

Pardeck® LM Excipient System

3 in 1

Reduce complexity in
your formulation and
optimize results

**Discover the one step solution:
lubricant, filler and binder.**

Perfect dosing and acceleration of
your manufacturing process in batch
or continuous manufacturing with
Pardeck® LM.



SAFC®

Pharma & Biopharma
Raw Material Solutions

MERCK

Solving your handling issues in lubrication

Self-lubricated filler-binder for batch and CM use

Lubrication with most widely used magnesium stearate has its difficulties both in batch and continuous manufacturing of tablets. Overlubrication is often cited as an issue and dosing of the poorly flowing Mg-Stearate is an issue for continuous manufacturing (CM). **Parateck® LM Excipient System** will give you the perfect flow.

- **Parateck® LM** is easy to dose in a continuous manufacturing line.
- It is robust and helps reduce mixing times.
- **Parateck® LM** is a combination of mannitol and Mg-Stearate – only one product but comprising three functions: Filler + binder + lubricant.
- Two grades are offered: **Parateck® LM Low** for low dose applications and less requirement for lubrication. **Parateck® LM High** will address higher API loads and more demanding cases with regards to lubrication.
- **Parateck® LM** is applicable in direct compression, wet granulation, roller compaction or dry granulation as well as capsule filling.
- It comes with the **Emprove® Program** providing comprehensive and thorough documentation, supporting supply chain transparency, risk mitigation and qualification processes, thus accelerating time-to-market.



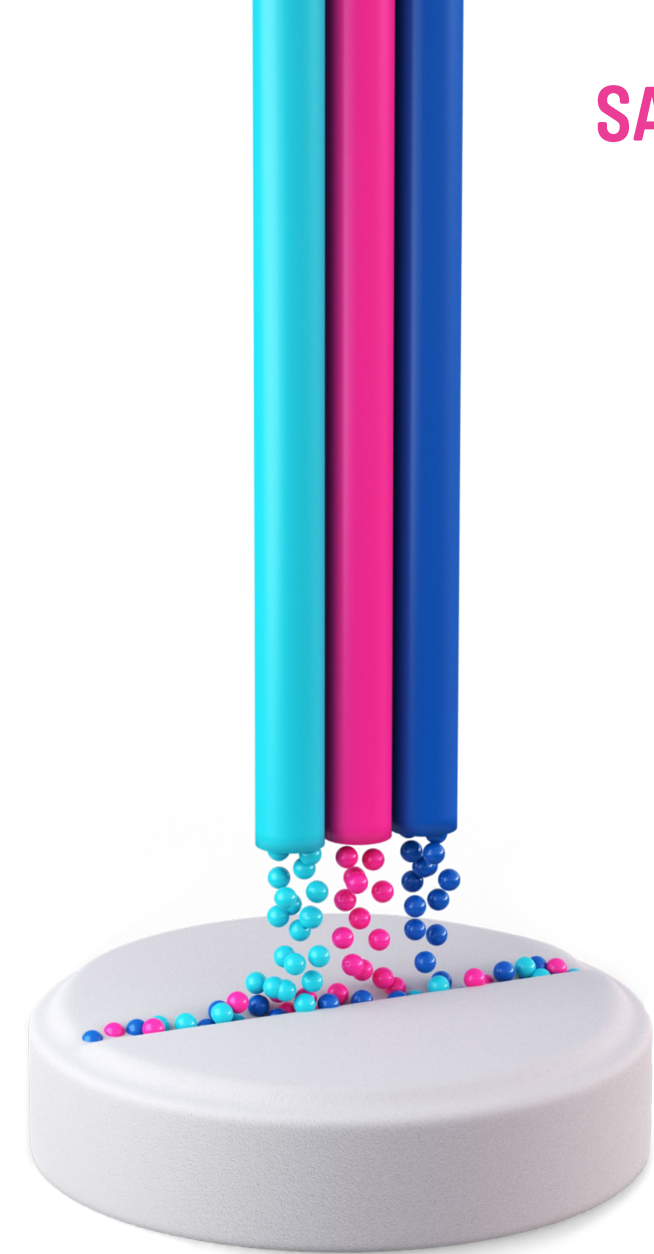
Interested in learning more?

You can count on our extensive global network of scientists, engineers, regulatory experts and state-of-the-art Application Service Labs to support you in your request.

