The patented, new nest design that adaptiQ is based on now offers a solution to this problem for the first time ever. The vials are held by the neck and can all be lifted up or out of the nest together. Furthermore, the bottom is freely accessible and thus ensures the perfect temperature transition, especially during lyophilization. Here, the patented design developed by SCHOTT follows the common format of syringe manufacturing to ensure that adaptiQ can also be processed on existing nest filling lines.

Premiere at the trade exhibition CPhI

Visitors to booth 41D21 will have the chance to see adaptiQ vials for the first time from October 22 – 24, 2013. In addition, Product Manager Gregor Deutschle will be presenting SCHOTT adaptiQ as part of the CPhI Speakers' Corner (10/23, 10:30 – 10:55 AM).

Picture ID: 215956

With adaptiQ, SCHOTT will be unveiling a new concept of ready-to-use pharmaceutical vials that allows for vials to be subjected to all of the processing steps while inside the nest.

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