Current Good Manufacturing Practices

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Colorcon is the global leader in regulated printing inks. We have built our reputation with almost four decades of experience in the printing ink industry. Contacts in the food, pharmaceutical, cosmetic and medical device industries have asked us why we are not currently ISO 9000 certified. The following is our position on the subject.

Currently, our Colorcon, No-Tox® Products, Chalfont, PA, USA facility is not registered ISO 9001. Our Colorcon Limited, European facility and our Colorcon, Inc. West Point PA are certified. However, they do not manufacture printing inks for the No-Tox Products business unit. Only pharmaceutical and food excipients (dispersions and coating systems) are produced in those facilities.

All Colorcon products are manufactured using current Good Manufacturing Practices (cGMP). Customer audits have placed a stronger emphasis on cGMP than ISO 9001.

We are closely involved with the International Pharmaceutical Excipient Council (IPEC). This group has published a GMP Guide for Excipient Bulk Pharmaceutical Chemicals which has been reviewed by the U.S. Food & Drug Administration (FDA). Colorcon's control systems are aligned with the IPEC Guide, along with the guidelines established by the FDA in 21 CFR, Part110: "Current Good Manufacturing Practice in Manufacturing, Packing and Holding Human Food" and Part 820: "Quality System Regulation".

If you would like to discuss this or any issue regarding printing inks for the industries we serve, our Business Development Manager or Technical Service staff will accommodate you. Your business is our business.

Attached please find our current Good Manufacturing Practices (cGMP's) for the Production of Printing Inks and Coatings formulated for use on the Food Contact Surfaces of Food Packaging and Articles.

Contents

1. Scope and Objective

Colorcon adheres to cGMP's for the Manufacture, Processing, Packing or Holding of Drugs and Food Products as listed in the U.S. Food & Drug Administration, Title 21, Code of Federal Regulations (21CFR). These regulations specify responsibilities of the organization and personnel, buildings and facilities, equipment, control of chemical and packaging components, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports, and returned and salvaged products.

Colorcon's current Good Manufacturing Practices (cGMP's) apply to the manufacture of printing inks and coatings (referred to as "printing inks") intended for use on the food contact surfaces of food packaging and articles.

Procedures for formulation, production and control are defined in order to exhibit how Colorcon's printing inks:

- comply with existing regulations and generally accepted requirements for food packaging;
- are suitable for the purpose intended;
- meet agreed upon customer end use specifications.

2. Controls

2.1 Procedures

Detailed operational procedures cover order receipt, manufacture and product delivery to agreed upon standards. Recording systems ensure that the correct action has been taken at each stage.

Colorcon has written procedures describing in sufficient detail the receipt, identification, storage, manufacturing, handling, sampling, testing, and approval or rejection of components. Colorcon personnel are trained and follow the established procedures.

These written procedures, including any changes, are drafted, reviewed and approved by the appropriate organizational units and reviewed and approved by the quality assurance unit. Any deviation from the written procedures is recorded and justified.

2.2 Production Instruction Documents

To assure uniformity from batch-to-batch, master production and control records for each product are prepared, dated and signed by at least one person and then double-checked by a second person. The batch sheet details the raw materials, raw material lot numbers, quantities, equipment, manufacturing instructions and theoretical and actual percent yields.

2.3 Product Test Specifications

Colorcon establishes specifications for each product manufactured. Laboratory test methods and release specifications are established and met. Products failing to meet established specifications and any other relevant quality control criteria shall be rejected or reprocessed following appropriate procedures.

Colorcon performs analytical and microbiological testing, as appropriate, on incoming raw materials.

3. Quality Review Procedure

Colorcon has written procedures describing the handling of complaints and non-conformance. These procedures outline laboratory investigations of the customer complaint by utilizing quality reviews of the incoming, batch work-in-process and finished goods records. The investigations include, but are not limited to, a summary, root cause analysis, time-line and corrective action. Any investigations are thoroughly documented and approved by the quality assurance unit.

4. Personnel and Training

4.1 Commitment

Colorcon provides yearly cGMP training to the entire workforce involving all levels of management. Ongoing training with respect to processes, procedures and safety occurs throughout any given year.

5. Raw Material Controls

5.1 Objective

cGMP requires complete cooperation with suppliers. Colorcon requires raw material suppliers to meet 21CFR, EP, USP, and JP requirements whenever possible. If the above grades are not applicable, appropriate regulatory requirements are established and must be met prior to release.

5.2 Suitability

Raw materials are selected so that, when printing inks are correctly applied, the printed surface does not:

- pose a risk to human health.
- cause a deterioration in the organoleptic nature of the packed food product.
- produce an unacceptable change in the composition or quality of the packed food product.

Colorcon adheres to regulatory “exclusion lists” for each facet of our operation. We perform a thorough evaluation of new raw materials and suppliers prior to their use in Colorcon products. Colorcon performs vendor audits on new and approved suppliers, as appropriate.

5.3 Identification

Colorcon requires our raw material suppliers to label each container with the name of the product, batch number and raw material code number, at a minimum, for traceability purposes. All materials arrive at our facility in sealed containers.

