

Good Manufacturing Practice (GMP) Guidelines/Inspection Checklist

February 12, 1997; Updated April 24, 2008

The [Federal Food, Drug and Cosmetic Act](#) prohibits the introduction or delivery for introduction into interstate commerce of cosmetics that are adulterated or misbranded (Sec. 301).

A cosmetic may be deemed adulterated (Sec. 601) for essentially four reasons, namely:

1. It may be injurious to users under conditions of customary use because it contains, or its container is composed of, a potentially harmful substance.
2. It contains filth.
3. It contains a non-permitted, or in some instances non-certified, color additive.
4. It is manufactured or held under insanitary conditions whereby it may have become injurious to users or contaminated with filth.

A cosmetic may be deemed misbranded (Sec. 602) for reasons of:

1. False or misleading labeling.
2. Failure to state prominently and conspicuously any information required by or under authority of this act.
3. Misleading container presentation or fill.

To determine whether cosmetic firms manufacture, hold or deliver for introduction into interstate commerce cosmetics that are adulterated or misbranded, and to prevent these and other practices violating Sec. 301 of the FD&C Act, the law gives the agency the authority to enter the establishments of such firms and inspect their facilities as well as all pertinent equipment, finished and unfinished materials, containers and labeling therein. See Sec. 704(a) of the FD&C Act.

Rigorous adherence to good manufacturing practice minimizes the risk of adulteration or misbranding of cosmetics. The following cosmetic establishment instructions, excerpted from FDA's Inspection Operations Manual, may serve as guidelines for effective self-inspection. A good inspection score means that an establishment follows good manufacturing practice.

Guidelines

1. **Building and Facilities.** Check whether
 - a. Buildings used in the manufacture or storage of cosmetics are of suitable size, design and construction to permit unobstructed placement of equipment, orderly storage of materials, sanitary operation, and proper cleaning and maintenance.
 - b. Floors, walls and ceilings are constructed of smooth, easily cleanable surfaces and are kept clean and in good repair.

- c. Fixtures, ducts and pipes are installed in such a manner that drip or condensate does not contaminate cosmetic materials, utensils, cosmetic contact surfaces of equipment, or finished products in bulk.
 - d. Lighting and ventilation are sufficient for the intended operation and comfort of personnel.
 - e. Water supply, washing and toilet facilities, floor drainage and sewage system are adequate for sanitary operation and cleaning of facilities, equipment and utensils, as well as to satisfy employee needs and facilitate personal cleanliness.
2. **Equipment.** Check whether:
- a. Equipment and utensils used in processing, holding, transferring and filling are of appropriate design, material and workmanship to prevent corrosion, buildup of material, or adulteration with lubricants, dirt or sanitizing agent.
 - b. Utensils, transfer piping and cosmetic contact surfaces of equipment are well-maintained and clean and are sanitized at appropriate intervals.
 - c. Cleaned and sanitized portable equipment and utensils are stored and located, and cosmetic contact surfaces of equipment are covered, in a manner that protects them from splash, dust or other contamination.
3. **Personnel.** Check whether:
- a. The personnel supervising or performing the manufacture or control of cosmetics has the education, training and/or experience to perform the assigned functions.
 - b. Persons coming into direct contact with cosmetic materials, finished products in bulk or cosmetic contact surfaces, to the extent necessary to prevent adulteration of cosmetic products, wear appropriate outer garments, gloves, hair restraints etc., and maintain adequate personal cleanliness.
 - c. Consumption of food or drink, or use of tobacco is restricted to appropriately designated areas.
4. **Raw Materials.** Check whether:
- a. Raw materials and primary packaging materials are stored and handled in a manner which prevents their mix-up, contamination with microorganisms or other chemicals, or decomposition from exposure to excessive heat, cold, sunlight or moisture.
 - b. Containers of materials are closed, and bagged or boxed materials are stored off the floor.
 - c. Containers of materials are labeled with respect to identity, lot identification and control status.
 - d. Materials are sampled and tested or examined in conformance with procedures assuring the absence of contamination with filth, microorganisms or other extraneous substances to the extent necessary to prevent adulteration of finished products. Pay particular attention to materials of animal or vegetable origin and those used in the manufacture of cosmetics by cold processing methods with respect to contamination with filth or microorganisms.
 - e. Materials not meeting acceptance specifications are properly identified and controlled to prevent their use in cosmetics.

