

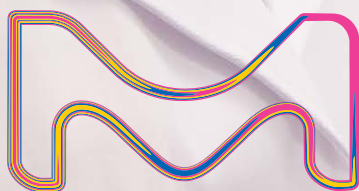


MERCK

Formulation and Technology Centers

your partner in formulation excellence

Let's collaborate to solve your
toughest formulation challenges
and advance innovation



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

Developing final drug products is becoming increasingly complex, with challenges such as API stability, release kinetics, and bioavailability limitations – particularly low API solubility – standing in the way of a successful market entry.

We understand you need a global partner who you can trust. A partner who not only provides the products and technologies but also the expertise and technical know-how to help you navigate the intricacies of formulation development.

Our Formulation and Technology Centers offer unparalleled formulation support, tailored solutions for bioavailability enhancement, and customized development services. With our cutting-edge technologies and extensive expertise, you can rely on us to support your projects throughout every stage of your product's life cycle.



Expertise. Technologies. Trust.

We provide formulation support and consulting to develop your drug and help you reach your patients faster.



intelligent formulation made easy

With functional excipients tailored
to solve formulation challenges

Our formulation portfolio

Our comprehensive product portfolio has been developed to meet your formulation needs. It includes high-quality excipients such as fillers, lubricants, binding agents, sweeteners and additives, as well as many other application-oriented products and technologies specifically designed for solubility enhancement. This is supported by our regulatory expertise and Emprove® Program, helping you simplify your supplier qualification and speed up processes.

Our Parteck® portfolio

Our Parteck® product portfolio offers superior excipients created specifically for solid dosage forms. All Parteck® excipients demonstrate unique particle properties and outstanding individual functionalities like 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 Pardeck® excipients

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

- **Pardeck® CCS:**
Superdisintegrant for solid formulations
- **Pardeck® COAT:**
Polyvinyl alcohol for rapid preparation times and full flexibility in film coatings
- **Pardeck® LUB:**
Range of vegetable-origin stearates for reliable lubrication
- **Pardeck® LM:**
Self-lubricating filler/binder for all tableting processes, batch and continuous
- **Pardeck® M:**
Mannitol for direct compression, wet granulation and roller compaction, combining excellent compressibility, stability and rapid disintegration
- **Pardeck® SI:**
Directly compressible sorbitol, combining excellent flowability and great mouthfeel
- **Pardeck® TA:**
Calcium carbonate with an optimized particle size distribution, ideal as titanium dioxide alternative in film coatings for enhanced opacity

For more information, visit:
SigmaAldrich.com/solid-formulation

Optimized drug delivery

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

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

Enhanced solubility

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

- **Meglumine:**
Organic base serving as counterion or functional excipient to enhance API solubility, improve API stability and adjust pH value
- **Parreck® MXP:**
Polyvinyl alcohol range optimized for hot-melt extrusion and spray-drying, allowing for stable and high drug loads in amorphous solid dispersions
- **Parreck® PLX 188:**
Particle-optimized poloxamer for dissolution rate enhancement and lubrication
- **Parreck® SLC:**
Silica drug carrier with a large surface area for stabilization of amorphous APIs



Addressing your formulation challenges

We're committed to helping you navigate formulation development and clear any obstacles that block your path.

Our promise to you: Pay only if we deliver successful results.



Formulation and Technology Center collaboration

Offering

- Feasibility studies using our Parateck® product range, cyclodextrins, and meglumine

Technologies

- Direct compression
- Wet granulation
- Inorganic drug carriers (silica loading)
- Hot melt extrusion
- Spray drying

Dosage forms

- Tablets (ODT, SR, IR, coated and dispersible)
- Minitablets
- Orodispersible films (ODFs)
- Powders for reconstitution
- Capsules

Analytics

- All standard galenic characterizations
- Basic and advanced solid dispersions tests
- Disintegration, dissolution, solubility testing
- Real-time & accelerated stability

API handling

- Small molecules
- Restrictions apply for hormones, oncological and highly potent drugs (EHS evaluation)