5.4 Specifications

Colorcon requires each batch of components to be held in “virtual” quarantine until the batch has been sampled, tested, examined as appropriate, and released for use by quality control. Each raw material is assigned an established specification, agreed upon by the supplier and/or governed by regulatory agencies. The raw material must meet specifications before being released for use.

5.5 Conformity

Colorcon requires each raw material component to be tested for conformity with all appropriate specifications. In lieu of such testing, a Certificate of Analysis may be accepted from the supplier of a component, provided that at least one specific identity test is conducted. Every fourth lot of a given raw material is required to undergo full testing.

In some instances pre-delivery samples representing the batch may be submitted to the ink maker for special tests prior to the delivery being accepted.

5.6 Traceability

Colorcon maintains traceability of raw materials by assigning a consecutive numerical batch control number, specific to the delivered material upon receipt, referencing the vendor batch number.

5.7 Storage

Colorcon raw materials are stored in appropriate conditions to segregate batches, and prevent contamination and deterioration. Rejected or quarantined components are identified and controlled under an electronic quarantine system designed to prevent their use in manufacturing. They are held in segregated areas of the facility when possible.

5.8 Usage

Colorcon rotates raw material inventory on a *"first expired – first out"* basis. Raw materials are re-tested based upon their shelf-life requirements to determine suitability for continued use.

6. Formulation

The following parameters are considered when formulating printing inks:

- Type of substrate and material combinations.
- Type of food, pharmaceutical, cosmetic or medical products to be packed.
- Type of printing processes and printing equipment.
- Package forming and product filling processes.
- End-user specifications.
- Compliance to health, safety and consumer protection regulations.
- Compliance with environmental policies for printing manufacturing processes and end-use.

Printing inks are formulated in such a way:

- as to have the necessary adhesion of the dry layer to the substrate and resistance to physical and chemical stress,
- as to be suitable for the method of application and for subsequent converting processes,
- as to have the binder/colorant/additive combination to meet product resistance specifications or other agreed upon end use specifications.

7. Production

7.1 Objective

Colorcon follows written procedures for production and process control designed to assure that our products possess the identity, quality and purity they purport to possess. Any deviation from the written procedures shall be recorded and justified.

7.2 Manufacturing Instruction Document

Manufacturing instructions are issued and followed for each batch, giving details of the raw materials, the quantities and the equipment to be used. Colorcon performs in-process testing throughout the manufacturing process. This testing is routinely documented and verified.

7.3 Manufacturing Formulation

Colorcon manufactures with approved components, from approved suppliers. Colorcon manufactures batches by following a batch sheet that is a duplicate copy of the master formula. Colorcon dispenses the designated quantities of raw materials as shown on the batch sheet prior to beginning to manufacture.

7.4 Equipment

Colorcon uses calibrated equipment of appropriate design, adequate size and suitable location to facilitate operations for its intended use and for its cleaning and maintenance. Equipment and utensils are cleaned and maintained to prevent malfunctions and cross-contamination between each batch that is manufactured.

8. Quality Control

8.1 Objective

To carry out laboratory tests on printing inks produced to ensure that the products supplied to the customer are fit for application and end use and conform to customer specifications.

8.2 Production Quality Control

Testing of printing ink samples at selected stages of the process is carried out in order to establish whether the product is meeting the required quality standard. A procedure is set up for the production personnel to adjust the process or product within the specified limits when necessary.

8.3 Testing

Products are tested to meet specifications established at the formulation stage. Some additional test methods may be agreed upon with customers. Colorcon performs testing of finished goods to assure our products meet established specifications and are fit for customer use.

8.4 Test Equipment

All Colorcon analytical and manufacturing equipment is calibrated on a calibration schedule to ensure that the test results are accurate.

9. Product Information

9.1 Identification

Colorcon identifies our products by name, formula and batch number.

9.2 Conformity

Colorcon supplies Certificates of Analysis for each batch of product manufactured at our facilities, confirming that it meets specification.

9.3 Data Sheets

Colorcon supplies Material Safety Data Sheets on each formula, detailing relevant chemical, physical and safety data. Technical Data Sheets are also available for all of our ink systems.

10. Packaging

10.1 Specification

Colorcon selects packaging to protect products during shipping and storage, and conforms to the appropriate requirements for transport.

10.2 Cleanliness

Colorcon inspects packaging components for cleanliness and stores them in such a way as to prevent contamination.

10.3 Accurate Filling

Colorcon adheres to the required fill weights. Filling controls are accurate and all weighing equipment is calibrated and frequently inspected.

10.4 Labeling

Each Colorcon container has the minimum following information on labels:

- Identification of the producer
- Reference number and description of product
- Batch number
- Net weight
- Health, safety and transport information

11. Storage

All products and raw materials are stored in conditions to prevent any deterioration of the material. Where appropriate a procedure exists to test inventoried inks to assure they have not drifted from specification. Rejected inks are clearly marked and quarantined.

12. Delivery

All products are delivered in clean and clearly labeled suitable containers.

Colorcon®
No-Tox® Products

For more information, contact your Colorcon representative or call 1-800-724-0624
You can also visit our website at http://www.colorcon.com/notox