SCHOTT Expands Portfolio of Ready-to-use Pharma Vials as Adoption Increases

SCHOTT has expanded its portfolio of ready-to-use pharma containers to meet growing market demand from drug manufacturers. The latest nest format will be able to hold 2R–15R, 20R, 25R, or 30R ISO vials when it’s released in 2017, and will add to the existing 2R to 15R formats. The adaptiQ® concept permits pharma firms to fill different container formats on one production line while minimizing burdensome changeover times in between. SCHOTT developed adaptiQ® to be compatible with the industry’s filling and finishing equipment, and collectively, industry leaders such as Bausch + Strobel, Bosch Packaging Technology, groninger, OPTIMA, and Vanrx have tested and verified adaptiQ® on a large number of machine types.

This ready-to-use packaging solution enables pharma companies to react quicker to new industry trends without building specific manufacturing capabilities. The vials are nested securely, protecting them from scratches caused by vial-to-vial and vial-to-machine contact, and reducing breakage and contamination. As they are already sterilized, pharma companies can load them directly onto filling lines without expensive and time-consuming washing, sterilizing, and depyrogenation.

“Razor-thin margins and regulatory pressure have forced pharmaceutical manufacturers to make smarter packaging choices,” said Christopher Cassidy, VP Sales and Marketing for SCHOTT’s Pharmaceutical Systems Business in North America. “When the 20–30R ISO format comes online, SCHOTT will give pharma companies even more flexibility. The entire portfolio of ready-to-use vials allows pharma companies to trim costs while boosting efficiency, leading to higher profits.”

Dear Reader,

There is a lot of movement in the pharma industry at present. Just look at the many M&A activities and the thriving startup scene. In times as lively like these, it is good to have a reliable partner, also from a packaging perspective. Someone who understands the market and its demands, identifies trends, develops corresponding products and adapts processes. A partner who serves the entire spectrum, from the perfect glass at the beginning of the value chain to completely flexible filling concepts.

This is precisely our approach, and we underline it with a range of innovations: SCHOTT Vials Delamination Controlled, our adaptiQ® concept for sterile filling, or SCHOTT’s innovative Big Data approach for pharmaceutical tubing are just a few examples. All with the aim of allowing you more freedom to focus on your core business.

I hope you enjoy reading this new issue of newsflash.

Andreas Reisse
Executive Vice President
Pharmaceutical Systems
Why do Pharmaceutical Glass Containers Break: The Underestimated Power of Strength Testing & Fractography

In the pharmaceutical industry, glass is by far the dominant material used for the packaging of liquid and lyophilized drugs due to its impermeability and chemical inertness for drug product stability. Although glass breakage events occur at every pharmaceutical company, the methods of strength or reliability testing and fracture analysis (fractography) remain relatively unknown and severely underutilized to determine the root cause of failure and make the necessary changes to reduce future occurrences. Fractography is the science of analyzing the macroscopic and microscopic fracture patterns of cracked or broken objects to qualitatively and semi-quantitatively determine the root cause of failure.

Importance of appropriate strength testing strategies

Due to the high complexities and the low overall incident rate of glass breakage the strategy of the pharmaceutical industry today is to forgo strength testing and to assess the criticality of surface flaws/non-conformities by using optical/visual inspection with defect manuals. The danger in this approach is that defect manuals are designed for cosmetic assessment of containers and the categorization of non-conformities (disturbances) just by their lateral dimensions. They cannot provide an assessment to the criticality of the observed defects/non-conformities by using appropriate strength testing strategies and thus successively improve the strength of the product.

Fractographic investigations – three examples

SCHOTT pharma services was contracted to perform flange strength testing of glass vials and during post-fill inspection found approximately 20% of the lot had chalk marks / “scuffs” of varying size which were detected by visual inspection after processing. The pharmaceutical company was concerned about the risk of breakage at the clinic and contracted strength testing to be done to assess the strength criticality of the scuffs and whether or not the scuffed containers could be safely used. Burst pressure testing was done on 100 samples featuring scuffs, 92 samples without scuffs, and 43 control samples (vials processed but taken out after depyrogenation). Data evaluation revealed quite similar distribution functions processed but taken out after depyrogenation. Data evaluation revealed quite similar distributions with even a little higher extent of strength decrease and thus successively improve the strength of the product.

