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®

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 Centers 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. Find out more about these on page 9.

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 formula-tion 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[1)].
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	QUALITY MANAGEMENT DOSSIER	OPERATIONAL EXCELLENCE DOSSIER
Information to start a material qualification	Answers questions during risk assessment	Supports process optimization

[1)] Find out more: **MerckMillipore.com/emprove**

intelligent formulation made easy

With Parteck® excipients for solid dosage forms

Our Parteck® 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.

formulation excipients

Optimized drug delivery

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

- **Parteck® M DPI:**
  mannitol-based versatile alternative carrier for dry powder inhalation applications
- **Parteck® ODT:**
  rapid disintegration and exceptional strength for orally disintegrating tablets
- **Parteck® 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

- **Parteck® CCS:**
  superdisintegrant for solid formulations
- **Parteck® COAT:**
  rapid preparation times and full flexibility in film coatings
- **Parteck® Delta M:**
  convertible mannitol specifically designed for wet granulation
- **Parteck® LUB:**
  range of vegetable-origin stearates for reliable lubrication
- **Parteck® M:**
  directly compressible mannitol, combining stability and rapid disintegration
- **Parteck® SI:**
  directly compressible sorbitol, combining excellent flowability and great mouthfeel

Enhanced solubility

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

- **Parteck® SLC:**
  silica drug carrier with a highly functional surface area
- **Parteck® MXP:**
  polyvinyl alcohol for hot-melt extrusion, allowing for stable and high drug loads and with a high thermostability

For more information, visit:
MerckMillipore.com/parteck

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
  - Dry granulation / roller compaction
- **for selected applications:**
  - Immediate release tablets
  - Oral dispersible tablets
  - Sustained release tablets

Generic product development

- Excipient selection
- Proof of concept
- Product application consultancy

Feasibility studies

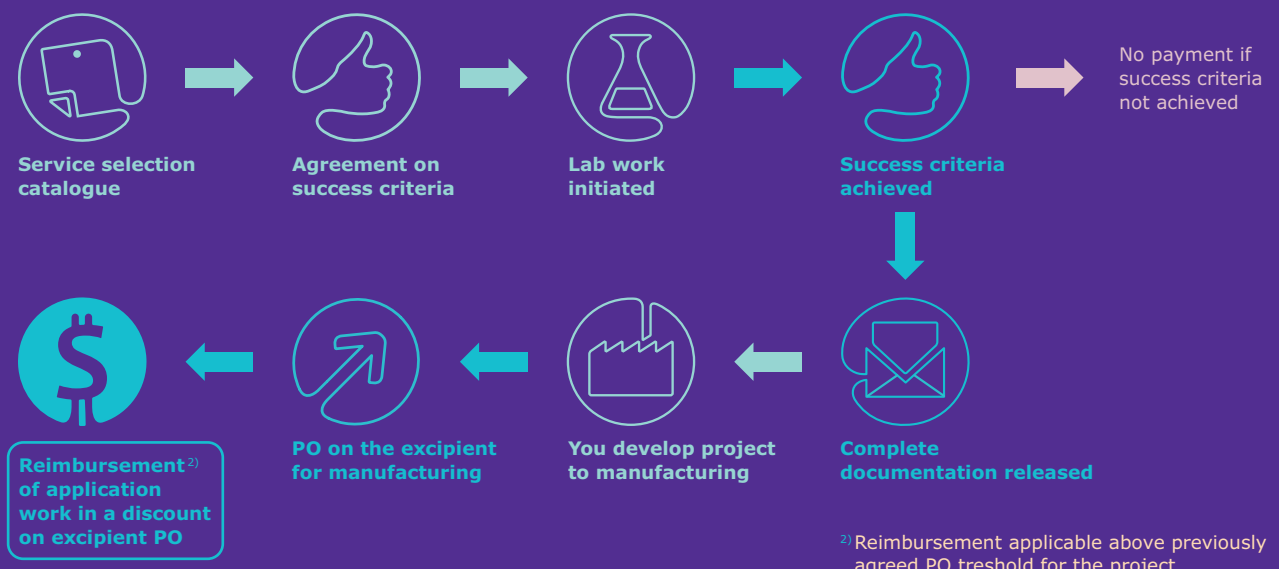
- Drug solubility enhancement by
  - Drug loading on carrier material
  - Hot melt extrusion

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



[2] Reimbursement applicable above previously agreed PO treshold for the project.

Home of Modern drug development.

