

Quality by Design.

Providing critical parameters
for your formulation design.



Precision design for your process

The pharmaceutical industry is facing a paradigm change. Regulatory authorities around the world recognize QbD (Quality by Design) as a state-of-the-art concept for pharmaceutical development, enforcing its implementation for both new drug applications and generic drugs. This requires the manufacturer to examine their process and define critical parameters for functionality, outline limits and have these limits assured by release specifications. Additionally ICH guideline Q8 requires manufacturers to provide regulatory authorities with information about critical parameters for excipients (e.g., particle size distribution (PSD), chemical impurities).

EMD Millipore understands these new requirements and the increasing need for information on excipients. We prepare parameters for a wide range of excipients that go beyond the pharmacopoeia requirements, which help to reduce your development time and lower your risks during development and production. When the quality parameters of an excipient that is relevant for your process are specified in the CoA, you can have control over the final product quality.

In addition, our Emprove® program, which is available for most of our product portfolio, can help obtain standardized documentation for these products, thus facilitating your qualification, risk assessment and process optimization efforts.

With our extensive knowledge of excipients and their functionalities, we provide you with the support you need.

Complete toolbox to enhance your formulation:

- Particle size distribution
- Chemical parameters
- Batch record history on critical parameters
- Elemental impurity information
- Technical support and scientific exchange

For more information about our formulation portfolio, visit www.emdmillipore.com/formulation or www.emdmillipore.com/formulationapp

If you want to know more about our Emprove® program, please visit: www.emdmillipore.com/emprove

Ord. No.	Product	Parameter in specification
100981	Benzyl alcohol, suitable for use as excipient EMPROVE® exp Ph Eur, BP, JP, NF	Benzene, Chlorobenene, Toluene
100987	Benzyl alcohol, suitable for use as excipient EMPROVE® exp Ph Eur, BP, JP, NF	Benzene, Chlorobenene, Toluene
142002	Calcium chloride dihydrate, suitable for use as excipient EMPROVE® Ph Eur, BP, JP, USP, FCC, E 509	Endotoxins, Bioburden
100056	Acetic acid (glacial) 100 %, suitable for use as excipient EMPROVE® exp Ph Eur, BP, JP, USP, E 260	Zinc
100590	Glycine cryst., suitable for use as excipient EMPROVE® exp Ph Eur, BP, JP, USP	Methanol, Residual Solvents, Endotoxins, Bioburden
106345	Sodium dihydrogen phosphate dihydrate, suitable for use as excipient EMPROVE® exp Ph Eur, BP, USP, JPE, E 339	Al, Endotoxins, Bioburden
100563	ortho-Phosphoric acid 85 %, suitable for use as excipient EMPROVE® exp Ph Eur, BP, JPE, NF, E 338	Zn, Cd
100201	Phenol, suitable for use as excipient EMPROVE® exp Ph Eur, JP, USP	Cl, SO4, Pb, Related Substances, Benzene, Methanol, Cumene
100892	Sucrose low in endotoxins, suitable for use as excipient EMPROVE® exp Ph Eur, BP, JP, NF	As, Pb, Endotoxins