5. **Production.** Check whether manufacturing and control have been established and written instructions, i.e., formulations, processing, transfer and filling instructions, in-process control methods etc., are being maintained. Determine whether such procedures require that:
 - a. The equipment for processing, transfer and filling the utensils, and the containers for holding raw and bulk materials are clean, in good repair and in sanitary condition.
 - b. Only approved materials are used.
 - c. Samples are taken, as appropriate, during and/or after processing, transfer or filling for testing for adequacy of mixing or other forms of processing, absence of hazardous microorganisms or chemical contaminants, and compliance with any other acceptance specification.
 - d. Weighing and measuring of raw materials is checked by a second person, and containers holding the materials are properly identified.
 - e. Major equipment, transfer lines, containers and tanks are used for processing, filling or holding cosmetics are identified to indicate contents, batch designation, control status and other pertinent information.
 - f. Labels are examined for identity before labeling operations to avoid mix-up.
 - g. The equipment for processing, holding, transferring and filling of batch is labeled regarding identity, batch identification and control status.
 - h. Packages of finished products bear permanent code marks.
 - i. Returned cosmetics are examined for deterioration or contamination.
6. **Laboratory Controls.** Check whether:
 - a. Raw materials, in-process samples and finished products are tested or examined to verify their identity and determine their compliance with specifications for physical and chemical properties, microbial contamination, and hazardous or other unwanted chemical contaminants.
 - b. Reserve samples of approved lots or batches of raw materials and finished products are retained for the specified time period, are stored under conditions that protect them from contamination or deterioration, and are retested for continued compliance with established acceptance specifications.
 - c. The water supply, particularly the water used as a cosmetic ingredient, is tested regularly for conformance with chemical-analytical and microbiological specifications.
 - d. Fresh as well as retained samples of finished products are tested for adequacy of preservation against microbial contamination which may occur under reasonably foreseeable condition of storage and consumer use.
7. **Records.** Check whether control records are maintained of:
 - a. Raw materials and primary packaging materials, documenting disposition of rejected materials.
 - b. Manufacturing of batches, documenting the:
 - i. Kinds, lots and quantities of material used.
 - ii. Processing, handling, transferring, holding and filling.
 - iii. Sampling, controlling, adjusting and reworking.
 - iv. Code marks of batches and finished products.

- c. Finished products, documenting sampling, individual laboratory controls, test results and control status.
 - d. Distribution, documenting initial interstate shipment, code marks and consignees.
8. **Labeling.** Check whether the labels of the immediate and outer container bear:
- a. On the principal display panel:
 - i. In addition to the name of the product, the statements of identity and net contents,
 - ii. The statement "Warning--The safety of this product has not been determined" if the safety of the respective product has not adequately been substantiated. Determine whether and what toxicological and/or other testing the firm has conducted to substantiate the safety of its products. See 21 CFR 740.10.
 - b. On the information panel:
 - i. The name and address of the firm manufacturing the product or introducing it into interstate commerce.
 - ii. the list of ingredients (only on outer container) if intended for sale or customarily sold to consumers for consumption at home.
 - iii. The warning statement(s) required at 21 CFR 740.11, 740.12 and 740.17.
 - iv. Any other warning statement necessary or appropriate to prevent a health hazard. Determine the health hazard or their basis for a warning statement.
 - v. Any direction for safe use of product.
 - vi. In case of a hair dye product, the caution statement of Sec. 601(a) of the Act and appropriate directions for preliminary patch testing. This warning only applies to coal-tar hair dyes which, if so labeled, are then exempted from the adulteration provision of the Act.
9. **Complaints.** Check whether the firm maintains a consumer complaint file and determine:
- a. The kind and severity of each reported injury and the body part involved.
 - b. The product associated with each injury, including the manufacturer and code number.
 - c. The medical treatment involved, if any, including the name of the attending physician..
 - d. The name(s) and location(s) of any poison control center, government agency, physician's group etc., to whom formula information and/or toxicity data are provided.
10. **Other.** Check whether the firm is:
- a. Participating in the program of voluntary registration of:
 - i. Cosmetic manufacturing establishments (21 CFR 710).
 - ii. Cosmetic product ingredient and cosmetic raw material composition statements (21 CFR 720).
 - b. Using a color additive which is not listed for use in cosmetics (21 CFR 73, 74, and 82) or which is not certified (21 CFR 80).
 - c. Using a prohibited cosmetic ingredient (21 CFR 700).