

# Regulations on Inspection of Exported Drugs and Management of Export Certificates for Pharmaceutical Manufacturers

China – NMPA National Medical Products Administration

## Main information

### Scope of Application:

**Supervision of inspections and the issuance of export certificates for pharmaceutical products manufactured in China for export in other Countries**

### Effective Date:

**January 1<sup>st</sup>, 2026**

### Related Provisions:

- Drug Administration Law
- Good Manufacturing Practice (GMP) for pharmaceuticals
- Good Supply Practice (GSP) for pharmaceuticals

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# Key Topics

## Framework

- Distinction between routine export inspections (for customs clearance) and certification-based inspections (to prove GMP compliance for foreign regulators). This bifurcation allows manufacturers to obtain either a basic "**Export Certificate**" or a more rigorous "**GMP Compliance Certificate**" depending on the importing country's requirement.
- Explicitly apply only to pharmaceutical manufacturers holding a valid "Drug Manufacturing License" in China. They cover finished dosage forms, active pharmaceutical ingredients (APIs), and excipients, but **explicitly exclude traditional Chinese medicine decoction pieces, medical gases, and borderline** products like disinfectants.

## What's new

- **"One Window" Certificate System:** unified national digital platform for all export certificate applications, replacing fragmented provincial paper-based systems. Certificates are now issued with a unique QR code that links directly to the NMPA's verification database, enabling instant authentication by foreign buyers and regulators.
- **Risk-Based Inspection Protocol:** Manufacturers with a clean compliance record over the preceding 24 months and no product recalls may qualify for a streamlined document-review pathway, while high-risk products (e.g., sterile injectables, biologics) still require mandatory on-site inspections.
- **Harmonized Certificate Validity Period:** The regulation standardizes the validity period of all export-related certificates to **12 months**. Previously, validity periods varied significantly between provinces.

## Sensitive Factors

- **"Compassionate" Exports:** No longer allowed the common local practice of exporting unapproved finished drug products to less regulated markets, even on a compassionate use basis.
- If a **foreign regulatory authority requests verification** of a Chinese export certificate and raises specific quality concerns, the NMPA is empowered to conduct a targeted re-inspection within 15 business days.

## Drivers

- **Market Access to Stringent Regulatory Jurisdictions:** For manufacturers targeting highly regulated markets (e.g., EU, US, Japan, WHO prequalification), obtaining the GMP Compliance Certificate under this regulation is a prerequisite. The certificate's digital QR code and NMPA-backed verification system are increasingly required by foreign buyers as a condition of tender participation
- **Operational Efficiency via Digital Submission:** The mandatory "One Window" digital platform reduces certificate processing time from an average of 20–30 working days (under old provincial systems) to a maximum of 10 working days. Companies that fail to digitize their internal documentation for submission will face competitive disadvantages against faster-moving peers
- **Risk Mitigation for Supply Chain Contracts:** Buyers in overseas markets are now routinely requesting the QR code-enabled certificate as proof of legitimate origin. Pharmaceutical exporters must implement internal tracking systems to ensure batch-level traceability



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