Key parameters Parateck® LM

	Parateck® LM High #104409	Parateck® LM Low #104429
Magnesium stearate [%]	5	3
Angle of repose [°]	36 - 40	32 - 36
Bulk density [g/mL]	0.57 - 0.62	0.56 - 0.64
Tapped density [g/mL]	0.68 - 0.73	0.66 - 0.73
Hausner ratio	1.19 - 1.25	1.12 - 1.18
Loss on drying [%]	0.1	0.1
BET measurement Surface area [m ² /g]	3.10	3.43
PSD[μm]		
D(10)	10 - 70	25 - 85
D(50)	80 - 220	80 - 220
D(90)	170 - 520	170 - 520

Typical technical data for general characterization. Specification available at [SigmaAldrich.com](https://www.sigmaaldrich.com)



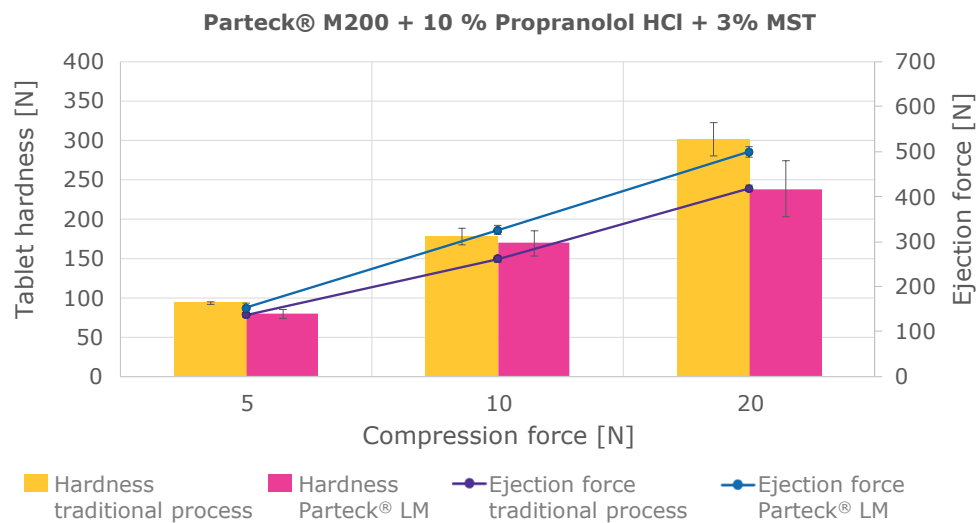
Formulation examples Parateck® LM

Model API & Dosage	Composition	Tablet weight & size	Tablet properties @ 10 kN (*6 kN, **15 kN, ***30 kN)					
			Hardness [N]	Tensile Strength [MPa]	Friability [%]	Disintegration Time [s]	Ejection Force [N]	Weight Variation [%]
Bisoprolol 2.5 mg	57.5% Parateck® LM Low + 2.5% Bisoprololhemifumarate + 30% MCC, Type 102 + 10% Parateck® CCS	100 mg; Ø 7mm, flat & faceted	42	1.77	0.33	35 - 41	263	0.64
Amlodipine 5 mg	61.53% Parateck® LM High + 3.47% Amlodipine-besylate + 30% MCC, Type 102 + 5% Parateck® CCS	200 mg; Ø 10mm, flat & faceted	36	1.04	0.03	18 - 20	83	0.39
Ezetimib 10 mg	50% Parateck® LM Low + 10% Ezetimib + 35% MCC, Type 102 + 5% Parateck® CCS	100 mg; Ø 7mm, flat & faceted	43*	1.91*	0.31*	17 - 22*	228*	0.87*
Loratadine 10 mg	59.6% Parateck® LM High + 5.4% Loratadin + 30% MCC, Type 102 + 5% Parateck® CCS	185 mg; Ø 10mm, flat & faceted	39	1.19	0.05	28 - 37	109	0.79
Propranolol HCl 25 mg	95% Parateck® LM Low + 5% Propranolol HCl	500 mg; Ø 11mm, flat & faceted	139	1.77	0.20	343 - 387	207	0.63
Propranolol HCl 25 mg	95% Parateck® LM High + 5% Propranolol HCl	500 mg; Ø 11mm, flat & faceted	133	1.74	0.22	259 - 291	254	0.58
Sildenafil 50 mg	40% Parateck® LM High + 17.78% Sildenafil-citrate + 36.22 MCC, Type 102 + 5% Parateck® CCS + 1% highly dispersed silicon dioxide	400 mg; Ø 11mm, biconvex	136**	1.79**	0.12**	35 - 43**	262**	0.63**
Sildenafil 100 mg	40% Parateck® LM High + 17.78% Sildenafil-citrate + 36.22 MCC, Type 102 + 5% Parateck® CCS + 1% highly dispersed silicon dioxide	800 mg; 19x13 mm, biconvex	227***	185***	0.19***	47 - 55***	366***	0.37***
Ascorbic acid 200 mg	40% Parateck® LM High + 40% Ascorbic acid + 20% MCC, Type 102	500 mg; Ø 11mm, flat & faceted	57**	0.82**	0.52**	146 - 170**	170**	0.37**
Ibuprofen 200 mg	40% Parateck® LM High + 40% Ibuprofen + 20% MCC, Type 102	500 mg; Ø 11mm, flat & faceted	102	1.21	0.27	239 - 302	300	0.96
Ibuprofen/Parateck® SLC 37.5 mg	23% Parateck® LM Low + 25% Parateck® SLC-loaded with Ibuprofen +49% MCC, Type 102 + 2% Parateck® CCS + 1% highly dispersed silicon dioxide	500 mg; Ø 11mm, flat & faceted	42***	0.55***	0.30***	8 - 10***	503***	1.65***
Metformin 292.5 mg	30% Parateck® LM Low + 50% Metformin HCl + 20% MCC, Type 102	750 mg; 19x13 mm, biconvex	36***	0.30***	100***	74 - 87***	310***	0.20***

