MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 15th December, 2020

G.S.R. 763(E).—Whereas a draft of the Cosmetics Rules, 2018, was published, with a view to codify separately and to update the rules relating to cosmetics,by the Central Government in exercise of the powers conferred by section 12 and section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), *vide* notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health and Family Welfare) number G.S.R. 1153(E), dated the 29thNovember, 2018, in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), inviting objections and suggestions from persons likely to be affected thereby, before the expiry of a period of forty-five days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas copies of the Gazette were made available to the public on 30thNovember, 2018;

And whereas, objections and suggestions received from the public on the said rules have been considered by the Central Government;

Now, therefore, in exercise of the powers conferred under section 12 and section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules, namely:–

CHAPTER I

PRELIMINARY

1. **Short title.**– (1) These rules may be called the Cosmetics Rules, 2020.

   (2) They shall come into force on the date of their publication in the Official Gazette.

2. **Application**.- These rules shall be applicable to the cosmetic as defined in clause (aaa) of section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940).

3. **Definitions.-** In these rules, unless the context otherwise requires,-

   (a) "Act" means the Drugs and Cosmetics Act, 1940 (23 of 1940);

   (b) "Actual manufacturer" in relation to import of cosmetics, means a person who manufactures cosmetics at his own manufacturing site in a country other than India approved by National Regulatory Authority or any authorised competent authority in that country for that purpose, by whatever name called.

   Explanation.– for the purpose of this clause, person includes a company or a unit or a body corporate or any other establishment.

   (c) "Appendix" means the appendix appended to these rules;

   (d) "Authorised agent" means a person in India authorised by the manufacturer. The authorised agent shall be responsible for the business activities of the manufacturer in India including compliance to the provisions of the Act and rules made thereunder.

   Explanation.– For the purpose of this clause, person includes a company or a unit or a body corporate or any other establishment.

   (e) "Bureau of Indian Standards" means the Bureau of Indian Standards established under section 3 of the Bureau of Indian Standards Act, 2016 (11 of 2016).

   (f) "Central Licensing Authority" means the Drugs Controller General of India, appointed by the Central Government.

   (g) "Change in the constitution of a licensee" means in relation to,-

   (i) a firm, a change from proprietorship to partnership including Limited Liability Partnership or vice versa;

(ii) a company,–

(A) its conversion from a private to a public company, or from a public to a private company; or

(B) any change in the ownership of shares of more than fifty per cent. of the voting capital in the body corporate or in case of a body corporate not having a share capital, any change in its membership; and where the managing agent, being a body corporate is a subsidiary of another body corporate, includes a change in the constitution of that other body corporate within the meaning of this clause;

(h) "Director" means the Director of the Central Cosmetics Laboratory appointed by the Central Government under sub-rule 3 of rule 11;

(i) "Form" means a Form set out in Appendix to these rules;

(j) "Government Analyst" means, a Government Analyst appointed by the Central Government or the State Government under section 20 of the Act;

(k) "Import registration certificate" means a certificate issued under rule 13 by the Central Licensing Authority for registration of cosmetics manufactured for import into and use in India.

(l) "Inspector" means and includes an Inspector appointed by the Central Government or a State Government respectively under section 21 of the Act;

(m) "Laboratory" means the Central Cosmetics Laboratory established or notified for carrying out analysis or test of cosmetics by the Central Government under rule 11;

(n) "Legal manufacturer or brand owner" in relation to import of cosmetics, means a person, who authorise the other manufacturer from India or overseas countries for the manufacture of cosmetics, by way of an authorization referred under rule 12.

Explanation.– For the purpose of this clause, person includes a company or a unit or a body corporate or any other establishment.

(o) "Licence" means a licence granted by the State Licensing Authority under rule 25;

(p) "Loan licence" means a licence granted by the State Licensing Authority under rule 25, for manufacturing a cosmetic, to a person who intends to utilize the manufacturing site of another licensee for manufacturing the cosmetic manufactured by the licensee at that site;

(q) "Manufacturer" in relation to import of cosmetics means the actual manufacturer or the legal manufacturer.

(r) "New cosmetic" means a cosmetic which contains a novel ingredient which has not been used anywhere in the world or is not recognised for use in cosmetics in any National or International literature.

(s) "Schedule" means a Schedule appended to these rules;

(t) State Government in relation to a Union Territory means the Administrator thereof;

(u) "State Licensing Authority" means the state drugs controller by whatever name called and authorised by the Government of a State or a Union territory, as the case may be, to perform the duties of Licensing Authority under these rules in the State or Union territory and includes any person to whom powers of the Licensing Authority may be delegated by the Government of the State or Union territory;

(v) "Subsidiary" means an entity in India owned by the manufacturer.

(w) "Use before" or "date of expiry" means the date recorded on the container, label or wrapper as the date upto which the cosmetic shall retain its characteristics as per standards at proposed storage condition stated on label;

(x) The words and expressions used in these rules and not defined herein but defined in the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Drugs Rules, 1945 shall have the same meaning as assigned to them in that Act and rules respectively.

CHAPTER II

AUTHORITIES, OFFICERS AND LABORATORY

4. **Licensing Authorities**.– (1) The Central Licensing Authority shall be the competent authority for enforcement of these rules in matters relating to,-

(i) import of all categories of cosmetics;

(ii) co-ordination with the State Licensing Authorities.

(2) The state drugs controller, by whatever name called, shall be the State Licensing Authority and the competent authority for enforcement of these rules in matters relating to,–

(i) manufacture for sale or distribution of all categories of cosmetics;

(ii) sale, stock, exhibit or offer for sale or distribution of all categories of cosmetics.

(iii) grant of approval to the laboratory which applies for carrying out tests on cosmetics and their raw materials under Chapter VIII.

5. **Delegation of powers of Licensing Authorities**.– (1) The Central Licensing Authority, may with the prior approval of the Central Government, by an order in writing, delegate all or any of its powers to any other officer of the Central Drugs Standard Control Organisation not below the rank of Assistant Drugs Controller.

(2) The officer to whom the powers have been delegated under sub-rule (1) shall exercise the powers of the Central Licensing Authority under its name and seal.

(3) The State Licensing Authority may, with the prior approval of the State Government, by an order in writing, delegate all or any of its powers to any officer not below the rank of Assistant Drugs Controller or equivalent under its control.

(4) The officer to whom the powers have been delegated under sub-rule (3) shall exercise the powers of the State Licensing Authority under its name and seal.

6. **Controlling officer**.– Any officer not below the rank of Assistant Drugs Controller, by whatever name called, shall be the controlling officer to supervise and give instructions to any officer subordinate to such controlling officer to exercise powers and functions under these rules for areas and purposes specified, by an order, of the Drugs Controller General of India or the Drugs Controller, by whatever name called, of the State respective.

7. **Government Analyst**.– The Central Government or a State Government may appoint by notification in the Official Gazette, the Government Analyst for the purpose of these rules as provided in section 20 of the Act and rules made thereunder.

8. **Functions of Government Analyst**.– (1) The Government Analyst shall cause to be analysed or tested such cosmetics as may be sent to him by an Inspector or any person under the provisions of Chapter IV of the Act and shall furnish reports of the results of test or analysis in accordance with these rules within a period of sixty days of the receipt of the sample:

Provided that where it is not possible to test or analyse the sample within the specified period, the Government Analyst shall seek extension of time from the concerned Government giving specific reasons for delay in such testing or analysis.

(2) A Government Analyst shall, from time to time, forward to the Central Licensing Authority, reports giving the result of analytical work and research with a view to their publication at the discretion of the Central Government.

9. **Powers, duties and functions of Inspectors specially Authorised to inspect manufacture and sale of cosmetics**.– (1) Subject to the instructions of the controlling officer, it shall be the duty of an Inspector appointed under section 21 of the Act by the State Government, authorised to inspect the manufacture of cosmetics,–

(i) to inspect not less than once in a three year, all premises licensed to manufacture cosmetics within the area allotted to him to satisfy himself that the conditions of the licence and provisions of the Act and Rules thereunder are being observed;

(ii) to send a detailed report after each inspection to the controlling officer indicating the conditions of the licence and provisions of the Act and rules thereunder which are being observed and the conditions and provisions, if any, which are not being observed;

(iii) to institute prosecution in respect of breach of the Act and Rules thereunder.

(iv) take samples of cosmetics manufactured or imported for sale, or stocked or exhibited for sale in respect of which the inspector has reason to suspect contravention of the provisions of the Act or these rules and send them for test or evaluation;

(v) maintain a record of all inspections undertaken, drawing of samples, seizure of stocks and action taken by inspector in exercise and performance of duties and to furnish copies of such record to the Central Licensing Authority or the state Licensing Authority, as the case may be;

(vi) make such enquiries and inspections as may be necessary to detect the manufacture or sale of cosmetics in contravention of any provision of the Act and these rules;

(vii) investigate any complaint made in writing relating to cosmetic to the inspector or any other senior officer in accordance with the direction of the controlling officer;

(viii) review technical dossier of cosmetic furnished with the application under these rules or any other duties assigned by the Central Licensing Authority or state Licensing Authority, as the case may be, related to these rules:

(2) Without prejudice to the duties and functions assigned to the Inspector appointed by the State Government under sub-rule (1) such duties and function may, as and when directed by Central Licensing Authority or Drugs Controller General of India or controlling officer shall be discharged by the Inspector appointed by the Central Government under section 21 of the Act.

10. Prohibition of disclosure of information.– Except for the purposes of official business or when required by a court of law, an Inspector shall not, without the sanction in writing of his official superior, disclose to any person any information acquired by him during the course of his official duties.

11. Establishment and functions of the Central Cosmetics Laboratory.– (1) The Central Government may, by notification, establish Central Cosmetics Laboratory for the purpose of,-

(a) to analyse or test such samples of cosmetics as may be sent to it under sub- section

(2) of section 11, or under sub-section (4) of section 25 of the Act; or

(b) functioning as an appellate laboratory; or

(c) to carry out any other function as may be specifically assigned to it.

(2) Without prejudice to sub-rule (1), the Central Government may also designate or notify any laboratory under its control and the Director of such laboratory having facility for carrying out test and evaluation of cosmetics as Central Cosmetics Laboratory for the purposes specified in sub-rule (1):

Provided that no Laboratory shall be so designated unless it has been duly accredited by the National Accreditation Body for Testing and Calibration Laboratories.

(3) The Central Cosmetic Laboratory shall be headed by a Director who shall be appointed or designated by the Central Government.

CHAPTER III

IMPORT AND REGISTRATION

12. Import of cosmetics.– (1) No cosmetic shall be imported into India unless the product has been registered in accordance with these rules by the Central Licensing Authority or by any officer to whom such powers may be delegated under sub-rule (1) of rule 5.

(2) An application for registration of a cosmetic product intended to be imported into India shall be made through the online portal of the Central Government in Form COS-1 either by the manufacturer himself or by his authorised agent or the importer in India or by the subsidiary in India authorised by the manufacturer.

(3) An authorisation by the manufacturer to his agent in India shall be duly authenticated either in India before a first class Magistrate or in the country of origin before the authority competent under the laws of that country or by an authority specified in the First Schedule.

(4) The applicant referred to sub-rule (2) above shall furnish along with the application such other information and documents as specified in Part I of the Second Schedule:

Provided also that in the event of application for import of bulk finished formulation ready to fill, the following additional documents shall also required to be furnished:

(i) a valid manufacturing license for the finished formulation of the cosmetic ready to fill in finished form from the State Licensing Authority; and

(ii) details of registered brand owner of the finished product in India;

(5) The application for registration in accordance with sub-rule (2) shall be accompanied by a copy of the receipt of fee having been deposited as specified in Third Schedule.

(6) The fee shall be such for each category of cosmetic along with each manufacturing site with additional fee for each category of cosmetic and variant specified in the Fourth Schedule.

(7) Till such time, the online portal becomes operational for this purpose, offline application in Form COS- 1 may be made either by the manufacturer himself or by his authorised agent or by the importer in India or by the subsidiary in India authorised by the manufacturer for registration of a cosmetic referred to in sub-rule (1).

(8) The applicant shall be liable to pay testing fees directly to the testing Laboratory approved by the Central Government referred in rule 11, for examination, test and analysis of imported cosmetics in respect of cosmetics identified for such examination as specified in the Fifth Schedule.

(9) The applicant shall pay the fee as specified in the Third Schedule in connection with the expenditure to be incurred for inspecting or visiting the manufacturing premises of cosmetics approved in the foreign countries by officers authorised by Central Licensing Authority, as considered necessary.

13. Grant of import registration certificate.– (1) After examination of documents furnished with the application under sub-rule (2) of rule 12 the Central Licensing Authority may, on being satisfied, grant import registration certificate in Form COS- 2 or may reject such application for which reasons shall be recorded in writing within a period of six months from the date of application.

(2) In the event of rejection, the applicant may appeal to the Central Government within a period of forty-five days and that Government, may, after such enquiry into the matter, as considered necessary, pass orders in relation thereto within a period of ninety days from the date of appeal.

(3) In case of a new cosmetic, the applicant shall obtain prior permission in Form COS- 3 as provided in Chapter V from the Central Licensing Authority before registration of import of new cosmetic into India.

(4) A single application may be made and a single registration certificate in Form COS-2 may be issued in respect of import of one or more cosmetics manufactured by the same manufacturer:

Provided that the cosmetics are manufactured at one factory or more than one factory functioning conjointly as a single manufacturing unit for cosmetic intended for registration.

(5) A fee as specified in the Third Schedule shall be paid for a duplicate copy of the registration certificate, if the original is defaced, damaged or lost.

14. Validity of import registration certificate.–(1) A registration certificate granted under rule 13 shall remain valid in perpetuity, subject to payment of registration certificate retention fee as specified in the Third Schedule before completion of the period of five years from the date of its issue, unless, it is suspended or cancelled by the Licensing Authority.

(2) If the licensee fails to pay the required registration certificate retention fee on or before the due date as referred to in sub-rule (1), the registration certificate holder shall, in addition to the registration certificate retention fee, be liable to pay a late fee calculated at the rate of two per cent. of the registration certificate retention fee for every month or part thereof within one hundred and eighty days and in the event of non-payment of such fee during that period, the registration certificate shall be deemed to have been cancelled.

15. Fresh application in case of change in constitution.– (1) In case of change in constitution of a registration holder or overseas manufacturer, after grant of registration under sub-rule (1) of rule 13, an application shall be made under sub-rule (2) of rule 12 for grant of fresh registration within a period of one hundred and eighty days from the date of such change in constitution:

Provided that the existing registration shall be deemed to be valid till such time, fresh registration is issued or application is rejected by the Central Licensing Authority.

(2) In case of any change in respect of labelling or composition or testing of registered product or its specifications, the Central Licensing Authority shall be informed by manufacturer or by the authorised agent or the importer or the subsidiary in India authorised by the manufacturer within fifteen days along with an undertaking that products comply with standards laid down by the Bureau of Indian Standards as referred in the Ninth Schedule.

(3) In case of change in name or address of a registration holder or overseas manufacturer, after grant of registration under sub-rule (1) of rule 13, an application for amendment shall be made in online portal of Central Government for prior approval from the Central Licensing Authority for the said changes in registration certificate within a period of sixty days from the date of such change.

16. Suspension and cancellation of Registration Certificate.– If the manufacturer or authorised agent or importer fails to comply with any of the conditions of the Registration Certificate, the Central Licensing Authority may, after giving him an opportunity to show cause as to why such an order should not be passed, by an order in writing, stating the reasons therefore, suspend or cancel the registration certificate for such period as it thinks fit either wholly or in respect of some of the cosmetics to which it relates:

Provided that a person who is aggrieved by the order passed by the Central Licensing Authority may, within thirty days of the receipt of the order, appeal to the Central Government and that Government may, after such enquiry into the matter as it considers necessary and after giving the said appellant an opportunity of being heard, pass such orders as considered appropriate in the facts and circumstances of the case.

17. Import of cosmetics already registered for import.- (1) A cosmetic manufactured in a foreign site and already registered under rule 13 for import and sale in India, may be imported by any person or entity by making an application in online portal of the Central Government in Form COS-4 with an undertaking as specified in Sixth Schedule.

(2) After examination of documents furnished with the application under sub-rule (1), the Central Licensing Authority may, on being satisfied, subject to the conditions, grant import registration number in Form COS- 4A, or may reject such application for which reasons shall be recorded in writing within a period of six months from the date of application.

(3) An import registration number granted under sub-rule (2) shall remain valid for a period of three years from the date of its issue, unless it is suspended or cancelled.

(4) If the importer fails to comply with any of the conditions of the Import Registration Number issued in Form COS-4A, the Central Licensing Authority may, after giving him an opportunity to show cause as to why such an order should not be passed, by an order in writing, stating the reasons therefore, suspend or cancel the import registration number for such period as it thinks fit.

18. Prohibition of import of certain cosmetic.- (1) No cosmetic, the manufacture, sale or distribution of which is prohibited in the country of origin, shall be imported under the same name or under any other name except for the purpose of examination, test or analysis.

(2) No cosmetics shall be imported unless the "Use Before or use by'' date shown on the label, wrapper or container of the cosmetic is later than six months from the date of import.

(3) No cosmetic containing hexachlorophene shall be imported.

(4) No cosmetic that has been tested on animals after the 12th day of November 2014 shall be imported into the country.

19. Documents to be supplied to the Commissioner of Customs.– Before any cosmetics are imported, a declaration signed by manufacturer or on behalf of the manufacturer or by importer or on behalf of the importer that the cosmetics comply with the provisions of Chapter III of the Act, and the rules made thereunder, shall be supplied to the Commissioner of Customs.

