PHARMAPACK
Drug Delivery & Packaging

INNOVATION GALLERY eBOOK

2022

Patient / User Safety

Ease of Use

Eco-friendly

Patient Adherence

Cost Effective

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www.pharmapackeurope.com

informa markets

INDEX 2022

EXHIBITOR INNOVATIONS

Aidaptus® 2 step disposable auto-injector platform

2022

Company name: Owen Mumford Pharmaceutical Services

Country: United Kingdom

Product name: Aidaptus® 2 step disposable auto-injector platform

Product type: Routes of Administration

Date of launch: 04/10/2021

Current development phase: Commercialization

Patent: EU Registered design 007735782-0001

Target markets: Global

Target clients: Pharmaceutical Companies

FACT SHEET

PRODUCT DESCRIPTION

Aidaptus® is a disposable auto-injector platform which provides versatility for pharmaceutical companies and intuitive medication delivery for patients' self-treatment.

Aidaptus can be used with both 1mL and 2.25mL ISO syringes (cropped and small round flange) in the same base device with minimal change parts, it is also designed to work with a range of fill volumes. This minimises the level of validation testing and regulatory requirements when selecting a device for each drug and formulation. It provides flexibility for pharmaceutical companies during the clinical trial phase of drug development and for life cycle management when varying formulations may be required

APPLICATION AREAS

- Aidaptus is a platform disposable auto-injector for the subcutaneous administration of drugs. The product is designed for use by a patient, carer or healthcare professional. Aidaptus has undergone thorough Human Factors testing to ensure it is suitable for use by a wide variety of patient demographics and therapy areas as well as healthcare professionals. This also includes patients across a range of ages and those with dexterity challenges.
- Aidaptus automatically provides needle shielding before, during and after use and so protects the user from needle-stick injuries and also complies with needle-stick prevention regulations. The concealed needle can help to make injections less intimidating for patients and may encourage treatment adherence as a result.
- Aidaptus is designed to accommodate both 1mL and 2.25mL primary container prefilled syringes in the same device with only minimal change parts and so is suitable for a range of formulations including biologics.
- Aidaptus is designed so that it is simple & intuitive to use with minimal user steps. It has both visual and audible indicators to guide the patient successfully through the drug delivery procedure and help achieve therapy compliance. The device is small, lightweight and discreet for easy storage and use.
- Aidaptus is suitable for a variety of therapy areas which require subcutaneous administration of drugs including Rheumatoid arthritis, Crohns' disease and multiple sclerosis.

Website: www.ompharmaservices.com/products/aidaptus-auto-injector/

Aidaptus® 2 step disposable auto-injector platform

KEY FEATURES

- Timescales from drug development to clinical trials and final regulatory approval have shortened in recent years. This places some pressure on drug delivery devices, as they should ideally be able to accommodate modifications to the drug during the formulation, development and life-cycle management process – without significantly impacting the final product timelines. Aidaptus' design aims to provide pharmaceutical manufacturers the option to modify drug volumes and viscosities, without needing to change their selected delivery device.
- Aidaptus disposable auto-injector can be used with both 1mL and 2.25mL ISO syringes (cropped and small round flange) in the same small base device with minimal change parts. The innovative self-adjusting plunger also allows for use with a range of different fill volumes with no change parts. A choice of delivery springs allows options for higher viscosity formulations such as biologics. This provides true flexibility for pharmaceutical companies during the clinical trial phase of drug development and also for life cycle management when varying formulations may be required.
- Aidaptus features automatic needle insertion, enabling consistency of injection experience for patients. In addition, the two-phase independent needle insertion and dose delivery help to prevent device related wet injections, drug wastage & syringe breakage. This helps to ensure that the patient receives the full dose of medication for their treatment.
- Aidaptus has audible notifications to provide clear feedback to the user after needle insertion and also once the drug delivery is complete. In addition, there is a visual confirmation at the end of dose delivery via a yellow plunger in the device window. This helps to provide the patient with reassurance & confidence that they have successfully completed their drug administration. The large window also allows the patient to check drug clarity and colour prior to use.

Aidaptus is available in two base platform options: a clear outer body or opaque solid housing. Both versions provide a choice of window sizes to align with the fill volume of the syringe. Custom designs and information can be added via an outer wrap. This provides versatility for branding and customisation as well as options for market segmentation and life cycle management.

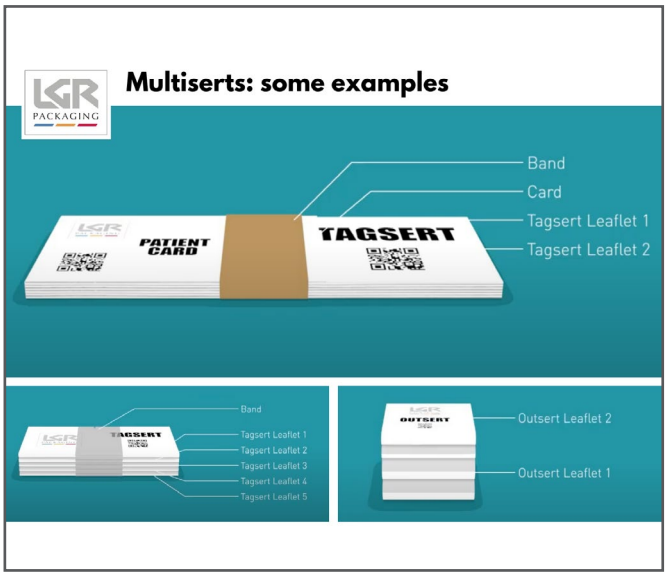
The patented technology in Aidaptus provides true platform benefits in robustness and also reduced time to market, cost and risk.

ADDITIONAL RESOURCES

Please see https://www.ompharmaservices.com/explore-aidaptus/

Multisert

2022



Company name: LGR PACKAGING

Country: France

Product name: Multisert

Product type: Routes of Administration

Date of launch: 01/04/2021

Current development phase: Commercialization

Patent: None

Target markets: Worldwide

Target clients: Pharmaceutical companies

FACT SHEET

PRODUCT DESCRIPTION

The multisert is a combination and assembly of two up to six different leaflets – simple or complex leaflets, as well as patient cards, from same or various sizes – through bands, stickers or glue dots.

This complex construction is a solution to keep a compact and condensed leaflet in the folding carton, despite a growing quantity of information to mention. It particularly enables patients and caregivers to quickly get right and accurate medical information for critical pharmaceuticals to avoid any drug misuse.

APPLICATION AREAS

The multisert concept is intended for value-added pharmaceutical treatments requesting a large quantity of information dedicated to different people.

The assembly of the different documents in one compact leaflet is an improvement for laboratories and copackers on their packing lines and for patients and caregivers who get the right information.

Website: https://www.lgr-packaging.com/en/multiserts.html

Multisert

2022

KEY FEATURES

The USP of the multisert concept lies both in the product itself and in the technology implemented to produce such complex product.

INNOVATION:

When pharmaceutical products require more than one leaflet for medical purposes or very large leaflets due to important information to mention, the leaflet can become a problem on packing lines for laboratories or CMOs: management of several leaflets or too large products. The possibility to combine up to 6 different kinds of leaflets in a compact assembly is a new service and makes the packing operation easy: there is only one reference to manage, and the product is dimensionally optimized.

To produce such complex combinations, an outstanding high-level process has been specifically developed. Feeding, assembly and unloading of leaflets are carried out at a very quick pace. The equipment can be adapted to various kinds of constructions. It is above all fitted with quality controls throughout the process, with automatic ejection of non-compliant products: presence and position of leaflets, glue dots, stickers or bands, control of codes and texts, but also the assembly's thickness. These controls are led in real time by online HD-sensitive cameras to make sure that 100% quality is achieved.

PATIENT EXPERIENCE AND EASE OF USE:

The multisert concept aims at improving patient adherence: some elements of the assembly are dedicated to the patient; the other ones are for caregivers. Each person gets a quick access to the relevant information. It is particularly important for specific and critical treatments with added value.

The presence of one or many patient cards is a complementary asset for the treatment adherence, as the person can keep this card with him/her to check the posology or the prescription calendar at any time, or to inform in case of emergency that he/she has a specific treatment.

The concept is easy to use for patients and HCPs, as each person gets quickly its personalized information.

It is also easy to use for laboratories and CMOs during their packing operations.

SUSTAINABILITY:

The multisert leaflet is a recyclable paper product, made up of very thin materials (between 40g and 50g). The fibre required for leaflets comes from recycling and industrial residues. Paper leaflets are collected and recycled, closing the loop in the paper production.

Bundles may be made of kraft or white paper, and glues are water-based to reduce the environmental impact of the products.

ADDED VALUE:

The concept is offering new possibilities for the pharmaceutical industry.

Paper leaflets still represent the only failsafe method to ensure vital information reaches the patient at any time: they are highly regulated, directly inserted in the medicines packaging, protected against counterfeiting – especially when leaflets are complex – , cyberattacks and internet breakdowns.

For treatments which are more and more specific and complex, it is particularly important that patients and HCPs have the appropriate and detailed information. The quantity of data to provide them is growing, and packaging specialists must find solutions to pack these larger leaflets without problem.

The multisert product proposed by LGR Packaging offers many possibilities to increase the communication area for personalized information, while keeping a performant industrial packaging process. It improves the use of all players in the supply chain: laboratories and copackers, caregivers and healthcare professionals, patients.

ADDITIONAL RESOURCES

Please see https://www.youtube.com/watch?v=rKetdUvrK9E

PiccoJect™

2022

Company name: Haselmeier™ a medmix Brand

Country: Germany

Product name: PiccoJect™

Product type: Routes of Administration

Date of launch: 18/05/2022

Current development phase: Prototype

Patent: Pending

Target markets: Worldwide

Target clients: Biopharmaceutical companies

Business model: Direct sales

FACT SHEET

PRODUCT DESCRIPTION

"Excellence through simplicity" sums up the key features of PiccoJect™.

The device is a compact, customizable and intuitive 2-step autoinjector for the safe and convenient self-administration of subcutaneous injections. Its ease-of-use and sustainability set this platform apart from existing offerings in the marketplace. The device is supported by a full set of services including final assembly, labeling, and packaging.

PiccoJect™ accommodates any standard 1 ml long and 2.25 ml pre-filled syringe with a small round or cut flange. The same mechanism is available with two different cross-sections, tailored to the syringe size to provide a discrete and patient-friendly form factor.

APPLICATION AREAS

PiccoJect™ is applicable for the use in any drug product that is packaged in a prefilled syringe. This includes novel biologics in indications such as arthritis, asthma, cancer, cardiovascular disease, diabetes, autoimmune diseases, genetic disorders, and some viral diseases such as hepatitis. In addition the use in biosimilars of existing drugs like adalimumab and etanercept is also a focus.

The PiccoJect™ platform would be customized for the unique requirements of the drug product. This includes part color, the size of the dose window, or spring force.

The device is designed for patients and non-professional care givers to give an injection in the home setting. But it would also be suitable for use by nurses and other health care professionals in the clinic.