Strength testing methods in combination with fractographic investigations and appropriate evaluation procedures are available to provide the pharmaceutical industry the methodology for determining the root cause and help in identifying effective corrective actions for glass breakage events during processing, filling, shipping, or during administration.

Conclusion

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SCHOTT’s New Rigid Caps Add a New Twist to Prefilled Syringes

Advanced closure systems for glass and polymer syringes improve patient safety while securing packaging supply chains. SCHOTT has added new closure systems to its already extensive portfolio of prefilled syringes (PPS), offering more flexibility for pharmaceutical companies while keeping patients safe.

In New Screening Study SCHOTT Vials DC Demonstrate Resistance Against Delamination

A new series of studies has once again demonstrated the effectiveness of SCHOTT Vials Delamination Controlled (DC). These pharmaceutical vials have a particularly high chemical durability and are therefore less susceptible to delamination. SCHOTT has this property confirmed in various storage studies. First, substances were used that have already caused product recalls due to delamination. In a second series of studies, the question of how effectively buffer systems can be stored in the new bottle was examined more closely. The result: if the respective substances were stored in SCHOTT Vials DC, the vials remained stable and no glass delamination was observed. A detailed presentation of results was published in the November/December issue of the PDA Journal.

The delamination studies were conducted in accordance with USP1660 using two different types of formulations: a 15-percent potassium chloride solution and a 10-percent sodium thiosulfate solution for which recalls due to delamination had been announced. Nevertheless, established buffer formulations or those that are often used to develop drugs were also tested, for instance ultrapure water, citrate buffer, phosphate buffer, sodium bicarbonate buffer and EDTA (ethylenediaminetetraacetic acid).

Both series of studies clearly show that switching to SCHOTT Vials DC as primary packaging materials significantly reduces the risk for pharmaceutical manufacturers to experience delamination recalls, says Florence Buscke, Product Manager Vials.

Available in many different sizes, SCHOTT Vials DC, pharmaceutical companies now have an interesting alternative course of action against the phenomenon of delamination i.e. the detachment of flakes from the inner glass surface due to interaction of the formulation with the pharmaceutical vials. SCHOTT Vials DC are based on established hot-forming principles without any additional post process steps and can therefore replace the packaging that is already being used with approved drugs without causing expensive re-registration. The vials are available in the ISO 2R to 10R. SCHOTT has also already produced larger sizes to meet individual customer needs, for example, a large-scale 50 ml vial for a biotech company based in the United States.

In quality control, details matter. When it comes to pharmaceutical primary packaging such as vials, cartridges or syringes, fluctuations in tubing dimensions such as the inner diameter or wall thickness can have a significant impact on the container performance – for instance, the filling or dosing accuracy for high potential drugs. The vials are available in the ISO 2R to 10R. SCHOTT has already equipped various plants worldwide with the perfeXion™ process. The roll-out to other facilities in South-America and Asia has started. By doing so, SCHOTT is not just passing another milestone of its future-oriented quality roadmap. More importantly, the company’s pharmaceutical glass will enable even more sophisticated primary packaging solutions for advanced medical treatment than it already does today.

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Towards zero defect SCHOTT Tubing recognizes that glass tubing manufacturers need to advance and continuously improve uncompromised quality standards as certain critical container parameters are directly determined by the quality of the tube. The challenge lies in monitoring and measuring the curved tubing surface with 100% accuracy, in a high speed production process. This is achieved by using a combination of line scan and area cameras, laser and IR inspection systems that literally investigate the entire glass tube on-line. The measurement data is then collected and evaluated by a holistic inter-connected IT solution. This system recognizes even the smallest defective spots in the ‘endless’ glass tube that comes from the melt. It is then able to attribute these spots to a certain position at a single tube once the cooled down glass string is being cut. This sophisticated system enables SCHOTT to customize the quality level to the specific needs of the industry.

Worldwide implementation in progress SCHOTT has already equipped and validated all FIOLAX® tubes in Europe according to the perfeXion™ process. The roll-out to other facilities in South-America and Asia has started. By doing so, SCHOTT is not just passing another milestone of its future-oriented quality roadmap. More importantly, the company’s pharmaceutical glass will enable even more sophisticated primary packaging solutions for advanced medical treatment than it already does today.