20. Procedure for import of cosmetics.– (1) If the officer appointed at the port of entry by the Central Government has reason to believe that any cosmetic contravenes any of the provisions of the Act or the rules made thereunder, he may take sample of the cosmetic from the consignment for inspection.

(2) If on examination of the sample drawn as per sub-rule (1) defects are noticed, the officer shall advise the Commissioner of Customs about further action to be taken.

(3) If the suspected contravention of the provisions of the Act or the rules is such as may have to be determined by test, the officer shall send the sample to the Laboratory established for the purpose for performing such tests and the consignment of the said cosmetic shall be detained till such time, the test report on that sample is received from the Director of the said Laboratory or any other officer of the Laboratory empowered by him in this behalf:

Provided that if the importer gives an undertaking in writing not to dispose of the cosmetic without the consent of the Commissioner of Customs and to return the consignment or such portion thereof as may be required, the Commissioner of Customs may, make over the consignment to the importer.

(4) If the importer who has given an undertaking under proviso to sub-rule (1) is required by the Commissioner of Customs to return the consignment or portion thereof, he shall return the consignment or portion thereof within ten days of receipt of the notice.

(5) If the Director of the Laboratory established for the purpose by the Central Government or any other officer of the laboratory empowered by him in this behalf with the approval of the Central Government, reports to the Commissioner of Customs or to the officer mentioned in sub-rule (1) that the sample of any cosmetic in a consignment contravenes provisions of Chapter III of the Act or rules made thereunder and that the contravention is such that it cannot be remedied by the importer, the Commissioner of Customs shall communicate the report forthwith to the importer who shall within two months of receiving such communication either send back all the cosmetic of that description in the consignment to the country in which it was manufactured or to the country from which it was imported or hand it over to the Central Government which shall cause it to be destroyed:

Provided that the importer may, within thirty days of receipt of the report, make a representation against the report to the Commissioner of Customs who shall forward the representation with a fresh sample of the cosmetic to the Central Licensing Authority, who shall if necessary, after obtaining the report of the Director of the Central Cosmetics Laboratory, pass orders thereon which shall be final.

(6) If the Central Licensing Authority or any other officer empowered by the said authority in this behalf with the approval of the Central Government, reports to the Commissioner of Customs after inspection of the sample of the cosmetic and where necessary, after obtaining a test report thereon, that the sample of the said cosmetic contravenes any provision of the Act or the rules made thereunder and that contravention is such that it can be remedied by the importer, the Commissioner of Customs shall communicate the report forthwith to the importer and permit him to import the cosmetic on his giving an undertaking in writing not to dispose of the cosmetic without the permission of the officer authorised in this behalf by the Central Government.

21. Import of cosmetic for personal use.– Small quantities of cosmetics the import of which is otherwise prohibited under section 10 of the Act, may be imported for personal use subject to the following conditions:–

(i) The cosmetics shall form part of a passenger's baggage and shall be the property of and intended for, the bonafide use of the passenger; and

(ii) The cosmetics shall be declared to the Customs authorities, if they so direct.

22. Import through points of entry.– No cosmetic shall be imported into India except through the points of entry as specified in rule 43A of the Drugs and Cosmetics Rules, 1945.

CHAPTER IV

MANUFACTURE OF COSMETICS FOR SALE OR DISTRIBUTION

23. Application for grant of license or loan license to manufacture cosmetics for sale or for distribution.–(1)Any person who intends to manufacture cosmetics shall make an application for grant of a licence or loan licence to manufacture for sale or for distribution to the state Licensing Authority.

(2) Application under sub-rule (1) shall be made through an identified online portal in Form COS-5 for licence or in Form COS-6 for loan licence accompanied with a fee, as specified in the Third Schedule along with respective documents as specified in Part II of the Second Schedule.

Provided further that till such time the online portal is not operational for this purpose, offline application in Form COS- 5 for licence or in Form COS- 6 for loan licence may be made for manufacturing of cosmetic referred to in sub-rule (2).

(3) In case of a new cosmetic, the applicant shall obtain prior permission in Form COS- 3 as provided in Chapter V from the Central Licensing Authority and no licence to manufacture any cosmetic shall be granted by the State Licensing Authority without such permission.

(4) In addition to the documents specified in part II of the Second Schedule, the applicant shall furnish a self-declaration in Form COS-7 conforming compliance with Good Manufacturing Practices, requirements of premises, plants and equipment for manufacture of cosmetics as specified in the Seventh Schedule.

(5) On receipt of the application under sub-rule (1) accompanied such fee and such documents as provided in sub-rule (2) and (3), for grant of a licence or loan licence, the State Licensing Authority shall grant a licence or loan licence within a period of forty-five days from the date application after scrutiny of application and documents it is of the opinion that requirements of the Act and these rules have been fulfilled:

Provided where the State Licensing Authority considers that the applicant has not fulfilled the requirement of the Act and these rules, the same shall be conveyed to the applicant within forty-five days from the date the application has been made.

(6) On receipt of the licence or loan licence referred in sub-rule (5), the applicant may manufacture cosmetics for sale or distribution, after uploading a copy of such licence on the website of the Central Drugs Standard Control Organisation.

(7) The State Licensing Authority within thirty days from the date of grant of licence or loan licence, shall inspect or authorise any other officer subordinate to such authority to inspect the site and verify the information given in self-certificate in Form COS-7 referred in sub-rule (4).

(8) Where the State Licensing Authority or any other officer authorised to do so fails to inspect and verify the site of the licence or loan licence within the period referred in sub-rule(7), the licence or loan licence shall be deemed to be valid for all purposes.

(9) In case, it is found at the time of inspection that the self-certificate contained any false information, the Licensing Authority may, after giving the licensee an opportunity to show cause, the licence or loan licence may be cancelled:

Provided that where the State Licensing Authority is of the view that deficiencies can be removed, the said authority may issue the directions to the holder of the licence or loan licence to stop the manufacturing till the requirements are complied with, and when it is complied with, it shall be informed to Licensing Authority by the applicant and the Licensing Authority if satisfied may issue the directions to restart the manufacturing within five working days of receipt of such compliance.

(10) In case, the original license or loan licence is defaced, damaged or lost; a duplicate copy of the licence or loan licence may be requested for from the State Licensing Authority on payment of fee as specified in the Third Schedule.

24. Manufacture at more than one premises.– If cosmetics are manufactured at more than one premises, a separate application for each of such premises shall be made and a separate license obtained for each such premises.

25. Form of license or loan licence to manufacture cosmetics for sale or distribution.– A license or loan licence to manufacture cosmetics for sale or distribution shall be granted in Form COS- 8 and loan licence in Form COS- 9.

26. Conditions of license or loan licence for manufacture of cosmetics.– A license in Form COS- 8 shall be subject to the conditions stated therein and to the following other conditions, namely:–

(a) Manufacture of cosmetics shall be conducted under the direction and personal supervision of competent technical staff consisting at least one person who is a whole-time employee and who possesses any one of the following qualifications–

(i) holds a Diploma in Pharmacy approved by the Pharmacy Council of India under the Pharmacy Act, 1948 (8 of 1948), or

(ii) is registered under the Pharmacy Act, 1948 (8 of 1948), or

(iii) has passed the Intermediate Examination with Chemistry as one of the subjects or an examination recognised by the Licensing Authority as equivalent to it.

(iv) holds a bachelor degree in Cosmetic Technology from recognized university.

(b) The factory premises shall comply with the requirements and conditions specified in the Seventh Schedule.

(c) The manufacturer shall either–

(i) provide and maintain adequate staff, premises and laboratory equipment for testing the cosmetics manufactured, and the raw materials used for manufacture in such cosmetics, or

(ii) make arrangements with a laboratory approved by the Central Licensing Authority under Chapter VIII of the rules and accredited by National Accreditation Board for Testing & Calibration Laboratories (NABL) for carrying out such tests.

(d) The applicant shall maintain documentary evidence for the following–

(i) documents in respect of the ownership or occupation on rental or other basis of the premises, specified in the application for license or in the license granted,

(ii) constitution of the firm, or

(iii) any other document that may be required for verifying the correctness of the statements made by the applicant or the licensee, while applying for or after obtaining the license as the case may be.

(e) The licensee shall comply with the provisions of the Act and the rules made thereunder and with such further requirements, if any, as may be specified in any rules to be made hereafter under Chapter IV of the Act.

(f) The licensee shall keep record of the details of each batch of cosmetic manufactured by him and of the raw materials used therein as per particulars specified in the Eighth Schedule and such records shall be retained for a period of three years after the date of expiry of the batch.

(g) A license in Form COS- 9 shall be deemed to have been cancelled or suspended, if the license issued, in Form COS- 8, in respect of manufacturing facilities is cancelled or suspended.

(h) The licensee shall test each batch or lot of the raw materials used for manufacturing the cosmetics and also each batch of the final product and shall maintain records or registers showing the particulars in respect of such tests. The records or registers shall be retained for a period of three years from the date of manufacture.

(i) The licensee shall allow an Inspector appointed under the Act to enter with or without prior notice any premises where the manufacture of a substance in respect of which the license is issued, is carried on, to inspect the premises and to take samples of the manufactured products for which a receipt shall be issued in Form COS- 10.

(j) The licensee shall allow an Inspector to inspect all registers and records maintained under these rules and shall supply to the Inspector such information as he may required for the purpose of ascertaining whether the provisions of the Act and rules made thereunder have been complied with.

(k) The licensee shall maintain an Inspection book in Form COS-11 to enable an Inspector to record his impression and the defects noticed;

The manufacturer shall inform the Licensing Authority within thirty days, in writing, in the event of change in labelling or composition or testing, or specification or in documentation of any of the cosmetic pertaining to this license along with an undertaking that the products comply with standards laid down bythe Bureau of Indian Standards as referred in the Ninth Schedule.

(l) The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the license. Where any change in the constitution of the firm takes place, the current license shall be deemed to be valid for a maximum period of six months from the date on which the change takes place unless, in the meantime, a fresh license has been taken from the Licensing Authority in the name of the firm with the changed constitution.

(m) In case of change in name or address of a manufacturer, after grant of licence or loan licence under sub-rule (5) of rule 23, an application for amendment shall be made to state Government for prior approval from Licensing authorities for the said changes in manufacturing license within a period of sixty days from the date of such change.

Provided that clauses (c) and (d) shall not apply to the manufacture of soap and the procedure for testing of raw materials and the records to be maintained by a manufacturer of soap shall be such as are approved by the "Licensing Authority".

27. Grant or refusal of license.—(1) If the Licensing Authority, after such further enquiry, if any, as he may consider necessary, is satisfied that the requirements of the rules under the Act have been complied with and that the conditions of the license, loan licence and the rules under the Act shall be observed, he shall grant a license in Form COS-8 or Form COS-9 as the case may be.

(2) If the Licensing Authority is not so satisfied, he shall reject the application and shall inform the applicant of the reasons for such rejection and of the conditions which must be satisfied before a license can be granted or renewed and shall supply the applicant with a copy of inspection report.

28. Further application for licence or loan licence after rejection. —If within a period of six months from the rejection of an application for a licence or loan licence, the applicant informs the State Licensing Authority that the requirements laid down in the Act and these rules have been fulfilled and deposits a fee as specified in the Third Schedule, the State Licensing Authority may, after causing further scrutiny, and on being satisfied that the requirements for grant of licence or loan licence have been complied with , issue a licence in Form COS-8 or Form COS- 9.

29. Appeal to the State Government. —Any person who is aggrieved by the order passed by the Licensing Authority refusing to grant a license under this Chapter may within ninety days from the date of receipt of such order, appeal to the State Government and the State Government may, after such enquiry as considered necessary, and after giving the said person an opportunity for representing the case, pass such order as it thinks fit.

30. Validity of licence.– (1) A licence or loan licence issued in Form COS- 8 or Form COS- 9 shall remain valid in perpetuity, subject to payment of licence or loan licence retention fee as specified in the Third Schedule before completion of the period of five years from the date of its issue, unless, it is suspended or cancelled by the State Licensing Authority.

(2) If the licensee fails to pay the required licence or loan licence retention fee on or before the due date as referred to in sub-rule (1), the licence or loan licence holder shall, in addition to the licence or loan licence retention fee, be liable to pay a late fee calculated at the rate of two per cent.of the licence or loan licence retention fee for every month or part thereof within one hundred and eighty days and in the event of non-payment of such fee during that period, the licence shall be deemed to have been cancelled.

31. Inspection for verification of compliance.–(1) The premises licensed for manufacturing cosmetics shall be inspected by Inspector appointed by the Central Government and State Government to verify the compliance with the conditions of licence and the provisions of the Act and these rules, not less than once in three years or as needed as per risk based approach.

(2) The inspectors appointed by the Central Government shall, when so required by the controlling officer or the Central Licensing Authority, carry out special inspection of the identified manufacturing facilities for ensuring compliance with the provisions of this Act and Rules thereunder.

CHAPTER V

PERMISSION FOR IMPORT OR MANUFACTURE OF NEW COSMETIC

32. Permission for import or manufacture of new cosmetic.–(1) Any person who intends to import or manufacture a new cosmetic, shall apply to the Central Licensing Authority in Form COS- 12 along with requisite fee and the data on safety and effectiveness of cosmetic.

(2) If the Central Licensing Authority, after being satisfied that the cosmetic if permitted to be manufactured or imported shall be safe and effective for use in the country, may issue a prior permission in Form COS-3, subject to the condition specified therein.

(3) The prior permission obtained in Form COS-3 shall be furnished along with the application for import under Chapter III or manufacture under Chapter IV of such new cosmetics.

(4) Methods of test or analysis to be employed for safety evaluation of new cosmetic shall be complied by manufacturer as specified in the IS 4011 : 2018 methods of test for safety evaluation of cosmetics, published by the Bureau of Indian Standards as amended from time to time.

CHAPTER VI

LABELLING, PACKING AND STANDARDS FOR SALE OR DISTRIBUTION OF COSMETICS

33. Prohibition of sale or distribution.– Subject to the other provisions of the act and these rules, no person shall sell or distribute any cosmetic unless the cosmetic, if of Indian origin, is manufactured by a licensed manufacturer and labelled and packed in accordance with these rules.

34. Manner of labelling.– (1) Subject to other provisions of the rules, a cosmetic shall carry on both the inner and outer labels:

(a) the name of the cosmetics,

(b) the name of the manufacturer and complete address of the premises of the manufacturer where the cosmetic has been manufactured. If the product has not been manufactured in a factory owned by the manufacturer, the name and address of the actual manufacturer or the name of the country where it has actually been manufactured as “Made in ..... (name of country)" should be there on the label:

Provided that if the cosmetic is contained in a very small size container as 30gm or less if the cosmetics are in solid or semi-solid state and 60 ml or less if the cosmetics is in liquid state, where the address of the manufacturer cannot be given, the name of the manufacturer and his principal place of manufacture shall be given along with pin code.

(c) use before or date of expiry(month and year) or use by or expiry date or expiry XX months from manufactured or date of manufacturing or expiry date.

(2) (a) A distinctive batch number, that is to say, the number by reference to which details of manufacture of the particular batch from which the substance in the container is taken are recorded and are available for inspection, the figures representing the batch number being preceded by the letter "B" or the words "Batch No." or "B. No." or "Batch" or "Lot No." or "Lot" shall carry on the inner or outer labels:

Provided that this clause shall not apply to any cosmetic containing 10 grams or less if the cosmetic is in solid or semi-solid state and 25 milliliters or less if the cosmetic is in a liquid state:

Provided further that in the case of soaps, instead of the batch number, the month and year of manufacture of soap shall be given on the label.

(b) Manufacturing licence number, the number being preceded by the letter 'M' or "M. L. No" or "Mfg. Lic. No." shall carry on the inner or outer labels,

Provided that in case of imported products, if such provision is not mandatory in country of origin, such cosmetics may be allowed without mentioning manufacturing license number, subject to fulfillment of other import regulations.

(3) The outer label of the cosmetics shall carry a declaration of the net contents expressed in terms of weight for solids, fluid measure for liquids, fluid measure or weight for semi-solids, combined with numerical count if the content is sub-divided:

Provided that this statement need not appear in case of a package of perfume, toilet water or the like, the net content of which does not exceed 60 ml or any package of solid or semi-solid cosmetic the net content of which does not exceed 30 grams.

(4) In case of cosmetics; where a hazard exists, every inner label shall clearly indicate

(a) adequate directions for safe use,

(b) any warning, caution or special direction required to be observed by the consumer,

(c) a statement indicating the names and quantities of ingredients that are hazardous or poisonous.

(5) In the case of imported cosmetics to be marketed in India, import registration certificate number shall be mentioned on the label of unit pack preceded by letter "RC" or "RC No" or "Reg. Cert. No" along with name and address of the importer;

(6) Where a package of a cosmetic has only one label, such label shall contain all the information required to be shown on both the inner and the outer labels, under these rules.

(7) In all cases, the list of ingredients, present in concentration of more than one percent. shall be listed in the descending order of weight or volume at the time they are added, followed by those in concentration of less than or equal to one percent, in any order, and preceded by the words 'INGREDIENTS'.

Provided that this statement need not appear for packs of less than or equal to 60 ml of liquid and 30 gm of solid and semi-solids.

(8) The cosmetic shall comply with labelling requirement, if any, specified in the relevant Indian standard as laid down by the 'Bureau of Indian Standards' for the cosmetics covered under the Ninth Schedule.

(9) No cosmetic shall be imported unless it is packed and labelled in conformity with these rules and the label of imported cosmetics shall bear registration certificate number of the product and the name and address of the registration certificate holder for marketing the said product in India:

Provided further that in cases where the imported cosmetics require India specific labelling, the same shall be allowed to be stickered on the unit pack at the bonded warehouses.