Ord. No.	Product	Parameter in specification
107653	Sucrose, suitable for use as excipient EMPROVE® exp Ph Eur, BP, JP, NF	Endotoxins
106432	tri-Sodium citrate dihydrate cryst., suitable for use as excipient EMPROVE® exp Ph Eur, BP, JP, USP, E 331	Al, Hg
106447	tri-Sodium citrate dihydrate, suitable for use as excipient EMPROVE® exp Ph Eur, BP, JP, USP, E 331	Al, Hg
108881	Zinc sulfate heptahydrate, suitable for use as excipient EMPROVE® exp Ph Eur, BP, JP, USP, FCC	Se, Endotoxins, Bioburden
112120	Calcium carbonate precipitated (≤ 0.0001 % Al), suitable for use as excipient EMPROVE® exp Ph Eur, BP, USP, JP, FCC, E 170	Al
102064	Calcium carbonate precipitated (≤ 0.002 % Fe), suitable for use as excipient EMPROVE® exp Ph Eur, BP, USP, JP, FCC	Fe
102119	Calcium hydroxide precipitated (≤ 0.0005 % Al), suitable for use as excipient EMPROVE® exp USP, FCC, E 526	Al
141350	Polyvinyl alcohol 4-88, suitable for use as excipient EMPROVE® exp Ph Eur, USP, JPE	Crotonaldehyde
141354	Polyvinyl alcohol 5-88, suitable for use as excipient EMPROVE® exp Ph Eur, USP, JPE	Crotonaldehyde
141351	Polyvinyl alcohol 8-88, suitable for use as excipient EMPROVE® exp Ph Eur, USP, JPE	Crotonaldehyde
141355	Polyvinyl alcohol 18-88, suitable for use as excipient EMPROVE® exp Ph Eur, USP, JPE	Crotonaldehyde
141352	Polyvinyl alcohol 26-88, suitable for use as excipient EMPROVE® exp Ph Eur, USP, JPE	Crotonaldehyde
141356	Polyvinyl alcohol 28-99, suitable for use as excipient EMPROVE® exp Ph Eur, USP, JPE	Crotonaldehyde
141353	Polyvinyl alcohol 40-88, suitable for use as excipient EMPROVE® exp Ph Eur, USP, JPE	Crotonaldehyde
106290	Sodium benzoate, suitable for use as excipient EMPROVE® exp Ph Eur, BP, NF, FCC, E 211	Benzene, Toluene, PSD
102144	Calcium hydrogen phosphate anhydrous extra fine powder, suitable for use as excipient EMPROVE® exp Ph Eur, BP, USP, FCC, E 341	PSD
100661	Parateck® LUB STA 50 (Stearic acid 50 vegetable grade), suitable for use as excipient EMPROVE® exp Ph Eur, BP, JP, NF	PSD
100663	Parateck® LUB MST (Magnesium stearate vegetable grade), suitable for use as excipient EMPROVE® exp Ph Eur, BP, JP, NF, FCC	PSD
100664	Parateck® LUB CST (Calcium stearate vegetable grade), suitable for use as excipient EMPROVE® exp Ph Eur, BP, JP, NF, FCC	PSD
100805	Titanium(IV) oxide, suitable for use as excipient EMPROVE® exp Ph Eur, BP, USP, JP, E 171	PSD
100894	Sucralose powder, suitable for use as excipient EMPROVE® exp Ph Eur, NF	PSD
100895	Sucralose granular, suitable for use as excipient EMPROVE® exp Ph Eur, NF	PSD, Flow*
102143	Calcium phosphate dried, suitable for use as excipient EMPROVE® exp Ph Eur, BP, E 341	PSD, Flow, Bulk Density*
102146	Calcium hydrogen phosphate dihydrate extra fine powder, suitable for use as excipient EMPROVE® exp Ph Eur, BP, USP, FCC, E 341	PSD, Flow, Bulk Density*
102304	Calcium hydrogen phosphate anhydrous extra fine powder, suitable for use as excipient EMPROVE® exp Ph Eur, BP, JP, USP, FCC, E 341	PSD, Flow, Bulk Density*
102310	Parateck® CCS Croscarmellose Sodium, suitable for use as excipient EMPROVE® exp Ph Eur, JP, NF	PSD
103140	Parateck® SI 400 (Sorbitol), suitable for use as excipient EMPROVE® exp Ph Eur, BP, JSFA, NF, E 420	PSD, Flow, Bulk Density*
103557	Parateck® SI 450 (Sorbitol), suitable for use as excipient EMPROVE® exp NF, FCC, JSFA	
103583	Parateck® SI 150 (Sorbitol), suitable for use as excipient EMPROVE® exp Ph Eur, BP, JP, NF, JSFA, E 420	PSD, Flow, Bulk Density*
105828	Magnesium hydroxide carbonate light extra pure Ph Eur, BP	PSD, Flow
108070	Parateck® LUB Talc, suitable for use as excipient EMPROVE® exp Ph Eur, BP, JP, USP	PSD
105862	Magnesium oxide light extra pure Ph Eur, BP, E 530	PSD
105867	Magnesium oxide heavy, suitable for use as excipient EMPROVE® exp Ph Eur, BP, USP	PSD
100493	Parateck® M 100 (Mannitol), suitable for use as excipient EMPROVE® exp Ph Eur, BP, JP, USP, E 421	PSD
100419	Parateck® M 200 (Mannitol), suitable for use as excipient EMPROVE® exp Ph Eur, BP, JP, USP, E 421	PSD
112635	Parateck® Delta M (Mannitol), suitable for use as excipient EMPROVE® exp Ph Eur, BP, USP, JP, E 421	Reducing Sugar, Polymorphic State
100490	Parateck® ODT, suitable for use as excipient EMPROVE® exp	Reducing Sugar*
120091	Parateck® SLC 500 USP, Ph Eur	PSD

The typical technical data above serve to generally characterize the excipient. These values are not meant as specifications and they do not have binding character. The product specification is available separately, from the website: www.emdmillipore.com

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For more information and documentation please contact:

Phone: +1 800 645 5476

Email: pcs.salessupport@emdmillipore.com

www.emdmillipore.com/qbd



EMD Millipore Corporation
290 Concord Road
Billerica, MA 01821
USA

www.emdmillipore.com

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