SCHEME OF TESTING AND INSPECTION FOR CERTIFICATION OF SKIN CREAMS ACCORDING TO IS 6608:2004

1. Laboratory - A laboratory shall be maintained which shall be suitably equipped and staffed to carry out the different tests in accordance with the methods given in the Indian Standards.

2. Test Record - All records of analysis and tests shall be kept in suitable forms approved by the Bureau of Indian Standards.

2.1 Copies of any records that may be required by BIS shall be made available at any time on request.

2.2 Quality Control - It is recommended that, as far as possible, Statistical Quality Control (SQC) methods may be used for controlling the quality of the products as envisaged in this Scheme [See IS 397 (Part 1): 2003, IS 397 (Part 2): 2003 and IS 397 (Part 3): 2003].

2.2.1 The following instruments/equipments are required to be brought under calibration control, as per frequency to be decided depending upon the usage.

2.3 In addition, effort should be made to gradually introduce a Quality Management System in accordance with IS/ISO 9001:2000.

3. Standard Mark :- The standard mark(s) as given in column (1) of the first schedule of the licence shall be printed/stenciled on the container or on the label applied to it, provided always that the material in each container to which the Standard Mark is thus applied conforms to every requirement of the specification.

4. Marking - In addition, the following information shall be marked on each container or on the label applied to it:

a) Name of the material;
b) Manufacture’s name and/or recognized trade mark if any;
c) Net mass of the material;
d) Month and year of manufacturing/packing;
e) Batch No. in Code or otherwise to enable the lot of manufacture to traced back from firm’s record;
f) Expiry date or “Best use before……………..” (Month and year to be declared by the firm)*
g) List of key ingredients**
h) Any other information required by statutory authorities and k) BIS Licence no. CM/L……………………..)
* Note 1. This is exempted in case of pack size of 10 g/25 ml or less and if the declared shelf life of the product is more than 24 months.

** Note 2. This is exempted in case of pack sizes of 30 g/60ml or less.

5. Packing – The material shall be packed in suitable well-closed containers.

6. Levels of Control: - The tests as indicate in Table 1 and at the levels of controls specified therein, shall be carried out on the whole production of the factory which is covered by this scheme and appropriate records and charts maintained in accordance with item 2 above. All the production which conforms to the Indian Standard and covered under the scope of this licence shall be marked with the Standard Mark.

6.1 Control unit – For the purpose of this scheme the total quantity of the Skin Cream mixed at a time shall be considered as one Control Unit.

6.1.1 On the basis of test results, the decision regarding conformity or otherwise of a Control Unit to the given requirements shall be made as follows:

6.1.2 One sample shall be drawn from each of the vessel in which material pertaining to a particular Control Unit is kept for cooling and a composite sample shall be made from the same. The composite sample shall be tested for all the requirements of the specification. If the sample fails in any of the requirements tested, the entire Control Unit represented by the composite sample shall be considered unfit for the purpose of marking.

7.0 Raw Materials – The raw materials used in the manufacture of skin cream shall conform to the requirements described in the relevant Indian Standards where such standards exist and proper records maintained, where the supplier of the raw materials given certificate regarding quality of the product such certificate shall be made available to the Bureau on request.

7.1 Skin cream shall not be manufactured from any carcinogenic ingredients. Product package shall display a list of key ingredients in descending order of quantity of product.

7.1.1 The manufacturer shall ensure that the raw materials used are such that in the concentration in which they would be present in the finished skin creams after interaction with other raw materials used are free from any harmful effects.

7.2 The dyes used in the manufacture of skin creams shall comply with provisions of IS 4707 (Pt 1):2001, subject to the provision of Schedule Q of the Drugs and Cosmetics Act and Rules issued by the Govt. of India.

7.3 Ingredients other than dyes shall comply with the provision of IS 4707(Part 2):2001.
8. **Rejection** - A separate record shall be maintained giving information relating to the rejection of units of Skin Cream, which do not conform to the specification and the method of their disposal. Such material, if packed in containers, shall in no case be stored together with that conforming to the specification.

9. **Samples** - The licensee shall supply, free of charge, the sample or samples required in accordance with the Bureau of Indian Standards (Certification) Regulations from his factory or godown. BIS shall pay for the samples taken by it from the open market.

