IS 11377 (2001): Guidelines for Hygienic Manufacture of Cosmetics [PCD 19: Cosmetics]

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भारतीय मानक

सौंदर्य प्रसाधनों के स्वच्छतापूर्वक निर्माण हेतु मार्गदर्शी सिद्धान्त

(पहला पुनरीक्षण)

Indian Standard

GUIDELINES FOR HYGIENIC MANUFACTURE OF COSMETICS

(First Revision)

ICS 71.100.70

BUREAU OF INDIAN STANDARDS
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NEW DELHI 110002

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Price Group 2

FOREWORD

This Indian Standard (First Revision) was adopted by the Bureau of Indian Standards, after the draft finalized by the Cosmetics Sectional Committee had been approved by Petroleum, Coal and Related Products Division Council.

Over the years the manufacture of cosmetics has evolved both in quantity and quality and has acquired a status that has required the manufacture of cosmetics to be brought under the purview of the *Drugs and Cosmetics Act*, 1940. Cosmetics being widely used consumer products, the consumer is entitled to be protected from the harmful effects of the cosmetics that could arise out of myriads of variables in the quality of raw materials, manufacturing process and packaging materials.

An attempt has been made in this standard to lay down broad guidelines for the manufacture of cosmetics and to set up a Quality Assurance Code that would cover all aspects of good manufacturing practices and documentation, so that the ultimate consumer is assured of the quality of the final cosmetic.

Rule No. 139 of *Drugs and Cosmetic Act* lays down general requirement for manufacture of cosmetic under MII schedule. It is imperative that the manufacturing units comply with the same.

The fact that the cosmetics are being increasingly manufactured in the small scale industry sector, where technical assistance may be limited makes the need for this standard all the greater.

This standard is designed to provide broad guidelines to manufacturers both in the small scale sector and the organized sector, as well as to the inspectors of the local Drugs Administration to monitor the hygiene in manufacture of cosmetics. It has to be borne in mind that the quality assurance programme is a philosophy and as such, the points raised in this standard require to be periodically appraised and assessed and modified so that the overall standards are progressively raised for all sectors engaged in manufacturing operations. Thus the consumers should be protected irrespective of the source of the cosmetics.

These guidelines are essentially divided into two sections (a) Code of hygiene, and (b) Code of General Requirements. It needs to be emphasized that boih Sections are of equal and complimentary importance and only constitute two sides of the same coin — compliance has to be assured to both sections which are divided only for convenience.

Considerable assistance has been derived in the preparation of this standard from J. Sec Cosmet. Chem. 21, 739, 1970 and 21, 719, 1970 issued by the Council of the Society of Cosmetic Chemists of Great Britain and a citizen petition submitted by The Cosmetic, Toiletry and Fragrance Association Inc., USA (CFTA) to Food and Drug Administration (FDA) in USA.

No ISO standard has been published by the International Organization for Standardization on the subject.

Indian Standard

GUIDELINES FOR HYGIENIC MANUFACTURE OF COSMETICS

(First Revision)

1 SCOPE

This standard is divided into two sections. Section 1 of this standard covers code of hygiene in the manufacture of cosmetics and Section 2 includes guidelines and indicators for proper and hygienic traceability of raw materials to finished products including end process quality control.

2 CODE OF HYGIENE IN THE MANUFACTURE OF COSMETICS

2.1 General Principles

In order to ensure proper hygienic quality of cosmetics in manufacture, packaging and also to enable traceability of the finished cosmetics to its batch sheet, it is necessary that various systems, methods and record keeping procedure, as indicated in this standard are adopted. Cosmetic manufacture does not at present require the end product to be sterile. However, it is expected that the bacterial count should not exceed 1 000 micro-organisms/g with no pathogens. To achieve this, the normal practice is to have adequate preservatives added in the product with built-in self-sterilizing capacity. Nevertheless, hygienic operating procedures require awareness on a continuous basis. Some of these aspects are being discussed in this standard. The extent to which the principles laid down in this standard could be practicable in a particular manufacturing process would largely depend on the scale of production, the susceptibility of the product to contamination and the extent of exposure to contamination.

2.2 Hygienic Methods

Hygienic methods are in essence procedures for maintaining a high standard of cleanliness in order to ensure that the product is not unnecessarily subjected to contamination from various sources. Some of the sources which may cause contamination are listed below:

a) Air and water are quite often the more important source of contamination;

b) Plant design or operating procedures that would allow dust to enter into the product would also encourage air-borne contamination. Stagnant residues of product in the plant shall not be kept beyond acceptable dwell time for that particular product between the processing of successive batches which may otherise lead to multiplication of micro-organisms. This should apply to residues not only in manufacturing vessels and tubing, but also on the areas of plant, floor and walls; and

c) Efficient cleaning of the plant is desirable and could be achieved by mopping and sweeping with suitable disinfectant solution.