(10) In case, the cosmetic is meant for export then the labels on packages or container of cosmetic shall meet the specific requirements of law of the country to which the cosmetic is to be exported, but the following particulars shall appear in a conspicuous manner on the label of the inner most pack of the

cosmetic in which the cosmetic is packed and every other outer covering in which the container is packed:–

(a) name of the cosmetic;

(b) the distinctive batch number or lot number or serial number preceded by the word "Lot No." or "Lot" or "Batch No." or "B. No." or "Serial No." or "B";

(c) use before or date of expiry, if any;

(d) the name and address of manufacturer and address of actual premises where the cosmetic has been manufactured;

(e) licence number preceded by letters "Licence No. or Lic. No.";

(f) internationally recognised symbols *in lieu* of text, wherever required:

Provided that where a cosmetic is required by the consignee to be not labelled with the name and address of the manufacturer, the labels on packages or containers shall bear a code number as approved by the state Licensing Authority.

35. Prohibition against altering inscription on containers, labels or wrappers of cosmetic.– No person shall alter, obliterate or deface any inscription or mark made or recorded by the manufacturer on the container, label or wrapper of any cosmetic:

Provided that nothing in this rule shall apply to any alteration, inscription or mark made on the container, label or wrapper of any cosmetic at the instance or direction or with the permission of the Central Licensing Authority.

36. Prohibition against false or misleading claims.– No cosmetic may purport or claim to purport or convey any idea which is false or misleading to the intending user.

37. Labelling of hair dyes containing dyes, colours and pigments. – Hair dyes containing Para-phenylenediamine or other dyes, colours and pigments shall be labelled with the following legend in English and local languages and these shall appear on both the inner and the outer labels:

"Caution**.**– This product contains ingredients which may cause skin irritation in certain cases and so a preliminary test according to the accompanying directions should first be made. This product should not be used for dyeing the eyelashes or eyebrows; as such a use may cause blindness."

Each package shall also contain instructions in English and local languages on the following lines for carrying out the test:

"This preparation may cause serious inflammation of the skin in some cases and so a preliminary test should always be carried out to determine whether or not special sensitivity exists. To make the test, cleanse a small area of skin behind the ear or upon the inner surface of the forearm, using either soap and water or alcohol. Apply a small quantity of the hair dye as prepared for use to the area and allow it to dry. After twenty-four hours, wash the area gently with soap and water. If no irritation or inflammation is apparent, it may be assumed that no hypersensitivity to the dye exists. The test should, however, be carried out before each and every application. This preparation should on no account be used for dyeing eyebrows or eyelashes as severe inflammation of the eye or even blindness may result."

38. Special provisions relating to toothpaste containing fluoride.–

(i) Fluoride content in toothpaste shall not be more than 1000 ppm and the content of fluoride in terms of ppm shall be mentioned on the tube and carton.

(ii) Date of expiry should be mentioned on tube and carton.

39. Standards of cosmetics.–(1) No cosmetic shall be imported or manufactured unless it complies with the specifications prescribed under the Ninth Schedule or any other standards of quality and safety, applicable to it, and other provisions under the rules. In case, the cosmetic is not included under the Ninth Schedule, it shall meet the requirements under these rules and specifications and standards applicable to it in the country of origin.

(2) Raw materials specified in ANNEX A of the Indian Standard IS: 4707 Part 2, as amended from time to time, shall not be added in the cosmetic product.

(3) No Cosmetic shall be imported or manufactured which contains Dyes, Colours and Pigments other than the one specified by the Bureau of Indian Standards (IS: 4707 Part 1 or IS: 4707 Part 2, as amended) and included the Tenth Schedule.

The permitted Synthetic Organic colours and Natural Organic Colours used in the Cosmetic shall not contain more than:–

(i) 2 parts per million of Arsenic calculated as Arsenic Trioxide.

(ii) 20 parts per million of lead calculated as lead.

(iii) 100 parts per million of Heavy Metals other than lead calculated as the total of the respective metals.

(4) No cosmetic containing hexachlorophene shall be manufactured:

Provided that in case of soaps, hexachlorophene may be used in concentrations not exceeding one per cent weight by weight:

Provided further that the following cautionary note shall be printed and shall appear in a conspicuous manner on the wrapper of package of each soap, namely. "Contains hexachlorophene - not to be used on babies".

(5) Cosmetics imported or manufactured in the country shall contain mercury in the following proportions, namely,–

(a) in cosmetics intended for use only in the area of eye, the level of mercury not exceeding seventy parts per million (0.007 per cent.) of mercury, calculated as the metal, as a preservative;

(b) in other finished cosmetic products, unintentional mercury shall not exceed one part per million (1 ppm).".

(6) The use of lead and arsenic compounds for the purpose of colouring cosmetics is prohibited.

(7) No person shall use any animal for testing of cosmetics.

CHAPTER VII

PROCEDURE OF SAMPLING FOR TEST OR ANALYSIS, SEIZURE AND REPORT

40. Testing of Cosmetic from a purchaser.– An application from a purchaser for test or analysis of a cosmetic under section 26 of the Act shall be made to the Government Analyst in Form COS- 13 and the report of the test or analysis of the cosmetics made on such application shall be supplied to the applicant in Form COS- 14.

41. Procedure for sampling.– The Inspector while exercising powers under section 22 of the Act shall follow the procedure provided in section 23 of the said Act.

42. Forms of receipts for seized cosmetic, record register, document or any other material object.– A receipt for the stock of any cosmetic or for any record, register, document or any other material object seized by him under clause (c) or clause (cc) of sub-section (1) of section 22 of the Act shall be given in Form COS-15.

43. Manner of certifying copies of seized documents.– The Inspector shall return the documents, seized by him under clause (cc) or produced before him under clause (cca), of sub-section (1) of section 22 of the Act within a period of twenty days of the date of such seizure or production to the person from whom they have been seized or as the case may be, the person who produced them, after copies thereof or extracts therefrom have been signed by the concerned Inspector and the person from whom they were seized or as the case may be, who produced such records.

44. Form of intimation of purpose of taking samples.—(1) When an Inspector takes a sample of a cosmetic for the purpose of test or analysis, he shall intimate such purpose in writing in Form COS- 10 to the person from whom he takes the sample.

(2) In cases, where the fair prices tendered is refused by the person from whom sample has been taken, the Inspector shall record the fact in the receipt in Form COS-16.

45. Procedure for dispatch of sample to Government Analyst.— (1) The portion of the sample or the container sent by an Inspector to the Government Analyst for test or analysis under sub-section (4) of section 23 of the Act shall be sent by registered post or by hand in a sealed packet, enclosed together with a memorandum in Form COS-17.

(2) A copy of the memorandum and a specimen impression of the seal used to seal the packet shall be sent to the Government Analyst separately by registered post or by hand.

46. Form of order not to dispose of stock.— An order in writing by an Inspector under clause (c) of section 22 of the Act requiring a person not to dispose of any stock in his possession shall be in Form COS- 18.

47. Prohibition of sale.— No person in possession of a cosmetic in respect of which an Inspector has made an order under clause *(c)* of sub-section *(*1*)* of section 22 of the Act shall, in contravention of that order, sell or otherwise dispose of any stock of such cosmetic.

48. Procedure on receipt of sample.— On receipt of a package from an Inspector containing a sample for test or analysis, the Government Analyst shall compare the seals on the packet or on the portion of sample or container with the specimen impression received separately and shall note the condition of the seals on the packet or on portion of sample or container. After the test or analysis has been completed, he shall forthwith supply to the Inspector a report in triplicate of the result of the test or analysis in Form COS- 19, together with full protocols of the tests or analysis applied.

Explanation.— It shall be deemed to be full and sufficient compliance of the requirement of the rule in respect of the supply of the "protocol of the tests or analysis applied", if—

(1) for the category of cosmetics for which standards specified in the Ninth Schedule are applicable and followed, a reference to the specific tests or analysis carried out as per standards stipulated therein is given in the report.

(2) For those cosmetics for which methods of test are not available and have been evolved by the Government Analyst, a description of tests applied is given in the report.

49. Dispatch of samples for test or analysis by order of court.— (1) Samples for test or analysis under sub-section (4) of section 25 of the Act shall be sent by registered post or by courier or delivered in person in a sealed packet, enclosed, together with a memorandum in Form COS- 20, with the outer cover being addressed to the Director.

(2) The packet as well as the outer cover shall be marked with a distinguishing number.

(3) A copy of the memorandum in Form COS- 20 and a specimen impression of the seal used to seal the packet shall be sent separately by registered post or courier to the Director.

50. Recording of condition of seals.— On receipt of the packet, it shall be opened by an officer authorised in writing in that behalf by the Director who shall record the condition of the seal on the packet.

51. Report of result of test or analysis.— After test or analysis, the result of the test or analysis, together with full protocols of the tests applied, shall be supplied immediately after completion of such tests or analysis to the sender in Form COS- 21.

52. Issuance of certificates.— Certificates issued under these Rules by the Laboratory shall be signed by the Director or by an officer authorised by the Central Government by Notification in the Official Gazette to sign such certificates.

53. Confiscation of cosmetics, implements, machinery etc.– (1) Where any person has been convicted for contravening any of the provisions of Chapter IV of the Act or any Rule made thereunder, the stock of the cosmetics in respect of which the contravention had been made, shall be liable to confiscation.

(2) Where any person has been convicted for manufacturing of any cosmetic deemed to be misbranded under clause (a), clause (b) or clause (c) of section 17C of the Act, or adulterated cosmetic under section 17E of the Act, or for manufacture for sale of any cosmetic without a valid licence as required under clause (c) of section 18 of the Act, any implements or machinery used in such manufacture and any receptacle, packages, or coverings in which such cosmetic is contained and the animals, vehicles, vessels or other conveyances used in carrying such cosmetics shall also be liable to confiscation.

54. Procedure for disposal of confiscated cosmetics.– (1) The Court shall refer the confiscated cosmetics to the Inspector concerned for report as to whether they are of standard quality or contravene the provisions of the Act or the Rules in any respect.

(2) If the Inspector, on the basis of Government Analyst's report, finds the confiscated cosmetics to be not of standard quality or to contravene any of the provisions of the Act or the Rules thereunder, he shall report to the Court accordingly. The Court shall, thereupon, order destruction of such cosmetics. The destruction shall take place under the supervision of the Inspector in the presence of such authority, if any, as may be specified by the Court.

(3) If the Inspector finds that the confiscated cosmetics are of standard quality and do not contravene the provisions of the Act or the Rules made thereunder, he shall report to the Court accordingly.

CHAPTER VIII

APPROVAL OF LABORATORY FOR CARRYING OUT TESTS ON COSMETICS AND THEIR RAW MATERIALS

55. Application for grant of approval for testing cosmetics.– (1) Any laboratory that meets the requirements and has been accredited by National Accreditation Body for Testing and Calibration Laboratories may grant of approval for carrying out testson cosmetics or the raw materials used in the manufacture thereof on behalf of licensees for manufacture for sale of cosmetics, shall be made in Form COS-22 to the State Licensing Authority of the state where such laboratory is to be established:

Provided that the applicant shall furnish to the State Licensing Authority such additional information as may be required in Form COS-22 in connection with the application.

(2) A separate application shall be made for grant of approval for carrying out tests on additional categories of cosmetics including raw materials used in the manufacture of these cosmetics.

(3) The application under sub-rule (1) shall be accompanied with the fee as specified in the Third Schedule.

(4) In case the original approval is defaced, damaged or lost, the fee for the duplicate copy of the approval shall be as specified in the Third Schedule.

56. Approval for carrying out tests on cosmetics on behalf of licensees.– (1) Approval for carrying out such tests on cosmetics as may be required under the provisions of these rules, on behalf of licensee for manufacture of cosmetics, shall be granted in Form COS-23.

(2) Before approval in Form COS- 23 is granted, the following conditions shall be complied with by the applicant.–

(i) The premises where the tests are to be carried out, shall be well lighted and properly ventilated except where the nature of tests of any cosmetic warrants otherwise. Wherever necessary, the premises shall be air conditioned so as to maintain the accuracy and functioning of laboratory instruments or to enable the performance of special tests such as microbiological tests, etc.

(ii) The applicant shall provide adequate space having regard to the nature and number of samples of cosmetics proposed to be tested:

Provided that the approving authority shall determine from time to time whether the space provided continues to be adequate.

(iii) The applicant shall provide and maintain suitable equipment having regard to the nature and number of samples of cosmetics intended to be tested which shall be adequate in the opinion of the State Licensing Authority.

(iv) The testing of cosmetics, shall be under the active direction of a person whose qualifications and experience are considered adequate in the opinion of the approving authority and who shall be held responsible for the reports of test or analysis issued by the applicant.

(v) The testing of cosmetics, shall be carried out by persons whose qualifications and experience of testing are adequate in the opinion of the State Licensing Authority.

(vi) The applicant shall provide books of standards recognized under the provisions of the Act and the Rules made thereunder and such books of reference as may be required in connection with the testing or analysis of the products for the testing of which approval had been applied for.

57. Inspection before grant of approval.– (1) Before grant of approval in Form COS-23, the State Licensing Authority shall cause the institution at which the testing of cosmetic is proposed to be carried out to be inspected jointly by the Inspector appointed by the Central Government and the State Government under section 21 of the Act, to examine the premises and the equipment intended to be used for testing of cosmetics and inquire into the professional qualifications of the expert staff to be employed.

(2) The report of the inspection shall be rendered within twenty four hours of the inspection and a copy thereof shall be made available to the laboratory inspected.

58. Procedure of approving authority.– (1) If the State Licensing Authority, after such further enquiry, if any, as may be considered necessary, is satisfied that the requirements of the rules made under the Act have been complied with and that the conditions of the approval and the rules made under the Act will be observed, he shall grant an approval in Form COS-23.

(2) If the State Licensing Authority is not so satisfied, the application shall be rejected and the applicant informed of the reasons for such rejection and of the conditions which must be satisfied before an approval could be granted.

59. Further application after rejection.– If within a period of six months from the rejection of an application for approval, the applicant informs the State Licensing Authority that the conditions laid down have been satisfied and deposits inspection fee as specified in the Third Schedule, the State Licensing Authority may, after a further inspection being carried out and on being satisfied that the conditions for grant of approval have been complied with, grant the approval in Form COS-23.

60. Validity of licence.– (1) A licence issued in Form COS- 23 shall remain valid, if the licensee deposits a licence retention fee referred in the Third Schedule before the completion of period of five years from the date of its issue, unless, it is suspended or cancelled by the State Licensing Authority.

(2) The licence retention fee referred in sub-rule (1) shall be equivalent to the fee required for grant of such licence as specified in the Third Schedule.

(3) If the licensee fails to pay licence retention fee on or before the due date as referred to in sub-rule (1), he shall be liable to pay licence retention fee along with a late fee calculated at the rate of two per cent of the licence fee for every month or part there of up to six months, and in the event of non-payment of such fee, the licence shall be deemed to have been cancelled.

61. Inspection for verification of compliance.– The premises licensed in the manner specified in these rules shall be inspected jointly by Inspector appointed by the Central Government and State Government to verify compliance with the conditions of licence and provisions of the Act and these rules at least once in three years based on risk based approach.

62. General conditions after approval.– An approval in Form COS-23, shall be subject to the following general conditions:–

(a) The laboratory that has been approved under this chapter for carrying out tests and analysis shall provide and maintain an adequate staff and adequate premises and equipment as specified in the Eleventh Schedule.

(b) The approved institution shall provide proper facilities for storage so as to preserve the properties of the samples to be tested by it.

(c) The approved institution shall maintain records of tests carried out on all samples of cosmetics and the results thereof together with the protocols of tests showing the readings and calculation in such form as to be available for inspection and such records shall be retained in case of substances for which an expiry date is assigned for a period of two years from the expiry of such date and in case of other substances, for a period of six years.

(d) The approved institution shall allow the Inspector appointed under this Act to enter with or without prior notice the premises where the testing is carried on and to inspect the premises and the equipment used for test and the testing procedures employed. The institution shall allow the Inspectors to inspect the registers and records maintained under these rules and shall supply to such Inspectors such information as they may be required for ascertaining whether the provisions of the Act and Rules thereunder have been observed.

(e) The approved institution shall from time to time report to the State Licensing Authority any changes in the person-in-charge of testing of cosmetics or in the expert staff responsible for testing and any material alteration in the premises or changes in the equipment used for the purposes of testing which have been made since the date of last inspection made on behalf of the State Licensing Authority before grant or renewal of approval.

(f) The approved laboratory shall furnish reports of the results of test or analysis in Form COS-24.

(g) In case any sample of a cosmetic is found on test to be not of standard quality, the approved institution shall furnish to the Central Licensing Authority and the Licensing Authority of the State where the manufacturer or sender of the cosmetic is located with a copy of the test report on the sample with the protocols of tests applied.

(h) The approved laboratory shall comply with the provisions of the Act and Rules thereunder and with any other requirement, if any, specified under Chapter IV of the Act.

(i) The approved institution shall maintain an Inspection Book in Form COS-11to enable the Inspector to record his impression or defects noticed.

63.Withdrawal and suspension of approval.– (1) The State Licensing Authority may, after giving the approved laboratory an opportunity to show cause why such an order should not be passed, by an order in writing, stating the reasons therefore, withdraw an approval granted under this Part or suspend it for such period as considered appropriate either wholly or in respect of some of the categories of cosmetics to which it relates, if in his opinion, the approved institution has failed to comply with any of the conditions of the approval or with any provisions of the Act or Rules made thereunder.

(2) Any approved laboratory whose approval has been suspended or withdrawn, may within three months of the date of the order, appeal to the concerned State Government which shall dispose of the appeal in consultation with a panel of competent persons appointed by it in this behalf and notified in the Official Gazette.

