



GDP Statement

Good Distribution Practices (GDP)

Colorcon S.A

Buenos Aires, Argentina

Colorcon, Inc. operates warehouse facility in Buenos Aires, Argentina. Products include the distribution of material manufactured by Colorcon at its global manufacturing facilities in addition to selected products from other manufacturers. 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. And Itacel Farmoquimica Ltda. to market products used in pharmaceutical applications: Microcel, Explosol, Solutab and Tabulose SC.

Products sold from Buenos Aires facility 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.A. is not subject to any compulsory inspections by regulatory agencies.

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 Buenos Aires warehouse are primarily supplied to the pharmaceutical industry however some products are supplied for food and dietary supplement manufacturers.

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