The global pharmaceutical market has seen a growing demand for prefilled syringes for years and this trend is expected to continue on a global level in the years to come. Ready-to-fill syringes answer the growing demand for speed and ease-of-use, while minimising dosage errors. With the growing number of new and highly sensitive drugs in the development pipeline of pharmaceutical companies, syringes must meet ever more complex requirements.

Injections generally produce better results and take effect more quickly than medications that are administered orally. There are also medications such as protein-based drugs, insulin and antibodies, that require parenteral administration due to the fact that, if they were to be taken orally, they would not be sufficiently reabsorbed by the bloodstream, or they would be broken down by enzymes in the digestive tract or destroyed by the hydrochloric acid inside the stomach.

A defined concentration can be set more easily in the blood with active ingredients administered in a parenteral manner than with orally administered medications, and so intravenous injections are becoming increasingly important, especially in emergency medicine. With the development of biomolecules and monoclonal antibodies, the pharmaceutical industry continues to develop more specific medications that are capable of combating diseases more effectively, yet are considerably more sensitive to contaminants.

To meet the requirements of such highly sensitive drugs SCHOTT has developed a completely unique packaging solution for the ...

“ALTHOUGH THE SYRINGE INCLUDES MANY SPECIAL FEATURES, THE SYRINGE IS DELIVERED WITH STANDARD NESTS AND TUBS AND CAN BE FILLED ON STANDARD FILLING LINES, JUST LIKE STANDARD SYRINGES.”
Figure 2: a) When the needle-shield is on, the InJentle™ seal remains in the closed state, and b) when the cap is removed, the seal opens.

The unique design of SCHOTT InJentle prevents the drug from flowing into the needle during storage. This prevents sensitive drugs from interacting with the adhesive or the metal of the needle. The innovative seal design prevents the drug from flowing into the needle until the very moment that the syringe is opened, that is, when the needle shield is pulled off. A robust tamper-evident closure is integrated in the unique design of the syringe. As soon as the system is opened, this part will break and cannot be reconnected. This allows physicians or patients to determine easily whether or not a syringe has already been used.

SCHOTT InJentle offers a number of other advantages. For example, the special geometry of the glass barrel does not require any tungsten to be used during the glass forming process. As a result, the syringe is completely tungsten-free.

Tungsten has been found to be a leachable tungsten-based particulate matter that leached into and interacted with the protein drug product. Tungsten pins are typically used to keep the fluid pad open at the nozzle end of the syringe during the glass forming process. Residual tungsten can migrate into the drug product and cause the protein to form protein-tungsten aggregates. This phenomenon appears to occur with specific proteins. Production techniques that rely on another heavy metal than tungsten have been on the market for some time, however it is clearly preferred by pharmaceutical companies to completely eliminate this critical metal, of course.

The development of InJentle started in 2006. Following extensive market analysis, SCHOTT initially purchased an existing patent, but then decided to overhaul the entire approach so extensively that this ultimately led to an entirely new product solution with its own patent. For the intensive development work, SCHOTT relied on technical partnerships with various industry experts.

INJENTLE SEAL DESIGN

How does the InJentle principle of the new seal design work? In the closed state, a small plastic arm presses against the rubber tube to seal the syringe (see Figure 2a). This means the container is closed by the arm. The part with the needle does not come into contact with the drug at all during the closed state. As soon as the needle shield is removed, the arm flexes out, removes the pressure and releases the seal (Figure 2b). The channel is now open and ready for the injection.

The unique design of SCHOTT InJentle means that the needle point is fully protected and does not touch the needle shield or any other material. This guarantees best needle lubrication and straight needles; hooks are avoided. The new syringe allows for the use of particularly thin needles of up to 32 gauge, which results in a reduction of pain for the patients during the injection.

No special training is required for healthcare personnel because SCHOTT InJentle is easy to handle and self-explanatory.

Although the syringe includes many special features, the syringe is delivered with standard nests and tubs and can be filled on standard filling lines, just like standard syringes.

The production process of InJentle is similar to that of standard syringes. The glass barrel is formed, washed and siliconised. The cap, needle holder, collar and bung are assembled in a sterile environment. Under laminar flow, the glass barrel and the sub-assembled plastic part are connected and then packed in the nest, tub and bag, as usual. Ethylene Oxide (EtO) sterilisation, batch release and shipment also take place in the same way as with other syringes from SCHOTT.

A production line is currently being built to manufacture the InJentle syringe, with mass production planned to start at the end of 2010 at the SCHOTT plant in Lebanon, Pennsylvania, US. Since October 2010, samples in 1ml long format have been available for functionality testing.

NEEDLE-SAFETY MECHANISM

To meet the packaging requirements of sensitive drugs also in the future, the developers at SCHOTT haven’t stopped here, but rather are...
continuing to work systematically on making further improvements.

For example, a protective needle safety mechanism that shields the needle immediately after injection to protect healthcare professionals from accidental needlestick injuries has already been developed. The safety device was developed in co-operation with Safety Syringes Inc (SSI). SSI is the market leader in safety solutions for prefilled glass syringes and this product is a modified version of their UltraSafe® Passive product line that has been in use worldwide for some time. It has been a great success, having been combined with more than 25 medications.

Needlestick injuries represent a significant global problem. Each year, between 600,000 and one million accidents solely involving needlesticks are reported in the US. In Europe, as well, it is estimated that roughly a million accidents, which mainly pose a risk to medical personnel, occur each year.

Policymakers have already taken action in many countries. For instance, the US adopted the “Needlestick Prevention Act” in 2000, which requires that special safety devices be used with syringes. In Canada similar legislation was passed in 2008. According to a recent EU council directive (2010/32/EU), the EU member states must adopt more stringent sharps injury legislation, which includes needlestick prevention, by the year 2013.

The benefits that the UltraSafe Passive® Needle Guard brings to InJentle are clear. A wider plunger head, finger flanges and a rounded body design offer qualified personnel safe support, and no special procedures are necessary to put the syringes into operation.

The safety feature is activated passively, shielding the needle automatically right after injection – a key requirement for effective needlestick protection, as a large portion of needlestick injuries happen when the bare needle is removed from the injection site. One-handed operation is possible, and no new injection technique is necessary. In addition, these syringes come pre-assembled in ready-to-use-packages.

SCHOTT will be presenting the new safety device complementing InJentle to industry experts and the broader public at CPhI (Paris, France, October 5-7, 2010) and at the PDA conference, Universe of Prefilled Syringes and Injection Devices (Las Vegas, NV, US, October 18-21, 2010).
SCHOTT InJentle™
Drug Friendly, Patient Friendly

Prefillable staked needle syringe

- Tungsten-free
- No leachables from adhesives
- No contact between drug and needle
- Tamper-evident closure
- Gentle application
- Thin needle
- Easy handling

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