



GMP Statement

Good Manufacturing Practices

Colorcon, North America

West Point, Pennsylvania and Humacao, Puerto Rico

The Colorcon North America, West Point and Humacao facilities, manufacture a range of dispersion products, lake pigments, enteric polymers, 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 the West Point and Humacao facilities 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 and dietary supplement applications. From a legal perspective, there is no binding GMP to which Colorcon North America must adhere and the facility is not subject to any compulsory inspections by a regulatory body.

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.

Colorcon North America has periodically been inspected by the US FDA (primarily related to the FD&C lake certification). These inspections have resulted in no adverse comments.

In addition, the QMS used by Colorcon West Point and Puerto Rico is independently certified as meeting the requirements of ISO9001:2015. 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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