packazine

PHARMA · Issue 01/2008

BOSCH
Invented for life

Persan | Detergent packaging gets full cycle
Heumann PCS | Be ahead with the GKF HiProTect
Zamodiet | Pharma package with a cosmetic cap

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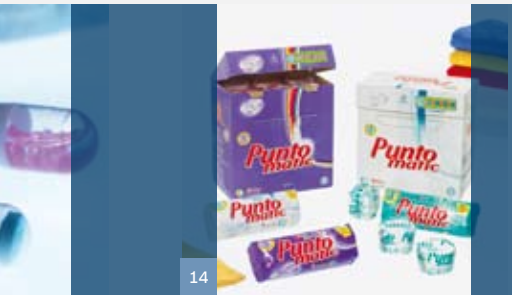
Bosch – your reliable partner for pharmaceutical solutions



Editorial

Dear Readers,

Bosch Packaging Technology is one of the leading companies in the world of packaging and process technology. As a one-stop provider we are gaining our customers' trust; through the power of innovation and cost-effectiveness; through reliability and quality. Our customer-focused activities now extend to 14 countries and 31 locations. All over the world we are engaged in the development and manufacture of products, offering a comprehensive service. By being so close to our customers we are able to meet your specific requirements as well as regional challenges and, through our performance, deliver superior customer value day after day – truly "Technology for Life".

Friedbert Klefenz
President
Bosch Packaging
Technology

An encouraging level of orders from the pharmaceutical industry demonstrates the attractiveness of our product range. We are aiming to expand our global position by offering new products and services and conquering growth markets. Global developments demand that, in doing so, we must take account of Asia, without neglecting other regions. Bosch Packaging Technology is already firmly established in Asia, which is why we have now opened a state-of-the-art plant in India, in addition to existing facilities in Japan and China.
Bosch Packaging Technology is facing the future with confidence. You can see for yourself at Interpack 2008, the world's largest packaging fair, from 24th to 30th of April. In Hall 6, on over 2000 square meters, we are showing concentrated Bosch competence. Here you will find trend-setting innovations as well as established solutions. We look forward to meeting you and exchanging views.

This latest edition of our customer magazine features an Interpack preview with many examples of profitable, innovative solutions – "Technology for Life".

I hope you all enjoy your reading.
Kind Regards

Friedbert Klefenz

Pharma-Trends: **Safety**

Safety is a key driver in the pharma industry, both from the perspective of an end-user patient as well as from an operational standpoint.

This article is the second in a series of articles examining the role packaging will play in the key trends impacting the pharma industry. Next issue, our final article will cover automation and efficiency.

Pharmaceuticals, such as oncology drugs, biopharmaceuticals and vaccines are all growth markets, but they also possess highly volatile properties. Cytotoxic agents and hormones have a higher risk of cross-contamination from harmful dust exposure during processing. In addition, certain formulations require minimal doses due to high potency levels. In light of these facts, automation is a key requirement in processing, in that it both protects workers and ensures reproducible, accurate dosage.

Automation and safety technologies made by Bosch

To prevent exposure to harmful products, Bosch has developed automation and safety technologies that can protect operators, such as barrier technology for aseptic filling lines, isolators and containment technology. These technologies have gained wider acceptance in order to meet the demands of the growth markets. In addition, FDA guidelines for aseptic manufacturing strongly recommend their use.

The industry is rapidly adopting isolators and restricted access barrier systems (***RABS***) because verification technologies are much improved. Again, integration in this realm can be key. An integrated isolator and filler offers advantages over two components from two suppliers. In this type of system, controls are integrated, as is the knowledge base behind the system.

Bosch has met this demand with the ***GKF HiProTect*** capsule filling system. ***HiProTect*** is a modular capsule filling line with integrated isolators, as well as an automated self-cleaning system. The unit also offers flexibility to expand into liquid capsules for more accurate dosing. Accurate dosing, for obvious health reasons, is also an urgent matter being addressed with greater automation.

