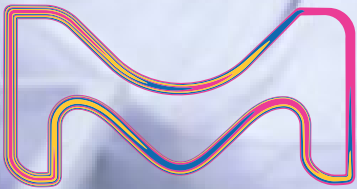


MERCK

# Application services

Let our excellence in excipients  
boost your business



The life science business  
of Merck operates as  
MilliporeSigma in the  
U.S. and Canada.

**SAFC**<sup>®</sup>

Pharma & Biopharma Raw  
Material Solutions

# Wide-ranging solutions. unrivalled support.

Solid dose formulations continue to be the most important dosage forms for pharmaceuticals. However, the complexity of manufacturing final drug products is becoming more and more challenging, and API stability, release kinetics and bioavailability limitations such as low API solubility are just a few of the many critical obstacles on the way to the market.

We understand you need a global partner that you can trust. One who not only has the products and technologies you require, but also the applications know-how.

Our Application Labs offer unparalleled formulation support, solutions for bioavailability enhancement and customized development. With our high level of expertise in oral solid dosage forms, you can rely on our support for your projects and throughout the entire life cycle of your products.



**Our world-class product portfolio is complemented by an equally-impressive range of additional services.**





## Dedicated Expertise

With our specialist formulation products, process chemicals and application lab services, we help you take your drug to the next level.

## Solid Formulation Portfolio

Manufacturing final drug products is a complex area that is becoming increasingly more challenging. Obstacles such as API stability, release kinetics and bioavailability limitations often stand in the way of getting products to market.

Our comprehensive product portfolio was developed to meet your solid dosage needs, worldwide. It includes high-quality excipients such as fillers, lubricants, binding agents, sweeteners and additives, as well as many other application-oriented items and products created specifically to address solid formulation challenges.

All of this is supported by our regulatory expertise and Emprove® Program, helping you simplify your supplier qualification and speed up processes, thus reducing the total cost of ownership.

## Regulatory Support and Risk Management

Ensuring the compliance of your pharma and biopharma products involves the compilation of a vast amount of data, which can be time and resource-intensive. In order to facilitate and accelerate this process, we developed our Emprove® Program<sup>1)</sup>. It includes 400 pharma raw and starting materials and a selection of filtration and single-use products.

All of the products in our broad Emprove® portfolio meet the highest quality standards such as EXCiPACT™ and are complemented with three different types of dossiers supporting you throughout the different stages of your operations: qualification, risk assessment, and process optimization all designed to help you speed your way through the regulatory maze:

### EMPROVE® DOSSIER LIBRARY

#### MATERIAL QUALIFICATION DOSSIER

Information to start a material qualification

#### QUALITY MANAGEMENT DOSSIER

Answers questions during risk assessment

#### OPERATIONAL EXCELLENCE DOSSIER

Supports process optimization

<sup>1)</sup> Find out more: [SigmaAldrich.com/emprove](https://SigmaAldrich.com/emprove)

# intelligent formulation made easy

With Pardeck® excipients  
for solid dosage forms

Our Pardeck® product portfolio offers superior excipients created specifically for solid dosage forms. It features unique particle properties and outstanding individual functionalities including, among others, solubility enhancement and controlled release. As formulators benefit from excellent tableting behavior and simplified formulation design, we make intelligent formulation an easy task for everyone.



## Simplified formulation with Parateck® excipients

### Optimized drug delivery

Functional excipients that modify the release kinetics of your formulation and for different routes of administration

- **Parateck® M DPI:**  
mannitol-based versatile alternative carrier for dry powder inhalation applications
- **Parateck® ODT:**  
rapid disintegration and exceptional strength for orally disintegrating tablets
- **Parateck® SRP 80:**  
polyvinyl alcohol-based excipient for consistent, sustained drug release of solid oral formulations

### Flexible tableting

Functional excipients for different tableting technologies that achieve high tablet hardness at a low compression force, as well as short disintegration time, and tailored API dosages thanks to the unique particle surface

- **Parateck® CCS:**  
superdisintegrant for solid formulations
- **Parateck® COAT:**  
rapid preparation times and full flexibility in film coatings
- **Parateck® LUB:**  
range of vegetable-origin stearates for reliable lubrication
- **Parateck® M:**  
directly compressible mannitol, combining stability and rapid disintegration
- **Parateck® SI:**  
directly compressible sorbitol, combining excellent flowability and great mouthfeel
- **Parateck® TA:**  
calcium carbonate with ideal morphology and particle size for enhanced opacity

### Enhanced solubility

Functional excipients that boost the efficacy of your final drug product by enhancing API solubility.

- **Meglumine:**  
applicable either as an advanced API intermediate or as a functional excipient
- **Parateck® MXP 3-82:**  
polyvinyl alcohol optimized for hot-melt extrusion and spray drying, for stable and high drug loads with excellent prolongation of the supersaturation and precipitation inhibition
- **Parateck® MXP 4-88:**  
polyvinyl alcohol optimized for hot-melt extrusion, for stable and high drug loads with perfect thermostability
- **Parateck® PLX 188:**  
dissolution rate enhancer and hydrophilic lubrication
- **Parateck® SLC:**  
a mesoporous silica, which acts as a drug carrier with a highly functional surface area

# Managing solid formulation challenges.

Rest assured our service does not stop with full service solutions for your drugs. We are here to help you solve any problems long after you start working with them.