2.3 Factory and Plant Design

The design of the building, in which the plant is to be housed should ensure that the walls, floors and ceilings have smooth, non-absorbent and easily cleanable surface with no hidden corners or edges in which dust and dirt could collect. The building shall be so constructed that it prevents encroachment/entry of insect, flies, rodents, etc. It would be of added advantage if air-conditioners could be provided in the manufacturing section. Common air-conditioners give rise to microbial contamination from the filter provided in it. A regular programme for disinfecting such filters and checking their efficacy should be ensured. The building should be designed in such a manner so that the production floor is least disturbed by people. Change rooms if provided should be kept away from the production area. Lavatories and toilets should not be connected directly with either change room or production area. Adequate washing facilities should be provided.

2.3.1 The design of the manufacturing plant should be such that it could be easily cleaned. Equipment used should be either of stainless steel or any other suitable material (in which case the material should be such that it could effectively and satisfactorily be cleaned). Transfer pipes used should be easily dismantable or should have facility to clean and sanitize properly at site. It may be ensured pipes are kept covered when not in use and checked for cleanliness at regular intervals. In case of flexible pipes, ensure proper facility for connecting, proper drainage of product and pipes are kept properly hooked and not left on floor.

It shall also be ensured that there are no dead ends

and stagnation point resulting in improper drainage.

In case of joints and washers used in joints, proper sanitization shall be ensured.

2.3.2 Generally speaking, the design of the plant should take into account the need to avoid contamination, the main requirements being that it should be easily dismantled, cleaned and should not provide any scope for dead-ends and corners where contamination can build up. The design of the equipment shall be such that during operation, no lubricant or contaminants could come in contact with the product being processed. The equipment should also be fitted with well-fitting covers capable of excluding dust particles and contamination from the surroundings.

There shall be written down and validated procedure for cleaning and sanitization of equipment and records of the same shall be maintained.

2.4 Water Supply

Water, one of the main raw materials, in cosmetic manufacture, is a potential source of contamination especially bacterial contamination which builds up during storage and in the resin beds in the demineralizing plant. It is advisable that instead of using tap water or tube-well water in the manufacture of cosmetics, demineralized water be used. Sterilization of ion exchange beds may easily be done with (0.1 percent formaldehyde). Water passed through demineralizer gets contaminated as demineralization unit acts as good filter and entraps organic matter. This entrapped organic matter acts as a source of nutrient for microbes and in turn, source of contaminant. A sterilized demineralizer unit gets contaminated soon. Hence demineralized water shall be treated to bring down microbial population.

Treatment could be:

a) Heat treatment by heating water to above 80°C for 1/2 hour,
b) Passing through ultra-violet light, and
c) Filtration.

As step (a) and (b) can leave dead cell or toxin still in water, one could consider usage of combination of steps (a) and (c) or steps (b) and (c).

When demineralized water is to be stored, it is advisable that this water is stored in stainless steel tanks fitted with thermostatically controlled heaters at 75°C. This system also provides the advantage that the water is available at the temperature normally required for emulsification.If water has to be stored, ensure water is not stored for more than 72 hours, as due to microbial multiplication, toxic matter and dead microbial cell could harm consumer.

In case storing of water at 75°C is not practical from manufacturing point of view, then water should be passed either through (a) ultra-violet irradiation sterilizer or (b) through filter cartridge suitable to hold back bacteria (0.22 m), before use. At regular interval water may be checked for total viable count (TVC) to ensure, ultra-violet light or filter are working efficiently. In case ultra-violet light is used, it may be advisable to also incorporate filters to eliminate dead microbial cells.

2.5 Other Sources of Contamination

Other likely sources of contamination includes sacks, bags, drums, vats, air-borne dust, cardboard and other packing materials used for the delivery of packaging components. It is advisable that packaging materials are delivered to the various areas in suitable cleaned bins or containers. A careful watch should also be kept for leakage from ceilings, lavatory, water tanks, etc, as these damp areas encourage growth of bacteria and fungi.

2.6 Personnel Sanitation Facilities

Adequate washing facilities should be provided in the plant for the use of employees together with soap, towel, etc. However, electric hand driers would be preferred in place of towels.

The use of suitable hair cover is also advisable in order to prevent contamination of products by falling hair, dandruff, etc. Gloves and shoes,wherever necessary, may also be used. Smoking should be strictly prohibited within the manufacturing premises.

Regular medical check up as per factory rule shall be undertaken to ensure no employee harbours any skin ailment or is suffering from communicable disease.

2.7 Effective Processing Conditions

The personnel responsible for the manufacture of cosmetic products should be adequate in number as per provisions of the *Drugs and Cosmetics Act*. Operating personnel should be insisted upon to maintain a high degree of personal cleanliness. Personnel should normally not be permitted to bring in their personal belongings like food, beverages, tobacco, etc, in manufacturing, packaging and allied areas.

3 CODE OF GENERAL REQUIREMENTS

NOTE — Rule 142(c) of the *Drugs and Cosmetics Rules* lays down that the manufacturer shall test each batch or lot of the raw materials used by him for the manufacture of the cosmetics. It is, therefore, imperative that cosmetics raw materials shall not be used until they have been identified and tested as per standards available.

