



---

## GDP Statement

### Good Distribution Practices (GDP)

---

#### Colombia and Mexico

Colorcon, Colombia and Colorcon, Mexico maintain warehouse and distribution services with external suppliers who are qualified and audited periodically to assure they meet all regulatory requirements and maintain the quality of the product. Products distributed from these locations include Colorcon manufactured products as well as selected products from Dow Pharma Solutions. Colorcon works together with DuPont through the Controlled Release Alliance to market products used in pharmaceutical applications: METHOCEL™ premium cellulose ethers; ETHOCEL™ premium ethylcellulose polymers; POLYOX™ water soluble resins; AFFINISOL™ polymers for solubility enhancement; ENTERACT™ polymers for enteric tablet coatings; AMBERLITE™ and DUOLITE™ ion exchange resins and Aquacoat® products.

Products distributed from the facilities in Colombia and Mexico are managed using Good Distribution Practices (GDP) for packaged excipients as defined in the current version of the IPEC Good Distribution Practices Guide for Pharmaceutical Excipients. Colorcon's Quality Management System (QMS) is aligned with the IPEC GDP Guide and our operations are in compliance with applicable local regulations. Colorcon's facilities in Colombia and Mexico are not subject to any compulsory inspections by regulatory agencies.

The Colorcon manufacturing facilities providing products for distribution from Colombia and Mexico follow Good Manufacturing Practices (GMP) as defined in the current version of the Joint IPEC-PQG (International Pharmaceutical Excipients Council-Pharmaceutical Quality Group) Good Manufacturing Practices Guide for Pharmaceutical Excipients and have procedures to identify and qualify the source of raw materials and other quality critical materials used in the production of these products.

The products stored in Colombia and Mexico warehouses are primarily supplied to the pharmaceutical industry however some products are supplied for food and dietary applications.

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

The information contained herein, to the best of Colorcon Inc's knowledge, is true and accurate. Any recommendations or suggestions of Colorcon, Inc. with regard to the products provided by Colorcon, Inc. are made without warranty, either implied or expressed, because of the variations in methods, conditions and equipment which may be used in commercially processing the products, and no such warranties are made for the suitability of the products for any applications that you may have disclosed. Colorcon, Inc. shall not be liable for loss of profit or for incidental, special or consequential loss or damages."

---

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, 2019. All trademarks, except where noted, are property of BPSI Holdings LLC.

METHOCEL™/ETHOCEL™/POLYOX™/ENTERACT™/AFFINISOL™/AMBERLITE™/DUOLITE™/Aquacoat® are trademarks or registered trademark of affiliates of DuPont de Nemours, Inc.