

A flexible material and the deep South!



Dear Customers,

I want to wish you all the best for the upcoming year and want to thank you again for the trust you have placed in Fresenius Kabi Product Partnering in recent years and especially in 2010.

The huge number of inquiries we discussed with you, our valued customers, last year makes us proud and is a clear mandate for us to keep our services at the levels reached so far and to improve as much as possible.

In the first Insight of 2011 we are pleased to provide you a view of our capabilities in plastic containers. We can offer a variety of flexible plastic containers from small ampoules up to big multi-chamber-bags holding several liters. An overview of the characteristics of the plastic materials, plastic containers, and the advantages of this exciting technology is given in the main article featured in this Insight.

Secondly, we have a plant in our Spotlight that is located at Port Elisabeth in South Africa. This plant is capable of manufacturing hormones as well as standard solutions and has long experience in contract manufacturing. It is ideally located for early patent expiry and therefore development of generic products. The main export regions are the Middle East and Europe.

Like every year you can meet us this year at several trade shows. You can see the dates on the schedule below. We would be glad to have the opportunity to meet you at one or the other of them. Please get in touch in advance to make an appointment for your visit, which helps us to meet your needs.

Again, I wish you a very successful 2011 and I am looking forward to seeing you soon!

Sincerely

Gerald Hofer

In this issue

Editorial

Flexible plastic containers
for sterile drug products and
infusion therapy

In the Spotlight:
Bodene Plant,
Fresenius Kabi South Africa

Exhibitions

- Interpex USA 2011
(March 29-31, New York - USA)
Booth 1465
- CPhI 2011
(Oct 25 - 27, Frankfurt - Germany)
Booth 31H21
- Interpex Japan 2011
(June 29 - July 1, Tokyo - Japan)
- PDA Pre-filled Syringes
and Infection Devices 2011
(Nov 8-9, Basel - Switzerland)
- Contract Pharma Table Top 2011
(Sep 22, New Brunswick, NJ - USA)

Flexible plastic containers for sterile drug products and infusion therapy

Sterile drug products and infusion therapy are becoming increasingly complex areas of medicine. Infusion protocols are becoming more specialized, for example in antibiotic therapy and chemotherapy. New drugs with complex handling protocols and stability issues are being introduced. And these challenges need to be met while at the same time improving safety and reducing costs.

The features of the container play an increasingly important role in fulfilling these requirements. This article reviews how different types of flexible plastic containers meet the demands of current sterile drug applications.

Today, a variety of non-glass, large volume containers (50 mL to 2.000 mL) and small volume containers (0.1 mL to 50 mL) for parenteral drug applications are available, and Fresenius Kabi has developed a broad competence in this flexible container technology.

Plastic bags

Fresenius Kabi's highly innovative freeflex® bags are made of inert plastic material. They meet the highest ecological and drug compatibility standards, and are highly transparent, flexible and lightweight.



Freeflex® bags are available as single- and multi-chamber-bags. They offer one or more separate ports with colour-coded, tamper-proof break-off closures, low weight, reduced waste volume and full collapsibility.

The bags are produced on state-of-the-art automated production lines. All production steps (bag production, filling, overwrapping, sterilisation, and packaging) are carried out in a single interruption-free process under clean room conditions.

Freeflex® bags can be sterilized in their overwraps at 121°C, and are available in the sizes 50 mL, 100 mL, 250 mL, 500 mL and 1000 mL.



Excellent Drug Compatibility

- Bag consists of multilayer film based on polyolefin (PP)
- No adsorption of the drug on the inner bag surface
- Inert material, compatibility with common drugs is comparable to glass
- No plasticizers or adhesives added, hence no migration into the solution
- More than 40 drugs have been tested, showing the same stability as with glass



Easy handling, enhanced safety

- Ergonomic design
- Large volumes of additional fluids can be added
- Easy drug reconstitution with Freeflex® transfer device or other compatible transfer devices
- Strictly air closed system
- Self-sealing septum in injection and infusion ports
- Port functionality - optimized design with ship-shaped ports for tear-proof sealing



Flexible plastic bottles



Turning to more rigid, but still very flexible containers, we come to KabiPac®, a light-weight, PVC-free alternative to glass bottles made of pure polyolefin. KabiPac® is moulded, filled and closed in a single inline, sterile “Blow-Fill-Seal” process, and is available as 100 mL, 250 mL, 500 mL and 1000 mL containers.

KabiPac® has an ergonomic design, is fully collapsible and is extremely cost-effective.

KabiPac® bottles are safe and easy to handle, environmentally friendly, and can be used for all standard infusion requirements.