10. **Replacement** - Whenever a complaint is received soon after the goods with the Standard Mark have been purchased and used, and if there is adequate evidence that the goods have not been misused, defective goods or their components shall be replaced or repaired free of cost by the licensee in case the complaint is proved to be genuine and the warranty period (where applicable) has not expired. The final authority to judge conformity of the product to the Indian Standard shall be with BIS. The firm should have its own complaint investigation systems as per IS 15400.

10.1 In the event of any damages caused by the goods bearing the Standard Mark, or claim being filed by the consumer against BIS Standard Mark and not "conforming to" the relevant Indian Standard, entire liability arising out of such non conforming product shall be of licensee and BIS shall not in any way be responsible in such cases.

11. **Stop Marking** - The marking of the product shall be stopped under intimation to BIS, if at any time, there is some difficulty in maintaining the conformity of the product to the specification or the testing equipment goes out of order. The marking may be resumed as soon as the defects are removed under intimation to BIS.

The marking of the product shall be stopped immediately if directed to do so by BIS for any reason. The marking may then be resumed only after permission by BIS. The information regarding resumption of marking shall also be sent to BIS.

12. **Production Data** - The licensee shall send to BIS as per the enclosed proforma to be authenticated by a Chartered Accountant or by the manufacturer by giving an affidavit/undertaking, a statement of quantity produced, marked and exported by him and the trade value thereof end of each operative year of the licence.
### Test Results and Levels of Control

<table>
<thead>
<tr>
<th>Clause</th>
<th>Requirements</th>
<th>Test Methods</th>
<th>Clause Reference</th>
<th>No. of samples</th>
<th>Frequency</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.1 Description</td>
<td>3.1 IS 6608:2004</td>
<td>One</td>
<td>Each control unit</td>
<td>In case of failure the control unit is rejected.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.2 Ingredients</td>
<td>3.2 -do-</td>
<td>One</td>
<td>Each lot of raw material</td>
<td>Appropriate records or copies of test certificates shall be maintained.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.3 and Table 1 Sr. No. i)</td>
<td>Thermal Stability Annex A -do-</td>
<td>One</td>
<td>Each control unit</td>
<td>In case of failure the control unit is rejected.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.3 and Table 1 Sr. no. ii)</td>
<td>(pH) Annex B -do-</td>
<td>One</td>
<td>-do-</td>
<td>-do-</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.3 and Table 1 Sr. no. iii)</td>
<td>Total fatty substance content Annex C -do-</td>
<td>One</td>
<td>-do-</td>
<td>-do-</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.3. and Table 1 Sr. no. iv)</td>
<td>Total residue Annex D -do-</td>
<td>One</td>
<td>-do-</td>
<td>-do-</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.3. and Table 1 Sr. no. v)</td>
<td>Heavy metal (as Pb) Annex E -do-</td>
<td>One</td>
<td>-do-</td>
<td>-do-</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.3. and Table 1 Sr. no. vi)</td>
<td>Arsenic Annex F -do-</td>
<td>One</td>
<td>-do-</td>
<td>-do-</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.3. and Table 1 Sr. no. vii)</td>
<td>Microbial content IS 14648 -do-</td>
<td>One</td>
<td>Every 5th control unit</td>
<td>In case of failure the control unit is rejected and first three control units should be checked and after confirmation only the frequency may be adopted. In case if there is any change in ingredients formulation the same may be got done before marking.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### PROFORMA 1

<table>
<thead>
<tr>
<th>Batch no.</th>
<th>Date of Mfg.</th>
<th>Quantity</th>
<th>Description</th>
<th>Ingredients</th>
<th>Thermal stability</th>
<th>pH</th>
<th>Total Fatty substance</th>
<th>Total residue</th>
<th>Heavy metal</th>
<th>Microbial test</th>
<th>Dermatologically Safe test</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1)</td>
<td>(2)</td>
<td>(3)</td>
<td>(4)</td>
<td>(5)</td>
<td>(6)</td>
<td>(7)</td>
<td>(8)</td>
<td>(9)</td>
<td>(10)</td>
<td>(11)</td>
<td>(12)</td>
<td>(13)</td>
</tr>
</tbody>
</table>
APPENDIX I
PROFORMA FOR OBTAINING PRODUCTION DETAILS
(Period to be covered by the Report being to )*

Name of Licensee

CM/L No.