CHAPTER IX

MISCELLANEOUS

64. Exemption of cosmetics.– (1) Cosmetics as may be specified in the Twelfth Schedule shall be exempted from the provisions of Chapter III and Chapter IV of the Act and the rules made thereunder to the extent and subject to the conditions specified in that Schedule.

65. Voluntary recall of cosmetics.– (1) If a manufacturer or authorised agent, as the case may be, considers or has reasons to believe that a cosmetics, which has been imported, manufactured, sold or distributed, is likely to pose risk to the health of a user during its use and therefore may be unsafe, such manufacturer or authorised agent shall immediately initiate procedures to withdraw the cosmetics in question from the market, indicating reasons for its withdrawal and inform the State Licensing Authority or Central Licensing Authority, as the case may be, of the details relating thereto.

(2) A manufacturer or authorised agent, as the case may be, shall immediately inform the State Licensing Authority or Central Licensing Authority, as the case may be, and co-operate with them, if there are reasons to believe that a cosmetic which has been placed in the market, may be unsafe for users.

(3) The manufacturer or importer or authorised agent, as the case may be, shall inform the State Licensing Authority or Central Licensing Authority, as the case may be of the action taken to prevent risk to the user and shall not prevent or discourage any person from cooperating, in accordance with the provisions of the Act and these rules, with the State Licensing Authority or Central Licensing Authority, as the case may be, where this may prevent, reduce or eliminate a risk arising due to use of such cosmetics.

66. Fees for examination of samples.– (1) The fee for test and analysis in respect of samples under sub-section (1) of section 25 of the Act shall as specified in the Fifth Schedule.

(2) The fees to be paid by a person submitting to the Government Analyst under section 26 of the Act for test or analysis of a cosmetic purchased by him shall be those specified in the Fifth Schedule.

67. Mode of payment of fee.– (1) The fees prescribed under these rules, in case of application made to the Central Licensing Authority, shall be paid through challan or by electronic mode, in the Bank of Baroda, Kasturba Gandhi Marg, New Delhi-110001 or any other branch of Bank of Baroda, or any other bank, notified by the Ministry of Health and Family Welfare in the Central Government, to be credited under the Head of Account "0210- Medical and Public Health, 04-Public Health, 104-Fees and Fines.

(2) Where the fee specified is payable to the State Licensing Authority, the same shall be paid through a challan or by electronic mode as may be specified by the State Government concerned.

68. Applicability in case of inconsistency.– If there is any inconsistency between these rules and any other rules made under the Act, the provisions of these rules shall prevail over such other rules.

69. Debarment of applicant.– (1) Whoever himself or, any other person on his behalf, or applicant submits misleading, or fake, or fabricated documents, may, be debarred by Licensing Authority for such period as deemed appropriate in the facts and circumstances of the case after giving an opportunity to show cause as to why such an order should not be made.

(2) Where an applicant is aggrieved by an order made by the Central Licensing Authority under sub-rule (1), such applicant may, within thirty days from the receipt of the order, make an appeal to the Central Government or the State Government, as the case may be, and the Central Government or the State Government, may, after such enquiry as it considers necessary, and after affording an opportunity of being heard, pass such orders in relation thereto as considered appropriate.

70. Digitalisation of Form.– The Forms prescribed under these rules may be suitably modified by the Central Drugs Standard Control Organisation for the purpose of digitalisation and such conversion into digital forms modification shall be deemed legally valid for all purposes.

71. Amendments in the Drugs and Cosmetics Rules, 1945 - The Drugs and Cosmetics Rules, 1945 is amended in the manner as specified in the Thirteenth Schedule.

72. Savings.– (1) Notwithstanding the non-applicability of the Drugs and Cosmetics Rules, 1945, the approvals or permissions or licenses or certificates issued under the provisions of the Act and the said rules in respect of cosmetics prior to commencement of these rules, shall be deemed to be valid for all purpose still its expiry or for a period of eighteen months from the date on these rules are notified, whichever is later, under the corresponding provisions of said rules;

(2) Any things done or any action taken or purported to have been done or taken, including any rule, notification, inspection, order or notice made or issued or any appointment or declaration made or any operation undertaken or any direction given or any proceedings taken or any penalty, punishment, forfeiture or fine imposed under the Drugs and Cosmetics Rules, 1945 shall, be deemed to have been done or taken under the corresponding provisions of these rules and shall always remain valid for all purposes.

First Schedule

[See rule 12(3)]

Authorisation from manufacturer

(To be authenticated in India either by a Magistrate of First Class or by Indian Embassy in the country of origin or by an equivalent authority through apostille)

Authorisation to accompany an application for issuance of import registration certificate

I ……...… working as …… authorised to sign this Authorisation on behalf of manufacturer M/s …… (Full addressor telephone number, e-mail) having manufacturing site at ……..……. (Full address, telephone no., e-mail), hereby delegate the Authorisation to M/s……..……., (full address, with telephone, fax and E-mail address), hereinafter to be known as authorised agent, intends to apply for registration certificate under the provisions of the Cosmetics Rules, 2020 to import into India for the following cosmetics manufactured at below manufacturing site.

Following are the details of cosmetics proposed to be imported (A separate list may be annexed, if required in below given format).

Serial No.	Product or brand of cosmetic	Brand name	Variant name	Pack sizes	Actual manufacturer and its premises-
1.					
2.					

(2) Our authorised agent shall act in the following respects:-

(a) to act as the official representative for obtaining registration certificate for and on behalf of M/s. _____ (Name and complete address of the overseas manufacturer/brand owner) in India.

(b) to submit all necessary documents in the name of _____ (Name and complete address of the overseas manufacturer or brand owner) for the registration certificate of cosmetics manufactured by _____ (manufacturer's name).

(3) I shall comply with all the conditions imposed on the registration certificate and with provisions of the Cosmetics Rules, 2020.

(4) I declare that M/s ……... is carrying on the manufacture of the listed cosmetics at the manufacturing site specified above.

(5) I shall allow the Central Licensing Authority or any person Authorised by it in that behalf to enter and inspect the manufacturing premise and to examine the process, procedure and documents in respect of any manufacturing site or to take sample of listed cosmetics for which the application for registration certificate has been made.

(6) In case of any violation of Drugs and Cosmetics Act, 1940 and Rules thereunder,

The authorised agent shall continue to be responsible even after withdraw of this

Power of Attorney for the cosmetics imported in India.

(7) I do hereby state and declare that all the photocopies or scanned copies in the

application are true copies of the original documents.

(8) I do hereby state and declare that all the documents submitted by the undersigned are true and correct.

Place:

Date:

Signature of the manufacturer

(Name and Designation)

Seal/Stamp

Undertaking from the authorised agent

I ……...…., age……., working as …… at M/s …… (full addressor telephone number, e-mail) agrees to act upon the Authorisation as the Authorised agent on behalf of manufacturer M/s …… (full addressor telephone number, e-mail) having manufacturing site at ……..……. (full address, telephone number, e-mail).

Place:

Date:

Signature of the authorised agent

(Name and Designation)

Seal/Stamp

Second Schedule

[See rules 12(4), 23(2) and 23(4)]

Part-I

Information and undertaking required to be furnished by the manufacturer or his authorised importer or distributor or agent with the application form for import registration certificate.

The format shall be properly filled in for each application in Form COS- 1.

1. Particulars of the manufacturer and manufacturing premises.
   (a) Name and address of the manufacturer and manufacturing premises to be registered along with telephone numbers, Fax numbers and e-mail address.
   (b) Name(s) and address of the Partners or Directors.
   (c) Name and address of the authorized importer or distributor or agent in India, responsible for the business of the manufacturer including name(s) and address of its Partners or Directors.
   (d) A brief profile of the manufacturer's business activity, in domestic as well as global market.

Note: In case the brand owner is a company registered in India, the name and registered office address of the company should be given.

2. Particulars of the cosmetics to be registered under registration certificate.
   (a) Names of cosmetics along with their brands name, category, pack sizes and variants to be registered and meant for import into and use in India.
   (b) Particulars of the manufacturing licenses or registration or product permission or marketing Authorisations or free sale certificate or (if any)under which the cosmetics are being manufactured in the country of origin along with the copy of the licenses or marketing Authorisation or free sale certificate or registration issued by the Regulatory Authority or any other competent authorities or associations of that country.

(c) List of countries where marketing Authorisation or import permission for the said cosmetic has been granted.

3. Chemical information of cosmetics.

(a) Name(s) of ingredients in the nomenclature of standard references, along with percentages contained in the cosmetic.

(b) Specifications and testing method for testing of the cosmetic(s).

(c) Manner of labelling as per the Cosmetics Rules, 2020.

(d) Package insert (if any).

4. Undertaking to declare that.—

(a) I/We shall comply with all the conditions imposed on the registration certificate for the import of cosmetics as required under the provisions of the Cosmetics Rules, 2020.

(b) I/We declare that we are carrying on the manufacture of the cosmetics mentioned in this Schedule, at the premises specified above, and we shall from time to time report any change of premises on which manufacture will be carried on and in cases where manufacture is carried on in more than one factory any change in the distribution of functions between the factories.

(c) I/We shall comply with the provisions of Chapter III of the Cosmetics Rules, 2020.

(d) Every cosmetic manufactured by us for import under the registration certificate into India shall conform to the standards laid down by the Bureau of Indian Standards as referred in the Ninth Schedule.

(e) No cosmetic manufactured by us shall be imported into India which has been tested on animals.

(f) I/We shall inform to Licensing Authority, in case of any change in respect of labelling or composition or testing of registered product or its specifications within thirty days along with an undertaking that products comply with the standards laid down by the Bureau of Indian Standards as referred in the Ninth Schedule.

(g) I/We shall from time to time report for any administrative action taken due to adverse reaction, viz. market withdrawals/regulatory restriction, or cancellation of authorisation and/or "not of standard quality report" of any cosmetic pertaining to the registration certificate declared by any Regulatory Authority of any country where the cosmetic is marketed/sold or distributed. The dispatch and marketing of the cosmetic in such cases shall be stopped and the Licensing Authority shall be informed immediately.

(h) I/We shall comply with such further requirements, if any, as may be specified, by the Government of India, under the Act and the Rules, made thereunder.

(i) I/We shall allow the Licensing Authority or any person authorised by him in that behalf to take samples of the cosmetics for testing if considered necessary by the Licensing Authority.

The information submitted above is true to the best of my/our knowledge and belief.

Place:

Date:

Signature of the manufacturer or his Authorised agent

Name and Designation:

Seal/ Stamp

Second Schedule

Part-II

Information and undertaking required to be furnished by the manufacturer with the application form for grant of manufacturing licence or loan licence:–

(1) (a) Receipt for the fees paid or challan, (the fees are as given in Third Schedule) as the case may be or their attested copies.

(b) Copy of Approved layout plan of the manufacturing area.

(c) Documents viz. rent receipt, purchase documents or its attested copies showing lawful possession of the premises.

(d) List of machinery and equipment.

(e) Documents relating to the constitution of the firm viz. partnership-deed, memorandum and article of association etc.

(f) Full particulars of the competent technical staff employed for manufacturing and testing of cosmetics along with copies of their educational qualifications and experience certificates approval letter as competent staff. The competent technical staff is required to furnish consent letter for full time employment with the applicant firm.

(g) List of Cosmetics along with their composition formula, manner of labelling in triplicate along-with undertaking to be submitted.

(h) Documents relating to the ownership of the brand of cosmetic whether it is registered or under trademark, if any.

(i) Full name of the proprietor or the partners, as the case may be shall be provided in the application. In case of private or public limited concerns, full name of the Directors who sign the application or the Authorised signatory, if any, shall be provided in the application.

(j) Self-certificate of compliance of Good Manufacturing Practices (GMP) for manufacture of cosmetics as specified in Form COS-7.

2) Undertaking to declare that**.**–

(a) I/We shall comply with all the conditions imposed on the license or loan license for the manufacture of cosmetics as required under the provisions of the Cosmetics Rules, 2020.

(b) I/We declare that we are carrying on the manufacture of the cosmetics mentioned in this Schedule, at the premises specified above, and we shall from time to time report any change of premises on which manufacture will be carried on.

(c) I/We shall comply with the provisions of Chapter IV of the Cosmetics Rules, 2020.

(d) Every cosmetic manufactured by us for sale or for distribution in India shall conform to the standards laid down by the Bureau of Indian Standards as referred in the Ninth Schedule.

(e) I/We declare that no cosmetic manufactured by us has been tested on animals.

(f) I/We shall inform to Licensing Authority, in case of any change in respect of labelling or composition or testing of licensed product or its specifications within thirty days along with an undertaking that products comply with standards laid down by the Bureau of Indian Standards as referred in the Ninth Schedule.

(g) I/We shall comply with such further requirements, if any, as may be specified, by the Government of India, under the Act and the Rules, made thereunder.

(h) I/We shall allow the Licensing Authority or any person authorised by him in that behalf to take samples of the cosmetics for testing if considered necessary by the Licensing Authority.

(i) I/We undertake that in case State Licensing Authority or any officer appointed by the authority found any deficiency during an inspection the State Licensing Authority have a full right to cancel or give any direction for improvement for Good Manufacturing Practice in the said premises in respect of the above said cosmetics. Further I will not claim any damages, etc. for any action of the State Licensing Authority in this regard.

The information submitted above is true to the best of my or our knowledge and belief.

Place:

Date:

Signature of the manufacturer/applicant

Name and Designation:

Seal/ Stamp

Third Schedule

[See rules 12(5), 12(9), 13(5), 23(2), 23(10), 28, 30(1), 32(1), 55(3), 55(4), 59, 60(1) and 60(2)]

Fee payable for licence, permission and registration certificate.

Serial Number	Subject	In rupees(INR) except where specified in dollars($)
1.	Registration Certificate	
	(a) Fee for the grant or retention of registration certificate for each category of cosmetic	$1000
	(b) Fee for the grant or retention of registration certificate for additional category of cosmetic	$1000
	(c) Fee for each variant of cosmetic for the grant or retention of registration certificate	$50
	(d) Fee for each manufacturing site for the grant or retention of registration certificate	$500
	(e) Fee for grant of permission for new cosmetics	$500
	(f) Fee for issue of duplicate copy of the registration certificate, if the original is defaced, damaged or lost	$200
	(g) Fee for inspection of each overseas manufacturing site of cosmetics	$5000
2.	Manufacturing Licence	
	(a) Fee for grant of licence in Form COS- 8 for manufacture of cosmetics for sale or for distribution up to ten items of each category of cosmetics	10000
	(b) Fee for grant of licence in Form COS- 8 for manufacture of cosmetics for sale or for distribution of each additional items of the category of cosmetic.	500
	(c) Fee for grant of licence in Form COS- 8 for manufacture of cosmetics for sale or for distribution of ten items of each additional category of cosmetic.	10000
	(d) Fee for grant of loan licence in Form COS- 9 for manufacture of cosmetics for sale or for distribution up to ten items of each category of cosmetics	10000
	(e) Fee for grant of loan licence in Form COS- 9 for manufacture of cosmetics for sale or for distribution of each additional items of the category of cosmetic.	500

	(f) Fee for grant of loan licence in Form COS- 9 for manufacture of cosmetics for sale or for distribution up to ten items of each category of cosmetics	10000
	(g) Fee for issue of duplicate copy of the licence in Form COS- 8 or loan licence in Form COS- 9, if the original is defaced, damaged or lost	500
	(h) Fee for further application after rejection	1000
	(i) Retention fee for licence in Form COS- 8 for manufacture of cosmetics for sale or for distribution up to ten items of each category of cosmetics	10000
	(j) Retention fee for licence in Form COS- 8 for manufacture of cosmetics for sale or for distribution of each additional items of the category of cosmetic.	500
	(k) Retention fee for licence in Form COS- 8 for manufacture of cosmetics for sale or for distribution of ten items of each additional category of cosmetic.	10000
	(l) Retention fee for loan licence in Form COS- 9 for manufacture of cosmetics for sale or for distribution up to ten items of each category of cosmetics	10000
	(m) Retention fee for loan licence in Form COS- 9 for manufacture of cosmetics for sale or for distribution of each additional items of the category of cosmetic.	500
	(n) Retention fee for loan licence in Form COS- 9 for manufacture of cosmetics for sale or for distribution up to ten items of each category of cosmetics	10000
3.	Fee for approval of laboratory carrying out test on cosmetics and their raw materials	
	(a) Fee for approval of laboratory in Form COS-23 for test and analysis of cosmetics	1000
	(b) Fee for issue of duplicate copy of the approval, if the original is defaced, damaged or lost	100
	(c) Fee for inspection of laboratory for further inspection after rejection of the application	500
	(d) Fee for retention of approval granted in Form COS- 23 for laboratory carrying out test and analysis of cosmetics	1000

Fourth Schedule

[See rule 12 (6)]

List of categories of cosmetics for import

Serial number	Category
1.	Face care products other than face mask
2.	Face mask
3.	Eye contour products
4.	Lip care products
5.	Hand care products

6.	Foot care products
7.	Body care products
8.	External intimate care products
9.	Chemical exfoliation products
10.	Mechanical exfoliation products
11.	Skin lightening products
12.	Other skin care products
13.	Soap products
14.	Bath / shower products
15.	Make-up remover products
16.	External Intimate hygiene products
17.	Other skin cleansing products
18.	Chemical depilatories
19.	Physical epilation products
20.	Other body hair removal products
21.	Bleach for body hair
22.	Products with antiperspirant activity
23.	Products without antiperspirant activity
24.	Shaving products
25.	Pre- / after-shaving products
26.	Other shaving and pre- / after- shaving products
27.	Foundation
28.	Concealer
29.	Other face make-up products
30.	Mascara
31.	Eye shadow
32.	Eye pencil
33.	Eye liner
34.	Other eye make-up products
35.	Lip stick
36.	Lipstick sealer
37.	Other lip make-up products
38.	Body or face paint , including "carneval make-up"
39.	Other make-up products
40.	Hydro alcoholic perfumes
41.	Non hydro alcoholic perfumes
42.	Before and after sun products Sun protection products
43.	Self-tanning products

44.	Other sun and self-tanning products
45.	Other skin products
46.	Hair conditioner
47.	Scalp and hair roots care products
48.	Anti hair loss products
49.	Other hair and scalp care and cleansing products
50.	Antidandruff products
51.	Oxidative hair colour products
52.	Non-oxidative hair colour products
53.	Hair bleaching and dye remover products
54.	Other hair colouring products
55.	Products for temporary hair
56.	styling Permanent wave products
57.	Hair relaxer / straightener products
58.	Other hair styling products
59.	Hair sun protection products
60.	Other hair and scalp products
61.	Nail varnish / Nail make-up
62.	Nail varnish remover
63.	Nail varnish thinner
64.	Nail bleach
65.	Other nail varnish and remover products
66.	Nail care products
67.	Nail hardener
68.	Other nail care / nail hardener products
69.	Nail glue remover
70.	Cuticle remover / softener
71.	Nail sculpting products
72.	Other nail and cuticle products
73.	Toothpaste
74.	Tooth cleansing powder / salt
75.	Other tooth care products
76.	Mouth wash
77.	Breath spray
78.	Other mouth wash / breath spray products
79.	Tooth whiteners
80.	Other oral hygiene products

Fifth Schedule

[See rule 12(8), 66(1) and 66(2)]

Fee for test or analysis by the Central cosmetics laboratories or by the state laboratories.