They also have excellent drug compatibility and can be safely used for admixing various commonly used drugs. It is self-standing, non-breakable and easy to transport and most importantly has separate infusion and addition ports on its unique Duocap.

KabiPac®’s collapsible design means it can be used with a pressure infusion in emergency situations. KabiPac® is a closed container with no air inlet, which reduces the bacterial contamination risk compared to glass bottles.



KabiPac® main features

- Highly efficient and safe production process
- Low-cost container
- No overwrap necessary
- Excellent water steam barrier
- allows shelf life comparable to glass containers
- Convenient and simple usage
- Low waste production method
- Non fragile, easy to store and transport



Plastic ampoules or vials

The last years saw also a strong and increasing market demand for plastic ampoules and plastic vials. These blow-fill-seal containers are sophisticated single-dose ampoules, sized 1-30 mL, or multidose vials sized 10-50 mL, and offer an innovative alternative to glass vials and glass ampoules.

Polyethylene and polypropylene have become the materials of choice for these medical containers. The blow-fill-seal manufacturing process offers a safe and sterile way of making, filling and sealing these containers in one production step lasting only a few seconds.

All in all, flexible plastic containers for sterile drug products and infusion therapy offer new features and are interesting alternatives to standard glass containers.

With its decades of experience in the manufacture of each of all these flexible plastic containers, Fresenius Kabi Product Partnering can provide you with the optimal solution to protect your product as well as your patients and staff.



In the Spotlight: Bodene Plant, Fresenius Kabi South Africa



This Fresenius Kabi South African site has been in operation since 1992 and is situated on the edge of a lake in industrial Port Elizabeth - overlooking the Nelson Mandela Stadium, which featured prominently in the 2010 World Cup. As its name implies, Port Elizabeth is a busy harbour city. The international airport is a mere 10 km from the factory.

The manufacturing site has one building spreading over four levels that add up a total production area of over 14.000 m². The bottom level is dedicated to double volume warehousing and stability chambers. The mezzanine level houses offices, locker rooms, the boiler house and canteen. The production areas and laboratories are on the middle level and the top level houses the heating, ventilation and air-conditioning plants, water loops and utilities.

The facility manufactures a wide range of Standard Solutions & IV drugs. Initially the large volume PVC bags for the Standard Solutions were produced, assembled and filled on-site. During 2009, the suite for hormonal products was extended and upgraded. Medroxy-Progestosterone, a contraceptive IV solution is mainly produced in the suite.

In 2011, a further extension will implement equipment for the production of Fresenius Kabi's proprietary Freeflex[®] bags. These innovative containers are made of inert plastic materials - free of PVC, plasticizers, adhesives and latex. They meet the highest ecological and drug compatibility standards.

In line with this new product development, South Africa is in a unique position to exploit time frames when considering the patent protection expiry. South Africa enjoys a complete year's head start when compared with European manufacturers.

In addition to supplying local state and private hospitals, Fresenius Kabi South Africa also exports products to Europe. The Port Elizabeth team has extensive experience of adapting manufacturing processes and packaging formats to meet the clients' exact requirements. To complete the value chain, this excellent production

know-how is coupled with outstanding analytical competence - from quality control of the starting materials, through IPC production surveillance to the release testing of the finished products. Climate chambers are available for stability studies according to the ICH requirements.

The chemistry & microbiology laboratories are located on the centre axis of the production floor. These are staffed by university-qualified employees. The nearby Nelson Mandela University is a resource pool of chemical analysts, microbiologists and pharmacists.

As our customer, you will not only benefit from the ongoing cost-containment initiatives, but also the integrated production experience, the highly motivated staff and the state of the art technologies at the Port Elizabeth manufacturing plant as well as from our excellent record with international health authorities and client quality audits.

Key data Fresenius South Africa - Bodene Plant

Markets:

International scope

Technologies:

Handling of antibiotics & hormonal products

Filling of ampoules, bottles & vials

Filling of IV bags (e.g. Freeflex[®], PVC etc)

Aseptic liquid filling

Terminal sterilisation

Batch-Sizes:

Bags - 1.500 L to 12.000 L

Bottles - 3.700 L to 7.000 L

Vials - 50 L to 600 L

Ampoules - 50 L to 400 L

Containers:

Bags - 50 mL to 3.000 mL

Bottles - 100 mL to 1.000 mL

Vials - 2 mL to 20 mL

Ampoules - 1 mL to 25 mL

Certifications:

SA MCC cGMP

EU GMP

ISO 9001 : 2008 (Quality)

Services:

QC Support

Stability Studies

Pharmaceutical Services

Supply Chain

Warehousing and Shipping

Regulatory Support