

## DOCUMENTS TO BE SUBMITTED FOR THE GRANT OF COSMETICS LICENCE.

1. **Application Form-31**
2. **Challan Form for Rs.3500** per application and fee the additional (@ Rs.100 per item excluding first 10 items per section) proposed to be manufactured credited separately in Government account as per the following codes.  
**Treasury Code: CT000      DDO Code: 115**  
**Major: 0210                  Sub-Major: 01                  Minor: 107                  Sub-Head: 01**
3. Affidavit on behalf of the applicant (Proprietor / Partner / Managing Director / General Power of Attorney Holder) duly attested by the Oath Commissioner / Notary (as per the Prescribed language)
4. **List of the Machineries to be installed.**
5. **List of the Laboratory Equipment to be provided**
6. **Certificate of Registration from the Industry Department (Attested photocopy).**
7. **Valid NOC from the Pollution Control Board. (Attested Photocopy).**
8. Registration papers of the land in case of owner attested -photocopy with recent copy of 'farad' from the Revenue Deptt.
9. **Rent/Lease agreement deed-attested photocopy.**
10. **Constitution of the firm-attested photocopy.**
11. **COMPETENT PERSON (S) RESPONSIBLE FOR MANUFACTURING**
  - i) Medical fitness certificate indicating complete investigation.
  - ii) Appointment letter of the employee-attested photocopy.
  - iii) Joining/acceptance letter of the employee-attested photocopy.
  - iv) Affidavit on behalf of the appointed competent person responsible for manufacturing (as per the prescribed language)
  - v) Qualification certificate-degree/diploma/matriculation-attested photocopy
  - vi) Certificate of approval as manufacturing chemist by the competent drug authority-attested photocopy.
  - vii) Experience certificate on the letter pad bearing license Nos. of the issuing firm-original copy
  - viii) Passport size photographs (1 attested and 4 plain).
12. **COMPETENT PERSON (S) RESPONSIBLE FOR TESTING**
  - i) Medical fitness certificate indicating complete investigation.
  - ii) Appointment letter of the employee-attested photocopy.
  - iii) Joining/acceptance letter of the employee-attested photocopy.
  - iv) Affidavit on behalf of the appointed competent person responsible for manufacturing (as per the prescribed language).
  - v) Qualification certificate-Degree/diploma/matriculation-attested photocopy.
  - vi) Certificate of approval as Analytical chemist by the competent drug authority-attested photocopy.
  - vii) Experience certificate on the letter pad bearing license Nos. of the issuing firm-original copy
  - viii) Passport size photographs-1 attested and 4 plain.
13. **List of the items proposed to be manufactured section wise, indicating the following details:**
  - Reference thereof
  - Ingredients, specification and qty, per unit pack.
  - Brief of the manufacturing including critical steps, if any
  - Testing method-both approved and in house developed for raw material, in- process and finished product.
  - Proposed packing presentation and packing material proposed to be used.
14. **Site Plan (to the scale) Location and Layout of the proposed premises clearly indicating size and definition of the area and details of the furniture and fixtures provided therein, drawn and certified by the competent authority-Blue Print (2-copies).**

**COSMETIC MANUFACTURING LICENCE.**  
**LANGUAGE OF AFFIDAVIT FROM THE COMPETENT PERSON RESPONSIBLE FOR**  
**MANUFACTURING AND TESTING.**

I \_\_\_\_\_ son/daughter/wife of Shri \_\_\_\_\_ age \_\_\_\_\_  
Years, permanent resident of village/town \_\_\_\_\_ P.  
O. \_\_\_\_\_ Tehsil \_\_\_\_\_ Distt. \_\_\_\_\_ of do hereby solemnly  
affirms and declare as under :