1.	*Fees for Physical tests*	*Rupees*
(i)	Adhesion Strength	150
(ii)	Ash Content	100
(iii)	Bleed Number	150
(iv)	Blush Time	150
(v)	Cleaning Efficiency	100
(vi)	Cloud Point	100
(vii)	Colour in a Cell on the Lovibond Scale	100
(viii)	Diameter of Slip	150
(ix)	Drying Time	150
(x)	Fineness	100
(xi)	Flash Point	100
(xii)	Foam Height	100
(xiii)	Foaming Power	100
(xiv)	Freedom from Cracking	100
(xv)	Freedom From Grittiness	100
(xvi)	Lather Test	100
(xvii)	Loss on Drying	100
(xviii)	Matter Insoluble in Boiling Water	100
(xix)	Melting Point	150
(xx)	Moisture & Volatile Matter	100
(xxi)	Mush	100
(xxii)	Non-Volatile Matter	100
(xxiii)	Odour	100
(xxiv)	Particle Size of Undispersed Pigments Microns	100
(xxv)	pH	100
(xxvi)	Polenske Value	100
(xxvii)	Refractive Index at 40°C	100
(xxviii)	Relative Density at 25°C	100
(xxix)	Relative Density at 30°/30°C	100
(xxx)	Saponification Value	100
(xxxi)	Softening Point	100
(xxxii)	Solid Content	200
(xxxiii)	Stability Test	100
(xxxiv)	Sulphated Ash	100
(xxxv)	Suspended Soilds	100
(xxxvi)	Thermal Stability	150
(xxxvii)	Total Active Matter	100
(xxxviii)	Total Solid	100
(xxxix)	Total Volatile Matter	100
(xl)	Transparency	100
(xli)	Viscosity	100

2.	*Fees for Chemical tests*	*Rupees*
(i)	Acid Insoluble Ash	200
(ii)	Acid Value	200
(iii)	Arsenic	200
(iv)	Assay (as Ammonium Bicarbonate)	200
(v)	Assay (as Oxygen Content)	200
(vi)	Assay (As Hydrogen Peroxide)	200
(vii)	Carbonization Substance	200
(viii)	Chlorides	200
(ix)	Cold Water Extract	200
(x)	Crude Fibre	200
(xi)	Extraneous Sand	200
(xii)	Free Acid & Alkali	200
(xiii)	Free Carbonated Alkali	200
(xiv)	Free Caustic Alkali	200
(xv)	Glycerol	200
(xvi)	Heavy Metals	200
(xvii)	Iodine Value	200
(xviii)	Lawsone Pigment	200
(xix)	Matter Insoluble In Alcohol	200
(xx)	Mineral Matter	200
(xxi)	Non Volatile Alcohol Matter	200
(xxii)	Peroxide Value	200
(xxiii)	PPD Content (By Gravimetry)	200
(xxiv)	Presence of Extraneous Dyes	200
(xxv)	Rosin Test	200
(xxvi)	Sulphur &Sulphide	200
(xxvii)	Synthetic Detergent	200
(xxviii)	Synthetic Surface Active Agent	200
(xxix)	Test For Rancidity	200
(xxx)	Titre of Total Fatty Acids	200
(xxxi)	Total Fatty Matter	200
(xxxii)	Unsaponifiable Matter	200

3.	*Fees for tests involving instruments*	*Rupees*
(i)	Arsenic	300
(ii)	Breaking Load Value	150
(iii)	Consistency	300
(iv)	Fluoride Ion	300
(v)	Heavy Metal	300
(vi)	Mercury	300
(vii)	Pay Off Test	150
(viii)	PPD Content (by HPLC)	1000
(ix)	Ultraviolet Absorption	300
(x)	Water Content	300

4.	*Fees for microbiological tests*	*Rupees*
(i)	Microbiological Limit Test (a) Gram Negative Pathogens (b) Total Yeast and Molds Count (c) Total Viable Count	500

Note -For tests not listed in the Schedule, charges will be determined by the Director or the Government Analyst of the laboratory or institute as the case may be.

Sixth Schedule

(See rule 17(1))

Undertaking for the import of cosmetics to be submitted by the importer with application form for Import Registration Number.

I/We.....S/o or D/o..... having premises in the name of M/s. ..... at (address)..... aged about ..... do hereby undertake that,-

1. I am the importer of..... (Name of the Cosmetics) from..... (Name and address and country of a company from whom the cosmetics are imported)..... which are manufactured by the manufacturer whose name and address is written on the label as per the Cosmetics Rules, 2020 (Name and full address of the Manufacturer) and are complying with the provisions of the Cosmetics Rules, 2020.

2. I shall bear the fees for testing if samples are required to be tested by the port officer or by any officer of CDSCO.

3. In case of any quality failures of the imported cosmetics product or if so directed by the Licensing Authority due to non-compliance of the Cosmetics Rules, 2020, I will withhold the further distribution of the product or recall the cosmetics from the market and follow the directions of the Licensing or registration authority as the case may be.

4. I shall maintain books and records of distribution of above said imported cosmetics.

5. I shall allow the Inspector appointed under the Drugs and Cosmetics Act, 1940 by the Government to inspect the books and records when so required.

Place:

Date:

(Signature)

Name:

Address:

IEC code:

Seal:

Seventh Schedule

[See rules 23(4), 26(b)]

Good manufacturing practices and requirements of premises, plants and equipment for manufacture of cosmetics

I. General requirements

(A) Location and surroundings.– The factory shall be located in a sanitary place any hygienic conditions shall be maintained in the premises. Premises shall not be used for residence or be interconnected with residential areas. It shall be well ventilated and clean.

In the manufacture of cosmetic products overall control and monitoring is essential to ensure that the consumer receives products of specified quality.

(B) Buildings.– The buildings used for the factory shall be constructed so as to permit production under hygienic conditions and not to permit entry of insects, rodents, flies, etc.

Effective measures should be taken to avoid any contamination from the surrounding environment.

The walls and floors of the room in which manufacturing operations are carried out, be free from cracks and open joints to avoid accumulation of dust. These shall be smooth, washable, coved and shall permit easy and effective cleaning and disinfection.

Buildings should be adequately lit and properly ventilated appropriate to the operations.

Testing laboratories should preferably be physically separated from the production areas.

Storage areas should be of adequate space provided with suitable lighting, arranged and equipped to allow dry, clean and orderly placement of stored materials and products.

The walls of the room in which manufacturing operations are carried out, shall be up to a height of above six feet from the floor.

(C) Personnel.– There should be an adequate number of personnel having, experience and capabilities relevant to their assigned function.

(D) Water supply.– The water used in manufacture shall be of potable quality.

(E) Disposal of waste.– The disposal of sewage and effluents (solid, liquid and gas) from the manufacturing premises shall be in conformity with the requirements of Environment Pollution Control Board.

(F) Health, clothing and sanitary requirements of the staff.– All workers shall be free from contagious or infectious diseases. They shall be provided with clean uniforms, masks, headgears and gloves wherever required. Washing facilities shall also be provided.

(G) Medical services.– Adequate facilities for first-aid shall be provided.

(H) Maintenance.– All equipment should be serviced and calibrated regularly, wherever required records should be maintained.

(I) Testing and release of raw materials &and finished cosmetic products.- Quality control of raw materials & finished cosmetic products is an essential part of Good Manufacturing Practices. It provides assurance that cosmetic products will be of consistent quality appropriate to their intended use.

A quality control system should be established to ensure that products contain the correct materials of specified quality and quantity and are manufactured under proper conditions according to standard operating procedures.

Quality control involves sampling, inspecting and testing of raw or packaging materials, in process, intermediate, bulk, and finished products.

Parametric release of raw material can be adopted provided vendors of raw materials are approved and such procedures are robust, validated, based on the trend of earlier testing experience for such purposes.

Parametric release for finished product can also be adopted, provided such procedures are robust, validated, based on the trend of earlier testing experience for such purposes, except for the cosmetics in the category of eye products, lipstick, and dental products.

Note: Each batch of raw material, finished product or in-process parameters need not required to be tested however it needs to be approved and released by quality control on the basis of standard operating procedure for parametric release.

(J) Working benches shall be provided for carrying out operations such as filling, labelling, packing, etc. Such benches shall be fitted with smooth, impervious tops capable of being washed.

(K) Adequate facilities shall be provided for washing and drying of glass containers if the same are to be used for packing the product.

II. Requirements of plant and equipment

List of categories of cosmetics for the purpose of grant of licence to manufacture for sale of cosmetic in the country

Category
(A) Powders
(B) Skin Powder for Infants
(C) Creams, lotions, emulsions, pastes, cleansing milks, shampoos, pomade, brilliantine, shaving-creams and hair-oils, etc.
(D) Nail Polishes and Nail Lacquers.
(E) Lipsticks and Lipgloss.
(F) Depilatories
(G) Preparations used for Eyes 1. Eyebrows, Eyelashes, Eyeliners. 2. Kajal and surma.
(H) Aerosol
(I) Alcoholic Fragrance solutions
(J) Hair Dyes
(K) Tooth-powders and toothpastes, etc. 1. Tooth-powder in General. 2. Tooth pastes. 3. Tooth — Powder (Black).
(L) Toilet Soaps

The following equipment, area and other requirements are recommended for the manufacture of.–

A. Powders.– Face-powder, cake make-up, compacts, face-packs, masks and rouges etc.

Equipments:

(a) Powder mixer of suitable type provided with a dust collector.

(b) Perfume and colour blender.

(c) Sifter with sieves of suitable mesh size.

(d) Ball mill of suitable grinder.

(e) Trays and scoops (stainless steel).

(f) Filling and sealing equipment provided with dust extractor.

(g) For compacts:-

(i) a separate mixer

(ii) Compact pressing machine.

(h) Weighing and measuring devices.

(i) Storage tanks.

An area of 15 square metres is recommended. The section is to be provided with adequate exhaust fans.

(B) Skin Powder for Infants.-

Equipments:

(a) Powder mixer of suitable type provided with a dust collector.

(b) Perfume and colour blender.

(c) Sifter with sieves of suitable mesh size.

(d) Ball mill of suitable grinder.

(e) Trays and scoops (stainless steel).Filling and sealing equipment provided with dust extractor.

(f) Weighing and measuring devices.

An area of 15 square metres is recommended. The section is to be provided with adequate exhaust fans.

(C) Creams, lotions, emulsions, pastes, cleansing milks, shampoos, pomade, brilliantine, shaving-creams and hair-oils, etc.-

Equipments:

(a) Mixing and storage tanks of suitable materials.

(b) Heating kettle — steam, gas or electrically heated.

(c) Suitable agitator.

(d) Colloidal mill or homogeniser (wherever necessary).

(e) Triple roller mill (wherever necessary).

(f) Filling and sealing equipment.

(g) Weighing and measuring devices.

An area of 25 square metres is recommended.

(D) Nail Polishes and Nail Lacquers.-

1. Equipments:

(a) A suitable mixer.

(b) Storage tanks.

(c) Filling machine - hand operated or power driven.

(d) Weighing and measuring devices.

An area of 15 square metres is recommended. The section shall be provided with flame proof exhaust system.

2. Premises.– The following are the special requirements related to Nail Polishes and Nail Lacquers :

(a) It shall be situated in an industrial area.

(b) It shall be separate from other cosmetic-manufacturing area by metal/brick partition up to ceiling.

(c) Floors, walls, ceilings and doors shall be fireproof.

(d) Smoking, cooking and dwelling shall not be permitted and no naked flame shall be brought in the premises.

(e) All electrical wiring and connections shall be concealed and main electric switch shall be outside the manufacturing area.

(f) All equipment, furniture and light fittings in the section shall be flameproof.

(g) Fire extinguisher like foam and dry powder and sufficient number of buckets containing sand shall be provided.

(h) All doors of the section shall open outwards.

3. Storage.– All explosive solvents and ingredients shall be stored in metal cupboards or in a separate enclosed area.

4. Manufacture.–

(a) Manufacture of lacquer shall not be undertaken unless the above conditions are complied with.

(b) Workers shall be asked to wear shoes with rubber soles in the section.

5. Other requirements.– No objection certificate from local Fire Brigade Authorities shall be furnished.

(E) Lipsticks and Lipgloss.-

Equipments:

(a) Vertical mixer.

(b) Jacketted kettle — steam, gas or electrically heated.

(c) Mixing vessels (stainless steel).

(d) Triple roller mill/Ball mill.

(e) Moulds with refrigeration facility.

(f) Weighing and measuring devices.

An area of 15 square meters is recommended

(F) Depilatories.–

Equipments:

(a) Mixing tanks.

(b) Mixer.

(c) Triple roller mill or homogeniser (where necessary).

(d) Filling and sealing equipment.

(e) Weighing and measuring devices.

(f) Moulds (where necessary).

An area of 10 square meters is recommended.

(G) Preparations used for Eyes.– Such preparations shall be manufactured under strict hygienic conditions to ensure that these are safe for use.

1. Eyebrows, Eyelashes, Eyeliners.–

Equipments:

(a) Mixing tanks.

(b) A suitable mixer.

(c) Homogeniser (where necessary).

(d) Filling and sealing equipment.

(e) Weighing and measuring devices.

An area of 10 square metres is recommended.

2. Kajal and surma.–

Equipments:

(a) Base steriliser.

(b) Powder steriliser (dry heat oven).

(c) Stainless steel tanks.

(d) A suitable Mixer.

(e) Stainless steel sieves.

(f) Filling and sealing arrangements.

(g) Weighing and measuring devices.

(h) Homogeniser (where necessary).

(i) Pestle and Mortar (for Surma).

An area of 10 square metres with a separate area of 5 square metres for base sterilization is recommended.

Other requirements for 1 and 2:

(a) False ceiling shall be provided wherever required.

(b) Manufacturing area shall be made fly proof. An airlock or an air curtain shall be provided.

(c) Base used for Kajal shall be sterilised by heating the base at 150º C for required time in a separate enclosed area.

(d) The vegetable carbon black powder shall be sterilised in a drying oven at 120º C for required time.

(e) All utensils used for manufacture shall be of stainless steel and shall be washed with detergent water, antiseptic liquid and again with distilled water.

(f) Containers employed for 'Kajal' shall be cleaned properly with bactericidal solution and dried.

(g) Workers shall put on clean overalls and use hand gloves wherever necessary.

(H) Aerosol:

Equipments:

(a) Air-compressor (wherever necessary).

(b) Mixing tanks.

(c) Suitable propellant filling and crimping equipments.

(d) Liquid filling unit.

(e) Leak testing equipment.

(f) Fire extinguisher (wherever necessary).

(g) Suitable filtration equipment.

(h) Weighing and measuring devices.

An area of 15 square meters is recommended.

Other requirements.– No objection certificate from the Local Fire Brigade Authorities shall be furnished.

(I) Alcoholic Fragrance solutions.–

Equipments:

(a) Mixing tanks with stirrer.

(b) Filtering equipment.

(c) Filling and sealing equipment.

(d) Weighing and measuring devices.

An area of 15 square meters is recommended.

(J) Hair Dyes.-

Equipments:

(a) Stainless steel tanks.

(b) Mixer.

(c) Filling unit

(d) Weighing and measuring devices.

(e) Masks, gloves and goggles.

An area of 15 square meters with proper exhaust is recommended.

(K) Tooth-powders and toothpastes, etc.-

1. Tooth-powder in General.

Equipments:

(a) Weighing and measuring devices.

(b) Dry mixer (powder blender).

(c) Stainless steel sieves.

(d) Powder filling and sealing equipments.

An area of 15 square meters with proper exhaust is recommended.

2. Tooth pastes.

Equipments:

(a) Weighing and measuring devices.

(b) Kettle—steam, gas or electrically heated (where necessary).

(c) Planetary mixer with de-aerator system.

(d) Stainless steel tanks.

(e) Tube filling equipment.

(f) Crimping machine.

An additional area of 15 square meters with proper exhaust is recommended.

3. Tooth — Powder (Black).

Equipments:

(a) Weighing and measuring devices.

(b) Dry mixer powder blender.