Website: https://www.araymond-life.com/en/customized-solutions

PiccoJect™

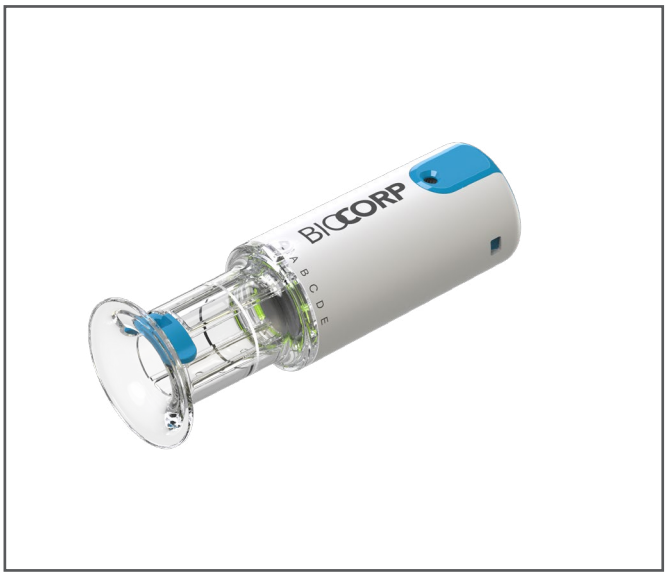
KEY FEATURES

There are six key features of PiccoJect™ that differentiate it from other autoinjectors on the market:

1) An extremely low part count (8 total parts) compared with other autoinjectors. This reduces manufacturing and scale up challenges resulting in a device with consistent and repeatable performance.
2) Small size and unique flat shape, which provides a better patient experience. In a recent human factors study, the smaller size was perceived as beneficial for people who carry the device or store it in the refrigerator. The shape was preferred by the majority of users (75%).
3) Low carbon intensity as a standard offering. We have a holistic approach to reduce our carbon footprint including utilizing materials with sustainable feedstocks, investment in green electricity, and development of regional supply chains for the US and Europe market.
4) A parallel spring layout, which moves the spring to the side of the syringe instead of inline. This allows the use a larger diameter springs, since the size is not limited by the inner diameter of the syringe.
5) Large wrap around window that allows ease of drug inspection. In the same human factors study, this feature was key in the popularity of the PiccoJect™, with 83% of participants preferring the window.
6) A full-service platform that includes combination product development, design verification, final assembly, secondary packaging, labeling, and serialization. This allows pharma companies (particularly small to medium companies with limited device experience) to receive a ready to file device, including necessary supporting documentation.

Sween

2022



Company name: BIOCORP

Country: France

Product name: Sween

Product type: Routes of Administration

Date of launch: 02/01/2023

Current development phase: Prototype

Patent: Pending

Target markets: Europe + North America

Target clients: Distributor

FACT SHEET

PRODUCT DESCRIPTION

Sween aims to make the act of self-injection of medication by patients using injection pens easier, more serene, and safer.
The device mechanically helps patient to insert needle inside skin at correct depth before injection and to reduce his/her fear during the whole injection process. It should then be used by first time user and regular user uncomfortable with needle insertion.
Needle phobia affects 5 to 9% of patients and 30% of people is refractory to needles(1).
This device can be re-used for the next injections and with the next injection pens.

(1) sources - Craske, Antony, & Barlow, 1997; Kleinknecht, 1987; Mark, 1988

Website: https://biocorpsys.com/en/sween/

Sween

APPLICATION AREAS

In terms of target, the main intended users are either patients, either family caregivers who are not used to inject drugs with injection pens by themselves, or people suffering from tryanophobia (fear of medical procedures involving injections or hypodermic needles).
The intended users that could use Sween include:
- children 6-17 years old and their parents,
- elder population, with physical limitation for auto-injection.
- first time users and regular users uncomfortable with needle insertion.

Sween is being developed to be used in different therapeutic areas such as:
- Diabetes: in particular - new diabetes patients, who start insulin therapy,
- Growth hormone: children needing growth hormone treatment
- Fertility disorders: women, taken in charge by medically assisted procreation process
- Osteoporosis: men and women who need to take injectable medication for osteoporosis

Sween is consequently compatible with different disposable and reusable injection pens including:
- Novo nordisk: FlexPen, Flextouch, Azempic, Novopens
- Eli Lilly: Kwikpen and Humapen Savvio, FlexPro (5, 10 and 15 mg excluded), Nordiflex 5 and 10 mg and Humatropen 6,12 and 24 mg
- Sanofi: Solostar and Allstar Pro
- Pfizer: Goquick Genotonorm 5 and 12 mg
- Merck: Aluetta 6, 12 and 20 mg, Gonal-F, l'Ovitrelle, Pergoveris
- Sandoz: Omnitrope Pen 5, 10 and 15 mg
- Ferring: Rekovelle
- Radius Health: Tymlos

Level of use: From rare to very frequent pen injections – meaning from few a month to several injections a day.

Some advantages are:
- its practicality: it provides a real drug delivery assistance
- its small size: easy to hold in hands
- its ease of use: few additional user steps, no change to the pen use itself
- Its sturdiness: reliable design concept and quality

In terms of geographical scope, marketing and promotion is foreseen firstly in Europe and then in the USA, in B2B2C distribution via distributors.

Sween

KEY FEATURES

Sween aims to help patients to perform the self-injection of their medication by offering a serene and safe assistance.

Sween is being developed as a class I medical device, under Medical Device Regulation 2017/745.

KEY FEATURES ARE:

- Innovation: One automated needle insertion device compatible with various injection pens. No need to disassemble/ reassemble the injection pen components to install Sween. No other equivalent device exists on the market to assist users with the needle insertion. (Penmate was only designed to fit with Novo Pens and is not available on the markets we intend to explore.)
- Patient Experience: with Sween we aim improving treatment adherence and increasing self-confidence.
- Ease of use: Easy and safe insertion of the pen, device arming and activation for needle insertion by the patient himself. Ergonomic handling of the device and few user steps without changing the pen instructions for use.
- Sustainability: Reliable eco-design, reusable and easily recyclable
- Added value: Cost effective
- Availability: Will be available in Europe first, and other countries such as USA in a second stage

INTENDED USERS

- children 6-17 years old and their parents,
- elder population, with physical limitation for auto-injection.
- first time users and regular users uncomfortable with needle insertion.

THERAPEUTIC AREAS

- Diabetes
- Growth Hormone
- Fertility
- Osteoporosis

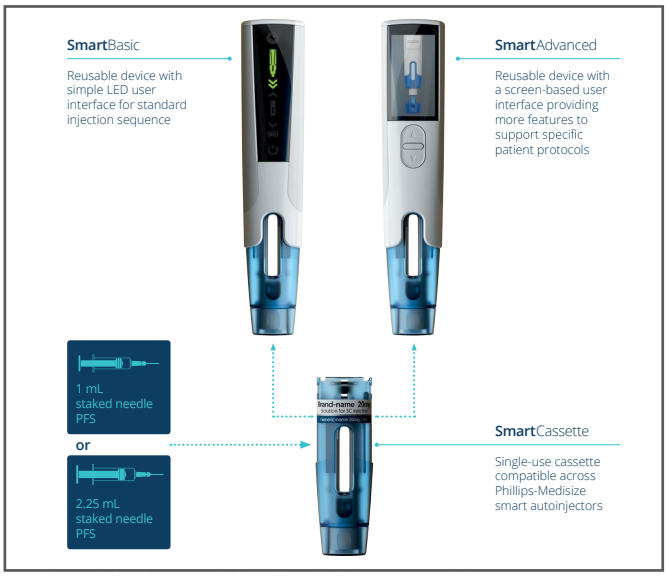
ACCESSIBILITY

The sales network of Sween will be based on B2B2C. Biocorp will sell the product to distributors based in various countries that offer direct to patient distribution through on-line shops or physical shops.

Public sales price around €25.

Aria Smart Autoinjector

2022



Company name: Phillips-Medisize

Country: United Kingdom

Product name: Aria Smart Autoinjector

Product type: Routes of Administration

Date of launch: 31/12/2023

Current development phase: Prototype

Patent: Pending

Target markets: North America, Europe, China, India, Japan

Target clients: Biopharmaceutical companies

FACT SHEET

PRODUCT DESCRIPTION

Aria is a novel reusable electronic autoinjector, designed to meet current and emerging needs of the self-injection market for biopharmaceuticals. It consists of a reusable electronic power unit, coupled with a disposable cassette, which contains either a 1ml or 2.25mL pre-filled syringe and provides needle safety, using a moveable shield, similar to most disposable devices. The reusable format significantly improves sustainability over conventional disposable autoinjectors, offers built in Bluetooth connectivity and clear audible and visual feedback to guide users through the injection process. It is being developed as a device platform for multiple therapies and pharmaceutical customers

APPLICATION AREAS

The Aria Smart Autoinjector is aimed at the subcutaneous self-injection market. Due to its reusable nature, with the reusable device part having a 3-year life, it is aimed at the large and growing market of injectable biologic drugs and other self-injectables used for chronic, long term, treatment rather than acute, short term, treatments. Due to the flexibility of this platform and the offering of a standard version with a simple User interface and a more advanced version with a screen-based user interface, the Aria platform can cover a range of dosing and injection regimens from simple once a week low viscosity through to more complex dosing and higher viscosities and volumes up to 2.25ml.

Aria aims to offer an improved performance vs alternatives in the market, enhanced usability, connectivity as standard and a more sustainable product, all whilst offering a competitive cost per injection and fast to market solution.

The device will advance into clinical trials with our lead customers later in 2022 and it will be ready for full market lunch in late 2023 subject to drug approvals.

ADDITIONAL RESOURCES

See our "day in the life" video about the Smart Autoinjector: https://vimeo.com/475493017/c7592ba3bb

Website: https://www.phillipsmedisize.com/products/smart-autoinjector/

Aria Smart Autoinjector

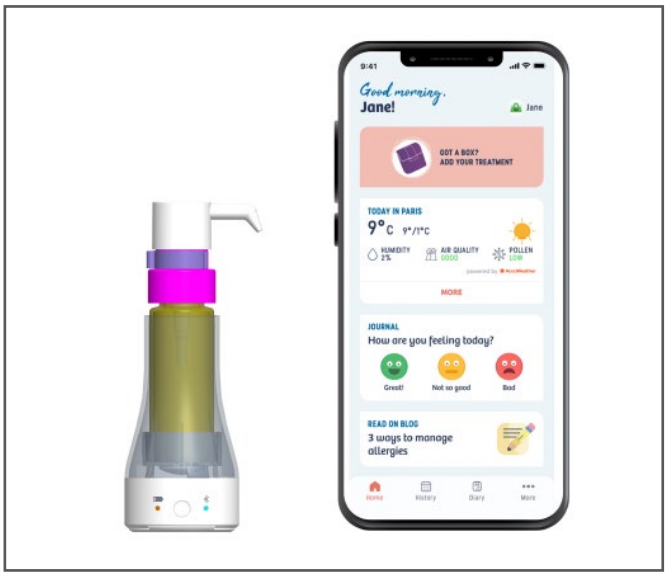
KEY FEATURES

The development of Aria was supported by extensive market and user research to understand the user and market requirements for the self-injection market. Although disposable mechanical autoinjectors, that have dominated this market since 2006, are generally well perceived, our research identified some limitations and also established some emerging market trends that could potentially be better addressed by a new device design. This work allowed us to define and optimise the key features and benefits. This research defined 4 main areas of benefit that the device platform should address

- Improved sustainability. By reusing the core drive unit, we have minimized the PFS housing and needle safety into a small, simple, passive cassette. This reduces the disposable waste associated with each injection and provides the added benefit of reduced space needed for transport and storage. This results in approximately 50% less waste and storage space than disposable autoinjectors. Additionally, the total environmental impact is reduced when both the reusable and disposable elements are taken into account, offering a 35% reduction in total environmental impact compared to disposables
- In Built Connectivity. The pervasiveness of smart phone technology is driving a rapid uptake in connected health applications, a situation further accelerated by the desire for more telehealth driven by the covid crisis. Aria includes integrated Bluetooth connectivity, providing medication dose data to companion devices. It integrates to our Connected Health Platform and patient companion Apps as well as well as other connected health systems. The benefit of built-in connectivity versus a reusable add-on connectivity module is better ease of use by not having to remove and transfer the module each time. And, although integrated connectivity in a disposable device offers good ease of use, this approach offers very poor sustainability compared to that for a reusable solution like Aria
- Flexible Platform Capability. The pharmaceutical industry is seeking to reduce the time, risk and uncertainty in bringing new drug delivery technology to market. As a result, there has been growing interest in the development of device platforms that allow for reuse and greater economies of scale. Aria offers a number of benefits that support this approach. The electromechanical drive can be easily configured to support a wide range of drug viscosities and fill volumes. The same cassette can be used with both the common prefilled syringe formats (1ml and 2.25mL). Conventional mechanical autojector platforms typically only work with one PFS volume and require careful adjustments of spring forces when moving from one drug to another.
- Improved Patient Experience and Usability. Aria is electromechanical and as such is able to provide a broader array of both audible and visual feedback versus conventional disposable mechanical autoinjectors. There are some practical advantages in that the dose completion signal includes any dwell time after the plunger has stopped moving that is required to ensure compete delivery. Most disposable devices give an audible end of dose signal when the plunger stops and thus require an extra step of manually counting during the dwell time prior to lifting the device from the skin. Evidence from user studies and published in research papers shows a significant number of users lift disposable, mechanical autoinjectors before the injection is complete. The better feedback from Aria reduces this risk, as we have observed in user studies. Furthermore, as the device is electromechanical, the injection immediately stops if the device is lifted early, preventing drug spray, drug waste and drug on the skin. As well as providing clear audio and visual signals to show correct completion of dose the device also feedback if a dose has not been correctly delivered, allowing a user to correct their technique for future injections.

