



GDP Statement

Good Distribution Practices (GDP)

Colombia and Mexico

Colorcon, Colombia and Colorcon, Mexico maintain warehouse and distribution services with external suppliers who are qualified and audited periodically to assure they meet all regulatory requirements and maintain the quality of the product. Products distributed from these locations include Colorcon manufactured products as well as selected products from Dow Pharma Solutions. Colorcon works together with Dow Pharma Solutions through the Controlled Release Alliance to market products used in pharmaceutical applications: METHOCEL™ premium cellulose ethers; ETHOCEL™ premium ethylcellulose polymers; POLYOX™ water soluble resins; AFFINISOL™ polymers for solubility enhancement; ENTERACT™ polymers for enteric tablet coatings; AMBERLITE™ and DUOLITE™ ion exchange resins.

Products distributed from the facilities in Colombia and Mexico are managed using Good Distribution Practices (GDP) for packaged excipients as defined in the current version of the IPEC Good Distribution Practices Guide for Pharmaceutical Excipients. Colorcon's Quality Management System (QMS) is aligned with the IPEC GDP Guide and our operations are in compliance with applicable local regulations. Colorcon's facilities in Colombia and Mexico are not subject to any compulsory inspections by regulatory agencies.

The Colorcon manufacturing facilities providing products for distribution from Colombia and Mexico follow Good Manufacturing Practices (GMP) as defined in the current version of the Joint IPEC-PQG (International Pharmaceutical Excipients Council-Pharmaceutical Quality Group) Good Manufacturing Practices Guide for Pharmaceutical Excipients and have procedures to identify and qualify the source of raw materials and other quality critical materials used in the production of these products.

The products stored in Colombia and Mexico warehouses are primarily supplied to the pharmaceutical industry however some products are supplied for food and dietary applications.

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