



GMP Statement

Good Manufacturing Practices

Colorcon, Bazainville

FRANCE

The Colorcon, Bazainville, France facility manufactures and distributes a range of Suglets® Sugar Spheres for pharmaceutical drug loading applications. .

Products manufactured at the Colorcon, Bazainville facility are produced using applicable Good Manufacturing Practices (GMP). Due to the nature of Colorcon, Bazainville's excipient 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 or dietary supplement applications. From a legal perspective, there is no binding GMP to which Colorcon, Bazainville must adhere, however the facility has undergone GMP inspection by ANSM (the competent authority of France) which concluded that appropriate compliance was achieved.

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, Bazainville is independently certified as meeting the requirements of ISO9001:2015 and ISO14001:2015.

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

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