Process efficiency in continuous and batch manufacturing

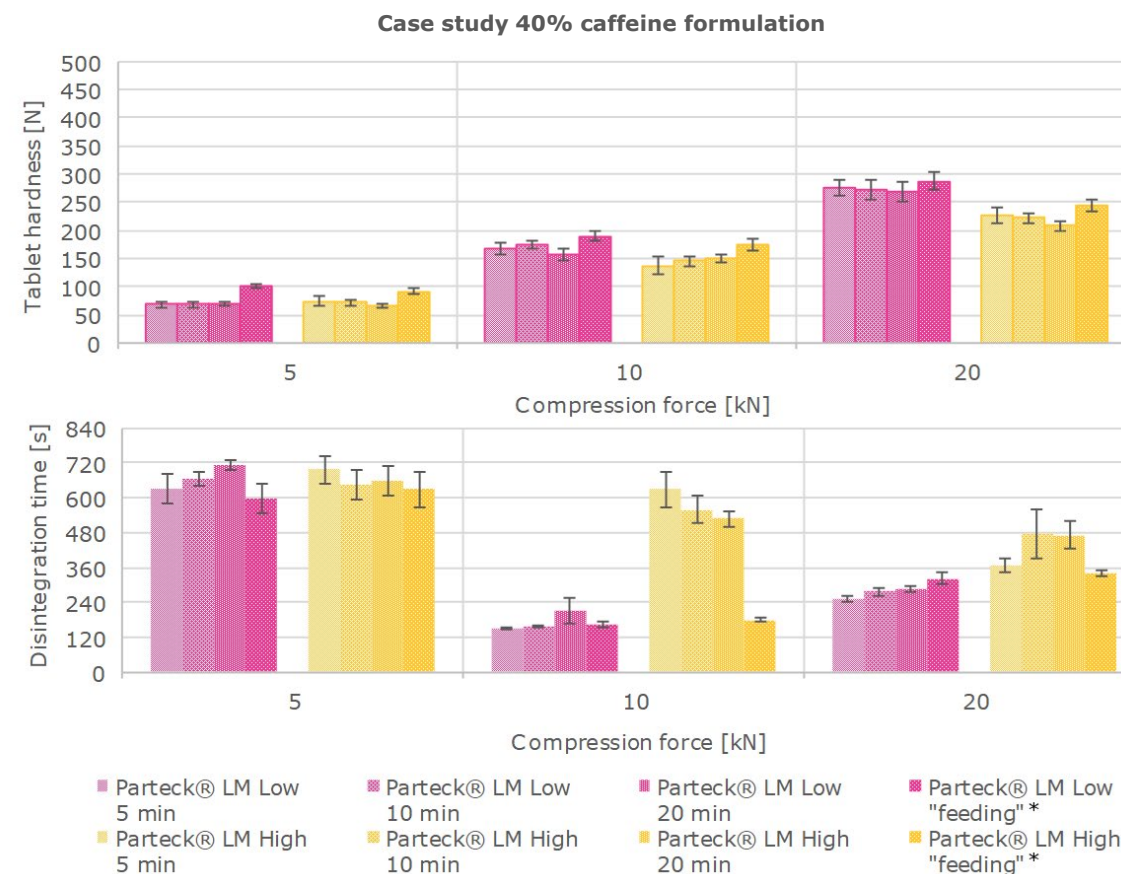
Parteck® LM in Continuous Manufacturing

Composed of raw materials complying to major pharmacopeias, **Parteck® LM** will deliver identical results as with the traditional formulation procedure of mixing of excipient, API and lubricant in a subsequent step - but with the ease of use of just one single dosing and mixing operation.