Aptar Pharma's Digital Health Device with Mobile App for Allergen Immunotherapy Treatment (AIT) Patients

2022



Company name: Aptar Pharma

Country: Germany

Product name: Aptar Pharma's Digital Health Device with Mobile App for Allergen Immunotherapy Treatment (AIT) Patients

Product type: Connected Devices & Wearables

Date of launch: 31/10/2022

Current development phase: Commercialization

Patent: Pending

Target markets: Europe

Target clients: Biopharmaceutical companies

FACT SHEET

PRODUCT DESCRIPTION

Aptar Pharma is maximizing leading-edge connected device technology with our platform solutions to improve patient outcomes.

Aptar Pharma has developed connected solutions and diagnostic tools covering a wide range of therapeutic areas including Injectables, Nasal and Dermal as well as Eye Care and Pulmonary drug delivery.

All our digital healthcare solutions can be integrated or added-to our broad range of drug delivery devices. We have proven expertise in bringing products to markets across a broad range of therapeutic areas and delivery routes, especially pulmonary, nasal, eye care, injectables and dermal.

Complemented by our partnerships with leading digital healthcare platforms and key stakeholders in healthcare delivery models, we are building a connected device eco-system for digital medicines around the world.

This pioneering connected drug-delivery device with mobile app is the first digital healthcare solution of its kind to improve adherence and compliance for patients undergoing Stallergenes Greer's allergen immunotherapy treatment (AIT) with sublingual solutions. The base-mounted sleeve of the connected device attaches seamlessly and discreetly to the primary packaging (a glass vial and dropper actuator). The integrated sensing and feedback elements then record data on self-administration events, informing the patient to non-compliance. All data is transferred via Bluetooth to the app, which can be configured to issue alerts and reminders to support ongoing adherence and, ultimately, improve health outcomes.

"Sometimes, we have to adjust the number of drops needed for treatment. Until now, I always had to monitor the changes by writing this information on my phone. If capturing this information could be done automatically, it would reassure me" – Mother of a six year old child.

"If it helps to not forget, and follow the prescribed treatment, that is great" – Ado, a 14 year old boy.

Website: https://www.aptar.com/pharmaceutical/digital-healthcare-solutions/

Aptar Pharma's Digital Health Device with Mobile App for Allergen Immunotherapy Treatment (AIT) Patients

2022

APPLICATION AREAS

The application area for this specific product is sublingual AIT; Staloral product by Stallergenes Greer.

Allergen Immunotherapy is the repeated administration of allergen extracts to allergic individuals in order to provide long-term relief of symptoms and improvement in quality of life during subsequent natural allergen exposure. The product in question is delivered sublingually. There are other means of delivering Allergen Immunotherapy however these involve the patient needing to have injections.

The marketed product that Aptar Pharma's connected drug delivery device with mobile app will support is a sublingual immunotherapy medication that involves the administration of drops of allergen extracts under the tongue with direction to retain for two minutes before swallowing.

Sublingual immunotherapy is more acceptable to children and adults who dislike needles. However, it is very important to take the medicine regularly (usually daily) and missing out on doses will cause it to fail. In order to support the patient who chooses to have the daily sublingual medication for a period of three years, this device is a valuable asset to enable them to remain compliant and get the most benefit from the medication over the total timeframe. The patient will be able to use the app to log and track symptoms and allergy triggers, enabling them to better understand the efficacy of their regimen.

The product, and its unique combination of device and app, will significantly enhance the patient's ability to monitor their adherence/ compliance to their medication. It also provides a digital support tool enabling parents and caregivers to follow and track behavior in relation to compliance with the dosing regimen.

KEY FEATURES

This product from Aptar Pharma meets a key patient need, as non-adherence to an AIT schedule and premature discontinuation of treatment are key drivers behind poor outcomes for allergy patients. The administration process is a challenging one, with the patient required to gradually increase the amount of allergen they administer. This is done by increasing the number of doses and gradually increasing the strength of the medication delivered. The patient is required to hold the medication under their tongue for two minutes prior to swallowing. Aptar Pharma's add-on digital health device and connected app reset this dynamic by providing the patient with greater control.

After the digital health device is attached to their medication, the patient follows a simple one-step pairing process, via Bluetooth, to connect the connected device to the application on their smartphone.

Whenever a dose is self-administered, the patient receives audible feedback to inform them that they have correctly completed the function of the pump, therefore expelling all the medication in the dosing chamber. The patient is also automatically notified when the two-minute sub-lingual dwell time is complete, improving compliance with the treatment regimen.

All administration events are logged by the digital health device, enabling the patient to monitor their daily performance on the app. The app also provides the patient with external information on symptom triggers, such as allergen levels and weather conditions, enhancing their ability to make informed decisions about how best to manage their condition.

To support adherence, the connected add-on device has been developed to enable the patient to set a daily reminder and provide them with a notification if they have not taken their medication that day. With a shelf life of 12 months, the device can simply and easily be transferred across a number of medication bottles, providing continuity for the patient.

In its design phase, the product – a connected drug-delivery device and companion mobile app – was subject to extensive user studies, which provided insight into the ideal form factor and features required. This process ensured the product meets the needs of the patient as well as any caregivers who may support and monitor the administration of the treatment on the patient's behalf.

The user studies we have done focused on the key demographics using the product – child, parent (who helps their child take their medication), adolescent and adult.

YpsoMate On

2022

Company name: Ypsomed Delivery Systems

Country: Switzerland

Product name: YpsoMate On

Product type: Connected Devices & Wearables

Date of launch: 31/12/2023

Current development phase: Prototype

Patent: Pending

Target markets: Global

Target clients: Pharmaceutical companies

FACT SHEET

PRODUCT DESCRIPTION

YpsoMate On is the world's first pre-filled autoinjector with integrated connectivity that automatically logs injections on the user's therapy management app. This new autoinjector adds connectivity but retains the market-proven 2-step handling of the YpsoMate autoinjector platform. YpsoMate On includes an advanced Bluetooth proximity measurement protocol which automatically connects the injection device and the smartphone. This simplifies the user journey by removing the need for pairing. The injection data is automatically transferred to the user's therapy management app and the associated cloud. As such, YpsoMate On provides connectivity without compromising ease-of-use.

APPLICATION AREAS

YpsoMate On is a single-use, disposable, prescription only autoinjector that administers a single fixed dose of an injectable drug or biologic from an integrated pre-filled syringe into subcutaneous tissue. As such, YpsoMate On might be applied in combination with the respective drug for the treatment of chronic diseases such as for example migraine, rheumatoid arthrits, psoriasis.

YpsoMate On is able to securely communicate with mobile app software. The injection data can be displayed in the therapy management app or webplatform to assist patients and/or health care professionals in adherence and therapy management.

The YpsoMate On is intended to be used by adults for self-injection as recommended by their physician or health care provider.

The YpsoMate On is not intended for the administration of drugs for emergency use (e.g. anaphylactic shock treatment).

KEY FEATURES

YpsoMate On was designed with a special focus on ease-of-use. Compared to other connected devices the YpsoMate On retains the market-proven 2-step handling process for the user. As such, YpsoMate On sets a new standard for passive capture of injection data. In addition, Ypsomed and Shore designed YpsoMate On in a way that the electronics and battery can be easily separated by the user or by a dedicated recycler to minimize the environmental impact of the device.Further steps related to take-back systems and environmental friendly electronics and battery are planned.

YpsoMate On consists of plastic, metal and electronic parts. To minimize the CO_2 footprint of the device Ypsomed plans to source chemically identical biobased plastics for the manufacturing of the majority of parts and use rPET for transport trays. The electronics and battery are minimized and only weigh 0.97g. In total the device parts (without syringe) weigh approximately 33.5 g.

Ypsomed has conducted several usability studies focusing on handling and user interface of the YpsoMate On.

Website: https://yds.ypsomed.com/en/products/autoinjectors/ypsomate-on.html

InsulCheck® DOSE

2022

Company name: Innovation Zed and SHL Medical

Country: Ireland and Switzerland

Product name: InsulCheck® DOSE

Product type: Connected Devices & Wearables

Date of launch: 01/07/2022

Current development phase: Commercialization

Patent: Pending

Target markets: Global

Target clients: Distributors

FACT SHEET

PRODUCT DESCRIPTION

InsulCheck® DOSE by Innovation Zed, designed in collaboration with SHL Medical, is a reusable pen injector add-on that uses Bluetooth® technology to automatically transfer injection time and number of dose units dialed to a mobile application.

InsulCheck DOSE is designed to be compatible with market-ready insulin pens or those under development through a customizable sleeve that can be tailored for different pens. Its proprietary multi-sensor technology enables detection of units dialed. A built-in firmware over-the-air (FOTA) capability further enables continuous optimization of the device's firmware even after deployment, therefore allowing InsulCheck DOSE to continually improve its device performance.

APPLICATION AREAS

InsulCheck® DOSE is the third-generation product from Innovation Zed's InsulCheck family, which includes InsulCheck CLASSIC and InsulCheck CONNECT.

The InsulCheck DOSE is currently designed and developed to support insulin-related treatments in pen injectors. Built with customizable sleeves and adjustable firmware, the InsulCheck DOSE can be tailored to accommodate a variety of reusable or disposable pen injectors on the market or under development. The InsulCheck DOSE thus aims to support a broader range of therapies in pen injectors, such as diabetes management, weight management, growth hormones, fertility treatment, oncology, and many more.

Website: www.innovationzed.com

InsulCheck® DOSE

KEY FEATURES

SIMPLE TO USE

Subtle form factor with no extra buttons to minimize interference with the end user's injection experience

DOSE DIALLED

Automatic capture of dose value dialed, date, time, ambient temperature, and device mounting/unmounting activities.

BLUETOOTH LOW ENERGY (BLE)

Seamless connection and transfer of injection data with paired health management apps and/or other technologies through Bluetooth Low Energy (BLE)

FOTA

Firmware Over The Air (FOTA) capability to optimize the technology performance– even after deployment

OLED DISPLAY

OLED display for high-quality visual feedback – even in challenging lighting conditions – to indicate the last dose unit, time elapsed since previous injection, and battery life

RECHARGEABLE

Rechargeable battery with 7 to 10 days' life per charge and a ~ 2-hour charge time

ON-BOARD MEMORY

Built-in storage memory to store a minimum of 30 days' worth of injection data without the need to sync with a companion disease management application

COMPATIBILITY

Comes with customizable sleeves that can be tailored for different injection pens

DATA MANAGEMENT

Data captured can be integrated with third-party software applications for automated logging, enabling easy sharing and data analysis

MARKET READY

CE marked in the EU and FDA registered in USA allows for immediate inclusion in product portfolios

BRANDING

Product branding and packaging available for branding customization based on different regions, languages, and regulatory requirements

Eitan Insights

2022

Company name: Eitan Medical

Country: Israel

Product name: Eitan Insights

Product type: Connected Devices & Wearables

Date of launch: 01/01/2023

Current development phase: Commercialization

Patent: None

Target markets: Global

Target clients: Biopharmaceutical companies

FACT SHEET

PRODUCT DESCRIPTION

Eitan Insights™ is a cloud-based platform, providing clinicians and homecare providers full remote visibility of Eitan Medical's suite of advanced infusion and drug delivery devices, which include the Sapphire™ infusion pump platform, Avoset™, a connected infusion system for the homecare market, and Sorrel™ a wearable drug delivery platform designed for on-body subcutaneous injections. Eitan Insights empowers healthcare providers to offer a wide range of therapies in the comfort of patients' homes.

