



GDP Statement

Good Distribution Practices (GDP)

Colorcon, Latin America

Argentina, Brazil, Colombia and Mexico

Colorcon, Inc. operates warehouse facilities in Latin America in Argentina, Brazil, Colombia and Mexico. Products include the distribution of material manufactured by Colorcon at its global manufacturing facilities in addition to selected products from other manufacturers, including Dow Pharma and Food Solutions products including: METHOCEL™ premium cellulose ethers; ETHOCEL™ premium ethylcellulose polymers and POLYOX™ water soluble resins.

Products sold from all Latin American facilities are managed using Good Distribution Practices guidance for packed excipients as defined in “The IPEC Good Distribution Practices Guide For Pharmaceutical Excipients 2006” as amended from time-to-time (“GDP”). Colorcon’s Quality Management System (QMS) is aligned with GDP and our operations are in compliance with applicable local regulations. Colorcon’s facilities in Latin America (Argentina, Brazil, Colombia and Mexico) are not subject to any compulsory inspections by regulatory agencies.

In addition, the QMS implemented by Colorcon Argentina, Brazil, Colombia and Mexico is independently certified as meeting the requirements of the ISO9001:2008 standard.

The global Colorcon manufacturing facilities providing products for distribution to Colorcon in Latin America follow Good Manufacturing Practices guidance as defined in “The Joint IPEC-PQG (International Pharmaceutical Excipients Council / Pharmaceutical Quality Group) Good Manufacturing Practices Guide for Pharmaceutical Excipients -2006” as amended from time-to-time (“GMP”) and have procedures to identify and qualify the source of raw materials and other quality critical materials used in the production of products.

The products stored in the Latin American warehouses are primarily supplied to the pharmaceutical industry however some products are supplied for food and dietary supplement manufacturers.

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