High efficiency and quality assurance

To increase accuracy, many of Bosch's packaging and processing applications integrate Process Analytical Technology (PAT). PAT is the FDA's risk-based approach, which enables high efficiency and quality assurance in pharmaceutical manufacturing by introducing inspection and controlling systems throughout the entire process.
Bosch offers equipment that provides in-line analysis and control of critical parameters for filling capsules and liquid pharmaceutical products. For example, the solid capsule filling process's quality parameters can be monitored and controlled, and capsules of a sub-standard quality can be identified and eliminated. Compressed air and vacuum-monitoring units constantly check operating pressure and stop the system before malfunctions arise. Problems are not just identified; they are fixed along the way in a closed loop, which identifies faults before they can reduce downtime.

These examples of increased automation in the production of pharmaceuticals are vital, not just for operational efficiency but to serve the needs of the growing markets for highly targeted and highly potent treatments.

For more information please contact:
Ulrike Probst
Phone +41 52 674 8053
ulrike.probst@boschpackaging.com

Combined line for cylindrical cartridges and vials

for Vetter Pharma-Fertigung GmbH & Co. KG

Since 1975, Vetter Pharma-Fertigung GmbH & Co. KG has been a global specialist in aseptic production of pre-filled application systems. Located in Ravensburg, Germany, this contract manufacturer, which specializes in the aseptic filling of liquid and lyophilized drugs for international biotechnology and pharmaceutical companies, supports customers in every phase of production: from the clinical phase to product development, through to successful product launches and commercial manufacturing.

Since 2004, Vetter has spent 36 months building its new €100 million, state of the art aseptic production facility, with new production lines designed for dual-chamber syringes, single and dual-chamber cartridges, and vials. To meet growing market demand and diverse customer requirements, the new facility started operation in October 2006 with two filling lines (***RVS I + II***).

The market for pre-filled application systems requires safe handling of sensitive products, high-end sterility assurance and validation, and sophisticated automation to separate personnel from the production environment. The market also requires cost-efficiency and product line concepts with a high degree of flexibility. To meet these challenges, Vetter and Bosch Pharma Liquid co-developed the combination line ***RVS II***, for single chamber cartridges and vials, to offer the maximum in environmental controls, while minimizing product contamination and reducing operator contact with the product.

To offer customers a variety of products, Vetter uses Restricted Access Barrier Systems (***RABS***) technology on this combination line. With ***RABS***, it is possible to connect all process parts of a production line (glass washer, dry heat tunnel, filling line, freeze dryer) into an automated line. ***RABS*** offers a high grade of product quality and safety from contamination, as almost no manual handling is necessary. It also offers a high degree of flexibility regarding format changes between two batches, taking half of the time when compared to isolators.

1 The Vetter Pharma plant in Ravensburg
2 Filling machine with ***RABS*** Technology
3 Loading of empty vials

The ***RVS II*** combination line fills sensitive protein products, highly specific molecules (such as monoclonal antibodies, hormones, and liquid formulations), and freeze-dried products for the clinical market. It offers flexibility between liquid and freeze-dried formulations, between single chamber cartridges and vials, and between different portfolio ranges.

"We chose Bosch Pharma Liquid as our service partner for this project because it is renowned for its years of experience and reliable product management", says Thomas Otto, Managing Director of Vetter Pharma-Fertigung GmbH & Co. KG, "and we are very satisfied that Bosch Pharma Liquid produced the combination line on time and to budget, to meet our Key Performance Indicators. Bosch is a very reliable partner for us". Bosch designed the line according to Vetter's URS (User Requirements Specifications).

In Oct 2007, within its first year of operation, the ***RVS*** won the "European Outsourcing Award" in the "Most improved Process/Plant/Facility" category, at the International Contract Services Expo. It also won the 2007 "Facility of the Year Award" in the "Process Innovation" category, for its technological innovations in the manufacturing of pre-filled syringes, cartridges and vials.

For more information please contact:
Klaus Schreiber
Phone +49 7951 402 367
klaus.schreiber@boschpackaging.com

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The Pharma Division of Heumann PCS, part of the French Fareva Holding, provides contract-manufacturing services to more than 50 customers worldwide, including a number of the top ten pharmaceutical companies. It is known for its first class facilities, technologies and experience in the manufacturing of solid dosage forms containing highly potent or toxic compounds.