The Insights system aggregates treatment data, providing caregivers with near real-time analytics, and offers homecare providers remote access to their pump fleet, paving the path for improved operational efficiency.

APPLICATION AREAS

The Eitan Insights platform is intended for three Eitan Medical drug delivery and infusion product lines: Sapphire™, Avoset™, and Sorrel™, specifically in the homecare market. Eitan's infusion and drug delivery solutions service patients across the continuum of care, in prehospital medicine, acute-care settings, emergency medical services, infusion centers, hospitals, and in patients' homes.

Through data collection and cloud-based processing, Eitan Insights provides clinicians with comprehensive patient infusion data, analytics and actionable insights in near real-time. Analyzed aggregated patient data allows caregivers to identify treatment patterns and make data-driven decisions to optimize care outcomes.

The recorded patient data offers a holistic view of the patient status and allows for continuity of care throughout the course of treatment and despite any changes in staffing/attending healthcare professionals.

Additionally, the connected platform aims to improve the patient experience by allowing treatments to become streamlined into their daily routine. Auto-documented data, reduced need for home visits from clinicians, and the knowledge of remote monitoring will increase patients' confidence in their treatment. In addition, constant monitoring may also increase patient compliance, leading to better health outcomes.

The Sapphire infusion pump family is commercially available globally, while both the Avoset and Sorrel platforms are currently under regulatory review and various stages of development. Eitan Insights is anticipated to commercially launch in 2023.

Website: www.eitanmedical.com

Eitan Insights

2022

KEY FEATURES

This shift from hospital to home has been accelerated by the pandemic, creating a need for hospital-grade solutions within the home setting to continue the delivery of high-quality patient care. With this paradigm shift in care, the healthcare industry has also put an increased focus on patient-centricity among care devices, creating an easier transition of care to the home environment.

Shifting infusion and injection treatments to the home presents several unique challenges for providers, including the lack of treatment visibility, difficulty in remotely monitoring patients to ensure compliance, lack of access to event logs and other treatment documentation, safety concerns resulting from not being notified of alarms and troubleshooting errors and a logistical challenge of remotely managing infusion pump fleets.

To address these challenges and optimize care from the home, there must be a direct and consistent connection between patient and clinician, reviewing treatment data and alerting providers of any problems in real-time.

Eitan Insights aims to provide clinicians with full remote visibility of Eitan Medical's suite of advanced infusion and drug delivery devices, which include the Sapphire™ infusion platform, Avoset™, a connected infusion system for the homecare market, and Sorrel™, a wearable drug delivery platform designed for on-body subcutaneous delivery of biologic medications.

Eitan Insights aims to provide a direct line of communication between the patient and provider, analyzing infused patient data and providing near real-time analytics and alerts to improve patient care and outcomes.

Bluetooth Returnable Transport Item (RTI) Solution

2022

Company name: Avery Dennison

Country: USA

Product name: Bluetooth Returnable Transport Item (RTI) Solution

Product type: Connected Devices & Wearables

Date of launch: 01/07/2022

Current development phase: Proof of concept

Patent: Pending

Target markets: Oral liquids, lab, animal

Target clients: Pharmaceutical companies

Business model: Direct sales

FACT SHEET

PRODUCT DESCRIPTION

Our product is the "IoT Pixel": a battery-free Bluetooth enabled smart label that powers itself by harvesting RF energy. By sticking a pixel onto plastic crates, pharmaceuticals, and packaging, they are instantly connected to the IoT; giving them constant connectivity, sensing, and visibility. This added intelligence will change the way they are made, distributed, sold, used, reused, and recycled.

APPLICATION AREAS

More than half of the drugs approved by the FDA are temperature sensitive [1]

The Drug Supply chain Security Act (DSCSA) demands that all drugs have unit-level traceability [2]

By applying Pixels to returnable transport items (RTIs) and the items that they carry, such as pharmaceuticals, healthcare products, and healthcare consumables, we can directly improve the supply chain by:

1. Ensure that the RTI payload is handled safely (within temperature) throughout transit. This is the difference between hoping a drug is still safe to use, and knowing it is.
2. Reduce lost / scrap RTIs
3. Improve inventory visibility, reducing the total inventory requirements, and ultimately enabling less waste
4. Solve discrepancies between outbound and inbound shipments

Website: www.rfid.averydennison.com; wiliot.com

Bluetooth Returnable Transport Item (RTI) Solution

KEY FEATURES

Until now, temperature and asset tracking of sensitive pharmaceuticals involved a litany of expensive and disconnected products, creating a fragmented solution suite. What customers want is automation, affordability, and simplicity in deployment. Until now, they could only choose 1.

Avery Dennison and the accompanying Wiliot cloud gives them all 3.

Pixel (Chip is a component of the Pixel):

- super low cost Bluetooth inlay, applied directly to assets

– Bluetooth offers two key advantages over UHF RFID: lower cost and simpler infrastructure that's already rapidly proliferating. We eventually plan to be compatible with most 3rd party bluetooth enabled access points.

- Pixels power themselves remotely by harvesting minute amounts of RF energy, typically supplied by low cost bridges. This makes them inherently continuously connected: once set up, no personnel is needed to actively scan assets - it's all automatic.

- Unlike UHF RFID, the Pixel ID is always encrypted, and only able to be decrypted by the pixel owner. This offers one more layer of security and privacy over most asset tracking solutions (barcode, RFID, etc).

- Temperature sensing (-30 to +80°C)

- Fill and proximity sensing (coming soon)

Cloud:

- Database that distributes data to only intended parties

- Machine learning layer that continually improves sensitivity and accuracy

- Ability to deploy new sensing modes and higher accuracy sensing after the hardware has already been deployed

- "Swarm sensing": with multiple low cost Pixel endpoints, higher accuracy sensing and higher resolution sensing can be achieved.

- API that allows you to connect any enterprise cloud

- Universal Automation Platform that allows you to build alerts and events with thousands of your favorite enterprise apps based on Pixel data, without any coding. That way anyone can create their own alert over email, text, or thousands of enterprise apps when there's a problem. This is a departure from typical traceability products, which usually only offers a report of all problems.- "Swarm sensing": with multiple low cost Pixel endpoints, higher accuracy sensing and higher resolution sensing can be achieved.

- API that allows you to connect any enterprise cloud

- Universal Automation Platform that allows you to build alerts and events with thousands of your favorite enterprise apps based on Pixel data, without any coding. That way anyone can create their own alert over email, text, or thousands of enterprise apps when there's a problem. This is a departure from typical traceability products, which usually only offers a report of all problems.

DuoDERM

2022

Company name: Pacifi Ltd.

Country: United Kingdom

Product name: DuoDERM

Product type: Primary Packaging

Date of launch: 30/01/2023

Current development phase: Prototype

Patent: GB2569984

Target markets: **Global**

Target clients: Biopharmaceutical companies

FACT SHEET

PRODUCT DESCRIPTION

DuoDERM is the first product variant in Pacifi's DuoVIAL® technology portfolio.

The DuoVIAL® is designed to Protect, Mix & Deliver, especially sensitive formulations, in a dual-chamber, glass, primary pack format.

Combining the advantages of ampoule & vial into a single unit, a more cost effective, safer and easier to use form factor is achieved, whilst maintaining established materials and processes. The unique application of advanced laser technologies (LACR) enables this innovation, evolving the very traditional formats within the pharmaceutical sector.

Packaging sustainability is core, wherein the minimal material utilisation, in combination with using 100% recyclable materials (glass & aluminium) and a refill-cartridge approach, minimizes our carbon footprint.

APPLICATION AREAS

Skin Microbiome Therapies - Acne, Eczema, Psoriasis, Healthy Aging, Dandruff, (UTI's) Urinary Tract Infections.

Dermal Probiotics consisting of Live Biological Products (LBP's) are often formulated as a lyophilised powder for stability. Reconstitution with their preferred Prebiotic (aqueous diluent + nutrients) provide a natural therapy with cell viability and associated efficacy maintained.

Oral Therapies – Sublingual sprays: e.g. Apomorphine an injectable for Parkinson's can be reformulated for sublingual application, however needs combining with a pH+ liquid buffer to neutralise the acidity prior to application.

Wound Care – Cyanoacrylate is typically stored in a glass 'onion-skin' capsule to prevent chemically reacting with moisture.

Lyophilised Parenteral Vaccines -

Website: www.duovial.com

DuoDERM

2022

KEY FEATURES

PROTECT:

- Impermeable materials (glass & aluminium), protects the active lyophilised biological from moisture. Optional nitrogen headspace fill.
- Glass membrane incorporating a Lasered Annular Cleave Ring (LACR), provides an impermeable barrier between Amp' Liquid and Vial' Powder chambers.
- Butyl Rubber & Silicone free, provides for relatively inert contact materials, mitigating biological compatibility issues.
- Applicator Tip (2K-SPP) Sintered Porous Polymer provides product filtration assurance, whilst eliminating the need for reconstitution with a filter needle.
- Sharps risks are mitigated, as no ampoule opening required.

MIX:

- Dual-Chamber system from a single-piece glass cartridge is fundamentally simple.
- The LACR'd membrane enables a 'clean-cleave' activation and opening for reconstitution.
- Alu-Foil Vial' Seal by Direct Induction, provides for an impermeable, but frangible seal, for the applicator tip to penetrate.

DELIVER:

- Screw-Cap mechanism, assembles the applicator tip and activates the system.
- Applicator Tip (2K-SPP), Sintered Porous Polymer tip is (2K) co-moulded in a combination of hydrophilic and hydrophobic materials. This single component both wicks liquid to the applicator surface and vents air into the cartridge, tailored according to formulation.
- This compact form factor doubles the units deliverable logistically.

COST EFFECTIVE:

- Glass forming and filling remains both scalable and high speed.
- LACR processing is scalable, high speed, non-contact, clean and uses negligible consumables.
- Base material costs are low, whilst reflecting upon volume used.
- Minimal component count and associated assembly mitigates costs.

SUSTAINABLE:

- Material utilisation is lower than that of a traditional vial + ampoule.
- Materials (glass & aluminium) are separable and 100% recyclable.
- This cartridge refill format utilises a reusable AppTivator device, minimising the packaging materials used and recycled.
- Decoration by USP Laser 'in-wall' Marking, rather than screen printing or labelling mitigates materials and consumables, whilst providing anti-counterfeiting and traceability.
- Amp' Liquid Sealing can alternatively be with CO2 laser, rather than carbon based propane gas.
- Applicator Tip materials will evolve to be cellulose based.

CONSUMER FOCUSED:

- With a clean and minimalist aesthetic the pack conveys health benefit, and aligns with 'clean' formulations desired by consumers, without the complexity of traditional formats or overly complex dual-chamber syringe systems.

