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Pharma & Biopharma Raw
Material Solutions

FAQ for new Excipient and API Manufacturing Plant in Nantong, China

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FAQ for new Excipient and API Manufacturing Plant in Nantong, China

This document contains frequently asked questions regarding the new manufacturing plant producing Excipients and APIs in Nantong, China.

Please visit www.merckmillipore.com/nantong for the latest information, or contact your Sales Representative or our Commercial Service team who will assist you with further enquiries.

Q1. Why did we establish a new manufacturing plant for excipients and APIs in China?

In order to respond to a strong demand for our multi-compendial inorganic salt portfolio, we are expanding capacity of our global manufacturing network with a new manufacturing plant in Nantong, China. Opened in April 2020, the new plant is fully owned and operated by Merck.

This major investment will enhance supply reliability of our multi-compendial EMPROVE® Excipients and APIs.

Furthermore, expanding our global manufacturing footprint into China will strengthen our ability to serve specific quality and regulatory requirements such as Chinese Pharmacopoeia compliance and Co-review registration.

Q2. Which products have been or will be manufactured in Nantong?

Please see table 1 for further details.

Table 1: Products in scope

Nantong item no.	Darmstadt item no.	Nantong product description	Sample available*
128218**	101816	Ammonium sulfate EMPROVE® EXPERT ChP,NF,ACS	May 2020
128205	137012	Sodium acetate trihydrate EMPROVE® EXPERT Ph Eur,BP,ChP,JP,USP	Dec 2020
128204	106235	Sodium acetate trihydrate EMPROVE® API Ph Eur,BP,JP,USP,FCC,E262	Jun 2021
128211	106643	Sodium sulfate anhydrous EMPROVE® ESSENTIAL Ph Eur,BP,ChP,USP,E514	Mar 2022
128225	137144	Sodium sulfate anhydrous EMPROVE® EXPERT Ph Eur,BP,ChP,USP	Mar 2022
128201	106281	Sodium acetate anhydrous EMPROVE® ESSENTIAL ChP,USP,FCC,E262	Mar 2022
128202	137046	Sodium acetate anhydrous EMPROVE® EXPERT ChP,USP	Mar 2022
128221	108915	Zinc chloride EMPROVE® EXPERT Ph Eur,BP,USP	Mar 2022
128220	108815	Zinc chloride EMPROVE® API Ph Eur,BP,JP,USP	Jun 2022
128222	103814	Iron(III)-chloride-hexahydrate EMPROVE® ESSENTIAL Ph Eur,JPE	Oct 2022
128209	108881	Zinc sulfate heptahydrate EMPROVE® ESSENTIAL Ph Eur,BP,ChP,JP,USP	Nov 2022
128210	108881	Zinc sulfate heptahydrate FCC,GB	Nov 2022
128223	101084	Aluminium chloride hexahydrate EMPROVE® ESSENTIAL Ph Eur,BP,USP	Aug 2024

* More precise timeline will be communicated in change notification process and updated on our Nantong webpage

** Excluding US, Canada and Puerto Rico due to trade regulations

Q3. How does this project impact existing products?

The products in table 1 will be transferred sequentially to the new plant in Nantong. Upon successful transfer, the products will be discontinued in Darmstadt and only be produced in Nantong. The only exception is ammonium sulfate. US, Canada and Puerto Rico will not be supplied out of Nantong. Darmstadt article will remain available exclusively for these regions. For more information please contact your Sales Representative.

For the products to be transferred, a comprehensive transition strategy has been put in place with last-order dates that will also be communicated in detail through our change notifications. Customers will also be provided with a comparability report to assess the transfer's impact on the product.

Q4. How will customers be informed about the upcoming changes?

A comprehensive communication plan has been developed, tailored to our customers' requirements. We will continuously provide the latest information on the new manufacturing site at www.merckmillipore.com/nantong. Meanwhile, general and product-specific change notifications as well as a comparability report per product can be provided to facilitate customer qualification.

