



GMP Statement

Good Manufacturing Practices

Colorcon, Stoughton

The Colorcon Stoughton, North America facility, manufactures a range of SureSpheres[®] and Suglets[™], drug layering substrate products.

SureSpheres and Suglets manufactured at our Stoughton 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 dietary supplement applications. From a legal perspective, there is no binding GMP to which Colorcon Stoughton 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 also uses this Guide when auditing its suppliers.

In addition, the QMS used by Colorcon Stoughton 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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