



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 distributes other Colorcon manufactured products globally. Colorcon is also the global distributor for Dow Pharma and Food Solutions products used in controlled release applications: METHOCEL™ premium cellulose ethers; ETHOCEL™ premium ethylcellulose polymers; and POLYOX™ water-soluble resins.

Colorcon products manufactured at our Shanghai 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 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 ISO9001:2008.

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

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