



## Where We Are

### 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)
    - full equipped analytical lab for pharmaceutical testing including stability chambers acc.to ICH standards



### The tesa Labtec manufacturing site, Germany

- 13,000 m<sup>2</sup> total with 6,000 m<sup>2</sup> GMP area
- EU GMP licenses in place for
  - clinical trial supplies
  - finished production including secondary packaging
- 1st Pre Approval Inspection (PAI) by FDA is passed successful



## About tesa Labtec

tesa Labtec is a wholly owned subsidiary of tesa. tesa is one of the world's leading manufacturers of technical adhesive tapes and self-adhesive system solutions (more than 7,000 products) for industrial and professional customers as well as end consumers. Since 2001, tesa SE (4,926 employees worldwide) has been a wholly owned affiliate of Beiersdorf AG (whose products include NIVEA, Eucerin, and la prairie).



100% affiliate of



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**BY YOUR SIDE  
FROM IDEA TO MARKET**

**We Are Your Full Service CDMO for  
Transdermal Patches and Oral Films**

Made in  
Germany  
EU cGMP  
FDA Serialized

# tesa LABTEC

By Your Side – From Idea to Market



As our customer, you may expect premium quality and full regulatory compliance. We allow you to reduce the number of contractors you currently work with and handle all steps of drug development and manufacturing.

Our products are made in Germany, safeguarded by our quality systems under full cGMP in high quality.

Considering the many changes affecting our industry, we fully comprehend your need for end-to-end services and are available as your reliable partner – always **by your side, from idea to market.**

## Ideas

We have the necessary expertise regarding patches and oral films, which allows us to develop product ideas together with our customers and provides you with advantages for all stakeholders.

## Intellectual Property

Our experts and our professional network will offer answers to all questions and develop the ideal strategy to protect your IP.

## Feasibilities & Formulation Development

Our development capability is exceptional, not only in formulation but also in analytical services and project management. tesa Labtec has a long history, vast experience and proven track record in successful patch and oral film development.

## Regulatory Support, Clinical Trials & Authorities

Our network or your network – whatever fits your needs better.

## Process Development, Scale Up & Manufacturing

Expertise, flexible batch sizes, pilot scale manufacturing (LabFactory, e.g. for clinical trials), scale-up and commercial manufacturing capability are our assets for your success.

## Launch Support & Customer Management

Our project management is always by your side. Launches will be planned just as professionally as the customer management will assist you during the entire project phase.

## Our Technologies

Specific solutions for various client profiles – start ups, big pharma, health markets and many more



## Buccal and Sublingual Films:

New possibilities for drugs with low bioavailability



Buccal delivery of a drug via thin films has the potential to

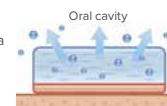
- Improve the action of drug
- Lower the dosing
- Enhance the efficacy and safety profile
- Avoidance of gastrointestinal drug degradation
- Bypasses first-pass metabolism



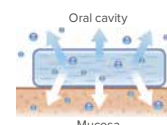
- Double layer film**
- Unidirectional route into buccal mucosal area
  - Bio-compatible backing
  - API containing mucoadhesive matrix



- Double layer film**
- Unidirectional route into oral cavity and for mucosal area
  - API containing dissolvable matrix
  - Slow dissolving mucoadhesive backing



- Single layer**
- Bidirectional route for sublingual / buccal application
  - Mucoadhesive matrix
  - API containing layer



## Fast Dissolving Oral Dispersible Films:

Meeting the needs for specific patient groups



## Benefits

### For Patients

- Ease of administration
- can be taken without water
- no need of chewing or swallowing

Tolerability and proven patient acceptance\*:

- Acceptability
- Swallowability
- Palatability

Safety:

- exact dosing – no spitting out possible
- no choking
- child resistant and single packaging

Prompter relief due to faster onset of action via buccal route

### For Medical Use

Guaranteed dose and treatment

Provides faster onset of action (buccal application)

Patient can be given medication lying in bed and without water

Reduces number of drugs which have to be chewed or swallowed

Provides solution for the unmet specific needs of the patient group

Type, frequency and dose of existing medication could remain unchanged

### Development & Manufacture

Fulfills regulatory requirements (PIP)

Variety of doses with only one formulation

Variety of films for different administration routes:

- oral
- lingual
- sub-lingual
- buccal

New innovative products for your portfolio

New technology provides opportunities for life cycle management



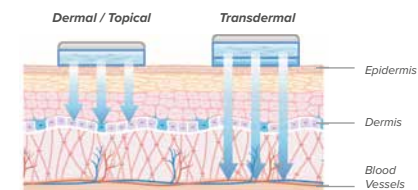
\*Acceptability of an Orodispersible Film Compared to Syrup in Neonates and Infants – A Randomized Controlled Trial  
V. Klingmann, C. Pohly, T. Meissner, E. Molyatepek, A. Moltner, M. Wargenau, J. Breitkreutz, HM. Bosse  
EUR. J. PHARM. BIOPHARM., Volume 151, June 2020, P. 239 ff

## Transdermal and Topical Patches:



Transdermal Systems aim to deliver drugs to the systemic circulation at a controlled and predictive rate

tesa Labtec has a vast track record of patch development and is a reliable contract manufacturer



Smart drug delivery – through the skin or into the skin