



GMP Statement

Good Manufacturing Practices

Colorcon do Brasil Ltda.

Indaiatuba, Brazil

The Colorcon do Brasil Ltda., Indaiatuba facility, manufactures a range of dispersion products and acts as a distributor of other selected products manufactured by Colorcon globally. 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 manufactured at our Indaiatuba facility are produced using applicable Good Manufacturing Practices (GMP). Due to the nature of Colorcon's excipient and colorant products, processes are controlled using slightly different techniques than those used for finished pharmaceutical products.

Products are primarily supplied to the pharmaceutical industry; however, some products are supplied for food or dietary supplement applications. Colorcon do Brasil Ltda. is, in compliance with ANVISA Excipient Good Manufacture Practices RDC nº 34, of August 07th, 2015, and is inspected annually by the Indaiatuba Health Surveillance.

Colorcon do Brasil Ltda is an active member of the International Pharmaceutical Excipients Council (IPEC) and has aligned its Quality Management System (QMS) with the Joint IPEC-PQG Good Manufacturing Practices Guide for Pharmaceutical Excipients. Colorcon uses this Guide when auditing suppliers.

The information contained in this document is proprietary to Colorcon and may not be used or disseminated inappropriately.

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