(c) Stainless steel sieves.

(d) Powder filling arrangements.

An area of 15 square meters with proper exhaust is recommended. Areas for manufacturing "Black" and "White" tooth-powders should be separate.

(L) Toilet Soaps.–

Equipments:

(a) Kettles or pans for saponification.

(b) Boiler or any other suitable heating arrangement.

(c) Suitable stirring arrangement.

(d) Storage tanks or trays.

(e) Driers.

(f) Amalgamator or chipping machine.

(g) Mixer.

(h) Triple roller mill.

(i) Granulator.

(j) Plodder.

(k) Cutter.

(l) Pressing stamping and embossing machine.

(m) Weighing and measuring devices.

A minimum area of 100 square meters is recommended for the small-scale manufacture of toilet soaps.

The areas recommended above are for basic manufacturing of different categories of cosmetics. In addition to that separate adequate space for storage of raw materials, finished products, packing materials shall be provided in factory premises.

Note I : The above requirements of the Schedule are made subject to the modification at the discretion of the Licensing Authority, if he is of the opinion that having regard to the nature and extent of the manufacturing operations it is necessary to relax or alter them in the circumstances of a particular case.

Note II : The above requirements do not include requirements of machinery, equipment and premises required for preparation of containers and closers of different categories of cosmetics. The Licensing Authority shall have the discretion to examine the suitability and adequacy of the machinery, equipment and premises for the purpose taking into consideration the requirements of the licensee.

Note III : This schedule specifies equipment and space required for certain categories of cosmetics only. There are other cosmetics items, viz. Attars, perfumes, etc., which are not covered in the above categories. The Licensing Authority shall, in respect of such items or categories of cosmetics, have the discretion to examine the adequacy of factory premises, space, plant and machinery and other requisites having regard to the nature and extent of the manufacturing operations involved and direct the licensee to carry on necessary modification in them.

Eighth Schedule

[See rules 26(f)]

I. Particulars to be shown in the manufacturing records:

(1) Serial number.

(2) Name of the product.

(3) Lot or Batch size.

(4) Lot or Batch number.

(5) Date of commencement of manufacture and date when manufacture was completed.

(6) Names of all ingredients, quantities required for the lot/batch size, quantities actually used.

(7) Control reference numbers in respect of raw materials used in formulation.

(8) Reference to analytical report numbers or unique code.

(9) Actual production and packing particulars indicating the size and quantity of finished packings.

(10) Date of release of finished packing for distribution or sale.

(11) Signature of the expert staff responsible for the manufacture.

II. Records of raw materials: Records in respect of each raw material shall be maintained indicating the quantity received, control reference number, the quantity issued from time to time, the names and batch numbers of the products for the manufacture of which the said quantity of raw material has been issued and the particulars relating to the proper disposal of the stocks.

Notes: (1) The Licensing Authority may permit the licensee to maintain records in such manner as is considered satisfactory, provided the basic requirements laid down above are complied with.

(2) The Licensing Authority may direct the licensee to maintain records for such additional particulars, as it may consider necessary in the circumstances of a particular case.

Ninth Schedule

(See rules 34(7), 39(1), 48)

Standards for cosmetics

Standards for cosmetics in finished form.– The following cosmetics in finished form shall conform to the Indian Standards specifications laid down from time to time by the Bureau of Indian Standards (BIS).

1. Skin Powders IS :3959
2. Skin Powder for infants IS :5339
3. Tooth Powder IS :5383
4. Toothpaste IS :6356
5. Skin Creams IS :6608
6. Hair Oils IS :7123
7. Shampoo, Soap – based IS :7669
8. Shampoo Specification IS : 7884
9. Hair Creams IS :7679
10. Oxidation hair dyes, Liquid IS :8481
11. Cologne IS :8482
12. Nail Polish (Nail Enamel) IS :9245
13. Aftershave Lotion IS :9255
14. Pomades and Brilliantines IS :9339

15. Depilatories Chemicals IS :9636
16. Shaving Creams IS :9740
17. Cosmetic Pencils IS :9832
18. Lipstick IS :9875
19. Toilet Soap IS :2888
20. Liquid Toilet Soap IS : 4199
21. Baby Toilet Soap IS : 10523
22. Shaving Soap IS :5784
23. Transparent Toilet Soap IS :11303
24. Lipsalve IS: 10284
25. Powder Hair Dye IS: 10350
26. Bindi (Liquid) IS : 10998
27. KumKum Powder IS: 10999
28. Henna Powder IS : 11142
29. Bathing Bars IS:13498
30. Sindoor IS: 14649
31. Liquid foundation make-up IS 14318
32. Coldwax-Hair remover IS : 15152
33. Face pack IS: 15153
34. Kajal IS : 15154
35. Oxidation Hair Dyes (Emulsion type) IS: 15205
36. Cream Bleach IS:15608
37. Hair Shampoo for Babies- Specification IS:17117

Note.–In case of any new or amended standards published by the Bureau of Indian Standards, the new or amended standards shall be mandatory to the cosmetics after six months from the date of publication.

Tenth Schedule

[See rules 39(1), 39(3)]

Part I

List of colourants allowed for use in cosmetic products as given under IS: 4707 (Part 1) as amended by the Bureau of Indian Standards from time to time.

Part II

List of colours permitted to be used in soaps.

Common Name of the colour	Colour Index Number	Chemical Names of the colour
(1)	(2)	(3)
Phthalocyanine Blue	74160	(phthalocyninate (2-) copper.
Citrus Red No.2	12156	1-2(2,5-dimethoxy phenylazo) 2-naphthol.
Aqueous Green Paste	74260	Polychloro copper Phthalocyanine.
Pigment Yellow 3	11710	2-(4-Chloro-2-nitrophenyl)-azo-N-(-2-Chlorophenyl)-3- Oxobutamide.

Irgalite Carmine F-P Powder or Pigments Red 5	12490	N-(5-Chloro-2, 4-Dimethoxy-phenyl)-4-(CS-diathylamine) Sulfonyl-2-methoxyphenyl)-azo-3-hydroxy-2-naphthalene carboxamide.
Monolite Red 4R HV Paste or Pigment Red 7	12420	N-(4-Chloro-2-methylphenyl-4-(4-Chloro-2-methylphenyl) azo 3-hydroxy-2-naphthalenol Carboxamide.

Note. – (1) In case of any new or amended standards published by the Bureau of Indian Standards, the new or amended standards shall be mandatory to the cosmetics after six months from the date of publication.

(2)This list of colour for use in soaps is in addition to those colours already given in Part I of the Tenth Schedule and are used for soaps.

Eleventh Schedule

[See rule 62(a)]

Good laboratory practices and requirements of premises and equipment

1. General Requirements:

(a) The laboratory or the organisation of which it is a part must be an entity that is legally authorised to function and can be held legally responsible.

(b) It is the responsibility of the management to ensure that the laboratory carry out its testing, calibration, validation, and all other technical activities in such a way as to meet Good Laboratory Practices (GLP) requirements.

(c) Laboratory management shall have a qualified individual to be known as quality manager or technical manager for carrying out all technical activities and for the implementation of documented quality system and shall report to the top management directly.

(d) The quality manager shall prepare a schedule for technical audit of the laboratory for GLP compliance by an expert or experts appointed by the top-management other than the in-charge of the laboratory and shall ensure the maintenance of documented quality system as per quality manual.

2. Premises:

(a) (i) the laboratories shall be designed, constructed and maintained so as to prevent entry of insects and rodents besides cross contamination;

(ii) interior surface (walls, floor, and ceilings) shall be smooth and free from cracks, and permit easy cleaning and disinfection;

(iii) adequate provision is made not only for space and equipment for carrying out necessary test but also for utilities like water, power and gas;

(iv) air ventilation system shall ensure dust free environment.

(b) The laboratories shall be provided with adequate lighting and ventilation and if necessary, air-conditioning to maintain satisfactory temperature and relative humidity that will not adversely affect the testing and storage of cosmetics or the accuracy of the functioning of the laboratory equipments or instruments.

(c) The drainage system facilities shall be such as to facilitate proper maintenance and prevent water logging in the laboratory.

(d) Tabletops shall be constructed with acid, alkali and solvent resistant material and shall be smooth and free from crevices as far as possible.

(e) All bio-medical laboratory waste shall be destroyed as per the provisions of the Biomedical Waste Management Rules, 2016 as amended from time to time.

(f) Bio-burden shall be routinely maintained in the controlled and uncontrolled area, (e.g. air locks)

3. Personnel:

(a) Staff in the laboratory shall possess necessary qualification, proper training and shall have adequate, experience for the assigned duties.

(b) A training record of all the personnel shall be maintained.

(c) Head of the laboratory must be of high professional standing with experience in cosmetics or drugs analysis and laboratory management who is responsible for.

(i) ensuring the control and maintenance of documents including the quality system as per the requirements of regulatory authorities which involves all raw data, SOPs, documentation exhibits, protocols, training charts, etc;

(ii) planning and organising the audit of the quality system and initiation as well as follow up action of the corrective actions, if any;

(iii) investigation of technical complaints;

(iv) taking final responsibilities for recommending any regulatory action in the event of noncompliance of tested samples.

4. Equipment:

(a) The laboratory shall be furnished with all types of equipment as may be necessary for carrying out the different activities within the laboratory.

(b) The analytical instruments shall be housed in dust-free environment and whenever required, conditions of temperature and humidity shall be maintained and periodic checks on temperature and humidity be made and recorded.

(c) The instruments, instrument bench and surrounding areas shall be kept clean and tidy at all times.

(d) Instruments requiring calibration shall be calibrated at regular intervals and records of such calibration or maintenance be maintained and there shall be written instructions in the form of Standard Operating Procedures for the operation, maintenance and calibration of instruments.

(e) Equipment records shall be maintained and such records shall contain the following:–

(i) name of equipment or machine or apparatus;

(ii) manufacturer's name, model number and type of identification;

(iii) serial number;

(iv) date on which equipment was received in laboratory;

(v) current location;

(vi) condition when received (e.g. new, used, re-conditioned);

(vii) copy of the manufacturer 's operating instructions;

(viii) frequency of calibration;

(ix) frequency of maintenance;

(x) log book (day to day entry including status of the equipment)

(xi) staff responsible for monitoring the calibration and maintenance status of the equipment;

(xii) calibrating records;

(xiii) list of authorised users or operators, if any;

(xiv) history of any damage, malfunction, modification or up gradation, repair and calibration;

(xv) list of spares and accessories, if any.

(f) A progress register for non-functional equipment and action for procurement of spares and accessories, monitoring thereof, shall be maintained.

(g) A standard operating procedure for preventive maintenance of machine or equipment or apparatus shall be prepared by the laboratory.

(h) Other equipment such as burettes, pipettes, volumetric flasks, weight boxes, thermometers, etc., shall be thoroughly checked for accuracy of calibration before acceptance for use.

(i) Maintenance procedure in the form of standard operating procedures must be prepared and regular servicing must be performed by the maintenance engineer or specialist

(j) Equipment, instruments giving anomalous results or defective must be labelled as 'out-of- order' till they are repaired and after instrument is repaired it should be calibrated before use.

(k) The maintenance of equipment for services like electricity, gas, water, steam, and compressed gas shall be handled by competent person.

(l) Autoclaves must meet the requirements described for operations, safety and validation procedures, and the validation carried out by the laboratory shall be recorded.

(m) Fume Cupboards.

Work involving the evolution of harmful and obnoxious vapours shall be carried out in a fume cupboard. The exhaust system of the fume cupboard shall be checked frequently to ensure that it is in order. Preferably, there should be a water drainage system inside the fume cupboard or near fume cupboard and shall be checked frequently to ensure that there is no water logging and it is in order.

5. Chemicals and Reagents:

(a) The storage and handling of chemicals and reagents shall be done in a manner considering the physicochemical properties of these substances and the hazards involved in their use.

(b) All reagents and solutions in the laboratory shall be properly identified with a label.

(c) A standardisation register shall be maintained by the laboratory along with its raw data and standard operating procedure for preparation and standardisation on stock solutions, standard solutions, volumetric solutions must be prepared for the guidance of staff.

(d) Containers of stock solutions and of standard solutions shall bear the following details:-

(i) name of analytical chemist who prepared the solution;

(ii) date of preparation;

(iii) Each volumetric solution shall have "use before date" depending upon the stability of the solution; and

(iv) standardisation records.

(e) The transfer of hazardous chemicals and regents from one container to another container shall be carried out with suitable equipment by taking the care of safety and no make-shift or hazardous methods must be resorted to.

6. Good house keeping and safety:

(a) General and specific written down instructions for safety shall be circulated to each staff member and the instructions be revised periodically as appropriate (e.g., poster displays, audio-visual material and by seminars or conferences)

(b) Standard operating procedure for safety, house-keeping and loss prevention shall be prepared in accordance with the various rules, and regulations of the Government of India and include the following requirements, namely:-

(i) safety data sheets must be made available to staff before testing is carried out;

(ii) drinking, eating and smoking shall not be permitted in the laboratories; food for human consumption shall not be kept in working or storage areas; food meant for test animals shall be handled by the workers under the guidance of a veterinary doctor or qualified person. In the animal house, the facilities for collection and disposal of animal waste or safe sanitary storage of waste before removal from testing be provided;

(iii) staff must wear laboratory coats or other protective clothing including gloves and face masks and eye protection wherever required;

(iv) the laboratories shall have adequate first aid kit and firefighting equipment located at the right places and the staff must be familiar and trained with the use of firefighting equipment including fire extinguishers, fire blankets and gas masks or any equivalent devices as approved under the Factory Act.

(v) operators carrying out sterility tests shall wear sterilised garments including headgear, face masks and shoes;

(vi) the staff must be educated in the first aid techniques, emergency care and use of antidotes; and

(vii) safety rules in handling cylinders of compressed gases must be observed and staff must be familiar with relevant colour identification codes;

(c) Protective precautions to be taken in laboratories:

(i) water showers shall be installed at appropriate places in the laboratory;

(ii) rubber suction bulbs must be used on manual pipettes and siphons;

(iii) warnings, precautions, and written instructions must be given for work with violent, uncontrollable or dangerous reactions (e.g. mixing water and acids, biological such as infectious agents, etc.);

(iv) appropriate facilities for the collection, storage, and disposal of wastes shall be made available;

(v) staff must be aware of methods for safe disposal of corrosive or dangerous products by neutralisation or deactivation and of the need for complete disposal of mercury and its salts.

(vi) staff must also be aware about the safety precautions to be adopted while handling potassium cyanide and cyanogen bromide;

(vii) a standard operating procedure for handling, collection, disposal of chemical and biological wastes be prepared.

7. Maintenance, calibration, and validation of equipment:

(a) All equipment, instruments and other devices used in the laboratory shall use appropriate methods and procedures for all tests or calibrations and they shall be regularly calibrated and validated. The frequency of calibration may differ from instrument to instrument.

(b) The original equipment manufacturer's recommendations along with the experience of the laboratory staff and the use of equipment per day may also be considered while fixing the frequency of calibration.

(c) For most of the equipment and instruments, Standard Operating Procedures for calibration and calibration schedule be prepared by the laboratory and a logbook shall also be prepared by each laboratory for proper documentation of calibration results.

8. Reference materials:

(a) Reference materials, if any, are necessary for the testing and, or calibration, validation or verification of a equipment, instruments or other devices and all such materials shall be traceable to agency authorised by Government of India or any other International body.

(b) Whenever, any new reference material is received by the laboratory, a code number shall be assigned and this code number shall be quoted on the laboratory note book and analytical work sheet. The working standard shall also be provided with identification code.

(c) A register pertaining to reference and working materials must be maintained by the laboratory. The following details may be mentioned in the register:

(i) source of supply;

(ii) code number of the reference material;

(iii) date of receipt;

(iv) batch number or identification number of the supplying agency;

(v) details like assay value, water content or any other information provided;

(vi) storage condition of the material; and

(vii) date of expiry, if any and date of manufacturing if possible

(d) All working standards shall be checked at appropriate intervals or before use to ensure that it has not deteriorated or decomposed during storage. These observations be recorded in a register: All the reference and working standards shall be stored at appropriate storage condition; those requiring storage between 2-8°C shall be stored in a refrigerator. Wherever recommended the material may not be allowed to be frozen.

9. Microbiological Cultures:

(a) Standard Operating Procedure for maintenance of microbial culture and sub-culture must be prepared by the laboratories.

(b) If the cultures have become non-viable or mutant, proper procedure shall be followed to destroy these cultures by autoclaving under an authorised personnel for biological testing. Preferably not more than five passages may be prepared.

(c) All activities be carried out in a aseptic area by authorised person.

(d) The laboratories shall perform standard biochemical tests on the sub-culture as given in literature to ensure their viability.

10. Quality system:

The quality system shall be designed to ensure the following objectives:-

(a) The measurements and calibrations shall fully conform to the compendial requirements and the methods demonstrably based on validation protocols are followed.

(b) It shall be effective in providing necessary assurance that the activities or processes or techniques or practices comply with planned arrangements.

(c) It helps in early detection and correction of non conformities.

(d) Remedial action on the observations by internal and external audits are taken appropriately and

(e) It shall have a documented quality policy for the organisation.

11. Internal quality system audits.-

(a) Internal audits are done to assure the integrity of the analysis and such audits shall be conducted periodically with a predetermined schedule and procedure with appropriate checklist, to verify that the operations continue to comply with the requirements of quality system and requirements of regulatory authorities. Internal quality audits shall be carried out by trained and qualified personnel who are independent of the activity to be audited.

(b) The periodicity of quality audit shall be fixed by the head of the laboratory so that each activity is audited at least once in a year.

(c) Head of the laboratory will be responsible for initiation of the corrective action arising from audits and verification of corrective action.