Generic product development and trouble shooting

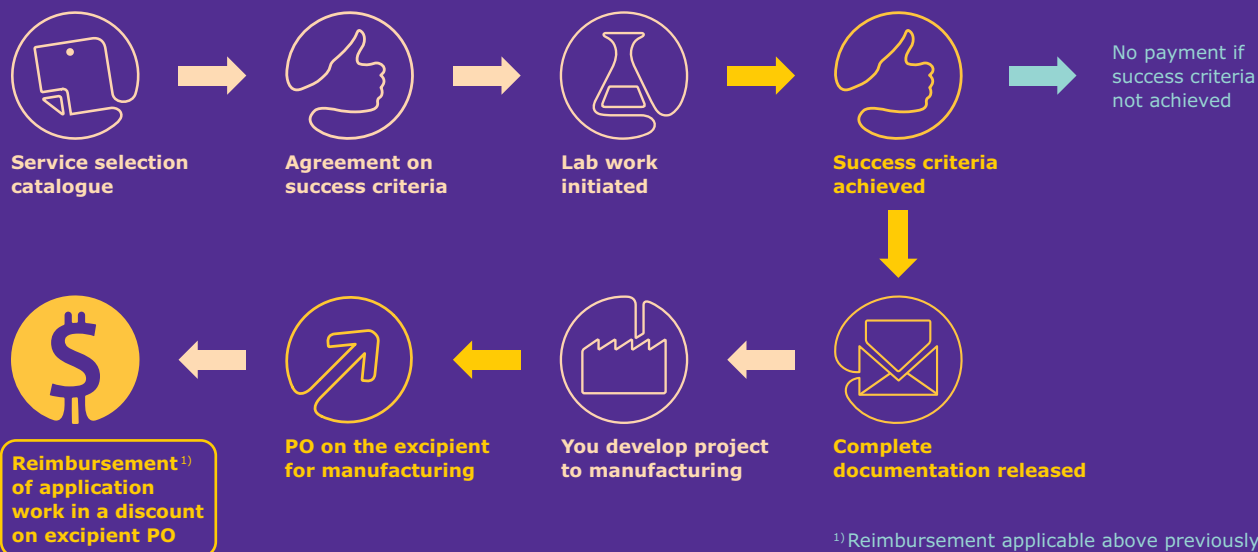
- Tackle formulation challenges such as poor solubility, poor content uniformity, poor stability and suboptimal dissolution profile
- Helping you with excipient selection, proof of concept, product application and process optimization for scale-up

Facility

- Non-GMP

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

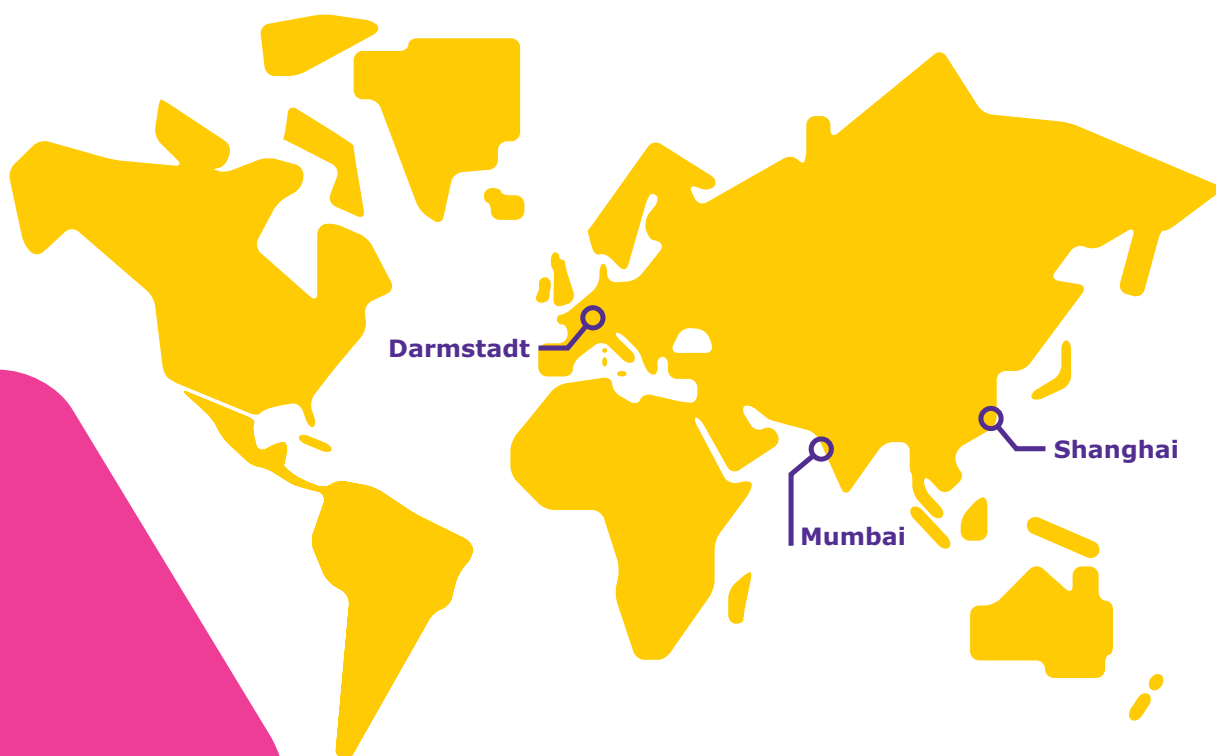
Service process



Home of Modern drug development

Close collaboration is key for success which is why we provide solid formulation development services in three major locations:

Our Formulation and Technology Development Center in **Darmstadt**, as well as our Formulation and Technology Centers in **Shanghai** and **Mumbai**.