To protect workers from hazardous drugs during manufacturing, and yet allow high flexibility, is a big technological challenge for equipment manufacturers, as well as for pharmaceutical companies. To meet such requirements, Heumann PCS looks for equipment with special features to ensure that manufacturing operations are in compliance with environmental, health and, of course, Good Manufacturing Practice (GMP) regulations. The new ***GKF HiProTect*** capsule-filling machine delivers such features, being engineered to satisfy

1 ***GKF HiProTect*** undergoing the cleaning process
2 Additional peripheral equipment with containment construction
3 Heumann PCS in Feucht (Germany)

One step ahead of the market: GKF HiProTect meets the needs of Heumann PCS

GMP requirements and safely processing potent compounds. It features an innovative, integrated isolation system developed by Bosch Packaging Technology.

The ***GKF HiProTect*** minimizes the risk of contamination by eliminating the contact between an operator and potent substances and also removes the need for expensive and restrictive air suits, masks and other safety equipment. Its advanced powder dosing station gives a highly accurate fill weight, while its innovative design helps avoid product loss and provides easy accessibility to the station.

HiProTect caters to Heumann PCS's special needs in two ways. On one hand, its modular design emphasizes flexibility, so it can switch between fill combinations or add capacity quickly. This provides flexibility for a wide range of filling combinations, including powder, tablets, pellets and liquids. It provides "containment without compromise", allowing opening capsules, check-weighing and filling as an integral process. On the other hand, the clear construction of all stations makes the entire system easy to clean; it has its own wash-in-place (***WIP***) function for product contact parts and is also easy to clean from outside.

"We are glad that Bosch Packaging Technology accepted the technological challenge and developed the ***GKF HiProTect*** capsule filling machine. In order to serve the needs of our clients as well as to guarantee the safety of our workforce we just bought its prototype. The combination of flexibility, containment and an easy-to-clean machine design is exactly what we need for capsule manufacturing under high containment conditions," said Mr. Weigelt, project manager at Heumann PCS. "We are very impressed at Bosch's project management, professional attitudes and solution-oriented research and development, as well as its willingness to accept the special requirements that we need for our customers."

The ***GKF HiProTect*** capsule-filling machine not only provides Heumann PCS with solutions, it is a step ahead of the market trend in answering the growing need of pharmaceutical researchers and producers to fully isolate operators from active substances during operation, maintenance, and cleaning. Through several key philosophies in its design – containment, flexibility, quality controls, cleaning, and accessibility – ***HiProTect*** provides a quantum leap for manufacturers and developers to meet the rising challenges in the marketplace beyond simply adding isolators to a filling line.

For more information please contact:
Felix Nink
Phone +49 711 811 57 526
felix.nink@de.bosch.com


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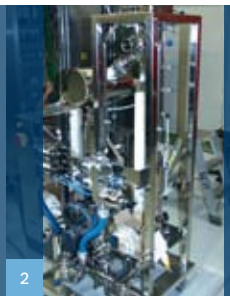
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High-end engineering from Saxony

Pharmatec celebrates 300 plants sold for highly purified media generation. Pure Steam and Water for Injection (WFI) – hardly any pharmaceutical company can do without them. Pharmatec was founded in 1993 and is part of Bosch Packaging Technology since June 2007.

Since it's foundation, numerous pharmaceutical manufacturers have profited from highly purified media generation produced by the company, which is based in Dresden, Saxony.

Reliable and energy-efficient in all performance areas

The Pharmatec Multi-Stage Distillation Unit and Pharmatec Pure Steam Generator are designed for the production of aseptic, pyrogen-free Water for Injection and Pure Steam. Production capacities range from 50 to 15,000 liters per hour (Distillation Unit) and 30 to 5,000 kilograms per hour (Pure Steam Generator).

The distillation method is based on the energy-saving multi-stage principle (with three to eight distillation columns). All equipment components have the necessary features to ensure the highest possible savings on energy and auxiliary media. Pure Steam generated in this way is suitable for sterilization in place (SIP) of equipment components like containers, preparation tanks, pipeline systems, filling plants and filters, as well as air humidification in (ultra-)clean rooms. The principle of Pure Steam and WFI generation is based on natural circulation.