EcoSecur type 2 glass

2022

Company name: Stoelzle Glass Group

Country: Austria

Product name: EcoSecur type 2 glass

Product type: Primary Packaging

Date of launch: 03/05/2021

Current development phase: Commercialization

Patent: None

Target markets: South America, EU, Russia, Belarus, Ukraine, South / East Asia, North Africa

Target clients: Pharmaceutical companies

FACT SHEET

PRODUCT DESCRIPTION

Stoelzle Pharma reached another milestone by developing a new, safe and resource-efficient process for the inner surface treatment of type 2 glass vials. This innovative technique enables reliable and precise dosing tailored to each bottle size, from the smallest 6 ml vials to much bigger. With EcoSecur injection and infusion vials Stoelzle Pharma has reinvented type 2 glass for parenteral and non-parenteral applications.

APPLICATION AREAS

EcoSecur type 2 glass is used for parenteral and non-parenteral applications for human medicine and veterinary medicine.

KEY FEATURES

PROCESS STABILITY

offers our highest product quality for smaller (starting with 6 ml) and bigger vials through automated, consistent and precise treatment solution dosing.

SUPERIOR GLASS QUALITY

increased product safety through automated process controls and 100% treatment detection.

MINIMISED ENVIRONMENTAL IMPACT

achieved through precise and optimal dosage of ammonium sulfate – as much as necessary, as little as possible.

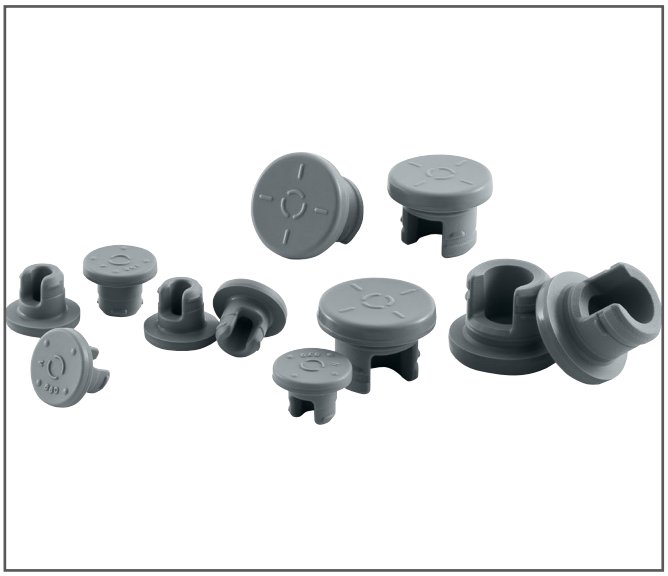
IMPROVED HYDROLYTIC RESISTANCE

suitable for most acidic and neutral aqueous preparations.

Website: https://www.stoelzle.com/pharma/innovation/type-2-glass/

4040 LyoTec® Westar® Lyophilization Stoppers

2022



Company name: West Pharmaceutical Services, Inc.

Country: USA

Product name: 4040 LyoTec® Westar® Select Ready-to-Sterilize (RS) and Ready-to-Use (RU) Lyophilization Stoppers

Product type: Primary Packaging

Date of launch: 01/04/2021

Current development phase: Commercialization

Patent: None

Target markets: Global

Target clients: Pharmaceutical companies

FACT SHEET

PRODUCT DESCRIPTION

West's new 4040 LyoTec® Westar® Select Lyophilization Stoppers use a state-of the-art elastomer formulation (4040/40) developed with multi-dimensional elastomer expertise and a Quality-by-Design (QbD) development approach. These lyophilization stoppers meet a broad range of requirements to protect drug quality and compatibility including ultra-low extractables and leachables, low moisture content, a low level of particulates, and low fragmentation and coring.

The 4040 LyoTec components provide drug manufacturers with confidence in a high-performing packaging product that will aid in de-risking their drug from development through patient administration. The LyoTec stopper designs with B2-coating are available in 13mm and 20mm igloo configurations proven to work across ISO glass vials of various blowback geometries, thus delivering high functionality and reliability. The new formulation features low particulates through our validated Westar® Select wash process and FluroTec® film on the flange prevents sticking to lyo shelves.

LyoTec®, FluroTec® and Westar® are registered trademarks of West Pharmaceutical Services, Inc., in the United States and other jurisdictions. FluroTec® and B2-coating technologies are licensed from Daikyo Seiko, Ltd.

Website: https://www.westpharma.com/products/vial-containment-solutions/stoppers/404040-formulation

4040 LyoTec® Westar® Lyophilization Stoppers

APPLICATION AREAS

West has reinforced that the primary packaging risk to drug product quality and compatibility is reduced when the primary closure is well understood at the material level using a QbD approach. Beginning with the end in mind, all packaging and delivery decisions were directly related to protecting drug product quality and compatibility with patient safety considerations foremost. In the development of 4040/40 Gray, West was focused on raw material selection, formulation chemistry and optimization for processing to significantly mitigate the risk of particulates, extractables/leachables, coring and fragmentation with efficient drying time. Figure 1 of the West Technical Report 2021/240: Quality by Design in Elastomer Formulation Development – 4040 Gray (attached) explains the chlorobutyl 4040 Gray formulation development and industrialization process.

West's Quality-by-Design (QbD) Approach:

The 4040 LyoTec® Westar® Select Ready-to-Sterilize (RS) and Ready-to-Use (RU) Lyophilization Stoppers were developed using 4040/40, a new state-of-the art elastomer, from West Pharmaceutical Services, Inc. ("West"). This elastomer was formulated with a heightened focus on improved quality and reduced packaging risks to drug product development. Scientific understanding of the formulation chemistry, extractable profiles and risk mitigation for raw materials and processing parameters were key in the elastomer quality-by-design (QbD) strategy. Using QbD principles coupled with a strong understanding of the increasing testing demands and regulatory scrutiny in injectable drug packaging, the 4040 LyoTec stoppers represent a significant step to mitigating the risk of extractables and leachables, particulates, coring and fragmentation, residual moisture and allowing for efficient drying following stopper processing. Please reference the attached West Technical Report 2021/240: Quality by Design in Elastomer Formulation Development – 4040 Gray.

High-quality stoppers for flexibility, machinability and processability:

These components use Westar® Select validated wash and sterilization (RU only) processes to deliver high quality and reliable product. And the QbD approach has resulted in igloo stoppers designed to be used with ISO glass vials of various blowback geometries (non-blowback, European blowback, and American blowback designs.) Evaluation of interference fit, insertion and removal forces, pop-up and container closure integrity testing have demonstrated the flexibility and suitability for use of this stopper. Please reference West Technical Reports 2019/211: Evaluation of Container Closure Integrity for 4040/40 Lyophilization Stoppers, 2019/215: Evaluation of Removal and Insertion Force for 4040/40 Lyophilization Stoppers and 2021/237: Evaluation of Machine Performance of 4040/40 Lyophilization Stoppers.

ADDITIONAL RESOURCES

https://drive.google.com/drive/folders/1IQC20qQmPI5V_olaYQvfyWN6fFpC2hkJ?usp=sharing

4040 LyoTec® Westar® Lyophilization Stoppers

KEY FEATURES

Ultra-low extractables & leachables:

4040 LyoTec® stoppers protect drug product quality and provide broad drug compatibility by reducing inherent packaging risk through ultra-low extractable & leachables. West has studied the leachables profile of 4040 LyoTec stoppers versus comparator West stoppers in partnership with Lyophilization Technology, Inc. (LTI) to gain a full understanding of impact of the entire container closure system and to assess suitability for intended use. Please refer to the attached presentation (Zurbriggen Presentation - Qepler Lyo Conference 2021) entitled, "Lyophilized Drug Product Case Study: Risk Mitigation of Primary Packaging through Physical and Chemical Testing." For additional information, you may wish to visit our OnDemand webinar, Lyophilized Drug Product Case Study: Risk Mitigation of Primary Packaging through Physical and Chemical Testing.

Well-characterized extractables:

Well-characterized extractables using a wide range of drug solvent systems reinforced that deliberate raw material selection, optimized manufacturing processes & a QbD approach results in reduced risk with 4040 LyoTec® stoppers. Our scientific findings support our goal to mitigate higher risk extractables and have an overall qualitatively smaller extractables profile when compared to legacy rubber formulations.

Low residual moisture content:

The 4040/40 elastomer formulation has been optimized for low moisture to prevent cake degradation. The 4040 LyoTec® Westar® Select RU stoppers have a residual moisture specification of 0.2% moisture which is the lowest of any of the West lyophilization stoppers. Please visit our Full Customer Presentation Slide Deck.

Low level of particulates:

Achieved through both deliberate raw material selection & Westar® Select validated wash processing, the 4040 LyoTec® stoppers have a low level of particulates. We have provided actual particulate data on initial batches in our Full Customer Presentation Slide Deck.

Optimized drying properties:

The 4040 LyoTec® stoppers have been designed to optimize drying properties while not sacrificing the benefits of ultra-low extractables and leachables. This may allow improved steam sterilization throughput, thus saving time. Our testing results are provided in our Full Customer Presentation Slide Deck.

Closed System Transfer Device (CSTD) compatibility:

While compatibility is CSTD dependent, 4040 LyoTec® Stoppers performed well in comparative testing of fragmentation and coring associated with five currently marketed CSTD's. The residual volume is not significantly impacted by the 4040 LyoTec stopper. Combined testing indicates that the 4040 LyoTec stopper is a well-considered choice for many chemotherapy drugs and other hazardous drugs when CSTD's may be used. Please reference West Technical Report 2021/241: An Evaluation of Elastomeric Stopper Compatibility with Closed System Transfer Devices.

Fragmentation/Coring:

As further testament to the QbD approach in which the elastomer formulation was optimized for reduced fragmentation and coring with both 18G and 21G needles. Comprehensive characterization of the 4040 LyoTec® stoppers shows excellent multi-puncture functionality as well as compatibility with West vial adapters making this a suitable option for multi-dose drugs. Please reference West Technical Report 2019/212: Evaluation of Needle and Vial Adapter Compatibility for 4040/40 Lyophilization Stoppers.

Compatibility with steam or gamma irradiation sterilization:

The 4040 LyoTec® stoppers have been tested for physical, chemical and functional attributes following steam sterilization or gamma irradiation (45kGy) demonstrating compatibility and providing processing flexibility to seamlessly integrate into a customer's existing operations. Please reference West Technical Report 2021/238: 4040/40 Lyophilization Stoppers - Aging and Gamma Irradiation Study.

BiKit

2022

Company name: Eurpack Giustini Sacchetti Srl

Country: Italy

Product name: BiKit

Product type: Primary Packaging

Date of launch: 13/10/2021

Current development phase: Commercialization

Patent: Italy 102020000006841

Target markets: Europe and North America

Target clients: Pharmaceutical companies

FACT SHEET

PRODUCT DESCRIPTION

The BiKit ia an innovative product, capable of combining two important needs: on the patients' side, the need for better intelligibility of the package leaflet and storage for subsequent consultation. On the pharmaceutical companies' side, the need to have a larger text area and to reduce complexity during the packaging phase, especially for markets that require multi language and/or multi component products.

APPLICATION AREAS

Pharmaceutical documentation (leaflet, inserts, booklets etc.) where multiple items need to be used such as patient information, medical guide, instruction for use and devices like alcohol pads, gloves, hand cleaning gel etc.

KEY FEATURES

- Versatility, overcoming the idea of folding the package leaflet.
- Saving up to 40% thickness, the text area available is larger and the thickness is reduced.
- Uniqueness, assembly of different information supports, according to the market (IFU MG PIL), product with different materials (coated paper and/or hand made paper).
- Presence of accessories, possibility of integrating BiKit with other accessories (wipes, gloves, daily cards, hand cleansing gel to support the continuity of the treatment).

