



---

## General Statement

### Quality Policy

---

#### Colorcon Indianapolis, US

The Colorcon, Indianapolis 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.

Colorcon is committed to providing the highest quality products and services that meet interested parties' requirements and to meet all applicable standards and requirements.

Colorcon pursues the aim of ensuring the continued growth and success of the company by using the best available technology, subject to economic viability and by continual improvements in all areas of our business. We have therefore introduced an integrated management system according to ISO 9001:2015, the principles of The Joint IPEC – PQG Good Manufacturing Practices Guide – current version which documents our processes and with which all employees are obliged to comply. Additionally, operations are certified to the EXCiPACT Standard for Pharmaceutical Excipient Suppliers. Through the application of our Quality Management System, we aim to ensure the satisfaction of our customers and support continual quality improvements whilst minimizing the impact on the local, national and global environment.

All necessary resources for the implementation of our company policy are provided. For our customers, we supply the requested Colorcon products, at the agreed quality, with a short lead time, on a reliable basis. In order to achieve this, we determine the requirements and expectations of our customers with the aim of increasing their satisfaction.

---

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

Global Headquarters

Colorcon

275 Ruth Road, Harleysville, PA 19438

Tel: +1 215.256.7700 Fax: +1 215.256.7799 Website: [www.colorcon.com](http://www.colorcon.com)

© BPSI Holdings LLC, 2018. All trademarks, except where noted, are property of BPSI Holdings LLC.

METHOCEL<sup>™</sup>/ETHOCEL<sup>™</sup>/POLYOX<sup>™</sup>/AFFINISOL<sup>™</sup>/ENTERACT<sup>™</sup>/AMBERLITE<sup>™</sup>/DUOLITE<sup>™</sup> are trademarks of The Dow Chemical Company.