Name of Articles(s) IS No.

Grade/type/Size/Variety/Class/ Rating

1.1 Brand/Trade/Name(s) of BIS Certification Marked Products

2. Total production of the article(s) licensed for certification marking

2.1 Total production of the article(s) conforming to Indian Standard

3. Production covered with BIS Certification Mark and its approximate value
   a) Quantity
   b) Value Rs.

3.1 Brand Name used on production covered under BIS Certification Mark

3.2 Calculation of marking fee on Unit-rate basis: Marking Fee per unit
   a) Unit
   b) Quantity covered with BIS Certification Mark
   -
   *Information to be filled up by BO before forwarding to the licensee.

Note: In case a clause is not applicable, suitable remarks may be given against it.

c) Marking fee rounded off in whole rupees as obtained by applying unit rates given in (a) on quantity given in (b)

4. Quantity not covered with BIS Certification Mark. If any, and the reasons for such non-coverage

4.1 Brand Name under which non certified goods were sold

5. Quantity Exported with BIS Standard Mark and its value
5.1 Brand Name under which BIS Certified goods are exported

6. Authentication by Chartered Accountant
Subject: Implementation of revised Indian Standard Specification for Skin Creams as per IS 6608:2004 and approval of revised STI.

Indian Standard Specification for Skin Creams as per IS 6608:1978 has been revised as Skin Creams IS 6608:2004. In this revision, the main changes are as follows:

In order to allow new innovations in skin creams, requirement limit of total fatty substance content has been lowered. The cosmetic industry has successfully produced acceptable creams with lesser content of fatty matter making it less sticky and oily on skin. Skin creams should not be the cause of bacteriological and fungal contamination. A requirement limit for microbial content has been specified, while requirement of pH has been modified. Important marking requirements for best use before, list of key ingredients on containers and ECO Mark certification have also been incorporated.

As per Buyer’s Guide, only one licence is in operation which is under ABO. ABO was requested to prepare draft STI of the revised version along with the discussion with the licensee. ABO has sent draft STI vide their note reference MDA/IS 6608/Policy/7508778 dated 31.10.2006.

Accordingly, STI has been revised as DOC: STI/6608/3, Dec 2006. In order to implement revised standard and revised Scheme of Testing and Inspection, following procedure shall be adopted:

For existing licensee:

1. Concerned BO to verify the manufacturing capability and availability of testing equipments as per revised specification with the licensees and obtain the declaration on CMD/PF 305 and 306. Factory testing/independent testing depending upon nature of tests shall be carried out during routine periodic inspection at the earliest possible for all the requirements to ensure the conformity of the product to the revised standard.
2. Endorsement in the licence as per revised standard shall be made after obtaining the following documents from licensees.
   a) Declaration regarding manufacturing capability and availability of testing equipment as per revised specification on CMD/PF 305 and 306.
   b) Acceptance of revised of STI.
   c) Test report indicating conformity of the product to the revised specification.
3. Stoppage of marking shall be imposed in case sample fails in factory/independent testing as per the revised version at the time of verification on the routine periodic inspection and further actions are to be taken as per Operation Certification Manual.
4. Action shall be taken as per OM-2004, if the licensee fails to submit the acceptance of STI in stipulated time.

For Applicants:

1. All new applications may be recorded and processed as per IS 6608:2004.
2. In case applicant sample is yet to be tested by Lab, necessary action may be taken immediately by BO for considering the case as per IS 6608:2004 after consulting the applicant.
3. New licence shall be granted during this period as per IS 6608:1978. ROs/BOs shall ensure that new licensee shall implement the revised standard and STI within the stipulated period.


All RO’s/BO’s are requested to take appropriate necessary action.

STI is already available on BIS intranet site and can be downloaded.

(N.K. Bansal)
JD (CMD II)

Sc.F&H(CMD-II)

Circulated to all RO’s/BO’s, CMD-I

Cc: PCD – with a request a gazette it w.e.f. 31 January 2007.