Tailor-made installations

Towards the end of 2007, Pharmatec received its 300th order for a pharmaceutical highly purified media generator (Pure Steam Generator) from Boehringer Ingelheim Austria (BIA) in Vienna. This company had been using two WFI distillation plants and two Pure Steam Generators since 2003. According to

1 Pure Steam Generator with integrated membrane degassing system
2 7-column Distillation Unit
3 Separation System for pyrogene removal

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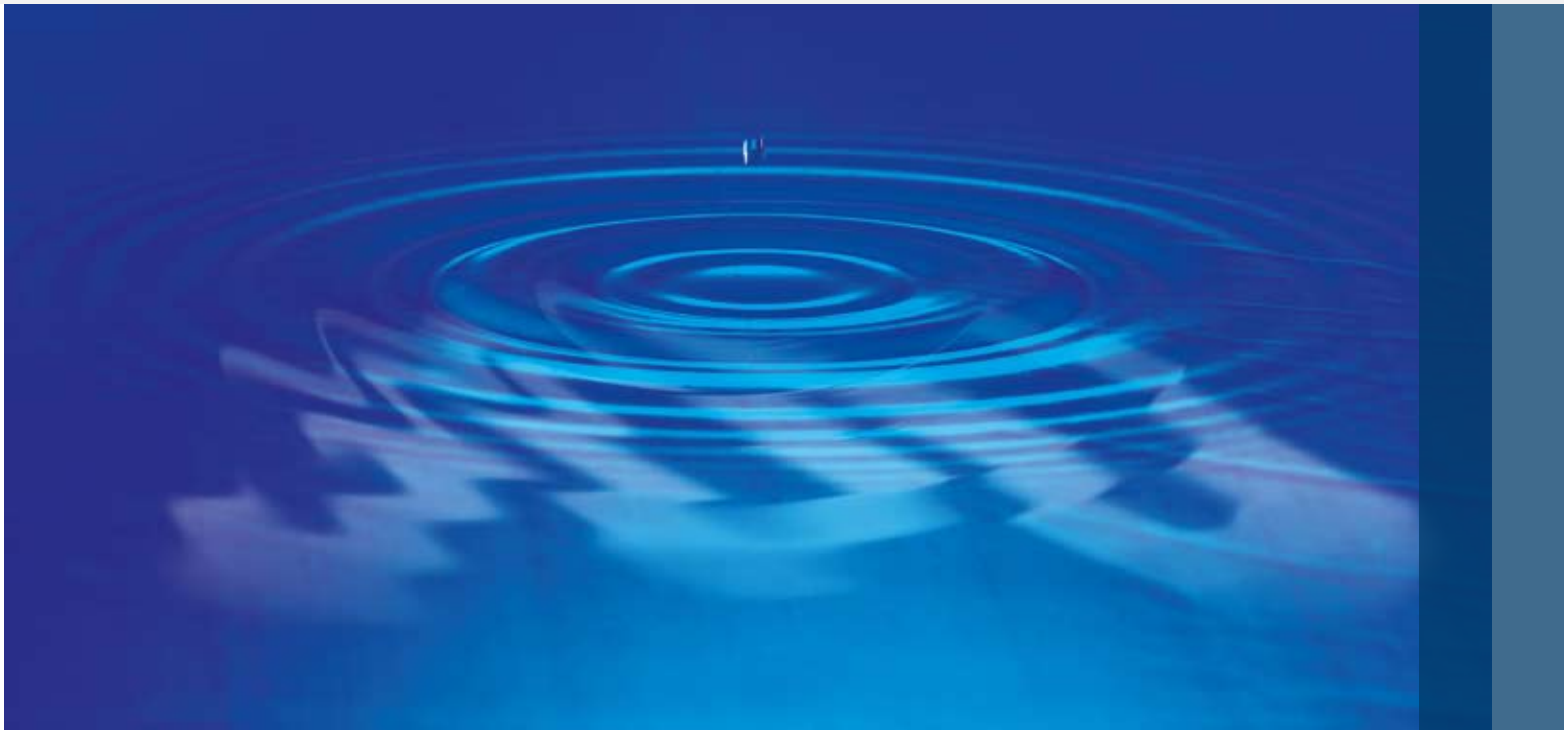
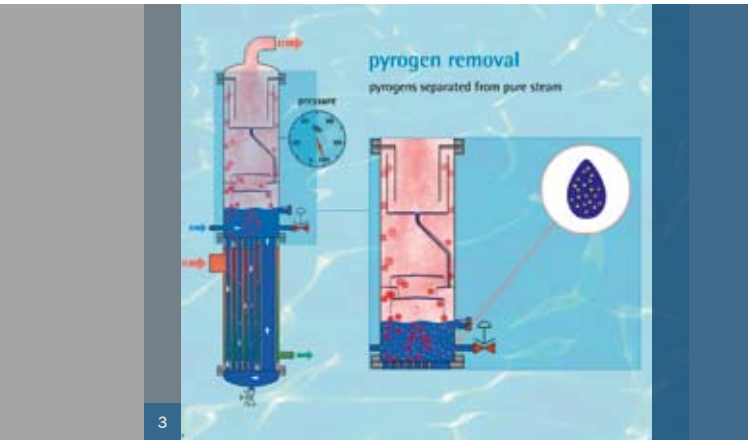