1. That I am full paid employee of the firm named as M/s \_\_\_\_\_ situated at  
\_\_\_\_\_ town / village \_\_\_\_\_  
P.O. \_\_\_\_\_ Tehsil \_\_\_\_\_ Distt. \_\_\_\_\_ of Himachal Pradesh  
from \_\_\_\_\_ (date) and Shri \_\_\_\_\_ prop./ managing partner of the firm, is  
my employer.
2. That I have never been convicted under any provision of the Drugs and Cosmetics Act, 1940 and  
Rules, 1945 made thereunder anytime and anywhere.
3. That I am the competent person responsible for manufacturing/testing of the cosmetics for sale  
and/or distribution of the above said firm, and possesses qualification as prescribed under Rules  
139(1)(a) or 139(1)(b) or 139(1)(c) of the Drugs and Cosmetics Rules 1945 i.e. B. Pharmacy/D  
Pharmacy/M.Sc./ other, and is not engaged anywhere else in any kind of services or business. I  
Possesses \_\_\_\_\_ Years working experience with M/s  
\_\_\_\_\_ situated at  
\_\_\_\_\_ from  
to \_\_\_\_\_ (mentioned in Chronological order).
4. That manufacturing/testing of the cosmetics, the firm entitled to manufacture, shall be affected  
under my personal supervision only.
5. That I shall intimate the Drugs Licensing Authority, Swasthya Sadan, Shimla-9 at least one  
month Before leaving the firm without any failure.
6. That I shall maintain proper record in accordance with provisions given in the Drugs and  
Cosmetics Rules, 1945, especially as prescribed under Schedule M II.
7. That I shall strictly observe the Good Manufacturing practices as detailed in Schedule M II and  
as amended from time to time.
8. That I shall abide by all the instructions issued under the provisions of the Drugs and Cosmetics  
Act, 1940 and Rules made hereunder as amended from time to time.

**DEPONENT**

**VERIFICATION:**

I the above said deponent further state on oath that the contents of the above affidavit are true to  
the best of my knowledge and nothing relevant has been concealed there from and as such I verify the  
same.

**PLACE** \_\_\_\_\_

**DATE** \_\_\_\_\_

**DEPONENT**

**COSMETICS MANUFACTURING LICENCE**  
(Regarding Formulation and Claim)  
**LANGUAGE OF ADDITIONAL AFFIDAVIT FROM A PROPRIETOR, PARTNER,**  
**MANAGING DIRECTOR, DIRECTORS, GPA HOLDER etc.)**

I, \_\_\_\_\_ son/daughter/wife of Shri \_\_\_\_\_ age \_\_\_\_\_ years resident  
of village/town \_\_\_\_\_ P.O. \_\_\_\_\_ Tehsil \_\_\_\_\_ Distt \_\_\_\_\_ of  
Himachal Pradesh do hereby solemnly affirms and declare as under :

1. That I am sole proprietor/managing partner/GPA holder of the firm named as M/s \_\_\_\_\_ situated at \_\_\_\_\_ town/village \_\_\_\_\_ P.O. \_\_\_\_\_ Tehsil \_\_\_\_\_ Distt \_\_\_\_\_ of Himachal Pradesh. Following are the partners of the said firm:
  1. \_\_\_\_\_
  2. \_\_\_\_\_
2. That the above said firm is hereby applying for the grant of manufacturing of Cosmetics for Sale and Distribution on FORM-31 for the first time.
3. That I am never been convicted/I have and any partners of the said firm has never been convicted under any provision of the Drugs and Cosmetics Act, 1940 anytime and anywhere.
4. That I am legal owner of the proposed premises/that shirk / Smt. \_\_\_\_\_ Son / Wife of Shri \_\_\_\_\_ is legal owner of the proposed premises, who is resident of village \_\_\_\_\_ P.O. \_\_\_\_\_ Tehsil \_\_\_\_\_ Distt \_\_\_\_\_ of Himachal Pradesh and has agreed upon to rent out the said premises in my favour for manufacturing cosmetic for sale and/or distribution and possesses an area as per the map being submitted here with to the Drugs Licensing Authority, at the above said location and address.
5. That Sh./Smt./Ms \_\_\_\_\_ son/daughter of Shri \_\_\_\_\_ age \_\_\_\_\_ permanent resident of village/town \_\_\_\_\_ Tehsil \_\_\_\_\_ Distt \_\_\_\_\_ is full time appointed competent person of the above said firm responsible for manufacturing of cosmetics for sale and/or distribution, who possesses qualification as prescribed under 139(1)(a) or 139(1)(b) or 139(1)(c) of the Drugs and Cosmetics Rules 1945 and he/she is not engaged anywhere else in my kind of service or business to the best my knowledge.
6. That Sh. / Smt. / Ms \_\_\_\_\_ son/daughter of Shri \_\_\_\_\_ age \_\_\_\_\_ permanent resident of village/town \_\_\_\_\_ Tehsil \_\_\_\_\_ Distt \_\_\_\_\_ is full time appointed competent person of the above said firm responsible for testing of all substances to be used for or incorporated in the cosmetics Rules 1945 and he/she is not engaged anywhere else in my kind of service or business to the best of my knowledge.
7. That manufacturing and testing of the cosmetics, shall be affected under personal supervision of the competent persons as detailed in Para 5 and 6 above respectively only. In case if any one leaves the said firm I shall intimate the Licensing Authority immediately and appoint a fresh person at least before one month of such change with prior permission of the Licensing Authority.
8. That I shall strictly observe the condition of the license as prescribed under Rule 142 and Schedule M II of the Drugs and Cosmetics Rules 1945.
9. That I shall maintain proper purchase, manufacturing, testing and sale or distribution records in Accordance with the Schedule M II of thee Drugs and Cosmetics Rules, 1945.
10. That I shall strictly observe the Good Manufacturing practices as detailed in Schedule M II and as Amended from time to time.
11. That I shall inform the Licensing Authority at least three moths before closing the business.
12. That I shall abide by all the instructions issued under the provisions of the Drugs and Cosmetics Act, 1940 and Rules, 1945 made there under as amended from time to time.
13. That in case there will be any change or alteration in the premises or name of the firm or constitution of the firm. I shall obtain a fresh license within the period of three moths of such change.

