



GMP Statement

Good Manufacturing Practices

Colorcon NP Pharm SAS, Bazainville

FRANCE

The Colorcon NP Pharm SAS, Bazainville, France facility manufactures and distributes a range of Suglets™, Sugar Spheres for pharmaceutical drug loading applications and homeopathic spheres (distribution only).

Products manufactured at the Colorcon NP Pharm SAS facility are produced using applicable Good Manufacturing Practices (GMP). Due to the nature of Colorcon NP Pharm SAS'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 NP Pharm SAS must adhere, however the facility has undergone GMP inspection by AFSSAPS (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 NP Pharm SAS is independently certified as meeting the requirements of ISO9001:2008 and ISO14001:2004.

Colorcon NP Pharm SAS is a subsidiary of Colorcon, Inc.

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