## Application Development Partnership

### Project work

- on various tableting technologies:
  - Direct compression
  - Wet granulation
  - Roller compaction
- for selected applications:
  - Immediate release tablets
  - Orally disintegrating tablets
  - Sustained release tablets

### Generic product development

- Excipient selection
- Proof of concept
- Product application consultancy

### Feasibility studies

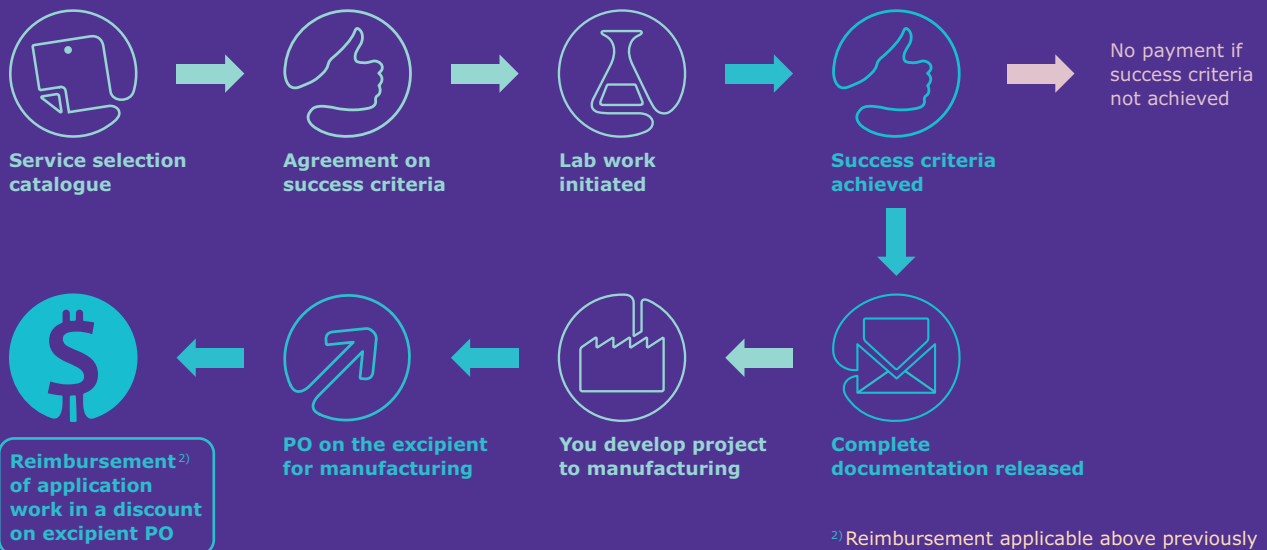
- Drug solubility enhancement by
  - Drug loading on carrier material
  - Hot melt extrusion

### Trouble shooting

- Formulation challenges such as
  - Poor content uniformity
  - Poor stability
  - Suboptimal dissolution profile

A clear process from initial drug development to a market-ready product.

## How it works



<sup>2)</sup> Reimbursement applicable above previously agreed PO threshold for the project.

# HOME OF MODERN drug development.

Your drug and formulation development is taken care of in three major locations: the Product & Technology Development Site in Darmstadt, the Global Application Center in Mumbai, and the M Lab™ Collaboration Center in Shanghai.

## Introduction to our Application Lab

### Processing:

- Direct compression
- Wet granulation
- Basic loading feasibility
- Basic HME

### Analytical:

- All standard galenic characterizations
- Basic and advanced solid dispersions tests
- Real-time & accelerated stability

### API handling:

- Restrictions for oncology, hormone & very toxic drugs (EHS evaluation)

### Facility:

- non-GMP

### Offering:

**Feasibilities on Pardeck® SLC, Pardeck® MXP and Pardeck® product range**





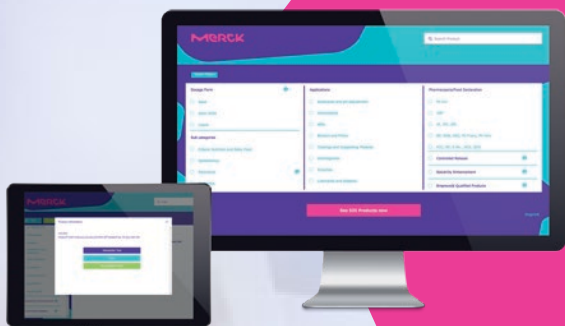
# SAFC®

Pharma & Biopharma Raw  
Material Solutions

## click. explore. learn more.

### FORMULATION PRODUCT FINDER APP

Find the right product for specific applications at:  
[formulation-app.sigmaaldrich.com](https://formulation-app.sigmaaldrich.com)



### PARTECK® PRODUCT PORTFOLIO

Excipients for oral solid dosage forms featuring unique particle properties and outstanding individual functionalities such as suitability for direct compression or controlled release.

For more information, visit:  
[sigmaaldrich.com/parteck-excipients](https://sigmaaldrich.com/parteck-excipients)

We provide information and advice to our customers on application technologies and regulatory matters to the best of our knowledge and ability, but without obligation or liability. Existing laws and regulations are to be observed in all cases by our customers. This also applies in respect to any rights of third parties. Our information and advice do not relieve our customers of their own responsibility for checking the suitability of our products for the envisaged purpose.

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