(d) Whenever any non-compliance or any diversion is noticed by the team in implementing quality policy or quality system, protocols, the same will be attended by the quality manager. The problem will be analysed and necessary actions will be taken with proper documentation.

(e) The quality manager shall maintain all the records of the analysis being conducted which includes test system, the type of analysis, date on which analysis is done, etc and quality manager shall also maintain copies of all protocols pertaining to different activities being checked by the audit team.

12. Management review:

Quality system reviews shall be conducted by the top management at least once in every twelve months and the agenda of review shall generally cover the following:-

(i) report or input of internal audits;

(ii) matter arising from previous reviews;

(iii) report of external audits, if any;

(iv) surveillance report, if any;

(v) result of proficiency testing;

(vi) complaints or feedback received from users of laboratory services;

(vii) details of in-house quality control checks;

(viii) need of amendment of the quality system and documentation;.

(ix) induction training of new staff; and

(x) any other requirements of the laboratory.

13. Standard operating procedures:

(a) Standard operating procedures are written procedures for different activities being conducted in a laboratory and shall include the following characteristics:

(i) they shall be written in a chronological order listing different steps leading to an analysis of cosmetics or calibration of an instrument:

(ii) testing laboratories shall have standard operating procedure manuals and have its periodic review;

(iii) it shall be user friendly documents and shall include designation of the person responsible for intended activity.

(b) Standard operating procedures in addition to those recommended under various activities shall also be prepared to the minimum in respect of the following:

(i) sample handling and accountability;

(ii) receipt identification, storage, mixing and method sampling of the test and control articles;

(iii) record keeping, reporting, storage and retrieval of data;

(iv) coding of different studies, handling of data including use of computerized data system;

(v) operation of technical audit personnel in performing and reporting audits, inspections and final report reviews;

(vi) routine inspection of cleaning, maintenance, testing, calibration and standardisation of instruments;

(vii) action to be taken in respect of equipment failure;

(viii) analytical data methods;

(ix) the raw data;

(x) data handling and storage retrieval;

(xi) health and safety protection;

(xii) storage and maintenance of microbial cultures;

(xiii) use and storage of reference standards;

(xiv) procurement of stores and equipment;

(xv) monitoring of testing of samples;

(xvi) method of retention of unexpended samples, their location, maintenance and disposal;

(xvii) document control;

(xviii) redressal of technical complaints;

(xix) housing-keeping;

(xx) corrective and preventing action;

(xxi) working procedure (test methods);

(xxii) calibration manual; and

(xxiii) training manual.

14. Protocols and specifications archive:

(a) Every laboratory shall have a specification archive and current versions of all necessary specifications shall be kept as per the requirements of the Act and the Rules made thereunder and the Bureau of Indian Standards.

15. Raw data:

(a) Raw data refers to the laboratory work sheet, note books or analysis sheet, records, and other activities and such raw data shall include hand written notes, photographs, software, drawings, computer printouts, spectral charts, dictated observations or recorded data from automated equipment. The raw data also includes result of environmental monitoring, calibration, records of equipment, integrator output from analytical equipment, including work-sheet used to read a note, information from light emitting diode display of any equipment.

(b) A single line shall strike through the data being changed; the correct information shall be recorded along with the old data and the reason of change. The analyst making the change shall be identified by his signature with date. In case of automated data collection system, the person responsible shall be identified at the time of data output. The original entry must be saved and the system have00000audit trial for all the data.

(c) Data integrity and security shall be maintained and the data shall not be accessible to any unauthorised person.

16. Storage and archival:

(a) The residual sample shall be retained in proper storage condition for a period of one year after the final report.

(b) The laboratory must establish and maintain procedures for the identification collection, indexing, retrieval, storage, maintenance, and disposal of all quality documents.

(c) All the raw data, documentation, standard operating procedures, protocols, and final reports are to be retained and there shall be archives for orderly storage and expeditious retrieval of all raw data, documentation, protocols, interim and final report. The archive shall provide a suitable environment that will prevent modification, damage, or deterioration and/or loss.

(d) The condition under which the original documents are stored must ensure their security and confidentiality,

(e) Paper documents shall not be kept for long periods under high humidity and raw data in the form of tape and discs are to be preserved with care,

(f) In case of storage of only optical disc, the life of disc shall be longer than the storage time,

(g) Raw data on thermal paper might fade away with time; therefore, a photocopy of the thermal paper shall also be retained in the archive.

(h) Time for which records are retained shall be prescribed in the documents.

Twelfth Schedule

[See rule 64(1)]

Class of cosmetics	Extent and conditions of exemption
1. Cosmetics	The provisions of Chapter IV of the Act and Rules made thereunder, which require them to be covered by a licence for the sale, provided that the cosmetics sold, if of Indian origin, are manufactured by licensed manufacturers.
2. Hair Fixers, namely mucilaginous preparations containing gums, used by men for fixing beard.	The provisions of Chapter IV of the Act and the rules thereunder.

3. The following categories of cosmetics:- (i) Cosmetics in bulk for repackaging for 100% export to other countries. (ii) Cosmetics for research and development purposes like packaging trials, consumer studies, shelf life studies and transport studies. (iii) Cosmetics for sale to overseas passengers in duty free shops situated within international airports. (iv) Cosmetics in amenity kits for exclusive use of International passengers on complimentary basis if not be used for domestic sale. (v) Cosmetics imported for use in hotels exclusively for their captive consumption and after providing notarized undertaking to this effect.	The provisions of Chapter III of the Act and rules thereunder which required them to be covered by registration certificate subject to the following conditions.- (i) the cosmetics shall not be used for domestic sale.
4. Cosmetics imported in the form of a Kit to be marketed in India as such, wherein all individual products of the Kit are already registered for import into India under Cosmetics Rules, 2020.	The provisions of Chapter III of the Act and rules thereunder which required them to be covered by registration certificate.

Thirteenth Schedule

(See rule 71)

1. In the Drugs and Cosmetics Rules 1945 (hereinafter to be referred as said rules) in sub-rule (1) of rule 1 the words “and cosmetics” shall be omitted.
2. In the said rules, in sub-rule (1) of rule 45 the words “and cosmetics” shall be omitted.
3. In the said rules, in rule 48 the words “or cosmetic” shall be omitted.
4. In the said rules, in rule 52 the words “or cosmetics” shall be omitted.
5. In the said rules, in sub-rule (1) of rule 52 the words “or cosmetics” shall be omitted.
6. In the said rules, in sub-rule (4) of rule 52 the words “or cosmetics” shall be omitted.
7. In the said rules, in rule 54A the words “or cosmetics” wherever they occur shall be omitted.
8. In the said rules, in rule 55 the words “cosmetic” and “or cosmetic” wherever they occur shall be omitted.
9. In the said rules, PART XIII, PART XIV and PART XV and rules contained therein shall be omitted.
10. In the said rules, in PART XV(A) the words “cosmetics” shall be omitted.
11. In the said rules, in rule 150C the words “or items of cosmetics” wherever they occur shall be omitted.
12. In the said rules, in rule 150B the words “cosmetics”, “or cosmetics” and “and cosmetics” wherever they occur shall be omitted.
13. In the said rules, in rule 150C the words “cosmetics”, “or cosmetics” and “or cosmetics as the case may be” wherever they occur shall be omitted.
14. In the said rules, in rule 150E the words “or cosmetics” and “or a cosmetic” wherever they occur shall be omitted.
15. In the said rules, in rule 150F the words “or cosmetics” and “or cosmetics as the case may be” wherever they occur shall be omitted.
16. In the said rules, in rule 150C the words “or items of cosmetics” wherever they occur shall be omitted.

17. In the said rules, in SCHEDULE B the figures, brackets and words "III. Cosmetics Rupees 400-1500 (The exact amount of the fee shall be determined by the Director of Laboratory or the Government Analyst, as the case may be.)" wherever they occur shall be omitted.

18. In the said rules, in SCHEDULE B(1) the word "Cosmetics" shall be omitted.

19. In the said rules, in SCHEDULE D the word "and cosmetics" wherever they occur shall be omitted.

20. In the said rules, the SCHEDULE D(III) shall be omitted.

21. In the said rules, in SCHEDULE K the figures, brackets and words "16. Cosmetics" and the portion beginning with the "The provisions and ending with manufacturers" shall be omitted.

22. In the said rules, the SCHEDULE M(II) shall be omitted.

23. In the said rules, the SCHEDULE Q shall be omitted.

24. In the said rules, the SCHEDULE S shall be omitted.

25. In the said rules, the SCHEDULE U (I) shall be omitted.

26. In the said rules, in SCHEDULE A in Form 15 the words "cosmetics" wherever they occur shall be omitted.

27. In the said rules, in SCHEDULE A in Form 16 the words "or cosmetics" and "cosmetics" wherever they occur shall be omitted.

28. In the said rules, in SCHEDULE A in Form 17 the words "cosmetics" shall be omitted.

29. In the said rules, in SCHEDULE A in Form 18 the words "cosmetics" shall be omitted.

30. In the said rules, in SCHEDULE A the Form 31, Form 31A Form 32, Form 32A Form 33, Form 33A, Form 34, Form 42 and Form 43 shall be omitted.

31. In the said rules, in SCHEDULE A in Form 36 the words "cosmetics" and "items of cosmetics" wherever they occur shall be omitted.

32. In the said rules, in SCHEDULE A in Form 37 the words "cosmetics", "items of cosmetics" and "or items of cosmetics" wherever they occur shall be omitted.

33. In the said rules, in SCHEDULE A in Form 38 the words "cosmetics" and "items of cosmetics" wherever they occur shall be omitted.

34. In the said rules, in SCHEDULE A in Form 39 the words "cosmetic" shall be omitted.

35. In the said rules, in rule 150K the words "or items of cosmetics" shall be omitted."

36. In the said rules, in SCHEDULE A in Form 17A the words "or cosmetics" shall be omitted.

Appendix

Form COS- 1

[See rule 12(2), and 12(7)]

Application for issue of registration certificate for import of cosmetics into India

I/We*_____ *(Name and full address)* hereby apply for the grant of registration certificate to the manufacturer, M/ s _____ *(full address with telephone number, fax and e-mail address of the foreign manufacturer)* for his manufactured cosmetics meant for import into India.

1. Names of cosmetics along with their brand name and pack size(s) and variants for registration.

Serial number	Product or brand of cosmetic	Brand name	Variant name	Pack sizes	Actual manufacturer and its premises
1.					
2.					

2. I/We* enclose herewith the information and undertaking specified in Part-I of Second Schedule duly signed by the manufacturer for grant of registration certificate for the premises stated below:-

3. A fee of…… for registration of cosmetics for import as specified at serial number 2 above has been credited to the Central Government under the Head of Account "0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines" under the Cosmetics Rules, 2020 – Central*vide* Challan No....., dated....., (attached in original).

4. Particulars of premises to be registered where manufacture is carried on:

Address(s) :_____

Telephone :_____

Fax:_____

E-mail :_____

I/we undertake to comply with all the terms and conditions required to obtain registration certificate and to keep it valid during its validity period.

Place:

Date:

Signature_____

Name_____

Designation _____

Seal/Stamp of manufacturer or his Authorised agent in India.

(Note: In case the applicant is an Authorised agent of the manufacturer in India, an undertaking for the purpose of registration is to be enclosed as per Part-I of Second Schedule)

Form COS- 2

[See rule 13(1) and 13(4)]

Import registration certificate to be issued for import of cosmetics into India

Registration Certificate No. _____ Date _____

M/s _____ (Name and full address of registered office) having factory premises at _____ (full address) has been registered under rule 13 as a manufacturer and is hereby issued this Registration Certificate.

2. Name (s) of cosmetics, along with their brand names and pack size(s) and variants which may be imported under this registration certificate.

Serial number	Product or brand of cosmetic	Brand name	Variant name	Pack sizes	Actual manufacturer and its premises
1.					
2.					

3. This registration certificate shall be in force from_____ to _____unless it is sooner suspended or cancelled under the rules.

4. This registration certificate is issued through the office of manufacturer or his authorised agent or importer in India or by the subsidiary in India authorised by the manufacturer, namely M/s.....(name and full address)…… who shall be responsible for the business activities of the manufacturer, in India in all respects.

5. This Registration Certificate is subject to the conditions, stated below and to such other conditions as may be specified in the Drugs and Cosmetics Act, 1940 and the rules made thereunder, from time to time in this regard.

Place: _____

Date: _____

CENTRAL LICENSING AUTHORITY

Seal / Stamp

Conditions of the registration certificate

1. The registration certificate shall be produced by the authorised importer or distributer or agent as and when required by the Licensing Authority or regulatory authority.

2. The manufacturer or his authorised importer/distributor/agent in India shall inform the Licensing Authority forthwith in the event of any administrative action taken namely, market withdrawal, regulatory restrictions, or cancellation of authorisation, and not of standard quality report of any cosmetic pertaining to this registration certificate declared by the Regulatory Authority of the country of origin or by any Regulatory Authority of any other country, where the cosmetic is marketed/sold or distributed.

The dispatch and marketing of the cosmetic in such cases shall be stopped and the Licensing Authority shall be informed immediately. Further action in respect of such stopped marketing of cosmetic shall be followed as per the direction of the Licensing Authority. In such cases, action equivalent to that taken with reference to the concerned cosmetic in the country of origin or in the country of marketing shall be followed in India also, in consultation with the Licensing Authority. The Licensing Authority may, however, direct any further modification to this course of action, including the withdrawal of the cosmetic from Indian market within 48 hours time period.

3. The manufacturer or his authorised agent or importer or distributor or subsidiary in India shall inform the Licensing Authority within thirty days, in writing, in the event of change in labelling or composition or testing, or specification or in documentation of any of the cosmetic pertaining to this Registration Certificate along with an undertaking that the products comply with standards laid down by the Bureau of Indian Standards as referred in the Ninth Schedule.

4. The manufacturer or his authorised agent in India shall inform the Licensing Authority immediately in writing, in the event, of any change in the constitution of the firm operating under this registration certificate. Where any such change in the constitution of the firm takes place, the current Registration Certificate shall be deemed to be valid for a maximum period of one hundred and eighty days from the date on which the change has taken place unless, in the meantime, a fresh registration certificate has been taken from the Licensing Authority in the name of the firm with the changed constitution of the firm.

5. In case of change in name or address of a registration holder or overseas manufacturer, operating under this registration certificate, an application for amendment shall be made in online portal of Central Government for prior approval from the Central Licensing Authority for the said changes in registration certificate within a period of sixty days from the date of such change.

6. The importer shall notify to the Licensing Authority immediately in writing, on the class of the cosmetic product which present a risk to the human health and the corrective measure taken.

Form COS- 3

[See rule 13(3), 23(3), 32(2) and 32(3)]

Permission to import or manufacture new cosmetics in India

Number of the permission and date of issue…….M/s…….having address……is hereby permitted to import or manufacture the following new cosmetic under rule 32 of the Cosmetics Rules, 2020.

1. Name of the cosmetic
2. Category or intended use
3. Composition of the product
4. Any special instruction

Dated:

Signature:

Name and Designation of Central Licensing Authority:

Conditions for the grant of permission to import or manufacture new cosmetic

1. The cosmetic product shall conform to the specifications as permitted by the Central Licensing Authority
2. Name of the cosmetic shall be printed or written in indelible ink and shall appear in a conspicuous manner.
3. Any special instructions as permitted shall be printed on the label.
4. No claims other than those permitted shall be made on the label without the prior approval of the Central Licensing Authority

Form COS- 4

[See rule 17(1)]

Application for issue of Import Registration Number for Import of already registered cosmetics.

I/We*_____ *(Name and full address of importer)* hereby apply for the grant of registration number for Import of already registered cosmetics, meant for import into India.

1. Detail of cosmetics

Serial number	Name of cosmetic	(Name of manufacturer and address)	Pack sizes	Registration Certificate Number
1.				
2.				
3.				

2. I/We* enclose herewith the information and undertaking specified in Sixth Schedule duly signed.

3. I/we undertake to comply with all the terms and conditions required to obtain registration number and to keep it valid during its validity period.

Address(s) :_____

Telephone :_____

Fax:_____

E-mail :_____

Place:

Date:

Signature_____

Name_____

Designation _____

Form COS- 4A

[See rule 17(2)]

Import Registration Number to be issued for import of already registered cosmetics into India

Import Registration No.: _____ Date _____

1. M/s _____ (Name and full Address of importer) has been registered under rule 17 as an importer and is hereby issued this Import Registration Number for import of already registered cosmetics into India.

2. Detail of cosmetics

Serial number	Name of cosmetic(s)	Pack size(s)	Name and address of manufacturer
1.			
2.			

3. This Import Registration Number shall remain valid for three years unless it is sooner suspended or cancelled under the Cosmetics Rules, 2020.

4. This Import Registration Number is subject to the conditions stated below and to such other conditions as may be specified in the rules for the time being in force under the Cosmetics Rules, 2020.

Place: _____

Date: _____

Central Licensing Authority

Seal / Stamp

Conditions of the Import Registration Number

1. This Import Registration Number shall be produced by the importer as and when required by the Licensing Authority or regulatory authority.

2. The importer shall inform to the Licensing Authority forthwith in the event of any administrative action taken namely, market withdrawal, deletion of product from the original Registration Certificate holder's or any regulatory restrictions of any cosmetics pertaining to this registration.

3. The importer shall provide the statement of details of cosmetics imported by them annually to the Central Licensing Authority.