BIA‘s project manager, the reasons for this renewed order were technical reliability, economic operation, competitive pricing, operator-friendly equipment and a transparent design, as well as Pharmetec‘s excellent and fast customer service.

Apart from delivering all standard components of this Pure Steam Generator (such as DTS heat exchanger, pre-heater and sampling cooler) Pharmatec was able to provide a special space-saving design, tailor-made to suit local conditions. This meant that there was no need for elaborate on-site alterations or rerouting of pipework.

At the customer‘s special request, a compact degassing system will be integrated as part of the installation. Using a compact, efficient membrane degasification device, Pharmatec is able to meet more stringent requirements regarding inert gas content of Pure Steam in accordance with EN 285 and HTM 2010.



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Innovative and customer-focused
As an innovative producer of devices for the pharmaceutical sector it is Pharmetec‘s declared objective to develop packaging units and complete installations with efficient and customer-specific procedures and technologies.

For example, Pharmatec‘s highly purified media generators can be designed to be earthquake-proof, intrinsically safe in accordance with ATEX guidelines or suitable for different feed waters, as well as for continuous or batch operation. To accomplish this, Pharmatec performs a sequence of complex operations in development, engineering, assembly, commissioning and qualification.
Till this day, Pharmatec is an acknowledged supplier of highly purified media generators and pharmaceutical installations in high-end process and biotechnology.

For more information please contact:
Albrecht Voigt
Phone +49 351 2827 814
albrecht.voigt@pharmatec.de

The workhorse of the vial filling industry

Bosch's *FLC* line brings longevity and flexibility to a dynamic market

Customer Statement

"The *FLC* lines are the key in our production. The machines operate ten hours a day and are very reliable. These positive experiences were crucial in making the decision to invest into two more *FLC* lines", says Mr. Ding, Director of the Chengdu Institute for Biological Products, China. "We increased our flexibility significantly, which allows us to compete more effectively since the *FLC* lines have been integrated."

In 2003, Bosch introduced the *FLC* filling machine type series for vials and infusion bottles, expanding its product portfolio into the medium output range. The launch came after extensive market research and consultation with Bosch's core base of pharmaceutical customers. This approach – carefully matching design concepts with customer needs – reflects the Bosch product development philosophy.
After five years and more than 50 *FLC* lines installed worldwide, this approach to bringing capital-intensive equipment to market has paid off.

