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## GMP Statement

# Good Manufacturing Practices

## Colorcon, Indianapolis

The Colorcon Indianapolis, North America facility, manufactures a range of these products: Starch 1500<sup>®</sup>, partially pregelatinized maize starch; StarCap 1500<sup>®</sup>, co-processed starch excipient; and Surelease<sup>®</sup>, aqueous ethylcellulose dispersion, 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<sup>™</sup> premium cellulose ethers; ETHOCEL<sup>™</sup> premium ethylcellulose polymers; POLYOX<sup>™</sup> water soluble resins; AFFINISOL<sup>™</sup> polymers for solubility enhancement; ENTERACT<sup>™</sup> polymers for enteric tablet coatings; AMBERLITE<sup>™</sup> and DUOLITE<sup>™</sup> ion exchange resins.

Products manufactured at our Indianapolis 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 food or dietary supplement applications. From a legal perspective, there is no binding GMP to which Colorcon Indianapolis 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 Indianapolis regularly undergoes voluntary GMP inspections with the Indiana Board of Health, which have resulted in no adverse findings.

In addition, the QMS used by Colorcon Indianapolis is independently certified as meeting the requirements of ISO9001:2015 and EXCiPACT. The QMS reflects activities associated with both product manufacture and distribution.

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

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