Form COS- 5

[See rule 23(2)]

Application for grant of a license to manufacture cosmetics for sale or for distribution

1. I/We ..... of.....hereby apply for the grant of a License to manufacture on the premises situated at ..... the following cosmetics:

2. Details of cosmetic products:

Serial Number	Name of cosmetic	Name of ingredients	Specifications or Standards or Grade of ingredients	Percentage of Ingredients	Function of ingredients

3. Names, qualifications and experience of technical staff employed for manufacture and testing.....

4. A fee of rupees ..... has been credited to Government under the head of account.....

Date.....

Signature.....

Note: The application should be accompanied by a plan of the premises.

Form COS- 6

[See rule 23(2)]

Application for grant of a loan license to manufacture cosmetics for sale or for distribution

1. I/We ..... of.....hereby apply for grant of a loan license to manufacture cosmetics, for sale, on the Premises situated at .....C/o..... the following cosmetics:

2. Details of cosmetic products:

Serial Number	Name of cosmetic	Name of ingredients	Specifications or Standards or Grade of ingredients	Percentage of Ingredients	Function of ingredients

3. The names, qualifications and experience of the expert staff actually connected with the manufacture and testing of the specified products in the manufacturing premises.

4. I/We enclose

(a) A true copy of a letter from me/us to the manufacturing concern whose manufacturing capacity is intended to be utilized by me/us.

(b) A true copy of a letter from - the manufacturing concern that they agree to lend the services of their expert staff, equipment and premises for the manufacture of each item required by me / us and they will analyse every batch of and maintain the registers of raw materials, finished products and reports of analysis separately in this behalf.

(c) Specimens of labels, cartons of the products proposed to be manufactured.

5. A fee of rupees….....has been credited to Government under the head of Account.....

Date..... Signature.....

Enter here the name and address of the manufacturing concern where the manufacture will be actually carried out and also their license number.

Form COS- 7

[See rule 23(4) and 23(7)]

Self-certificate of compliance of Good Manufacturing Practices (GMP) for manufacture of cosmetics

(To be given by the applicant along with Form COS- 5 or Form COS- 6 at the time of application for manufacturing licence or loan licence)

1. I/We ..... of.....hereby applied for the grant of a License to manufacture at premises situated at…… the following cosmetics.

1. ……
2. ……
3. ……

2. I/We hereby declare that the above premises having facilities of good manufacturing practices, requirements of premises, plants and equipment for manufacture of above cosmetics as per the Seventh Schedule of the Cosmetics Rules, 2020.

3. I/We undertake to provide facility to inspect the above premises as per the Cosmetics Rules, 2020 to the State Licensing Authority or any officer appointed by the authority.

4. I/We undertake that in case State Licensing Authority or any officer appointed by the authority found any deficiency during an inspection the State Licensing Authority have a full right to cancel or give any direction for improvement for Good Manufacturing Practice in the said premises in respect of the above said cosmetics. Further I will not claim any damages, etc. for any action of the State Licensing Authority in this regard.

Date:

Place:

Name:

Signature:

Designation:

Form COS- 8

[See rule 25, 26(g), 27(1), 28 and 30(1)]

License to manufacture cosmetics for sale or for distribution

Number of license and date of issue.....

1.....is hereby licensed to manufacture on the premises situated at ..... the following cosmetics under the supervision of the following technical staff

(a) Details of cosmetic products:

Serial Number	Name of cosmetic	Name of ingredients	Specifications or Standards or Grade of ingredients	Percentage of Ingredients	Function of ingredients

(b) Names of the technical staff.....

2. The licence unless sooner suspended or cancelled shall continue to remain valid. However, the compliance with the conditions of licence and the provisions of the Drugs and Cosmetics Act and Rules shall be assessed at least once in a year.

3. The license is subject to the conditions stated below and to such other conditions as may be specified in the Cosmetics Rules, 2020.

State Licensing Authority

Signature.....

Designation.....

Date of issue.....

Conditions of License

1. This license shall be kept on the approved premises and shall be produced at the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.

2. Any change in the technical staff shall be forthwith reported to the Licensing Authority.

3. If the licensee wants to manufacture for sale additional items he should apply to the Licensing Authority for the necessary endorsement to the license as provided in rule 23. This license shall be deemed to extend to the cosmetics so endorsed.

4. The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the license. Where any change in the constitution of the firm takes place, the current license shall be deemed to be valid for a maximum period of sixmonths from the date on which the change takes place unless, in the meantime, a fresh license has been taken from the Licensing Authority in the name of the firm with the changed constitution.

Form COS- 9

[See rule 25, 26(g), 27(1), 27(3), 28 and 30(1)]

Loan license to manufacture cosmetics for sale or for distribution

1. Number of license and date of issue.....

2. ..... of ..... is here by granted a loan license to manufacture the following cosmetics on the premises situated at . . . . .C/o. ..... under the direction and personal supervision of the following technical staff :

a. Names of the technical staff.....

b. Details of cosmetic products

Serial Number	Name of cosmetic	Name of ingredients	Specifications or Standards or Grade of ingredients	Percentage of Ingredients	Function of ingredients

3. The licence unless sooner suspended or cancelled shall continue to remain valid. However, the compliance with the conditions of licence and the provisions of the Drugs and Cosmetics Act and Rules shall be assessed at least once in a year.

4. The license is subject to the conditions stated below and to such other conditions as are specified in the rules for the time being in force under the Drugs and Cosmetics Act, 1940.

State Licensing Authority

Date.....

Signature.....

Designation.....

Conditions of Licence

1. The license shall be kept on the approved premises and shall be produced at the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.

2. Any change in the technical staff shall be forthwith reported to the Licensing Authority.

3. If the licensee wants to manufacture for sale additional items he should apply to the Licensing Authority for necessary endorsement to the license as provided in rule 23. This license shall be deemed to extend to the cosmetics so endorsed.

4. The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the license. Where any change in the constitution of the firm takes place, the current license shall be deemed to be valid for a maximum period of six months from the date on which the change takes place unless, in the meantime, a fresh license has been taken from the Licensing Authority in the name of the firm with the changed constitution.

Form COS- 10

[See rule 26(i) and 44(1)]

Intimation to person from whom sample is taken

I have this day taken from the premises of ……. situated at..... samples of the cosmetics specified below for the purpose of test or analysis.

Date..... *Inspector……*

Details of samples taken

Date..... *Inspector……*

Form COS- 11

[See rule 26(k) and 62(i)]

Form in which the inspection book shall be maintained

A. The cover of the Inspection Book shall contain the following particulars, namely :

1. The name and address of the licensee .....

2. License number and the date up to which the license is valid .....

B. (i) The pages of the Inspection Book shall be serially numbered and duly stamped by the Licensing Authority. The pages, other than the first and the last pages, shall have the following particulars:-

Name and designation of the Inspector who inspects the premises of the licensee:-

Date of Inspection .....

Observations of the Inspector .....

Signature of the Inspector

(ii) The first and last pages of the Inspection Book shall be endorsed by the Licensing

Authority with the following word, namely :-

'Inspection Book maintained by M/s. ..... situated at..... for license number ..... in Form .....under the Cosmetics Rules, 2020.

Seal and signature of the Licensing Authority.

Notes:

(i) Printed copy of the Inspection Book may be obtained by the licensee from the Licensing Authority on payment.

(ii) The Inspection Book shall be maintained at the premises of the licensee.

(iii) The observations made by the Inspector shall be in triplicate. The original copy shall be retained in the inspection Book to be maintained in the premises of the licensee. The duplicate copy shall be sent to the Licensing Authority. The triplicate copy shall be taken as record by the Inspector.

Form COS- 12

[See rule 32(1)]

Application for grant of permission for new cosmetics for obtaining import registration certificate or manufacturing license

I/We*_____ *(Name and full address)* hereby apply for the grant of permission to import or manufacture a new cosmetics in India. The necessary information or data is given below:-

1. Particulars of new cosmetic:-

a. Name of the cosmetic

b. Category of cosmetic/intended use

c. Composition of the product

d. Test protocols/specification of the raw materials and finished product

2. Assessment of the safety for human health of the finished product, its ingredients, their chemical structure and level of exposure
3. Existing data on undesirable effects on human health resulting from use of the cosmetic product
4. Supporting data for the claimed benefits of cosmetic products should be made available to justify the nature of its effect
5. Draft of the product label and carton
6. Whether the product is marketed in any other country; list thereto
7. Any other data generated on safety, efficacy and quality parameters
8. A total fees of …….. USD……(in words)……has been credited to the Government under the head of account…….(photocopy of receipt is enclosed)

Signature of the Manufacturer/Importer/Authorised agent

Name:

Designation:

Stamp/Seal

Place:

Date:

Form COS- 13

[See rule 40]

Application from a purchaser for test or analysis of a cosmetic under Section 26 of the Drugs and Cosmetics Act, 1940

1. Full name and address of the applicant .....
2. Occupation.....
3. Name of cosmetic purporting to be contained in the sample .....
4. Name and full address of the concern where the cosmetic was purchased……
5. Date on which purchased.....
6. Reasons why the cosmetic is being submitted for test or analysis……

A fee of .....has been credited to Government under the Head of Account "0210- Medical and Public Health, 04-Public Health, 104-Fees and Fines" under the Drugs and Cosmetic Rules 1945, - Central *vide* Challan No ..... dated .....(attached in original)

I hereby declare that the cosmetic being submitted for test was purchased by or for me. I further declare that the sample of the cosmetic being sent for test or analysis is exactly as it was purchased and has not been tampered with in any way.

Date:..... *Signed*……

Form COS- 14

[See rule 40]

Report of test or analysis by Government Analyst under Section 26 of the Drugs and Cosmetics Act, 1940

1. Name of person from whom sample received .....
2. Date of receipt .....
3. Name of cosmetic purporting to be contained in the sample .....
4. *Opinion of the Government Analyst*—The sample referred to above is/is not of standard quality as defined in the Drugs and Cosmetics Act, 1940 and Rules thereunder.

Date :..... *Government Analyst……..*

Form COS- 15

(See rule 42)

Receipt for stock of cosmetics for record, register, document or material object seized under section 22 (1) (c) or (cc) of the Drugs and Cosmetics Act, 1940

The stock of cosmetics for records, registers, documents or material objects detailed below has / have this day been seized by me under the provisions of clause (c) or clause (cc) of sub-section (1) of section 22 of the Drugs and Cosmetics Act. 1940 (23 of 1940) from the premises of .....situated at.....

Date..... *Inspector……..*

Details of cosmetics, records, registers, documents or material objects seized.

Date..... *Inspector……..*

Form COS- 16

[See rule 44(2)]

Receipt for samples of cosmetics taken where fair price tendered thereof under sub- section (1) of section 23 of the Drugs and Cosmetics Act, 1940 is refused

To .....

Whereas I, this..... day of ..... 20....., have taken from the premises of…….. situated at..... samples of cosmetics as specified below:-

Details of Samples……

And whereas I had offered to pay you rupees ..... as the fair price of the samples of cosmetics taken:

And whereas, you have refused to accept the fair price tendered thereof.

Now, therefore, I give you the receipt as the fair price tendered for the samples of the cosmetics- taken by me.

Date..... *Inspector……..*

Form COS- 17

[See rule 45(1)]

Memorandum to Government Analyst

Serial No. of Memorandum .....

From:

To

The Government Analyst,

……

……

The portion of sample or container described below is sent herewith for test or analysis under the provisions of clause (i) of sub-section (4) of Section 23 of the Drugs and Cosmetics Act, 1940.

The portion of sample/container has been marked by me with the following mark.

Details of portion of sample or container with name of cosmetic which it purports to contain—

Date..... *Inspector*.....

Form COS- 18

(See rule 46)

Order under section 22 (1)(c) of the Drugs and Cosmetics Act, 1940 requiring a person not to dispose of stock in his possession

Whereas, I have reasons to believe that the stocks of cosmetics in your possession, detailed below contravene the provisions of section 18 of the Drugs and Cosmetics Act, 1940;

Now, therefore, I hereby require you under clause (c) of sub-section (1) of section 22 of the said Act not to dispose of the said stock for a period of ..... days from the date of this order.

Date..... *Inspector*.....

Details of stock of cosmetics

Date..... *Inspector*.....

Form COS- 19

[See rule 48]

Report of tests or analysis of cosmetics by the Government Analyst.

1. Name of the officer or Inspector from whom received.....
2. Serial number and date of the Officer's/Inspector's memorandum.....
3. Number of sample.....
4. Date of receipt.....
5. Name of the cosmetic purporting to be contained in the sample.....
6. Condition of seals on the packet or on portion of sample or container...

7. Results of test or analysis:-

The sample of cosmetics -

(a) contain a prescribed colour only or does not contain a prescribed colour.

(b) does not contain harmful ingredients or contains harmful ingredients.

(c) conforms to claims made on the label as to the nature and quality of or does not conform to claims made on the label as to the nature and quality of the cosmetic.

(d) contains not more than ..... parts per million of lead and ..... parts per million of Arsenic .....contains more than ..... parts per million of Lead and .....parts per million of Arsenic.

Date..... *Government Analyst.*

Form COS- 20

See rule 49(1) and 49(3)]

Memorandum to the Director, Central Cosmetic Laboratory

Serial Number .....

To the Director, Central Cosmetic Laboratory .....

From.....

I send herewith, under the provisions of section 25 (4) of the Drugs and Cosmetics Act,1940, sample(s) of a cosmetic purporting to be .....for test or analysis and request that a report of the result of the test or analysis may be supplied to this Court.

2. The distinguishing number on the packet is .....

3. Particulars of offence alleged .....

4. Matter on which opinion is required .....

5. A fee of Rs .....has been deposited in Court.

Date.....

……

Magistrate

Form COS- 21

(See rule 51)

Report of test or analysis by the Central cosmetic laboratory

Certified that the sample bearing number ..... …….. purporting to be a sample of. ..... received on ..... with memorandum No .....dated.....from..... has been tested or analysed and that the result of such test or analysis is as stated below.

2. The condition of the seals on the packet on receipt was as follows: —

*3. In the opinion of the undersigned the sample is of standard quality is not of standard quality as defined in the Drugs and Cosmetics Act, 1940 and Rules thereunder for the reasons given below:–

Director,

Date…….. Central cosmetic laboratory or other authorized officer

Details of results of test or analysis with protocols of test applied

Director,

Date…… Central cosmetic laboratory or other authorized officer

*If opinion is required on any other matter, the paragraph should be suitably amended.

Form COS-22

[See rule 55(1)]

Application for grant of approval for carrying out tests on cosmetics or raw materials used in the manufacture thereof on behalf of licensees for manufacture for sale of cosmetics

1. *I/We…….of…….hereby apply for the grant of approval for carrying out tests on the following items of cosmetics or raw materials used in the manufacture thereof on behalf of licensees for manufacture for sale of cosmetics.

2. Items of cosmetics:

(1) ……..

(2)……..

(3)……..

3. Name, qualifications and experience of expert staff employed for testing and the person-in-charge of testing.

4. List of testing equipments provided.

5. I/We enclose a plan of the testing premises showing the location and area of the different sections thereof.

6. An application fee of rupees..... or an inspection fee (in case of further application after rejection) of rupees..... has been credited to Government under the Head of Account.....

Date..... Signature…….

Form COS- 23

(See rule 56(1), 56(2), 58(1), 59, 60(1) and 62)

Approval for carrying out tests on cosmetics and raw materials used in their manufacture on behalf of licensees for manufacture for sale of cosmetics

1. Number of approval and date of issue:……

2. Approval is hereby granted to.....…….for carrying out tests for identity, purity and quality on the following items of cosmetics and the raw materials used in the manufacture thereof on the premises situated.....

Items of cosmetics

(1) ……..

(2)……..

(3)……..

3. Names of competent technical staff employed for testing and the person-in-charge of testing.

4. The approval shall be in force from.....to.....

5. The approval is subject to the conditions stated below and such other conditions as may be specified in the rules for the time being in force under the Act.

Date..... Signature.....

State Licensing Authority

Conditions of Approval

1. This approval shall be kept in the approved premises and shall be produced at the request of the Inspectors appointed under the Act.
2. If the approved institution wishes to undertake during the currency of the approval the testing of any other items of cosmetics it should apply to the State Licensing Authority for necessary endorsement as provided in rule 56.This approval will be deemed to extend to the item so endorsed.
3. Any change in the analytical staff or in the person-in-charge of the testing shall be forth with reported to the State Licensing Authority.
4. The approved institution shall inform the State Licensing Authority in writing in the event of any change of the constitution of the institution operating under this Form. Where any change in the constitution of the institution takes place, the current approval shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless in the mean time, a fresh approval has been taken from the State Licensing Authority in the name of the institution with the changed constitution.

Form COS- 24

[See rule 62(f)]

Report of test or analysis by approved institution

1. Name of manufacturer from whom sample received together with his manufacturing licence number under the Act and under the rules made thereunder.

2. Reference number and date of the letter from the manufacturer under which the sample was forwarded

3. Date of receipt of the sample.

4. Name of cosmetic/raw material purporting to be contained in the sample.

5. Details of raw material/final product in bulk/final product (in finished pack) as obtained from the manufacturer:

(a) Original manufacturer's name in the case of raw materials repacked.

(b) Batch number.

(c) Batch size as represented by sample.

(d) Date of manufacture, if any.

(e) Date of expiry, if any.

6. Results of test or analysis with protocols of test or analysis applied.

In the opinion of the undersigned, the sample referred to above is *of standard quality/is not of standard quality* as defined in the Act and the rules made thereunder for the reasons given below.

Date..... .....

Signature of Person-in-charge of testing

Note:-Final product includes repacked material.

[F.No. X.11014/35/2018-DR]

Dr. MANDEEP K BHANDARI, Jt. Secy.

Note : The principal rules were published in the Gazette of India *vide* notification number F.28-10/ 45-H. (1), dated 21st December, 1945 and last amended *vide* notification number G.S.R. 166(E), dated the 11th March, 2020.

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