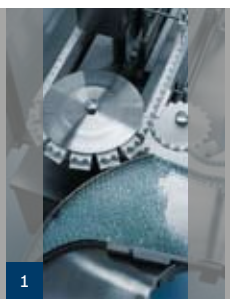
Flexibility: Quick changeover

The *FLC* can process vial sizes from 2 ml to 500 ml, at up to 400 vials per minute. While speed and adaptability to size differences are key performance indicators, Bosch has also developed this system with broader production parameters in mind. Within the size range, only three sets of size-parts are required, allowing numerous vial sizes to be run on the same size-parts.
The machine is controlled by a touch screen with graphic operator guidance, which stores all production data and processing parameters. With just a few commands, the user can call up a filling and closing process, which then operates with precisely reproducible results.

Keeping filling options open

Innovation in the biotech and biopharmaceutical fields is a strong market driver. Firms looking to capitalize on novel formulations must assess the filling

1 Container infeed with turntable and infeed wheel
2 Processing of infusion bottles
3 Piston pump filling station
4 *RABS* (Restricted Access Barrier System)



requirements, based on product characteristics, and select product contact parts accordingly. For the ***FLC***, rolling diaphragm pumps are well suited to sheer sensitive products. Time pressure filling systems, piston pump filling systems, and mass flow measurement systems are also options.
Reproducible precision filling is achieved by means of programmable, pump-stroke servo-movements for each filling head and for the filling-needle movement. Filling programs can be saved and activated from a control panel.

Modularity: Technology that adapts
A key focus of Bosch's design strategy is modularity. Equipment modules that can be added, and integrated, provide the versatility that pharmaceutical companies need when developing production concepts.
The infeed turntable incorporates a laminar flow design, which has taken into account the specific needs of the pharmaceutical sector. The special surface design allows the processing of nearly unstable containers.

Another modular component is the "CleanFeed" stopper feed system at the rubber stopper fitting station, which minimizes particle risk and germ contamination. Rubber stoppers are separately supplied and sorted. With CleanFeed, the sorting bowl is loaded directly with the correct quantity of stoppers, up to the height of the sorting bowl base.

Customer Statement

"We have chosen the ***RABS*** compatible ***FLC*** to allow for more flexibility in our production operation", says Hartwig Hönerloh, Associate Director, Technology Service and Validation and Qualification.
"Thanks to the optional modules – for example, CIP (Clean in Place), SIP (Sterilize in Place) or IPC (In-Process Control) – critical processes are automated and validated and we are able to adapt to new market demands promptly. In addition, the easy operability was an important criterion of our decision. Since we acquired the ***FLC***, we are able to enter extensive recipe parameters via a touchscreen interface. Furthermore, we save costs and above all time thanks to the option of maintaining the plant through remote control."

Finally, the ***FLC*** is particularly well suited for various protection concepts and installations, such as in a traditional sterile room, in wall installations, in combination with ***RABS*** (Restricted Access Barrier System) or with isolator technology.

The Bosch Philosophy
The ***FLC*** illustrates how the realization of Bosch's pharmaceutical customers' requirements has led to the development of an innovative filling and closing machine, which has been very well received on the market since its launch in 2003. 50 machines later, the line is still a defining force in the pharmaceutical market.

For more information please contact:
Dieter Bandtel
Phone +49 7951 402 362
dieter.bandtel@de.bosch.com

Detergent packaging gets full cycle from Sigpack Systems

Persan, a family run company, is Spain's largest producer of detergents. Outside its home country's borders it is still largely unknown, but is expanding rapidly and is increasing sales in the wider European market.

In 2006, when planning a new packaging solution for an established product, Persan was not only interested in the purchase of hardware, but also in a complete support service; including consultations, the running of trials and the preparation of samples for market studies, right through to the supply of a turnkey packaging system.

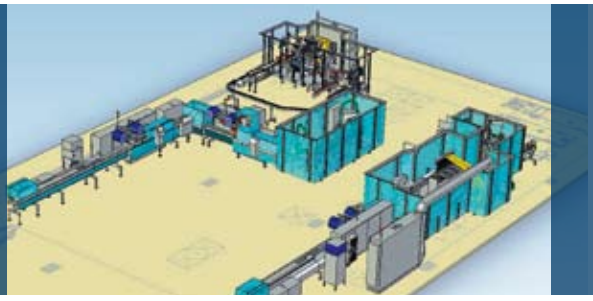
Success through service

For many years, Persan successfully sold its "Puntomatic" washing detergent tablets in a conventional, but inflexible and consumer-unfriendly, packaged roll. In order to develop a new packaging style, but retain the traditional image, Persan contacted Sigpack Systems.

