

Curia's Approach to Regulatory Compliance in China



As a global leader in CDMO services, Curia has proactively embraced the evolving regulatory landscape in China. Leveraging decades of experience in complex global regulatory environments, Curia has built strong expertise in navigating the specific demands of Chinese regulations. Our dedicated Local Regulatory Affairs Team in China plays a critical role in supporting our customers, ensuring successful regulatory outcomes, and facilitating smooth market access.

One notable achievement are the approvals of Betamethasone Dipropionate Micronized API and Aztreonam which were granted "A" status (approved) by the NMPA. This success underscores Curia's expertise in navigating China's regulatory processes and further solidifies our commitment to helping our customers succeed in this dynamic market.

China's Evolving Regulatory Framework for Active Pharmaceutical Ingredients (APIs)

In recent years, China has significantly reformed its regulatory framework for Active Pharmaceutical Ingredients (APIs) to align more closely with international standards. These changes are designed to ensure the quality, safety, and efficacy of pharmaceuticals entering the Chinese market. The regulatory environment, while demanding, provides a structured approach for API manufacturers to meet high standards. Below, we highlight the key aspects of China's regulatory requirements for APIs:



1. Drug Master File (DMF) Submission

A central component of China's regulatory framework is the Drug Master File (DMF). API manufacturers must submit a comprehensive DMF to the National Medical Products Administration (NMPA), detailing the manufacturing process, quality control measures, impurity profiles, and stability data for the API. The DMF must be submitted in Chinese and undergo a thorough review by the Center for Drug Evaluation (CDE).

Additionally, the China National Institute for Food and Drug Control (NIFDC) will conduct independent testing of the API samples to verify compliance with regulatory standards, ensuring that the product meets the required safety and quality benchmarks providing comments, if any, to the specification (whether items should be modified-method, limit; whether additional test should be involved).

2. Good Manufacturing Practices (GMP) Compliance

Manufacturers who want to supply APIs in China are required to adhere to Good Manufacturing Practices (GMP), which ensures that the production facilities maintain strict quality standards. Compliance involves establishing and maintaining GMP-compliant manufacturing facilities, which are subject to routine inspections by the NMPA. These inspections assess the facility's adherence to GMP regulations, ensuring the safety and efficacy of the APIs produced.

3. Regulatory Fees

In March 2020, the NMPA introduced an activation fee of approximately \$50,000 for DMF submissions. This fee covers various administrative evaluations, local testing, and the review process necessary for the activation of the DMF. The regulatory fee reflects the extensive resources required to assess each API thoroughly.

4. Registration Process for Imported APIs

For international API manufacturers wishing to enter the Chinese market, the registration process involves several critical steps:

- **Preparation of the Registration Application:** Manufacturers must gather and submit all necessary documentation, including technical data, quality control information, and detailed descriptions of the manufacturing process. Compliance with Chinese regulations and guidelines is essential at this stage.
- **DMF Submission:** The complete DMF (including both applicant and restricted parts) must be translated into Chinese and submitted to the CDE of the NMPA. In addition, a GMP certificate must be provided with the DMF and all documents must be notarized and apostilled for the submission.
- **Evaluation and Technical Review:** The CDE reviews the submitted DMF and conducts a thorough technical evaluation to assess the safety, quality, and efficacy of the API. This process often includes laboratory testing and may involve site inspections to verify compliance.
- **Approval and Certificate Issuance:** Once the evaluation is complete and the API meets all required standards, the NMPA issues an approval certificate, granting authorization for the legal importation and use of the API in China.

Curia's journey in China

Curia's commitment to regulatory excellence is reflected in our strong track record of API submissions in the Chinese market. In recent years, we have successfully obtained regulatory approvals for multiple APIs, demonstrating our capacity to adapt and thrive in the ever-changing regulatory environment. In the last years we have registered 20+ APIs already achieving "A" status in 7 of them: Vecuronium Bromide, Minocycline HCl, Olopatadine HCl, Azelastine HCl, Tyloxapol, Betamethasone dipropionate Micronized and Aztreonam.



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