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

Introduction to our Application Lab

Processing:

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

Analytical:

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

API handling:

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

Facility:

- non-GMP

Offering:
Feasibilities on Parteck® SLC & MXP and Parteck® product range

Catalogue lab services:

	Work package	Sr. No.	Formulation type	Item code	Cost in Euro
Basic	1. Pre-formulation study: API physical characterization, API Assay testing, drug -excipient physical compatibility study 2. Formulation prototype trials 3. Drug product analytical method development and testing (assay or impurity or dissolution testing) 4. Process optimization trial 5. Development report	1	Immediate release uncoated tablets	Y40000	10,000
		2	Immediate release film coated tablets	Y40002	10,000
		3	Orally disintegrating tablets	Y40006	10,000
		4	Dispersible tablets	Y40008	10,000
		5	Immediate release Capsules	Y40004	10,000
		6	Powder for reconstitution	Y40014	6,000
		7	Modified release tablets	Y40010	18,000
		8	Sustained release Tablets	Y40012	18,000
Advanced (Basic+)	1. Pre-formulation study: API physical characterization, API assay testing, drug -excipient physico-chemical compatibility study, particle size measurement, API related substances testing, marketed/innovator product evaluation, literature search 2. Formulation prototype trials 3. Drug product analytical method development and testing (assay + impurity or dissolution testing + content uniformity) 4. Process optimization trial and DOE trials 5. Three media dissolution testing 6. Stability batches 7. Stability study (n=3, 3M) 8. Development report	1	Immediate release uncoated tablets	Y40001	22,000
		2	Immediate release film coated tablets	Y40003	22,000
		3	Orally disintegrating tablets	Y40007	22,000
		4	Dispersible tablets	Y40009	22,000
		5	Immediate release Capsules	Y40005	22,000
		6	Powder for reconstitution	Y40015	12,000
		7	Modified release tablets	Y40011	30,000
		8	Sustained release Tablets	Y40013	30,000

Feasibility study:

	Work package	Sr. No.	Formulation type	Item code	Cost in Euro
Solubility enhancement	1. Pre-formulation study: API physical characterization, API assay testing, DSC of API 2. Solvent selection 3. Development trials 4. Product powder characterization by DSC, assay, dissolution/solubility 5. Product analytical method development for drug content & dissolution testing 6. Residual solvent measurement in product (if applicable) 7. Development report	1	Drug carrier method using Parteck® SLC	Y40050	7,000
		2	Hot melt extrusion using Parteck® MXP	Y40051	7,000
		3	Complexation or other methods	Y40052	4,000

Introduction to Darmstadt Lab

Processing:

- Direct compression
- Wet granulation
- **Advanced** loading feasibility
- **Advanced** HME

Analytical:

- All standard galenic characterizations
- **Advanced** solid dispersions tests
- Real-time & accelerated stability

API handling:

- Up to OEB 4
- Rotary press up to OEB 2

Facility:

- non-GMP

Offering:
Feasibilities on Parteck® SLC & MXP

Feasibility studies offering Darmstadt Lab

Parteck® SLC Loading Feasibility

Work package	Cost in Euro
Total	10,000

Parteck® Portfolio:

Designing solid dosage requires a fine balance. The active ingredient, bioavailability enhancement, release kinetics, a specific dosage, packaging, shelf life – each of these deserves careful consideration. Selecting the right excipient is key for a successful formulation. Since we know that every solid dosage form has its own challenges, we have developed an entire brand family of excipients for you: Parteck®.

Parteck® excipients are distinguished by outstanding individual functionalities and a unique particle structure. When you choose Parteck® excipients, you will find that your solid dosage forms are easier to design. You'll also have Merck's stringent quality control and full regulatory support at your fingertips.

We have developed with the sole purpose of enhancing your API solubility: Parteck® MXP is a flexible excipient designed specifically for hot melt extrusion while Parteck® SLC Excipient with its unique pore structure is a silica drug carrier that enables you to reformulate many drug molecules.

Parteck® MXP Extrusion Feasibility

Work package	Cost in Euro
Total	12,500

Our Parteck® Portfolio Provides:

Enhanced solubility.

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

Optimized drug delivery.

Functional excipients that influence the release kinetics of your formulation

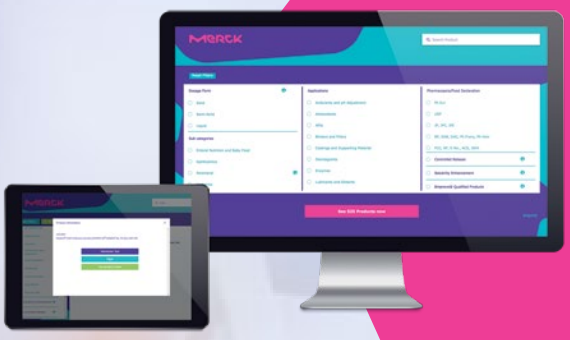
Flexible tableting.

Functional excipients for different tableting technologies that achieve high tablet hardness at low compression forces, short disintegration times, and tailored API dosages due to unique particle surface

SAFC®

Pharma & Biopharma Raw Material Solutions

click. explore. Learn More.



FORMULATION PRODUCT FINDER APP

Find the right product for specific applications at:
MerckMillipore.com/formulationapp

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:
MerckMillipore.com/parteck

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.

For additional information, please visit **MerckMillipore.com**. To place an order or receive technical assistance, please visit **MerckMillipore.com/contactPS**

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