

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](http://www.emdmillipore.com)

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# 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](http://www.emdmillipore.com/formulation) or [www.emdmillipore.com/formulationapp](http://www.emdmillipore.com/formulationapp)

If you want to know more about our Emprove® program, please visit: [www.emdmillipore.com/emprove](http://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 ( $\leq 0.0001$ % Al), suitable for use as excipient EMPROVE® exp Ph Eur, BP, USP, JP, FCC, E 170   | Al                                |
| 102064   | Calcium carbonate precipitated ( $\leq 0.002$ % Fe), suitable for use as excipient EMPROVE® exp Ph Eur, BP, USP, JP, FCC           | Fe                                |
| 102119   | Calcium hydroxide precipitated ( $\leq 0.0005$ % 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                               |