



GMP Statement

Good Manufacturing Practices

Colorcon, Japan

The Colorcon Japan facility, located in Fujinomiya City, Shizuoka, 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 Colorcon Japan 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 and Colorcon Japan operates under full pharmaceutical manufacturing license, and is inspected and approved, according to pharmaceutical GMP by The Ministry of Health, Labour and Welfare (MHLW).

Colorcon 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.

In addition, the QMS reflects activities associated with both product manufacture and distribution.

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

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