



pharmasolutions

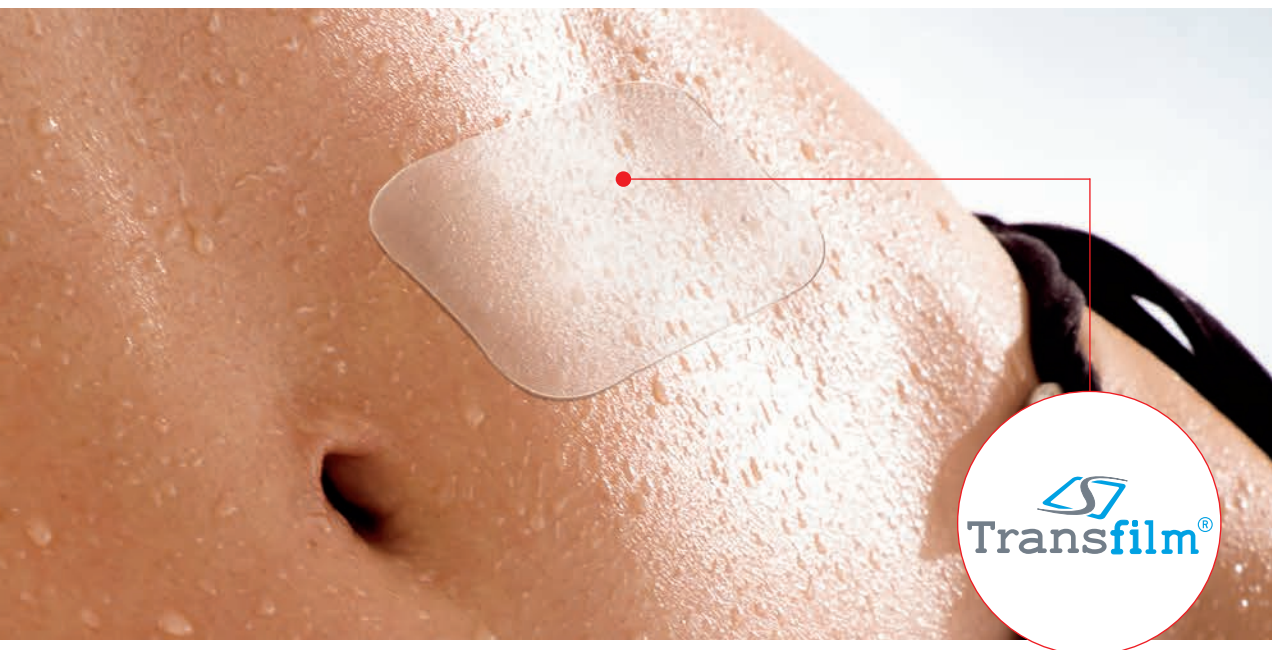
tesa Labtec GmbH – Innovative Drug Delivery Systems

drugdelivery

Innovative Patch & Film Technologies

Selecting the appropriate route of administration is an important issue in the development of a pharmaceutical product.

Therefore, tesa Labtec has focused on developing and manufacturing innovative drug delivery systems and has created the Transfilm®, Rapidfilm® and Mucofilm® technologies. Today, we serve a large number of clients in the pharmaceutical industry as Contract Developer and Contract Manufacturer.



Transdermal and topical patches – the Transfilm® technology

Transdermal drug delivery provides clear advantages for the patient, due to easy administration, which does not restrict daily activities. In addition, this non-invasive delivery system combines a reduced first-pass effect with constant drug levels and prolonged delivery over time to provide patients and clinicians with important benefits.

Transdermal patches offer a unique selling point for new and established drugs in competitive markets. tesa Labtec has a proven track record of bringing transdermal patches to the market. Our estradiol patch for hormone replacement therapy has been marketed in 41 countries worldwide since 1995 and our fentanyl patch has been conquering the European market and Canada since 2005. In Germany, Europe's biggest fentanyl patch market by far, our patch has become #1. Currently, we are developing the next generation analgesic opioid patch.

Topical patches deliver the drug to the local site of action. This convenient and safe way of administering a locally active drug offers considerable advantages compared to gels and creams and is generally extremely well-received by the patients. tesa Labtec established innovative ways to apply this principle to other parts of the body. For example, our nail patch for treatment of fungal infections of the nails is the first of its kind.

Additionally, the Transfilm® technology is utilized for tesa Labtec's Labipatch which allows active ingredients to be applied to the lips with an extremely thin patch, improving the treatment of cold sores.



Oral, sublingual and buccal films – the Rapidfilm® and the Mucofilm® technology

Oral, sublingual and buccal films are placed on or under the tongue, or into the cheek. The great advantages of thin films have made them an excellent alternative to tablets or capsules.

Our Rapidfilm® technology makes oral films possible that dissolve and release the drug within seconds once in contact with saliva. It combines the application ease of an oral solution with the stability and dosing accuracy of a tablet.

Rapidfilm® is the ideal takeaway medicine; it can be taken without beverages and is especially suited for pediatric application.

We have developed several generic Rx Rapidfilm® products. Ondansetron Rapidfilm® obtained its marketing authorization from EU authorities in March 2010, making it the world's first Rx product to be approved that uses oral dissolvable film technology. The product is marketed in Europe by Norgine under the tradename Setofilm® and in Canada by Takeda under the tradename Ondisolve®.



Buccal films are placed on the inside of the cheek. Sublingual films are applied under the tongue. Both systems enable local or systemic drug delivery.

