DOCUMENT TO BE SUBMITTED FOR THE GRANT/RENEWAL OF DRUGS MANUFACTURING LICENCES.

1. Application Form-24/24-A and 27/27-A

2. Challan Form for Rs. 7500/- per application and fees for the additional (@ 300/- per Item excluding first 10 items per section) proposed to be manufactured to be separately in Government account as per the: -

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 Plant & Machinery installed.

5. List of the Laboratory Equipments 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 Department). Or
In case the Premises are Rented, Rent / Lease Agreement Deed (Attested photocopy).

9. Constitution of the firm (Attested photocopy).

10 . **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 (is).

vi) Certificate of approval as manufacturing chemist by the competent drug authority-attested photocopy.

vii) Experience certificate on the letter pad bearing licence Nos. of the issuing firm-original copy.

viii) Passport size Photographs.

11. **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 (is).

vi) Certificate of approval as Analytical chemist by the competent drug authority-attested photocopy.

vii) Experience certificate on the letter pad bearing licence Nos. of the issuing firm-original copy.

viii) Passport size Photographs.

12. List of the items proposed to be manufactured section wise and category wise (Biological and Non-Biological) indicating the following details:

- Reference thereof.
- Ingredients, specification and qty. per unit dose,
- Brief of the manufacturing including critical steps, if any

State Controlling & Licensing Authority
Food & Drugs Administration
C.G. Raipur

- Testing method-in case of non-pharmacopoeia drugs and ingredients
- Proposed packing presentation and packing material proposed to be used.

13. **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.**

State Controlling & Licensing Authority
Food & Drugs Administration
C.G. Raipur

DRUGS MANUFACTURING LICENCE

LANGUAGE OF AFFIDAVIT FROM THE COMPETENT PERSON RESPONSIBLE FOR MANUFACTURING.

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 time paid employee of the firm named as M/s _____ situated at _____ town/village _____ P.O. _____ Tehsil _____ Distt _____ of Himachal Pradesh from _____ (date) and Shri _____ Proprietor / Managing Partner/ Director 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 hereunder anytime and anywhere.

3. That I am the competent person responsible for manufacturing of the drugs for sale and/or distribution of the above said firm, and possesses qualification as prescribed under 71(1) (a) or 71(1) (b) and 76(1) (a) or 76(1) (b) of the Drugs and Cosmetics Rules 1945 i.e. B. Pharmacy, B.Sc. / M.Sc., other, and is not engaged anywhere else in any kind of services or business. I possess _____ Years working experience with M/s _____ situated at _____ from _____ to _____ (mention in chronological order).

4. That manufacturing of the drugs, the firm entitled to manufacture, shall be affected under my personal supervision only.

5. That I shall intimate the Drugs Licensing Authority, Swasthay Sadan, Shimla-9 at least one month before leaving the firm without any failure.

6. That I shall maintain proper manufacturing record in accordance with the provisions given in the Drugs and Cosmetics Rules 1945, especially as prescribed under Schedule U.

7. That I shall strictly observe the Good Manufacturing Practices as detailed in Schedule M and as amended from time to time.

8. That I shall abide by all the instruction issued under the provision of the Drugs and Cosmetics Act, 1940 and Rules, 1945 made there under as amended from time to time.

DEPONENT

State Controlling & Licensing Authority
Food & Drugs Administration
G.G. Raipur

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

State Controlling & Licensing Authority
Food & Drugs Administration
C.G. Raipur

DRUGS MANUFACTURING LICENCE

LANGUAGE OF AFFIDAVIT FROM THE COMPETENT PERSON RESPONSIBLE FOR 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 time paid employee of the firm named as M/s _____ situated at _____ town/village _____ P.O. _____ Tehsil _____ Distt _____ of Himachal Pradesh from _____ (date) and Shri _____ Proprietor / Managing Partner/ Director 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 hereunder anytime and anywhere.

3. That I am the competent person responsible for testing of the drugs for sale and/or distribution of the above said firm, and possesses qualification as prescribed under Rule 71(4-A) and/or 76(4-A) of the Drugs and Cosmetics Rules 1945 i. e. B. Pharmacy, B.Sc. / M.Sc., other, and is not engaged anywhere else in any kind of services or business. I possess _____ Years working experience with M/s _____ situated at _____ from _____ to _____ (mention in chronological order).

4. That testing of the drugs, the firm entitled to manufacture, shall be affected under my personal supervision only.

5. That I shall intimate the Drugs Licensing Authority, Swasthay Sadan, Shimla-9 at least one month before leaving the firm without any failure.

6. That I shall maintain proper testing record in accordance with the provisions given in the Drugs and Cosmetics Rules 1945, especially as prescribed under Schedule U.

7. That I shall strictly observe the Good Manufacturing Practices as detailed in Schedule M and as amended from time to time.

8. That I shall abide by all the instruction issued under the provision of the Drugs and Cosmetics Act, 1940 and Rules, 1945 made there under as amended from time to time.

DEPONENT

State Drugs Controlling Authority
Food & Drugs Administration
C.O. Baijnath

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

Food & Drugs Administration
C.C. Jaipur

DRUGS MANUFACTURING LICENCE

Language of affidavit from PROPRIETOR/PARTNER/GPAHOLDER etc.)

I _____ Son/daughter/wife of Shri _____ age _____ years, permanent 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/managing director/director/GPA holder of the firm/company named as M/s_____ situated at _____town/village_____P.O. _____Tehsil_____ Distt _____ of Himachal Pradesh. Following are the partners/directors of the said firm/company:
1. _____ 2. _____

2. That the above said firm/company is hereby applying for the grant of manufacturing of drugs for sale and distribution on FORM 24/24-A and/or FORM –27/27-A for the first time.