Parteck® LM in Batch Manufacturing

No impact of mixing time and feeding. Using **Parteck® LM** results in a robust product demonstrating constant tablet hardness and comparable DT, not impacted by further processing.

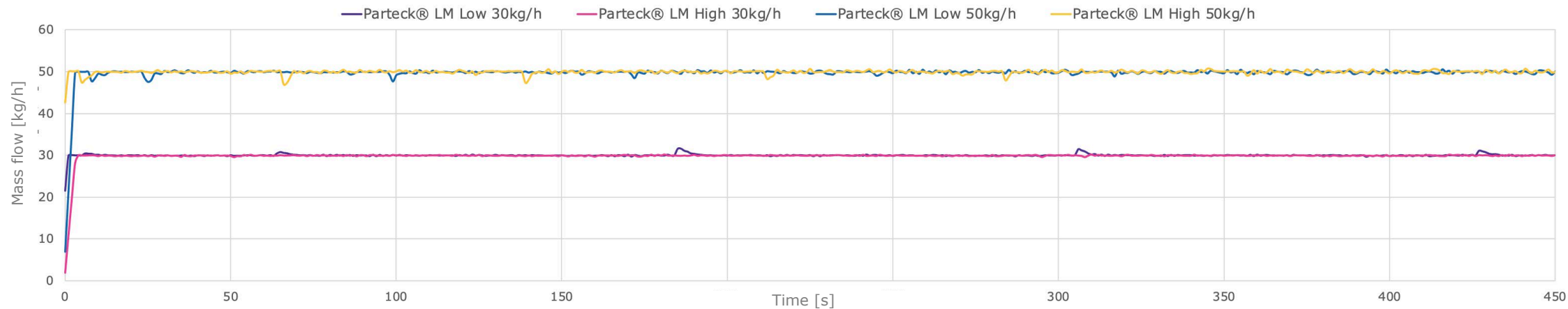


There's no such thing as a one-size-fits all formulation, all APIs have individual and specific needs. With our two grades of **Parteck® LM Excipient System** we provide you with the flexibility to serve the needs for high dose or low dose applications as well as demanding APIs.

* Feeding is representing continuous manufacturing, while the other measurements are representing traditional batch manufacturing.

Excellent dosing performance for Parateck® LM

GRAVIMETRIC RUNS



Compound	Used Gearbox	Screw Type	Mesh	Setpoint [kg]	Average Massflow [kg]	Average Deviation [kg/h]	RSB [%]
Parateck® LM high	63:1	20C	No	30.000	30.006	0.199	0.663
			No	50.000	49.897	0.339	0.680
Parateck® LM low	63:1	20C	No	30.000	29.963	0.090	0.301
			No	50.000	49.876	0.414	0.830
Mg-Stearate	455:1	10C	No	0.500	0.502	0.012	2.482
			Yes	0.500	0.498	0.009	1.906

Parteck® LM Benefits



Optimal Performance

High binding capacity and optimal lubrication efficiency also for demanding formulation cases



Flexible

Our **Parteck® LM** product offers in two grades support for both low and high dose formulations



Robust Handling

Parteck® LM is robust in handling regarding overlubrication



Easy Dosing

Precise dosing in continuous manufacturing and batch DC operation at high throughput

The Emprove® Program

Your fast track through regulatory challenges.

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. Our **Emprove® Program** helps you meet the latest regulatory requirements for risk assessment and offers assistance in developing more robust processes.

To help you optimize your process, our **Emprove® Program** provides comprehensive and thorough documentation for approximately 400 raw and starting materials as well as a selection of filters, single-use devices and components. It not only covers the latest regulatory requirements, but also anticipates industry expectations not yet covered by regulation. **The Emprove® Program** is organized into three different types of dossiers. Every dossier supports you throughout different stages of your operations: qualification, risk assessment, and optimization – so you can speed your way through the regulatory maze.

Find out more at:

SigmaAldrich.com/emprove



Ordering information

Cat. No.	Product	Pack size	Packaging
1.04429.1000	Parteck® LM low EMPROVE® ESSENTIAL	1 kg	PE bottle
1.04429.9025	Parteck® LM low EMPROVE® ESSENTIAL	25 kg	PE bag (in corrugated cardboard box)
1.04409.1000	Parteck® LM high EMPROVE® ESSENTIAL	1 kg	PE bottle
1.04409.9025	Parteck® LM high EMPROVE® ESSENTIAL	25 kg	PE bag (in corrugated cardboard box)

**Click. Explore.
Learn more.**

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

Formulation Product Finder App

Find the right product for specific applications at: formulation-app.sigmaaldrich.com

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