



GMP Statement

Good Manufacturing Practices

Shanghai Colorcon Coating Technology Limited

The Shanghai Colorcon Coating Technology Limited facility, located in the People's Republic of China, manufactures a range of dispersion products and acts as a distributor of other selected products manufactured by Colorcon globally. Colorcon works together with DuPont 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 Aquacoat® products.

Colorcon products manufactured at our Shanghai facility are produced using applicable Good Manufacturing Practices (GMP) for Pharmaceutical Excipients. Due to the nature of Colorcon's excipient and colorant products, processes are controlled using slightly different techniques than those for finished pharmaceutical products.

Shanghai Colorcon Coating Technology Limited operates under full pharmaceutical manufacturing license, is inspected and approved according to pharmaceutical excipient GMP by the China Food and Drug Administration (CFDA).

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 used by Shanghai Colorcon Coating Technology Limited is independently certified as meeting the requirements of ISO9001:2015.

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

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