

Context: Diva Pharmaceuticals is a global supplier of prescription drugs, vaccines, over-the-counter medications, active pharmaceutical Ingredients (API), and products supporting humanitarian and relief initiatives around the world. Diva Pharmaceuticals sources, vets and partners with North American suppliers to deliver only the highest quality brand and generic products to both established and developing global market purchasers. To maintain its high brand quality, Diva verifies its suppliers based on the information included below.

Supplier Information: At Diva Pharmaceuticals, we believe in fostering strong partnerships with reliable suppliers who share our commitment to quality, innovation, and customer satisfaction. We welcome you to join our network and contribute to our mission of improving global health outcomes. The following is the verification information that suppliers are requested to provide to join our exclusive global supplier network:

1. Company Information

- Business registration incl. legal company name, certificate of incorporation & business number.
- Corporate executive team contact information (names, telephone numbers & e-mails).
- Organizational structure identifying key personnel responsible for manufacturing/quality control.

N/A

2. Quality Management System

- Evidence of regulatory compliance (cGMP) -or- corporate statement attesting to compliance with GMP regulations.
- FDA registered facility number & documentation.
- Evidence of compliance with pharmacopeial standards (USP, EP), if applicable.
- Standard Operating Procedures (SOPs), Quality Policies & Procedures/Work Instructions.
- Operational standards certificates (e.g. ISO 9001), if applicable.
- Reports of adverse events, product recalls, regulatory non-compliance incidents, or FDA Warning Letters.
- Reports of previous internal or external (e.g. FDA) inspections or audits.
- Corrective and preventive action plans (CAPAs) that facility implemented in response to audit findings, if applicable.

3. Manufacturing & Distribution Facilities

- Company name & address of manufacturing & distribution facilities.
- Annual production capacity of manufacturing facilities.
- Maximum warehouse/inventory capacity of manufacturing & distribution facilities.
- Evidence of isolation of manufacturing areas to prevent cross-contamination, where required.
- Procedure for receiving, testing, storing & releasing raw materials & products.
- Health & safety policies & procedures incl. safety inspection reports & results from the past 3 years.

4. Supply Chain

- Supplier procedure for receiving, testing & storing final products.
- Traceability of raw materials and products against in-house specifications throughout supply chain.
- Evidence of compliance of raw materials & products with quality requirements throughout supply chain.
- Valid & applicable export permits & licenses from relevant regulatory institutions.

5. Quality Control & Change Control

- Statement of procedures for quality control & quality risk management.
- Change control procedures (to manage changes in processes, materials, or equipment).
- Statement of ongoing monitoring & review of product quality & Quality Management System.