In order to improve the product protection of an opened package, the current packaging was to be changed to a 4x2 multi-pack. Numerous variations on packaging styles were thought through, hand-made samples prepared and the appropriate machine system presented to Persan. The result was a package with primary and secondary packaging presented as flexible bags. This allowed a wide and diverse range of possibilities for product arrangement and an association with the previous tubular form of the package.

Consulting for solutions

Recommendations for a suitable film for the primary package, secondary package and the tear-open strip also resulted from consultations. The individual films had to be harmonized with each other to a greater extent than with other concepts, e.g. in order to prevent the films



System layout with details of handling, primary- and secondary packaging

The new convenient packaging concept! Portion pack of two/ flow pack and cardboard case as secondary package

sealing against each other, with the face sealing.
With the use of flexible bag technology, the major challenge was to manufacture smooth and tight packages. The most important precondition for this was a very close sealing of the tabs, for which special sealing jaws were developed. Before realization, the preferred concept had to be confirmed in a test market. For this, Sigpack Systems produced 2000 multi-packages from 8000 individual packages.

More than machine supply
Besides the excellent consultancy and service provisions, Persan profited from the efficiency, professionalism and experience of Sigpack Systems. The relationship shows that Sigpack Systems is more than just a machine supplier, which can be seen by the following overview of the services offered.

Consultancy
Consultancy is offered in the form of workshops. The advantages and disadvantages of various packaging variations are shown with numerous sample packages. New concepts are also developed and introduced up to the sample stage. The aims are the optimization of the packaging material design, improving the efficiency of the machine, adapting to the requirements of the market, and also to show a breakdown of the costs. Workshops can also be carried out with the packaging material supplier.

Trials
The machine performance specified is simulated on various machines, which cover all the standard technologies and formats and are suitable for trials with gas flushing.

High speed primary packaging, grouping and multipackaging

All the important quality control measuring procedures are available for seal integrity, sealing force, burst pressure and residual oxygen content.

Samples

Hand-made test samples visualize new packaging styles and serve to calculate the packaging dimensions. Besides market tests, or stability tests, the prototype machines are being frequently used for the production of semi-industrially manufactured initial samples.

Exceeded expectations

The machines for Persan Puntomatic were finally delivered at the end of May 2007 and have been in production since the beginning of July. Further contracts followed and have exceeded the expectations of the customer, with regards to both efficiency and performance.

For more information please contact:
Norbert Höchst (Packaging Materials)
Phone +41 52 674 64 84
norbert.hoechst@sigpacksystems.com

Urs Schweizer (Packaging System)
Phone +41 52 674 65 14
urs.schweizer@sigpacksystems.com

The traditional roll wrapped package (at the top) and at the bottom the new, faster and more flexible flow wrapped package with higher protection properties

Bosch on the menu **for “Housediet”**

“We are what we eat” is the slogan Natur House, the Spanish nutrition & diet company, has used over the past few years, during an expansion phase that has seen it become the market leader in this sector. Bosch has participated in this success, with the supply of filling and capping lines, for vials of “Housediet”, one of Natur House’s key products.

Natur House has more than 1,500 nutrition and dietetics assessment centers throughout Europe and America. Three years ago, Natur House asked Zamodiet, the Spanish food and dietary product manufacturer, to produce new vials for its “Housediet” product in a format designed by the Natur House marketing department. The product had previously been supplied in syrup and ampoule, with a double point end, but changing consumer tastes prompted Natur House to produce a new type of packaging, together with a modified formula.

Mid pharma – mid cosmetic packaging

According to Fernando Martín, plant manager of Zamodiet, “We were looking for packaging that fulfilled several functions: easy opening, easy to use and resistant. At the same time, we were looking for something more sophisticated than the previous packaging, innovative but comfortable to use”. After several tests, a combination of these factors led to a pharma package with a cosmetic cap.