Website: https://eurpack.it/solutions/?lang=en

Sycare Secure

2022

Company name: althena medical by Platinum Pharma Servicee

Country: Italy

Product name: Sycare Secure

Product type: Primary Packaging

Date of launch: 12/12/2022

Current development phase: Prototype

Patent: N° 102021000011435

Target markets: Europe, Middle East, North America

Target clients: Biopharmaceutical companies

FACT SHEET

PRODUCT DESCRIPTION

Sycare secure is a tamper proof system for pre-filled syringes. The cap cannot be unscrewed without breaking the tamper-evident system, even if using special tools or equipment. Sycare Secure ensures that the product in the barrel remains intact. In addition, thanks to Sycare's innovative design, the tamper-evident system remains within the overall dimensions of the barrel. This eliminates the need to change the secondary packaging and makes the system aesthetically pleasing. The threaded cap's two large parallel faces allows doctors to unscrew it easily, even when wearing gloves.

APPLICATION AREAS

Sycare secure is applied to prefill syringes made of plastic (COC, COP, etc.).

Sycare secure is the first tamper proof system specifically designed for plastic syringes.

The system connects the threaded cap to the barrel in such a way that, in order to unscrew the cap, the tamper evident must first be broken.

It is designed to make it easier for doctors to unscrew the threaded cap, as its design allows for a low torque to be applied and for a better grip of the cap. This is important because doctors usually wear gloves, so the two large parallel faces on the plug help unscrew the plug much better, unlike other circular tamper evident systems.

In addition, the sealing grommet inside the threaded cap does not wrap around the tip but is pushed against the tip inlet to prevent air from entering the barrel. This allows for a low frictional force between the grommet and tip, and therefore low torque is required to remove the plug from the barrel.

Since the threaded plug is secured to the barrel by the tamper evident, it does not move and cannot rotate relative to the barrel. So, in order to remove the plug, you just need to grasp the barrel with one hand, and the threaded plug across the two parallel faces with the other one, rather than grasping the threaded plug alone, as is the case today. This also facilitates the unscrewing of the cap.

Since the syringe has the same overall dimensions, with and without tamper evident, it can be placed in the same secondary packaging. This makes it possible to switch from the syringe with tamper evident to the syringe without tamper evident, without changing the secondary packaging. This is because the tamper evident is integrated in the barrel and the threaded cap. Thanks to this feature, the syringe is aesthetically pleasing. The threaded cap is usually as transparent as the barrel.

Finally, the tamper evident is attached to the threaded cap internally. It is inserted into the barrel through two semi-integrated slots. This means that it is impossible to remove the threaded cap, so doctors are sure that the product inside the barrel has remained intact.

Website: https://www.althenamedical.it/en/products/pre-fillable-syringes/

Sycare Secure

2022

KEY FEATURES

Sycare secure consists of a single component connected to both the threaded cap and the barrel simultaneously. To unscrew the threaded cap, the evident tamper must first be broken.

These are the main advantages of Sycare secure:

1) **Small footprint:** the tamper evident is attached to the threaded cap from the inside, not the outside. Therefore, it cannot be tampered with.
2) **low space:** Sycare secure remains within the overall dimensions of the barrel. So, you can use the same secondary packaging whether the syringe is provided with Sycare secure or not;
3) **Easily to handle:** thanks to its special design, the cap has two wide parallel faces so that the doctor can better grasp the unscrewing cap, even when wearing gloves;
4) **Low friction:** the rubber sealant inside the cap does not wrap around the syringe tip, so it has low friction with it. Therefore, less torque is needed to remove the cap.
5) **Economical:** being made from a single component, it is an economical system. Both because it is easy to assemble and because it is easy to manufacture.

Activated Rispharm

2022

Company name: Berry Global / Pylote

Country: USA & France

Product name: Activated Rispharm

Product type: Primary Packaging

Date of launch: 01/06/2022

Current development phase: Commercialization

Patent: France: 14 55871 & 14 54141

Target markets: Europe; USA/Canada; Asia

Target clients: Pharmaceutical companies

FACT SHEET

PRODUCT DESCRIPTION

Activated RispharmTM is a multidose eye dropper with nozzle and cap activated to kill bacteria and viruses continuously to deliver hygienic doses at each use and thus, to reduce infection risks. It offers the market with unprecedented competitive advantages in terms of patients' protection, time-to-market and sustainability

- Proven and certified mineral antimicrobial protection of dropper tip (85% of contaminations)
- Hygienic applications for every use with a multidose dropper
- Reduces the amount of plastic waste by 16 x for one month treatment compared to monodose
- No change in patient treatment methods
- Certified non-irritant and non-cytotoxic technology

APPLICATION AREAS

An unmatched benefit never seen in the market: real destruction of virus and bacteria in a eye dropper

- The risk of pathogen contamination of ophthalmic dropper is present during the manufacturing process, but is greatly increased during use by the consumer/patient. The products can be directly contaminated by hands, lacrimal fluids or environment. There is also a risk of cross- contamination when the same product is shared by several consumers/patient.
- Incorporated into multi-dose dropper tip (nozzle) and cap, Pylote technology ensures that the strains coming onto the surfaces are destroyed. Thus, the risk to deliver a contaminated doses is controlled.
- Proven and certified mineral antimicrobial protection of dropper tip where over 85% of the contamination is found* (see medical study Nentwich et al, Br J Ophthalmol 91(10): 1265-68)

In addition, the sealing grommet inside the threaded cap does not wrap around the tip but is pushed against the tip inlet to prevent air from entering the barrel. This allows for a low frictional force between the grommet and tip, and therefore low torque is required to remove the plug from the barrel.

Since the threaded plug is secured to the barrel by the tamper evident, it does not move and cannot rotate relative to the barrel. So, in order to remove the plug, you just need to grasp the barrel with one hand, and the threaded plug across the two parallel faces with the other one, rather than grasping the threaded plug alone, as is the case today. This also facilitates the unscrewing of the cap.

Since the syringe has the same overall dimensions, with and without tamper evident, it can be placed in the same secondary packaging. This makes it possible to switch from the syringe with tamper evident to the syringe without tamper evident, without changing the secondary packaging. This is because the tamper evident is integrated in the barrel and the threaded cap. Thanks to this feature, the syringe is aesthetically pleasing. The threaded cap is usually as transparent as the barrel.

Finally, the tamper evident is attached to the threaded cap internally. It is inserted into the barrel through two semi-integrated slots. This means that it is impossible to remove the threaded cap, so doctors are sure that the product inside the barrel has remained intact.

Website: https://www.althenamedical.it/en/products/pre-fillable-syringes/

Activated Rispharm

2022

KEY FEATURES

ANTIMICROBIAL OPHTHALMIC DROPPER ACTIVATED BY PYLOTE MINERAL TECHNOLOGY

A first-to-market multidose dropper to help prevent eye microbial infections for patients

Hygienic drops for patient protection
- Proven and certified mineral antimicrobial protection of dropper tip where over 85% of the contamination is found*
- Pylote technology integration into RispharmTM R2 reduces the risk of microbial contamination
- Activated Rispharm eye-dropper is notably proven effective against conjunctivitis virus, Escherichia Coli and Staphylococcus aureus bacteria.
- Allows patients to have hygienic applications for every use with a multidose dropper

Only positive changes
- Improvement to the existing RispharmTM range
- Self decontamination of eye dropper tip and cap
- Mineral and biocompatible technology: no irritation for the skin (ISO10993-10) & non cytotoxic ISO10993-5).
- No change in patient treatment methods
- No modifications required to packaging design nor existing manufacturing/filling processes

Breakthrough sustainable innovation
- Amount of plastic waste reduces by 16 times for one month treatment compared to monodose solutions
- Patented from production to application, Pylote antimicrobial mineral technology is 100% mineral, manufactured in France using in-house green chemistry process.

The use of an unmatched sustainable mineral technology
- Immediate, stable and permanent action with efficiency tested in independent laboratory on SARS CoV-2 and its Delta variant (>96% in 1h) and on bacteria (>99,999% in 24h + Tests in real conditions in situ with important circulation of people).
- Efficacy against other viruses such as influenza H1-N1, gastroenteritis, herpes and conjunctivitis, as well as many Gram-positive and Gram-negative bacteria.
- Mineral and biocompatible technology: no irritation for the skin (ISO10993-10) & non cytotoxic ISO10993-5).
- Technology certified Food Contact according to the EU regulation 1935/2004.
- Technology robustness validated in real conditions of use and drastic simulations without loss of efficiency
- Patented worldwide, from process to application

ADDITIONAL RESOURCES

https://berryglobal-my.sharepoint.com/personal/gracefile_berryglobal_com/_layouts/15/onedrive.aspx?id=%2Fpersonal%2Fgracefile%5Fberryglobal%5Fcom%2FDocuments%2FPylote)

Aptar Pharma's PremiumCoat® Platform

2022

Company name: Aptar Pharma

Country: Germany

Product name: Aptar Pharma's PremiumCoat® Platform of Products, Data and Services

Product type: Primary Packaging

Date of launch: 01/03/2023

Current development phase: Commercialization

Patent: Europe Ref: EP3055006A1

Target markets: Worldwide

Target clients: Biopharmaceutical companies

FACT SHEET

PRODUCT DESCRIPTION

Aptar Pharma's PremiumCoat® platform comprises an end-to-end package of products, data and services for containing and protecting sensitive drug formulations in vials or pre-filled syringes (PFS). PremiumCoat® ETFE film-coated Bromobutyl closure solutions include stoppers for 13mm/20mm vials, plungers for 1mlL PFS, and soon-to-be-released plungers for 1-3mL PFS.

Combining the expertise of Aptar Pharma's companies, we have developed a series of advanced evaluation protocols to test and demonstrate PremiumCoat®'s performance.

PremiumCoat® products can be supplied with critical technical data contained in the Data Package or as part of an integrated Service Package to support the de-risking and accelerating the development of drug products.

APPLICATION AREAS

The PremiumCoat® platform of Products, Data and Services Packages addresses key challenges for developing, commercializing or repurposing sensitive injectable drug products. PremiumCoat® solutions are being used to safely package mRNA Covid-19 vaccines, monoclonal antibodies, virus-like particles, recombinant adenovirus vectors or other sensitive molecules that need to be safeguarded from storage through to injectable administration.

The PremiumCoat® platform is also ideally suited for drug developers who want to facilitate their choice of packaging components and accelerate their drug development. The Service and Data Packages relieve our customers from the burden of performing all the tests necessary to guarantee the compatibility of their drug with the primary packaging that are required when filing for regulatory approval.

The ETFE film and clean rubber formulation of PremiumCoat® is key to the protection of complex drugs or developments that are highly time sensitive and therefore need to be derisked. This is the case for sensitive biotech drugs, monoclonal antibodies, Covid vaccines, adenoviral vector vaccines and other mRNA vaccines.

When considering vials, some of the most sensitive drugs need to be stored in deep-cold conditions. PremiumCoat® stoppers have demonstrated their ability to maintain Container Closure Integrity (CCI) down to -80°C.

When considering pre-filled syringes (PFS), PremiumCoat® demonstrates strong functional performance (break-loose and gliding forces), which helps facilitate the injection process. Even when working with highly viscous drugs, as may be the case for chronic disease treatments, the break-loose and gliding force remains well within patient's strength and capability even if they suffer from conditions such as Rheumatoid arthritis.

PremiumCoat® can be highly effective when subjected to aggressive solvents as the ETFE films acts as a barrier to prevent the degradation of the rubber and any potential contamination.

