



THE ALTERNATIVE FOR CANNABINOID ADMINISTRATION: FILM-SHAPED DOSAGE FORMS

Background

Oral thin films (OTF) and Transdermal Patches (TDS) are gaining more popularity due to their efficacy, convenience and discreteness. Also, in the rapidly increasing major cannabis markets both drug delivery forms could be a novel and alternative route of administration.

The active ingredients in Cannabis like Tetrahydrocannabinol (THC), Cannabidiol (CBD), other Cannabinoids and terpenes have a low oral bioavailability or are administered by smoking the hemp which impacts the respiratory tract of the patients.

OTFs and TDSs circumventing this problem, are easy to use and increase the efficacy and the patient convenience. Cannabinoids could be precisely dosed in each unit and patients who can't swallow will overcome this hurdle.

The film shaped dosage forms platform of tesa Labtec comprises the **Mucofilm**[®] and **Transfilm**[®] which bring advantages much needed for topical, transdermal and buccal cannabinoid administration.

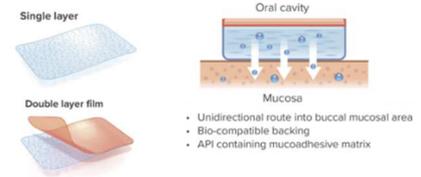
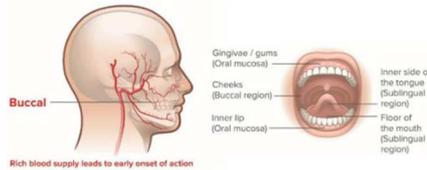


Oral Film and Transdermal Patch Systems

Our oral film platform containing the **Mucofilm®** - a controlled dissolving oral film with many more applicable advantageous properties.



- Advantages**
- Easy use without water
 - No chewing
 - Pain free application
 - No sterility issues
 - High dosing accuracy
 - Cold supply chain avoidable

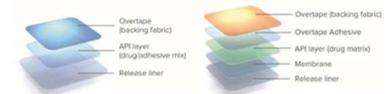
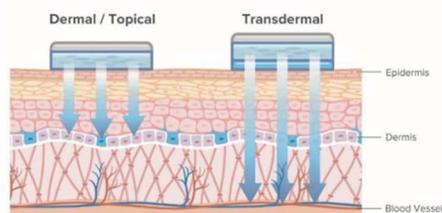


The direct application of oral thin films to the mucosal surface at either the buccal or sublingual tissue, ensures a swift uptake. A whole panel of options is available for the formulation of films including the addition of mucoadherence, the controlled disintegration and multilayer systems ensuring uptake of the cannabinoids is directed to the mucosa and further taste masking, flavoring, coloring etc.). Films can be tailored to meet the demand of each specific cannabis administration concept.

Our transdermal patch **Transfilm®** is a non-dissolving patch system for dermal or transdermal API delivery.



- Smart drug delivery**
Drug transfer:
- Through the skin into the dermis or
 - Into the skin permeating into blood vessels



Classical DIA (drug in adhesive) matrix design

- Ranging from monolithic to multilayer patches
- Ranging from rate controlling membranes to overtapes

Transdermal products not only act locally but are also suitable for systemic applications. The avoidance of the first-pass effect leads to better bioavailability and may result in fewer side effects. Consistent and controlled drug delivery can minimize or avoid periods of under- and overdosing. Transdermal cannabinoid patches deliver drugs over a longer period (weekly), thus allowing for reduced dosing frequency.

Both, our **Mucofilm®** and **Transfilm®** technologies, are easy to apply, provide a high dosing accuracy and are very convenient especially for the elderly population.

Oral film and transdermal patch technologies are specified and listed in international pharmacopoeias (Phar. Eur and USP) as well as the raw material used for production.

CAPABILITIES OF tesa LABTEC

Our R&D site is specialized in development and prototype formulation and new analytical methods up to clinical trial manufacturing on automated equipment under GMP conditions (“LabFactory”). Our development machinery is adjusted to our commercial manufacturing equipment for large scales, enabling us to perform safer upscaling processes. The supply chain and secondary packaging unit are prepared for packaging requirements worldwide. From prototype to market supply tesa Labtec covers all duties.

We could offer an all-in-one package, from early development stage, preclinical studies to large scale production at our GMP production site. Expertise, flexible batch sizes, pilot scale manufacturing via scale-up and commercial manufacturing capability – these are the pillars of our process development and production.

The tesa Labtec R&D site, Germany

Pharmaceutical development

- Formulation & analytical methods
- Manufacturing and release of clinical trial material (up to phase II)
- The “LabFactory” - fully automated pilot-production facility - operating under full cGMP - EU and FDA inspected



The tesa Labtec Manufacturing site, Germany

- 13 000 m² total with 6 000 m² GMP area
- Modular use for patches (TDS) and oral films (ODF)
- **All EU GMP licenses available for**
 - Clinical trial supplies
 - Finished product including secondary packaging
- **Pre-Approval Inspection (PAI) by FDA is passed successfully**
- Capabilities for a worldwide product supply



PARTNERING OPPORTUNITIES

tesa Labtec's well established platform of transdermal therapeutic systems and oral films offers patients, medical professionals and caregivers' reliable therapeutic efficacy with the highest level of convenience and comfort. Our 30+ years track record in serving a broad range of clientele from big pharma over midsize and Specialties to multinational generic companies enables us to be a trustful partner. We offer our expertise, infrastructure and equipment to partner and increase the efficacy and optimize the delivery of your cannabis concept.

KEY BENEFITS OF FILM-SHAPED DOSAGE FORMS

- ✓ Circumventing the first-pass metabolism
- ✓ No impact of patient respiratory tract (vs smoking)
- ✓ Dosing accuracy
- ✓ Easy and discreet administration)
- ✓ Reduce irritation of oral mucosa issue
- ✓ One stop shop of R&D and GMP

About tesa Labtec

We, tesa Labtec, have a vast expertise as a full service CDMO for transdermal therapeutic systems and oral films. With almost 30 years of experience, we develop innovative drug delivery systems that offer patients, medical professionals and caregivers' reliable therapeutic efficacy with the highest level of convenience and comfort. Our customers are pharmaceutical companies all over the world and appreciate our high-quality standards in development and manufacturing **Made in Germany**.

As a B2B partner to the pharmaceutical industry, we offer end-to-end solutions for all stages of drug development: from portfolio screening, development strategy, feasibility assessments, formulation development to clinical trial, production and packaging. We are your reliable partner and always **by your side – from idea to market**.

Contact info: Dr. Timo Taghizadeh, Head of Business Development & Marketing

Email: business.development@tesa.com

Phone: +49 2173 973599

www.tesa-labtec.com