DOCUMENT TO BE SUBMITTED FOR THE GRANT 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.
7. **(Attested photocopy).**
8. Valid **NOC** from the **Pollution Control Board (Attested photocopy).**
9. 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).
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 (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-1 (attested) and 4 (unattested).
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 (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-1 (attested) and 4 (unattested).
13. 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
    - Testing method-in case of non-pharmacopoeia drugs and ingredients
    - 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).**