Website: https://www.aptar.com/products/pharmaceutical/premiumcoat/

Aptar Pharma's PremiumCoat® Platform

2022

KEY FEATURES

- PremiumCoat® is a very tangible example of Aptar Pharma's commitment to offering the injectable market the integrated end-to-end solutions it demands. This approach brings together expertise in formulation, device development, and data to accelerate market readiness, minimize risk, assure quality and deliver on patient-centricity.
- PremiumCoat® is an advanced closure solution that combines Aptar Pharma's market-leading Bromobutyl formulation with an ETFE film and state-of-the-art manufacturing processes, including 100% camera control. PremiumCoat® stoppers are available in 13mm and 20mm formats for all sensitive drug applications in vial. PremiumCoat® syringe plungers are available in 1mlL and 1-3mL formats.
- Aptar Pharma's 6720GC Bromobutyl formulation is well known on the market for its purity and low levels of extractables and leachables (E&L). Augmenting elastomer products with PremiumCoat® ETFE film results in a barrier that further reduces the transfer of E&L into drug products.
- All PremiumCoat® products are based on the same Bromobutyl formulation and employ ETFE film technology, allowing customers to leverage a platform approache, derisking the joint validation of vial stoppers and pre-filled syringe plungers with customers' drugs. The platform approach enables drug life-cycle management strategies, such as transitioning a product from vial to pre-filled syringe.
- All PremiumCoat® products can be supplied Ready-To-Sterilize or Ready-to-Use as they have been gamma sterilized. Customized packaging requirements, including the use of port-bags for isolator applications, are supported by Aptar Pharma to accommodate customer's specific requirements.
- Aptar Pharma has developed a series of PremiumCoat® Data Packages to help customers understand the performance of the product across key parameters, such as probable leachables, chemical performance and compatibility with vials, and to facilitate regulatory submission (full Extractable file). PremiumCoat® Full Data Packages help our customers choose the right primary packaging for their drug and accelerate their development timeline. All data are available for steam-sterilized and gamma-sterilized components.
- Combining Aptar Pharma's in-house capabilities with the leading expertise of Aptar Pharma companies NextBreath and Gateway Analytical, PremiumCoat® Service Packages accompany customers with a tailored level of support to accelerate their specific drug development from the earliest stages. The three different service packages have been specially designed to address the most common issues faced during pre-clinical, clinical and regulatory filing phases through to market launch. These include multiple types of tests performed in cGMP conditions, including container closure integrity, leachable analyses and particulate testing, as well as project management by dedicated experts and regulatory support for accelerated filing.

ADDITIONAL RESOURCES

Video: PremiumCoat® video https://youtu.be/mzXObNO5n3g;

Aptar Pharma article May 2021: https://www.ondrugdelivery.com/ensuring-functional-performance-and-regulatory-compliance-of-elastomer-stoppers-for-multipiercing-situations/

Aptar Pharma article Sept 2021: https://drug-dev.com/premiumcoat-proven-compatibility-with-current-vial-standards

Aptar Pharma article Oct 2021: https://drug-dev.com/syringe-plunger-exploring-how-the-functional-properties-of-the-premiumcoat-1-3-ml-plunger-facilitate-its-implementation-on-filling-lines-enable-the-delivery-of-sensitive-vaccines-biotech-d/

+ Service packages technology showcase: https://drug-dev.com/wp-content/uploads/2021/10/October-2021-WEB-FRIENDLY-1.pdf

Aptar Pharma article Feb 2022: https://drug-dev.com/coating-technology-combining-a-state-of-the-art-bromobutyl-formulation-with-a-proven-etfe-film-for-exceptional-chemical-performance/

RayDyLyo®TearCap

2022

Company name: ARAYMONDLIFE SASU

Country: France

Product name: RayDyLyo®TearCap

Product type: Primary Packaging

Date of launch: Q4 2022

Current development phase: Prototype

Patent: EP 3763634 & EP 3763635

Target markets: Worldwide

Target clients: Pharmaceutical companies

FACT SHEET

PRODUCT DESCRIPTION

RayDyLyo® TearCap is the latest innovation in the RayDyLyo® range. A plastic Total Tear Off Cap for Ø 20 mm vials that eliminates the crimping operation and allows an easy access to the stopper after cap removal. Tear Off caps are recommended for mixing and reconstituting product, and for all applications that requires the complete removability of the cap to access the content. RayDyLyo® TearCap is are made of 2 different plastic raw materials to facilitate cap removal and secure the breakable section on the body part. RayDyLyo® TearCap is more ergonomic with reduced opening efforts and no sharp edges.

APPLICATION AREAS

Unlike alternative to the aluminum crimp cap, RayDyLyo® makes it possible to pre-assemble the stopper in the cap and simplify the production process.

It eliminates cosmetic defects on closures reducing rejects and batch recalls.

RayDyLyo® TearCap is suitable for many applications, for liquid, powder and solid forms.

- Biopharmaceuticals
- Injectables
- Vaccines
- Bone graft
- Cosmetics
- Drinkable solutions
- Food complements
- Rinsing solutions
- Contact lenses ...

ADDITIONAL RESOURCES

https://www.araymond-life.com/en/raydylyo-pharmaceutical-packaging

KEY FEATURES

RayDyLyo® TearCap is a total Tear Off Cap for Ø 20 mm vials. It replaces conventional Aluminum Tear Off seals.

It is an all plastic solution with the stopper preassembled in the cap. Manual capping is easy and safe needing only simple vertical pressure without any special tools. RayDyLyo® TearCap is compatible with existing filling and capping lines : capping takes place in the filling area (grade A).

RayDyLyo® TearCap eliminates cosmetic defects on closures.

- Eliminates the crimping operation for all applications
- Compatible with both Lyo and Serum stoppers (Iso standard)
- Vial closure by simple vertical pressure, manually or automatically
- No risk of jagged metal edges damaging gloves
- Easy access to the stopper after cap removal and body part dismantling
- Usable for mixing and reconstituting product
- Wide color range available for the cap
- Gamma sterilized
- Ready to Use
- Facilitates recycling of vial and plastic elements separately

Website: www.araymond-life.com

SCHOTT iQ® Integribag

2022

Company name: SCHOTT AG

Country: Germany

Product name: SCHOTT iQ® Integribag

Product type: Primary Packaging

Date of launch: 18/05/2022

Current development phase: Commercialization

Patent: Ongoing

Target markets: Global

Target clients: Pharmaceutical companies

FACT SHEET

PRODUCT DESCRIPTION

Sterile integrity is indispensable in aseptic fill-and-finish operations. Pharmaceutical companies pay highest attention to mitigating the risks of contaminated batches, which lead to recalls, high costs and reputation loss. Ensuring the sterility of all components when entering the aseptic filling core is possible, yet cumbersome with the RTU solutions that are currently available within the industry.

SCHOTT iQ® Integribag's quality-by-design approach design takes sterility one step further by not only the inside of the RTU tub, but also the outside of the tub and the protective tub layer. This is possible thanks to the bags material, which has a high puncture resistance. It leads to a lower probability of failures and complaints. Additionally, the bags seal is tamper-evident and can easily be inspected by pharma companies as well as CDMOs. With the SCHOTT iQ® Integribag, any additional decontamination steps, such as E-beam or manual alcoholic disinfection wipes, are no longer needed.- Certified non-irritant and non-cytotoxic technology

APPLICATION AREAS

SCHOTT iQ® Integribag is designed for pharmaceutical companies and CMO/CDMOs alike. Whenever RTU fill-and-finish processes are the preferred route, SCHOTT iQ® Integribag can cut out cumbersome decontamination processes at the time pharmaceutical containers are introduced into the aseptic filling suite.

This benefit especially pays off when looking at modern no-touch transfer solutions, where pharmaceutical containers such as syringes, cartridges and vials can be introduced in to the aseptic core fully automated.

ADDITIONAL RESOURCES

https://www.ejpps.online/post/vol26-4-end-to-end-qualification-of-ready-to-use-rtu-product-containers-in-packaging-suitable

Website: SCHOTT World of Innovations

SCHOTT iQ® Integribag

2022

KEY FEATURES

- **Better risk management for aseptic fill-and-finish processes with SCHOTT iQ® Integribag.**
- **Unique quality-by-design approach to enhance sterile integrity**
- **Unlike existing solutions, the SCHOTT iQ® Integribag does not only protect the inside, but also the outside of the tub and the protective tub layer.**
- **The bag material has a high puncture resistance, which leads to a lower probability of failures**
- **The bags seal is tamper-evident and can easily be inspected by pharma companies and CDMOs/CMOs)**
- **With the SCHOTT iQ® Integribag, any additional decontamination steps, which are often technically complex, hard to validate or that pose the risk of residuals in the fill-and-finish setup are no longer needed**

SCHOTT iQ® Integribag provides an new era of safety levels regarding the bagging and transport of pre-washed and sterilized pharmaceutical containers (cartridges, vials, pre-fillable syringes) into the aseptic filling suite which is based on a quality-by-design approach to enhance sterile integrity. Current bag solutions arrive in a double-bag system. Such system is neither designed nor validated as a sterile barrier. In this setup, the sterile barrier encompasses only the inside of the sealed tub holding the pharmaceutical containers and the Tyvek® inlay. Therefore, additional decontamination measures, such as E-beam or manual alcoholic disinfection wipes, are advised during the transfer step into grade-A filling zones to reduce the risk of contamination during infeed. Further, these bags only protect sterility of the inside of the tub (part of the secondary packaging), which carry the pharmaceutical containers (the primary packaging).

SCHOTT iQ® Integribag's design takes sterility one step further by protecting also the outside of the tub and the protective tub layer. The bag material has a high puncture resistance, which leads to a lower probability of failures and complaints. Additionally, the bags seal is tamper-evident and can easily be inspected by pharma companies as well as contract development and manufacturing organizations (CDMOs). With the SCHOTT iQ® Integribag, any additional decontamination steps, which are often technically complex, hard to validate or that pose the risk of residuals in the fill-and-finish setup are no longer needed.

Why is this important?

Regulatory requirements are becoming increasingly strict, and contamination control becomes more important, not only with highly automated systems. SCHOTT iQ® Integribag stays ahead of current regulatory requirements and allows pharma companies and contract manufacturing organizations (CDMOs) to significantly improve their risk management.

Huhtamaki Push Tab® blister lid with kpNext™ R1 bottom rigid film

2022

Company name: Huhtamaki together with Klöckner Pentaplast

Country: Germany

Product name: Huhtamaki Push Tab® blister lid with kpNext™ R1 bottom rigid film from Klöckner Pentaplast

Product type: Sustainability Initiative

Date of launch: 30/04/2022

Current development phase: Prototype

Patent: Ongoing

Target markets: Europe, but also all other countries

Target clients: Pharmaceutical companies

FACT SHEET

PRODUCT DESCRIPTION

In search of a blister solution that meets both environmental requirements and sustainability targets of clients, Huhtamaki and Klöckner Pentaplast teamed up to combine their specific packaging expertise in one product.

Huhtamaki Push Tab® blister lid is a 100% mono-PET blister lidding, available with push and peel opening options. In combination with kpNext™ R1 bottom rigid film from Klöckner Pentaplast it makes your package ready for the RIC 1 recycling stream. Additionally, this blister solution works on existing production lines and packaging designs, no compromises in output, no further investments needed. The blister provides a unique product presentation due to its overall superior optical clarity.

APPLICATION AREAS

Klöckner Pentaplast and Huhtamaki co-created a sustainable mono-material blister solution: The blister consists of the kpNext™ R1 bottom rigid film from Klöckner Pentaplast and the Huhtamaki Push Tab® blister lid, both using only mono-PET. That way it turns the package into a recyclable mono blister, designed to be recyclable in the RIC 1 recycling stream.This solution is meeting both environmental requirements and sustainability targets of the customers. Huhtamaki and Klöckner Pentaplast are working closely to ensure proven recyclability with experts among the recycling industry like PFE and HTP Cyclos.

ADDITIONAL RESOURCES

Video - https://vimeo.com/687929133/9d8eaf69fd

KEY FEATURES

Klöckner Pentaplast and Huhtamaki co-created a sustainable mono-material blister solution: The blister consists of the kpNext™ R1 bottom rigid film from Klöckner Pentaplast and the Huhtamaki Push Tab® blister lid, both using only mono-PET. That way it turns the package into a recyclable mono blister, designed to be recyclable in the RIC 1 recycling stream.

