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

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- 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.**

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