



**ORAL THIN FILMS CAN
DISRUPT VACCINE DELIVERY**

ORAL THIN FILMS FOR MUCOSAL VACCINE DELIVERY

Background

Over 90% of the pathogens enter the body via the mucosa. Still, the utmost majority of vaccines do not induce mucosal immunity. There is a substantial unmet medical need for safe and efficacious vaccines that can elicit mucosal immunity. Vaccination via the sublingual (and buccal) route is capable of inducing mucosal immunity and comes with a broad set of advantages. For example, sublingual vaccination can induce mucosal immunity in a broad array of target organs, is needle free, easy to use, does not require highly trained healthcare workers and, by applying the right dosage form, can be made thermostable. The oral film platform of tesa Labtec comprises the Rapidfilm® and Mucofilm®, which bring advantages much needed for sublingual and buccal vaccination and the induction of mucosal immunity.

Oral Film platform

Our oral film platform containing the Rapidfilm® - a fast dissolving oral dispersible film – such as the Ondansetron film (first registered in Europe) and the Mucofilm® - a controlled dissolving oral film with many more applicable advantageous properties- such as mucoadhesion, unidirectional. Both technologies are easy to apply, provide a high dosing accuracy and are very convenient for each age group including children and the elderly population (Klingmann et al. EUR. J. PHARM. BIOPHARM. 151 (2020) p239).



Advantages

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

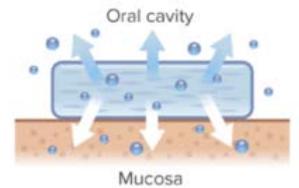


The direct application of oral thin films to the mucosal surface at either the buccal or sublingual region, ensures a swift uptake and can maximize the (mucosal) immune response. A whole panel of options is available for the formulation of films including the addition of mucoadhesive, the controlled disintegration and multi-layer systems ensuring uptake of the vaccine is directed to the mucosa. Films can be tailored to meet the demand of each specific vaccine concepts.

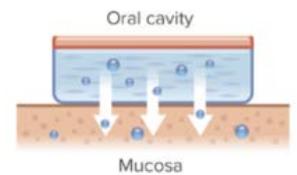
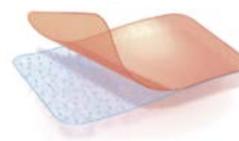
RAW MATERIALS / DESIGN OF LAYERS / CONTROL OF RELEASE DIRECTION

- Polymers
 - Polyvinyl alcohol (PVA)
 - Polyvinyl pyrrolidone (PVP/Kollidon)
 - Cellulose and derivatives
 - Starch and derivatives
 - Polyacrylic acid (Carbopol)
 - Alginates
- Plasticizers
 - Residual water and ethanol
 - Glycerol
 - Polyethylene oxide (PEO/PEG)
 - Propylene glycol
- (Fillers/Flavours/Taste Masking)

Single layer



Double layer film



Beside the pharmaceutical efficacy oral films can be designed individually by taste masking, flavoring, coloring etc. Raw material used in oral film technology are specified and listed in international pharmacopoeias (Phar. Eur and USP).

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 oral dispersible dosage forms offers a unique opportunity to drive immunity of mucosal vaccine. 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 for vaccine developers and manufacturers. With an increasing need for thermostable, pain free delivery of vaccines capable of eliciting mucosal immunity, we offer our expertise, infrastructure and equipment to partner and increase the efficacy and optimize the delivery of your vaccine concept.

KEY BENEFITS ODF IN VACCINE DELIVERY

- ✓ Mucosal immunity, offering protection at port of entry
- ✓ Protection in numerous sites (i.e. Respiratory tract, Gastro-intestinal tract, Genital tract, Blood)
- ✓ Needle free and pain free ad administration
- ✓ Thermostable dosage form (no cold chain)
- ✓ No sterility problems
- ✓ 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**.

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