This solution is meeting both environmental requirements and sustainability targets of the customers. Huhtamaki and Klöckner Pentaplast are working closely to ensure proven recyclability with experts among the recycling industry like PFE and HTP Cyclos".

Most importantly this recyclable ready blister works on existing production lines and packaging designs, no compromises in output, no investments needed.

Not containing aluminum makes this blister solution transparent, giving it a great visual feature compared to traditional pharma blisters. Its barrier properties, comparable to mono-PVC solutions offering a sufficient barrier for many health care applications, provide MOSH/MOAH protection for the use of recycled cardboard folding boxes.

With our recyclable blister you get the best of both worlds, sustainability and performance, plus so much more!

Website: www.huhtamaki.com

Aclar® Barrier Packaging

2022

Company name: Honeywell International

Country: USA

Product name: Aclar® Barrier Packaging

Product type: Sustainability Initiative

Date of launch: 19/06/1961

Current development phase: Commercialization

Patent: Ongoing

Target markets: Global

Target clients: Pharmaceutical companies

FACT SHEET

PRODUCT DESCRIPTION

Aclar® barrier films and Aclar Edge™ bottles protect medicines that improve the lives of individuals throughout the globe by providing the moisture barrier protection needed for drug stability and patient safety. Tried and trusted throughout the pharma industry, Honeywell has continued to innovate to meet the ever-growing needs of customers. One example of this is through our sustainability efforts. The Aclar® portfolio carbon footprint has improved by over 50% since 2012 and Aclar® films contain up to 25% virgin reclaim material from our production process. Recently, TerraCycle® has determined that Aclar Edge™ achieves technical recyclability.

APPLICATION AREAS

Applications for Aclar® Films:

- Oral solid medication: Over the Counter (OTC) and Prescription (Rx)
- Medical Device packaging
- Biopharma
- Industrial
- Crop Packaging

Applications for Aclar Edge™ Bottles:

- Liquid & Oral solid medication: Over the Counter (OTC) and Prescription (Rx)
- Pediatric liquid medication
- APIs
- Labware
- Personal Care

Other Applications - Custom bottles: in-house design under GMP standards by our engineering team to meet your specific specifications (various sizes, shapes, and colors)

Website: https://lifesciences.honeywell.com/us/en/products/barrier-packaging

Aclar® Barrier Packaging

2022

KEY FEATURES

Creating a safer and more sustainable future is a strategic imperative for both Honeywell and our pharmaceutical and biopharmaceutical customers. Honeywell has a long-term strategy to support this initiative both at the corporate and product offering levels. We are committed to providing a high quality, ultra-high moisture barrier to protect the efficacy of medicine that is also a more sustainable solution. As such, we have made many innovative advancements for this portfolio. The Aclar® portfolio carbon footprint has improved by over 50% since 2012 and we're not stopping there. The following are specific examples of how we're innovating in sustainability.

Technical Recyclability: Most recently, we've been awarded a new claim: Technical Recyclability for our Aclar Edge™ Bottles by TerraCycle®, a global leader in collecting and repurposing hard-to-recycle waste. Through this process, we've proven that Aclar Edge™ can be converted into a new usable format after initial use. We are in the process of proving technical recyclability for our Aclar® Films.

Recycled Content: Aclar® Films contain up to 25% virgin reclaim material from our production process. Our Aclar Accel™ portfolio can contain up to 100% virgin reclaim material.

Waste Reduction: We have reduced waste from Aclar® films production by 29%1

Packaging Reduction: With Aclar® you can use less packaging overall than other barrier solutions which not only costs less money, but also has a positive environmental impact. With Aclar®, we've proven that customers can reduce pack size and secondary packaging up to 55%.2 Aclar® can show up to 12% material reduction vs. competitive products.3

1. Over a 5-year period
2. Compared to the same material packaged in Alu/Alu
3. Aclar 2 mil compared to high barrier PVdC 120g & 180g

PVC Free: Aclar Edge™ bottles contain no PVC while offering robust protection without glass. In addition, we offer PVC-free laminate options available through our network of converter partners for Aclar® & Aclar Accel™ barrier films.

Bio-packaging with monitoring technology and medication support

2022

Company name: Neutroplast

Country: Portugal

Product name: Bio-packaging with monitoring technology and medication support

Product type: Sustainability Initiative

Date of launch: 25/11/2022

Current development phase: Proof of concept

Patent: Ongoing

Target markets: Europe, Clinical Trials, Healthcare

Target clients: Biopharmaceutical companies

FACT SHEET

PRODUCT DESCRIPTION

Neutroplast, in collaboration with PIEP, has produced pharma grade jars of two biopolymers. Two combinations were tried i. Polypropylene and eucalyptus nitens; ii. High density polyethylene and mussel shells. This is a solution that promises to innovate the market while reducing plastic consumption.

These packages are complemented by the DOSEA+ device. It has been developed within the DOSEA Smart Label project, by Neutroplast, Beyondevices and CeNTI, as a simple and eficient solution that promises to alert, control and manage medication taking both at professional and household levels. Due to its characteristics, the device can be applied in all types of treatment that requires strict control.

APPLICATION AREAS

Bio-packaging can be applied in several areas such as pharmaceutical, food and cosmetics. They are a global solution because their final characteristics can be adapted to the requirements of industries, using biinjection or coinjection technologies for their production and thus meet the demands of customers and the market.

Although DOSEA+ has been developed for the pharmaceutical field, as it is an alert and monitoring device, it can be attached to any packaging. It may be useful in the following situations:

- Monitoring adherence to treatment and so validating its effectiveness;
- Managing your own medication, that of dependent users (babies, animals) or that of several people at the same time (hospitals and nursing homes)

KEY FEATURES

- Packaging to reduce conventional raw material consumption
- More sustainable solution
- Smart packaging - alert, monitoring and treatment management
- Supports multiple treatments simultaneously.
- Reusable device

Website: www.huhtamaki.com

Pharmaceutical Grass paper Packaging

2022

Company name: Körber Pharma Packaging Materials AG

Country: Switzerland

Product name: Pharmaceutical Grass paper Packaging

Product type: Sustainability Initiative

Date of launch: 01/06/2022

Current development phase: Prototype

Patent: none

Target markets: EU / US / World

Target clients: Pharmaceutical companies

FACT SHEET

PRODUCT DESCRIPTION

Grass fibre production takes place purely mechanically without chemical preparation, causes up to 95 percent less CO2 emissions, requires hardly any precious water and only a little energy compared to virgin fibre pulp obtained from wood. Depending on the product, up to 30 percent of the pulp from wood can be replaced by grass fiber, with the same functionality and quality.

Made from renewable raw materials, grass paper is 100 percent recyclable and can be disposed of like waste paper. As an environmentally friendly alternative to traditional cardboard, grass paper is therefore very much trending and stands out for its natural look and the tactile feel of the natural fiber material.

APPLICATION AREAS

Sustainable Packaging Worldwide

KEY FEATURES

Advantages of grass paper:

- Fast-growing renewable raw material
- No use of chemicals
- Less water and energy consumption
- Reduction of greenhouse gases (CO2)
- Conserving wood as a resource
- Environmentally friendly packaging

Website: https://www.koerber-pharma.com/solutions/verpackungsmaterial/nachhaltige-verpackungen?

LVI-V20 On-Body Injector

2022

Company name: Sonceboz SA

Country: Switzerland

Product name: LVI-V20

Product type: On-Body Injection Device

Date of launch:

Current development phase: Preclinical

Patent: WO2018141697A1

Target markets: United States and Europe

Target clients: Biopharma

Business model: B2B and Licensing

FACT SHEET

PRODUCT DESCRIPTION

The LVI-V20 is an electromechanic wearable injection device capable of delivering up to 20mL of highly viscous large-molecule drugs into the subcutaneous tissue. The device is designed so you can continue using any standard glass vial - thus eliminating the need for complex primary container development and validation. This allows for a fast utilisation of this fully programmable and connected device in clinical investigations or lifecycle management initiatives. Since the LVI-V is part of the Sonceboz OBI platform with shared architecture, a transition from LVI-V to say LVI-P is a straightforward process.

APPLICATION AREAS

- Clinical investigations of drug/device combinations
- Oncology to deliver drugs such as immune checkpoint inhibitors
- Neuroscience to deliver high drug payloads to enhance efficacy
- Weight-based dosing
- 505B2 applications for reformulated drugs
- Assisted use by physicians and nurses
- Selfcare for training patients

KEY FEATURES

- Vial-ready
- Fully programmable
- Integrated connectivity
- Best-in class compactness for 20mL volume
- Easy and intuitive to use
- Automatic loading or manual filling
- Soft-Cannula delivery system
- Low noise emission
- Programmable dosing rate from 0.01mL to 3mL per minute
- High precision
- Benchmark Swiss quality and reliability

Website: www.sonceboz.com

Symbioze

2022

Company name: Nemera

Country: France

Product name: Symbioze

Product type: Wearables

Date of launch: 09/30/21

Current development phase: Prototype

Patent: On going

Target markets: North America, Europe

Target clients: Pharmaceutical companies

FACT SHEET

PRODUCT DESCRIPTION

Nemera's smart on-body injector platform, Symbioze, is an innovative, user-friendly and sustainable solution to self-inject a medication at home. Its unique positioning consists of delivering large volume drugs, especially biologics, in combination with a multiple-use approach, thanks to its reusable and disposable parts. It is suitable for various drug platform and compatible with market-proven cartridges, as well as standard manufacturing process. The cartridge is prefilled and preloaded in the disposable part for patient safety and ready-to-use feature. Symbioze is specifically designed to accommodate large volume injection (20 ml), with flexibility for adjustment to different volumes, flowrates, and viscosities. It also includes connectivity feature, to improve patients' adherence and compliance. To foster patient injection experience, our on-body injector offers a safe and reliable injection thanks to the state-of-the-art engineering, including automatic needle insertion and hidden needle.

APPLICATION AREAS

A rising number of pipelines in biologics and biosimilars requires adequate drug delivery device solutions to accommodate sensitive drugs for safe self-administration. In the Covid-19 pandemic context, patients wish for independence and convenience in managing their drug regimen with reassurance at home, without having to worry about being exposed to the virus at the healthcare facilities. Moreover, the switch from intravenous to subcutaneous drug administration in a home-care therapy setting is emerging, and requiring a robust, reliable drug delivery device to administer high volume and viscosity. To cater to these needs, our smart on-body injector, Symbioze, answers the needs for digital health to foster patient adherence and injection experience.

Our wearable platform is designed for flexibility to be adjusted to any pathology, targeted patient population and drug posology. It is sustainable and cost-efficient for multiple use, thanks to its reusable electronic and disposable parts. Thanks to its connectivity feature, patients and their healthcare professionals could stay in touch and better manage the treatment.

Symbioze offers a highly engineered solution and smart design with unique drug delivery system including following benefits:
- Adaptable to several drug volumes and viscosities
- Adjustable flowrate
- Flowrate control & Failure mode control
- Fully integrated in reusable

Our innovative design enables drug/device assembly in a non-aseptic environment with an embedded sterile connection between the drug container and the delivery system.

Website: https://www.nemera.net/products/parenteral/wearables-symbioze/

Symbioze

2022

KEY FEATURES

Key features:

- Sustainable and cost-efficient thanks to its reusable electronic and disposable parts
- Enables large volume injection (20 ml with flexibility for adjustments upon needs)
- Ready-to-use: prefilled and preloaded cartridge for patient safety
- Compatible with market-proven cartridges and standard manufacturing process

Key Benefits:

- Architecture can be tailored to match any drug specifications (dose volume, viscosity, flowrate...) which is particularly relevant to biologics drugs
- Secured injection with automatic needle insertion and hidden needle
- Recognition system between reusable and disposable parts for verification and locking
- Ergonomic needle safety cap removal and user-friendly adhesive liner removal
- Possible connectivity feature to improve patient compliance and adherence Key features