The change notification follows our global change notification process respecting existing quality assurance agreements in place. If you are interested in receiving change notifications, please contact your local representative. At product launch sample kits will be available as well as Emprove® Dossiers to facilitate customer qualification.

Q5. When can the new facility in Nantong be audited?

The facility is operational and has been inspected and certified according to ISO 9001:2015 and EXCiPACT™. Customer on-site audits can be arranged upon request. The acceptance of audit is subject to availability and activation of respective production line. Furthermore, Rx360 site self-assessment and Rx360 3rd party audit report are available for excipients. We additionally offer the possibility of a remote or virtual audit to reduce travel efforts. Please contact your Sales Representative if you have any requests.

Q6. Does the production process change?

The production process is comparable but not identical to the one in Darmstadt. In case the process change is notifiable, this will be part of the change notification. For more information about the production process, please refer to Emprove® Dossiers.

Q7. Will raw materials change?

Yes, most of the raw materials are sourced in China. They have been qualified according to our global supplier qualification process.

Q8. Any changes in the packaging and labeling?

The offered pack sizes of Nantong products are the same as for product manufactured in Darmstadt, covering the normal range of 1 – 100 kg.

For standard packaging information please refer to our product detail pages on www.merckmillipore.com or www.sigmaaldrich.com. For the availability of customer/region specific packaging, please contact your local representative.

Q9. Will the Emprove® Dossiers for excipients change?

The Emprove® Dossiers for Nantong excipient products will remain unchanged; certifications such as ISO 9001:2015, EXCiPACT™, Halal, Kosher, and BSE-, Allergen-, Aflatoxins-, GMO, Melamine-, Nitrosamine- and other statements will be available similar to the products manufactured in Darmstadt.

Long-term stability data will be uploaded into the corresponding Emprove® Dossiers once available. All customers with Emprove® Suite access will be able to access the full dossiers for Nantong products online.

Q10. Will the products be ChP compliant and Co-Review registered in China?

Our Nantong excipients are multicompendial including ChP (if applicable) and they will be registered for Co-Review in China upon customer needs. The status on the registration can be found in the table below. Please contact our Customer Service to request LOA.

Table 2: Chinese Co-review status

Product	Item no.	Co-review registration no.
Ammonium sulfate EMPROVE® EXPERT ChP,NF,ACS	128218	F2020000042
Sodium acetate trihydrate EMPROVE® EXPERT Ph Eur,BP,ChP,JP,USP	128205	F2020000498
Sodium sulfate anhydrous EMPROVE® ESSENTIAL Ph Eur,BP,ChP,USP,E514	128211	F20210000453
Sodium sulfate anhydrous EMPROVE® EXPERT Ph Eur,BP,ChP,USP	128225	F20210000452
Sodium acetate anhydrous EMPROVE® ESSENTIAL ChP,USP,FCC,E262	128201	F20210000487
Sodium acetate anhydrous EMPROVE® EXPERT ChP,USP	128202	F20210000488
Zinc chloride EMPROVE® EXPERT Ph Eur,BP,USP	128221	F20210000456
Iron(III)-chloride-hexahydrate EMPROVE® ESSENTIAL Ph Eur,JPE	128222	F20220000264
Zinc sulfate heptahydrate EMPROVE® ESSENTIAL Ph Eur,BP,ChP,JP,USP	128209	F20220000352

Q11. What is the impact on existing contracts (supply agreements, Quality Assurance Agreements and Change Notification Commitments)?

Since Nantong products have different product numbers compared to Darmstadt reference products, customers need to ask for an update of Quality Assurance Agreements and request new Change Notification Commitments after commercial launch of the Nantong product. Detailed information will be given through product specific change notifications.

Q12. Will there be any changes for APIs manufactured in Nantong?

For transferred APIs, the regulatory dossiers (CEP & US-DMF) are updated to add Nantong site, and customers are informed by the change notifications. ChP addition and coreview submission in China is in plan. Emprove® API information package is available for API products 128204 & 128220 to support customer qualification. Please contact your Sales Representative for any questions.

Merck KGaA

Frankfurter Strasse 250
64293 Darmstadt
Germany

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.