3.1 Raw Materials

3.1.1 All raw materials for use in the manufacture of cosmetics shall be properly labelled, stored and handled in a safe and orderly fashion.

3.1.2 The raw materials shall be examined visually for appropriate labelling, container damage, broken seals and contamination.

3.1.3 Each raw material shall be covered by standard specifications for the same where available and should include testing procedures.

3.1.4 Every raw material received in the stores shall be tested according to specifications and an analytical report shall be prepared according to the following:

a) Name of the materials;
b) Name of the manufacturer or supplier;
c) Manufacturers batch or lot number;
d) Quantity received;
e) Date of testing;
f) Tests performed and the result;
g) Remarks as to approval or rejection or disposal; and
h) Signatures of the persons responsible for testing and approval.

3.1.5 Where the unit does not have its own testing facility, the unit shall get its raw materials and finished products tested from an approved laboratory as per provisions of rule 139(5) (ii) of the *Drugs and Cosmetics Rules*.

3.1.6 All approved raw materials shall be so marked on the labels, when approved by quality control. Rejected materials shall be segregated and their use precluded from manufacturing or processing procedures for which they have been found unsuitable. Such materials shall be returned to the supplier or suitably disposed off.

3.1.7 First in first out system should be followed while issuing raw materials and packing materials for production.

3.2 Packaging Materials

3.2.1 Packaging materials shall be properly labelled and stored in such a manner as to prevent mix-up, contamination and damage. The handling procedure shall also ensure that mix-up damage, etc, does not take place.

3.2.2 All lots of packaging materials shall be inspected and tested as necessary and released for use.

3.2.3 All approved packaging materials shall be so marked when approved by quality control. Packaging materials not acceptable are to be properly marked, segregated and returned to the supplier or disposed off.

3.3 Finished Product

NOTES

1 Rule 142 (b-1) of the *Drugs and Cosmetics Rules* states that the manufacturer shall keep records of the details of each batch of the cosmetic manufactured by him and of the raw materials used therein as per particulars specified in Schedule U (1) and such records shall be retained for a period of three years.

2 Rule 142 (c) of the *Drugs and Cosmetics Rules* states that the manufacturer shall test each batch of the final product and shall maintain records or registers showing the particulars in respect of such tests. The records and registers shall be retained for a period of three years from the date of manufacture. In case the unit does not have its own testing facilities, the unit shall get the same tested from an approved laboratory.

3.3.1 Manufacturing records will normally contain the following information:

a) Name of the product;
b) Product formula covering namely, complete list of raw materials required for the manufacture of the product; and the amount of each raw material to be used in the formulation for the batch size;
c) Control reference number of raw material used;

   NOTE — Required as per schedule U(1) of *Drugs and Cosmetics Act* for traceability.
d) Date of manufacture;
e) Details of manufacturing instructions, including temperature, duration of mixing, etc;
f) Total quantity manufactured and details giving the number of units packed of the desired unit pack size;
g) Date of approval of packed units and date of release for distribution or sale; and
h) Signature of manufacturing officer and approving officer.

3.3.2 A product shall be manufactured according to the manufacturing record sheet and appropriately completed indicating completion of each operation. Upon completion of manufacture, the manufacturing record sheet shall be signed by the person in charge, ensuring that information required has been properly recorded.

3.3.3 A representative sample of the finished product shall be tested as per specifications and test results recorded. This shall normally have the following information:

a) Name of the product;
b) Batch No.;
c) Batch size;

d) Date of testing;
e) Tests performed and the results;
f) Approval or rejection or disposal of batch; and
g) Signature of persons responsible for testing and approval.

3.3.4 A product shall be released for sale only on obtaining approval from the quality control department.

3.4 Plant and Equipment

3.4.1 Suitable manufacturing and filling packing equipment shall be used. It should be suitable for the type of operation and facilitate easy cleaning and sanitizing. The material of construction shall not react with the product and withstand sanitization process.

3.4.2 The equipment shall have proper cover to prevent aerial contamination.

3.4.3 The layout of plant and equipment shall be such that:

a) It ensures proper flow of material;
b) Cross contamination does not occur; and
c) It facilitates operation and cleaning and sanitization.

3.4.4 Wherever felt necessary, there shall be a proper operating procedure.

4 IN-PROCESS QUALITY CONTROL

In-process quality control is strongly recommended as it ensures the quality of the final product. For this, production check points have to be determined and these have to be implemented by production and quality control. The quality control department should monitor the packaging operations also for under filling, wrong labelling, etc. In process control could detect errors in time for application of remedial measures avoiding the need for writing off a batch.

5 CALIBRATION

Calibration and validation of test equipment shall be undertaken.

6 DISPOSAL OF WASTE

The manufacturing unit shall comply with pollution board directives and shall have proper facility for disposal of solid waste, waste water and control of air pollutant.

Bureau of Indian Standards

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