120 million vials a year

The previous filling equipment used for the Natur House product was Spanish made. Although this equipment was working correctly, it did not offer the type of production required by Natur House’s new strategy. In 2005, Zamodiet purchased a Bosch production line consisting of an ***FRK 5181 CIP*** filling machine and a ***VRM 6080*** capping machine for a production of 250 vials per minute. However, the success of the revamped Housediet product soon saw consumer demand outstrip the production capacity. Impressed by the original increased production and the efficiency

Factory site of Zamodiet near Zamora, Spain

1

Bosch rotary capper
VRM 7120

of the installed Bosch filler and capper, Zamodiet then purchased a second line to keep up with the increased consumer demand.

With the second line also consisting of an ***FRK 5181*** CIP a filling machine but with a ***VRM 7120*** capping machine, production rose to 400 vials per minute, allowing a total production of 120 million vials per year. From the factory, production is distributed to the logistic centers and from there to more than 1,500 dietetic shops all around the world.

Exceeding expectations

The products filled by Zamodiet have different viscosities, from very fluid to very dense, and, furthermore, some products have solid particles in suspension, which is a major challenge for suppliers of filling machines. However, the Bosch lines exceeded all expectations in terms of design, high output and efficiency.

Fernando Martín has highly praised the input from Bosch, “The difference that put Bosch ahead other suppliers was the design of the lines, robust equipments, together with its great reputation and many years’ experience”.

Bosch and Zamodiet have also been delighted to be associated with Natur House, which, since its establishment more than 20 years ago, has been growing continuously and has become a reference point in the dietetics and nutrition world.

For more information please contact:
Karl-Heinz Horn
Phone +49 2162 248 369
karl-heinz.horn@de.bosch.com

1 Bosch piston filler ***FRK 5181 CIP***
2 Bosch rotary capper ***VRM 7120***

Events Food 2008

Date	Events	Location	Branch
24. – 30.04.2008	**Interpack**	Düsseldorf, DE	all
25. – 28.05.2008	**iran food & bev tec**	Teheran, IR	all
14. – 16.05.2008	**Packtech & Foodtech**	Shanghai, CN	all
03. – 06.06.2008	**Fispal Technologia**	São Paulo, BR	all
24. – 27.06.2008	**EXPO PACK Mexico**	Mexico City, MX	all
24. – 27.06.2008	**Rosupak / Foodmash**	Moscow, RUS	Food
09. – 11.07.2008	**ProPak China**	Shanghai, CN	all
15. – 18.09.2008	**Taropak**	Posen, PL	all
23. – 25.09.2008	**PPMA Show**	Birmingham, UK	all
30.09. – 03.10.2008	**Macropack**	Utrecht, NL	all
13. – 17.10.2008	**Agroprodmash**	Moscow, RUS	Food
14. – 16.10.2008	**ProPak CAPE**	Kapstadt, RSA	all
09. – 13.11.2008	**PackExpo International (PMMI)**	Chicago, US	all

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Robert Bosch GmbH

Editor in Chief
Central Marketing
Ulrike Probst
Phone +41 52 674 80 53
pa@boschpackaging.com

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Stuttgarter Straße 130,
D-71332 Waiblingen

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03. – 06.06.2008	**Fispal Technologia**	São Paulo, BR	all
24. – 27.06.2008	**EXPO PACK Mexico**	Mexico City, MX	all
02. – 04.07.2008	**INTERPHEX JAPAN**	Tokio, JP	Pharma/ Cosmetic
09. – 11.07.2008	**ProPak China**	Shanghai, CN	all
15. – 18.09.2008	**Taropak**	Posen, PL	all
23. – 25.09.2008	**PPMA Show**	Birmingham, UK	all
30.09. – 02.10.2008	**TechnoPharm**	Nürnberg, DE	all
30.09. – 03.10.2008	**Macropack**	Utrecht, NL	all
14. – 16.10.2008	**ProPak CAPE**	Kapstadt, RAS	all
09. – 13.11.2008	**PackExpo International (PMMI)**	Chicago, US	all