**DEPONENT**

**VERIFICATION**

I the above said deponent further state on oath that the contents of the above affidavit are true to the best of my knowledge and nothing relevant has been concealed there from and as such I verify the same

PLACE \_\_\_\_\_

**COSMETICS MANUFACTURING LICENCE**  
**(Regarding Formulation and Claim)**  
**LANGUAGE OF ADDITIONAL AFFIDAVIT FROM A PROPRIETOR / MANAGING**  
**DIRECTOR / DIRECTOR / PARTNER / GPA HOLDER etc.)**

I \_\_\_\_\_ son/daughter/wife of Shri \_\_\_\_\_ age \_\_\_\_\_  
resident of village/town \_\_\_\_\_ P.O. \_\_\_\_\_ Tehsil \_\_\_\_\_  
Distt \_\_\_\_\_ do hereby solemnly affirms and declare as under:

1. That I am sole proprietor/managing partner of the firm named as M/s \_\_\_\_\_ situated at \_\_\_\_\_ town/village \_\_\_\_\_ P.O. \_\_\_\_\_ Tehsil \_\_\_\_\_ Distt \_\_\_\_\_ of Himachal Pradesh. following are the Partners / Directors of the said firm:  
1. \_\_\_\_\_ 2. \_\_\_\_\_
2. That the above said firm is hereby applying for the grant of manufacturing of cosmetics for sale and distribution on FORM 31 and propose to manufacture cosmetics as per the contents of the list attached herewith only.
3. That patent and proprietary name/brand name as mentioned in the list does not resemble same to the patent/proprietary name of any other firm already available in the market to the best of my knowledge. In case if any such coincidence I undertake to withdraw the same.
4. That product presentation i.e. packing style, as proposed to be used for packing the drug does not resemble in any way to any firm already available in the market to the best of my knowledge. In case if there is any such coincidence I undertaking to withdraw the same.
5. That every cosmetic including patent and proprietary cosmetics, the above said firm propose to manufacture for sale or distribution.
  - I. Contains the constituent ingredients in quantities as determined in relation to the claims or condition for which the cosmetic are recommended for use or claimed to be useful.
  - II. Are safe for use in the context of the vehicles, excipients, additives and Pharmaceutical aids used in formulation, and under the conditions in which The formulation for administration and used are recommended.
  - III. Are stable under the condition of storage recommended; and
  - IV. Contain such ingredients and in such quantities for which there is justification.
6. That I and my firm shall not undertake manufacture of any drug other than as approved by the Licensing Authority, in any form, with alteration or modification without the approval and necessary permission of the Drugs Licensing Authority.
7. That I undertake hereby to withdraw any drug completely from the market, in case of any such instructions are received from the Licensing Authority.

**DEPONENT**

**VERIFICATION:**

I the above said deponent further state on oath that the contents of the above affidavit are true to the best of my knowledge and nothing relevant has been concealed there from and as such I verify the same.

Place \_\_\_\_\_

Date \_\_\_\_\_

**DEPONENT**

DOCUMENT (proposed) TO BE KEPT READY AT THE TIME OF INSPECTION.

As prescribed in Schedule M II of the Drugs and Cosmetics Rules 1945.

1. Master Formula Record for every product proposed to be manufactured
2. Record showing routine sanitation programme drawn up for
  - Specific area
  - Equipment
  - Material of cleaning
  - Interval
  - Person responsible
3. Raw material testing record-proposed proforma.
4. Packaging Record and Batch Packing Records.
5. Batch processing Record (BPR)
6. Records pertaining to Quality Control
7. Distribution Records
8. SOP's both functional and operational for every activity to be carried out.
9. Others as prescribed under Schedule M II.