Protect your drug approvals:

EMPROVE® api for use as active pharmaceutical ingredient

Regulatory requirements for actives are increasing all the time, and incomplete documentation can considerably delay your time to market. That's why Merck Millipore offers you EMPROVE® api: high-quality raw materials for use as active pharmaceutical ingredients that come with comprehensive documentation for shorter drug approval. Thus, EMPROVE® api helps you to achieve maximum product safety, lower costs of registration processes, and faster time to market.

Your benefits at a glance

- Shorter registration phase – faster time to market
- Customized solutions to meet your specific production needs
- Pharma raw materials manufactured under cGMP guideline ICH Q7
- Compliance with international regulatory standards
- Dedicated regulatory support

EMPROVE® api – Get your project on the fast track

With EMPROVE® api, you get a complete solution: safe and reliable raw materials that serve the entire drug development process chain, and comprehensive regulatory support to speed up registration. In other words: you obtain a ready-to-market API which otherwise might be difficult to qualify. This way, your qualification efforts are minimized and you have a greater assurance for a successful submission.

EMPROVE® api – Top quality and reliable compliance

As a matter of course, Merck Millipore's EMPROVE® api raw materials offer the excellent quality you have come to expect from a global pharmaceutical company with vast experience in drug research and production. EMPROVE® api products fulfil the high pharmaceutical quality and safety standards with regard to current and future regulatory requirements. All our API production plants are located in Western Europe, follow current environmental standards and are operated according to cGMP guideline ICH Q7. In addition to high-quality, ready-to-use raw materials, we also provide customized solutions as well as tailored packaging that meet your specific production needs.

EMPROVE® api – Dedicated regulatory support, comprehensive documentation

In order to make sure that your products comply with all international standards, the Merck Millipore Regulatory Affairs Team offers you dedicated regulatory support with access to US-DMF/CEP/ASMF. (Please note: There are no EMPROVE® dossiers available for EMPROVE® api products.) The provided documentation meets the CTD format requirements. And because it is our commitment to keep you on the safe side today as well as tomorrow, we are also constantly reviewing international regulatory developments to be able to anticipate upcoming changes.

For more information, please contact us.