3. That I have never been convicted. That neither I & nor any partner/directors of the firm/company have never been convicted under Drugs & Cosmetics Act, 1940 anytime and anywhere.

4. That I am legal owner of the proposed premises. That Sh. _____ is the legal owner of the 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 drugs 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_____permanentresidentofvillage/town _____Tehsil_____ Distt_____ is full to time appointed competent person of the above said firm responsible for manufacturing of drugs for sale who possess qualification as prescribed under Rule 71(1)(a) or, 71(1)(b) and 76(1)(a) or 76(1)(b) as he possesses qualification B. Pharma or B.Sc./M.Sc. and approved from _____ of the Drugs and Cosmetics Rules 1945 and he/she is not engaged any where else in any kind of services or business to the best of 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 drugs for sale and/or distribution, who possesses qualification as prescribed under Rule 71 (4-A) and 76(4-A) of the Drugs and Cosmetics Rules 1945 and he/she is not engaged anywhere else in any kind of services or business to the best of my knowledge.

7. That manufacturing and testing of the drugs, shall be affected under personal supervision of the competent persons as detailed in Para 5 and 6 above 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 licence as prescribed under 71 and 76 of the Drugs and Cosmetics Rules 1945.

Drugs Controlling & Licensing Authority
O/o Deputy Commissioner
C.C. Baijnath

9. That I shall maintain proper purchase, manufacturing, testing and sale or distribution records in accordance with the Schedule U of the Drugs and Cosmetics Rules, 1945.

10. That I shall strictly observe the Good Manufacturing Practices as detailed in Schedule M and as amended from time to time.

11. That I shall inform the Licensing Authority at least three months 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 alternation in the premises or name of the firm or constitution of the firm. I shall obtain a fresh license within the period of three months 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_____

DATE _____ **DEPONENT**

State Controlling & Licensing Authority
Food & Drugs Administration
C.G. Raipur

DRUGS MANUFACTURING LICENCE

Language of additional affidavit from a PROPRIETOR/PARTNER/GPA HOLDER etc.)

I _____Son / Daughter / Wife of Shri _____age _____ Years, Permanent resident of village/town _____ P.O. _____Tehsil_____Distt. ____.

1. That I am sole Proprietor / Managing Partner / Managing Director / Director / GPA holder of the named as M/S _____ situated at _____ Town / Village _____ P.O. _____ Tehsil._____ Distt. _____ of Himachal Pradesh. Following are the partners of the said _____ firm/company:
   i) _____ ii) _____ iii) _____
2. That the above said firm is hereby applying for the grant of manufacturing of drugs for sale and distribution on Form-24/24-A and/or Form-27/27- A and propose to manufacture drugs 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 there is 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 with any other firm to the best of my knowledge. In case if there is any such coincidence I undertake to withdraw the same.
5. That every drug including patent and proprietary medicines, the said firm proposes to manufacture for sale or distribution.

   I. Contains the constituent ingredients in therapeutic/prophylactic quantities as determined in relation to the claims or condition for which the medicines 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 use are recommended.

   III. Are stable under the condition of storage recommended; and

   IV. Contain such ingredients and in such quantities for which there is Therapeutic 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 from the Drugs Licensing Authority.
8. That the proposed list of drugs as submitted for approval does not include any new drug as defined in the Rule 122-E of the Drugs and Cosmetics Rules 1945 to the best of my knowledge. In case of any such coincidence I undertake to withdraw the same at any time at my own risk and responsibility.

State Controlling & Licensing Authority
Food & Drugs Administration
C.G. Raipur

9. That in case the firm propose to manufacture any New Drug as defined under Rule 122-E of the Drugs and Cosmetics Rules, 1945. I shall obtain necessary permission on Form No.46 from Drugs Controller General (India), New Delhi, under intimation to the State Drugs 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.

DEPONENT

State Controlling & Licensing Authority
Food & Drugs Administration
C.G. Raipur

DOCUMENT AS PROPOSED TO BE KEPT READY AT THE TIME OF INSPECTION AS PRESCRIBED IN SCHEDULE M PART 1 OF THE DRUGS AND COSMETICS ACT, 1940.

1. Master Formula Record for every product proposed to be manufactured.
2. Site Master File (SMF)
3. Record showing routine sanitation programme drawn up for
   .Specific area
   - Equipment
   - Material of cleaning
   - Interval

   .Person responsible
4. Raw material testing record
5. Packaging Record and Batch Packing Records
6. Batch processing Record (BPR)
7. Records pertaining to Quality Control
8. Distribution Records
9. SOP s both for every function and operation to be carried out in the premises
10. Others as prescribed under Schedule M.

State Controlling & Licensing Authority
Food & Drugs Administration
C.G. Raipur

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.
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
    ix) Passport size photographs .

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.

State Controlling & Licensing Authority
Food & Drugs Administration
C.G. Raipur

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.**

State Controlling & Licensing Authority
Food & Drugs Administration
C.S. Jaipur

COSMETIC MANUFACTUIRNG 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 _____situatedat _____ 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 _____YearsworkingexperiencewithM/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

State Controller & Licensing Authority
Food & Drugs Administration
C.C. Jaipur

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_____ year s 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_____situatedat _____ 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.

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_____

DATE _____

DEPONENT

Licensing Authority
Drugs Administration
C.G. Raipur

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
   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

Licensing Authority
Food & Drugs Administration
C.O. Kalpur

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

State Licensing Authority
Food & Drugs Administration
C.G. Raipur

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.

State Controlling & Licensing Authority
Food & Drugs Administration
C.G. Raipur