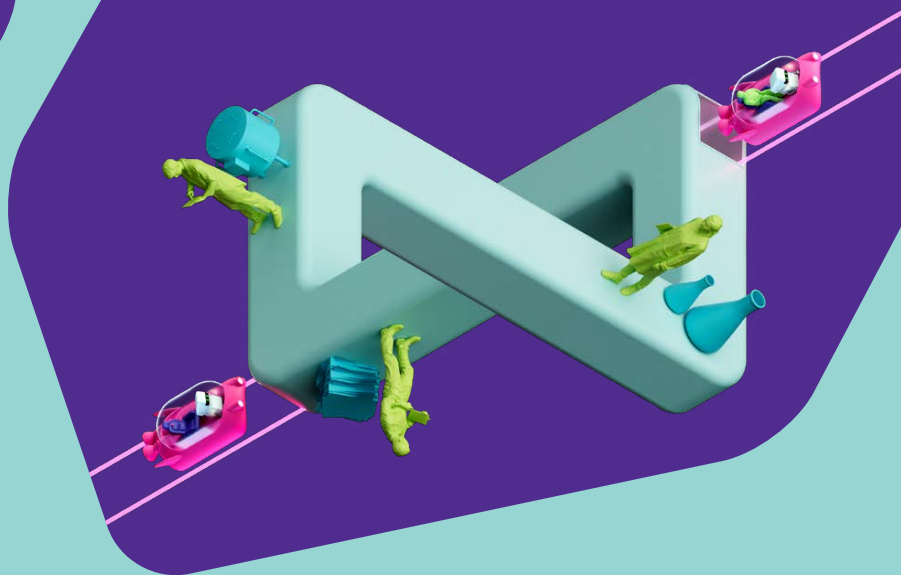


Catalogue lab services for all formulation types

Work package		Activities
<div>Basic</div> <div>Advanced (Basic+)</div>	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
	6	DOE trials
	7	Three media dissolution testing
	8	Stability batches
	9	Stability study (n=3, 3M)

Solubility enhancement techniques

Formulation type	Activities
<div>1 Drug carrier method using Parateck® SLC</div> <div>or</div> <div>2 Hot melt extrusion using Parateck® MXP</div> <div>or</div> <div>3 Complexation or other methods</div>	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) testing
	7 Development report



Regulatory support and risk Management

The Emprove® Program. The smart way to master compliance and control.

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.

Beside a selection of filtration and single-use components, it contains more than 500 pharma raw and starting materials addressing different levels of risk. Each product in the portfolio is complemented with different types of dossiers supporting you with reliable technical, regulatory, and supply information: API Information Package, Elemental Impurities Information, Material Qualification Dossier, Quality Management Dossier, and Operational Excellence Dossier.

For more information, please visit:
SigmaAldrich.com/emprove

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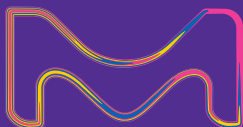
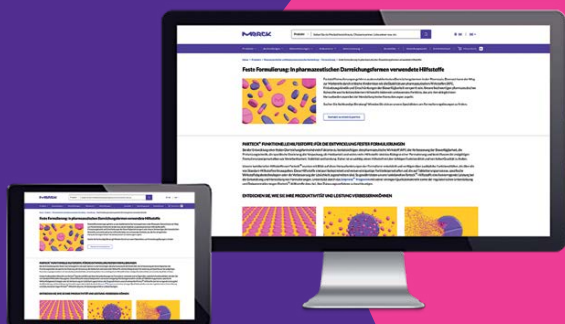
Pharma & Biopharma Raw
Material Solutions

click. explore. learn more.

Solid formulation portfolio

Explore our comprehensive portfolio of excipients for all solid formulation types. Discover our Parteck® range which features unique particle properties and outstanding functionalities tailored to the needs of specific applications such as direct compression, solubility enhancement, or controlled release.

For more information, visit:
SigmaAldrich.com/solid-formulation



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 **SigmaAldrich.com**
To place an order or receive technical assistance, please visit **SigmaAldrich.com/contactAF**

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