New Quality Approach perfeXion™ – From Statistical Quality Control to 100 % Inspection of Each Individual FIOLAX® Tube

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Innovative Solution Provider Keeping Pace with the Times

Everything for the sake of the patient. “That is the philosophy driving SCHOTT’s employees’ actions, and what our products stand for,” explains Michael Vollgold, Vice President, Global Sales & Marketing, Pharmaceutical Systems at SCHOTT. The better a drug’s packaging is adapted to its use, the more it contributes to the safety of the patient. Yet this is challenged by constant change in the pharmaceutical industry, which has to respond to ever-increasing regulatory requirements, rising cost pressures and the increasing digitalization of the industry. “To a large extent, we see the challenges of pharmaceutical companies as ours, too. Since our packaging materials always make up part of the drug, we also have to provide our customers with the packaging solution that meets their demands. We cater to our customers’ needs by providing tailor-made solutions,” Vollgold says.

The economics graduate knows what he is talking about. With over 20 years of professional experience in the pharmaceutical industry, he has a pretty good handle on its requirements. Yet, it hasn’t gotten boring for Vollgold: “In my job there is little routine. I am facing new challenges every day. This is one reason why global cooperation in my organization makes the job incredibly exciting.”

Industry knowledge and proximity to the customer are of great importance in Vollgold’s field “since an important task for our sales and marketing organization is to survey the market and to recognize the challenges faced by the pharmaceutical industry. From this, we derive trends, play them out at company-level, and develop corresponding solutions to introduce into the market.” With its technical expertise, its quality leadership in glass and its global presence with 16 production sites, SCHOTT does this very well. For example, the company has developed a ready-to-use packaging solution with adaptiQ® that allows pharmaceutical companies to react more quickly to new branch centers without having to set up specific manufacturing capacities. Vollgold adds, “with innovative product features and solutions to come we are very well prepared and will further improve the support of our clients in the future.”

SCHOTT Underscores Commitment to Russian Pharma Market

Against the backdrop of the 5th anniversary of its manufacturing site in Zavolzhe, SCHOTT has renewed its commitment to the Russian pharma market. For the Eastern European technology group, Eastern Europe represents one of the most exciting regions within the global pharma market, showing significant growth opportunities. During a symposium that accompanies the five year anniversary celebration industry experts discussed innovations and trends within the pharma industry. “Our intention is to keep working closely with the Russian pharma industry and to support their growth plan by offering just the right packaging solutions,” said Andreas Reise, Executive Vice President for SCHOTT Pharmaceutical Systems.

Innovation and local production are two key features of “Pharma 2020,” an initiative of the Russian government. Launched in 2009, this programme is dedicated to developing the domestic pharmaceutical and medical industry – and it also increases the need for high-quality packaging solutions. SCHOTT was the first international player to open a packaging production in Russia and invested roughly 12 million euros in this field. Every year, the site in Zavolzhe manufactures up to 500 million vials and ampoules.

The story of high quality packaging in Cordoba, Mexico, began a quarter of a century ago. Today, SCHOTT Mexico forms the hub for the company’s activities in Central America and supplies one of the broadest portfolios of ampoules, vials and cartridges to the market.

During the company’s 25 years anniversary celebration in October SCHOTT announced to increase its investment in its pharmaceutical packaging production in Cordoba to further support the pharmaceutical industry in North and Central America with high-class packaging products. Over the last few years, the company has already invested a high seven-digit number in Mexico, with this figure set to increase. In 2016 alone SCHOTT spent over 4 million euros in Cordoba for the benefit of the customers, emphasizing the commitment to establish SCHOTT as a long-term partner for customer business, with the objective to offer highest quality, delivery and reliability concepts to their customers.

During the celebratory event, SCHOTT representatives gave a comprehensive tour of the production site and showcased different packaging solutions to an interested customer audience. Every year, the site in Cordoba manufactures up to one billion vials, ampoules, and cartridges. All products manufactured in Cordoba work in line with GMP (Good Manufacturing Practice) principles and relevant ISO standards.