Our Mucofilm® technology creates a mucoadhesive film that enables transmucosal drug permeation. Thus gastrointestinal drug degradation cannot occur and the hepatic first-pass metabolism is bypassed. Therefore, buccal administration opens up completely new possibilities for molecules with low bioavailability. Mucofilms® are easy to apply, handle and store. Patients can benefit tremendously from the prompt relief delivered by our Mucofilm® technology.

Today several buccal films are under development by tesa Labtec GmbH.



tesa Labtec's business model follows a purely B2B approach and addresses pharmaceutical companies' need for innovative drug delivery systems. The model is based on three segments:



With our presence in Europe and our office in the USA we serve the biggest international markets and a broad variety of customers. This proximity to our customers ensures great accessibility and high responsiveness on inquiries.

Internal prototype development

We invest in the in-house development of patches and films. As a result tesa Labtec possesses a project portfolio which is open to global licensing.

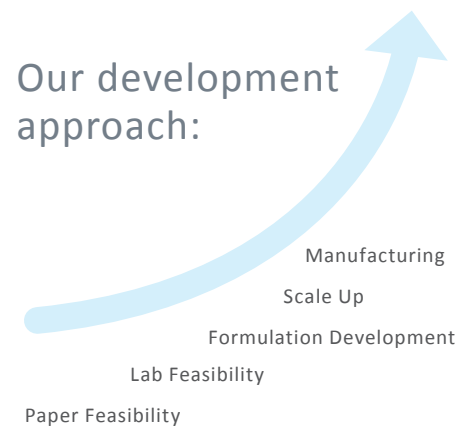
Contract development

When developing film or patch products we follow a structured approach for each project accompanied by professional project management. We determine the goal of each project together with our customers and define milestones and interim targets for the development process. All results from experiments are presented and discussed within the joint project team on a regular basis, so that full transparency regarding the progress of the project is ensured. From a very first paper feasibility up to the approval of the product, our expert team is ready to support customers in all phases of a development project.

Solutions for Pharma

Our R&D site in Langenfeld, Germany, is fitted with the most modern equipment for the development of innovative drug delivery systems. The formulation department has direct access to all of the necessary development tools. Our in vitro testing group routinely performs Franz cell tests. The analytical laboratory can offer a broad range of pharmaceutical testing from method development and validation to long-term stability testing for registration purposes. State-of-the-art equipment and modern information technology ensure timely, reproducible results at a reasonable cost.

Integrated quality assurance procedures and full cGMP compliance guarantee reliable results. We possess all of the equipment and personnel qualifications necessary to manufacture clinical trial supplies under cGMP conditions. Our integrated service includes scale up and tech transfer activities at our manufacturing site, located in Hamburg.



serviceprovider





LabFactory

Contract manufacturing

tesa Labtec is prepared to support their customers as a full-range product supplier from R&D lab-scale over pilot-scale to full-scale production. Our facilities are equipped to serve customers at every stage of a product's lifecycle and according to current production demand. The production plant in Hamburg, Germany, offers state-of-the-art equipment compliant with all cGMP requirements.

LabFactory: In 2014 tesa Labtec opened its "LabFactory", a fully automated pilot-production facility at the R&D site in Langenfeld equally operating under full cGMP. The new equipment provides the unique opportunity to close the gap between small-scale development and large-scale production. The LabFactory has been equipped to be comparable to our commercial-scale operation in Hamburg. Thus, it allows the assessment of critical process parameters as well as a first processability check of formulations already at an early stage of development.

However, the new LabFactory is also able to produce sufficient volumes of patches and films to supply even large phase II clinical trials directly from the R&D site.

Commercial production: tesa Labtec's production plant in Hamburg, Germany, is equipped with the latest state-of-the-art coating, converting and packaging equipment in a cleanroom environment. It is fully dedicated to manufacturing patches and thin films.



Our coating lines offer variable coating widths, which allow us to perfectly match customer's volume requirements, from small quantities up to several hundred million units. Depending on our customer's need, we produce bulk or secondary packed products. Machines and operating procedures are designed to fulfill the strictest legal and regulatory standards according to cGMP. If a reliable partner to scale-up a proprietary product formulation is required or if an experienced supplier for a marketed product is needed, we are the right partner.

Our technological capability and our know-how related to material are propositions that customers can count on to keep tight project timelines and reduce total processing costs. In addition, our customers can benefit from the full supply chain and worldwide distribution know-how of a tesa company.



longstanding competence

Compelling Competence in Drug Delivery, Adhesives and Coating



Compelling competence in drug delivery, adhesives and coating

With more than 25 years of experience, tesa Labtec is one of the leading drug delivery companies for film-shaped dosage forms like patches and thin films. Because of its innovative Transfilm®, Rapidfilm® and Mucofilm® technologies, the company considers itself a highly specialized full-service Contract Development and Manufacturing Organization (CDMO).

tesa Labtec is a wholly owned subsidiary of tesa SE, a member of the Beiersdorf group of companies, and represents the pharmaceutical business in a truly global family of companies by offering “Solutions for Pharma.”

Our parent company, tesa SE, is one of the world’s leading manufacturers of self-adhesive product and system solutions for industry, trade and consumers. The company’s 125 years of experience in coating technology and its development of adhesives and innovative product solutions have taken tesa to the top of the world market in many fields of application.

The unique combination of tesa Labtec’s pharmaceutical development know-how with tesa’s broad engineering experience and expertise offers valuable synergies and advantages to our customers.





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