CHECK LIST FOR APPLICATIONS FOR GRANT OF LICENCES IN FORM- 25, 25B, 28, 28B, 29 AND 32.

DOCUMENTS TO BE SUBMITTED TO THE DIRECTOR, DRUGS CONTROL ADMINISTRATION, BY THE APPLICANT ALL IN DUPLICATE.

1. Covering Letter:

2. Challan for the required amount under the Head of Account 0210-Medical and Public Health, 04-Public Health, 104-Fees, Fines etc.

3. Statutory Forms: FO RM: FEES for Five Years
24 Rs.7500-00
27 Rs.7500-00
24F (Schedule) Rs.7500-00

4. Plan and layout of the premises showing the Installation of Machinery and Equipment.

5. Attested copies of documents relating to the Ownership/Rent/Lease/Allotment of the Site building along with proof of ownership.

6. Declaration of the Proprietor/Partners/Directors etc., in Affidavit I,(Format enclosed) Attested copies of Partnership Deed/Memorandum and Articles of Association.

7. Affidavit-II (Format enclosed) Attested by Notary regarding the name, address and other details of the person responsible to the day to day affairs of the Company and for the conduct of business along with his Photograph duly attested.

8. Attested Copy of Ration Card or Passport or Electoral Card in support of proof of residential address of the responsible person.

9. Detailed list of Manufacturing and Analytical Equipment with copies of purchase Bills.

10. Attested copies of Certificates of academic qualification, experience Certificates, Bio-data and declarations of Technical Staff in the prescribed Proforma with attested photos (Proforma-I and II) (Formats enclosed).

11. Permission from the Municipality or Municipal Corporation or Panchayat authorities for construction and starting the Unit.

12. Clearance from Drugs Controller General(India), New Delhi in case of new drugs (Either Bulk drug or formulation) - New Drugs are defined under Rule 122 E of Drugs and Cosmetics Rules, 1945.

13. Permission from the Health Authorities of the area for setting up the manufacturing facility.

DOCUMENTS REQUIRED IN CASE OF APPLICATIONS FOR FORMULATIONS:

1. Consolidated list of formulations with packing particulars.

2. Specimen Labels.

3. Labels of similar products in respect of Non- Pharmacopoeal products.

4. Method of Test/Analysis for the finished products and also for the ingredients which are not official in any pharmacopiea or any official compendia of Drug Standards.

5. Copies of monographs of drugs, which are not included in I.P.

DOCUMENTS REQUIRED IN CASE OF APPLICATION FOR BULK DRUGS:

1. Permission from A.P. Pollution Control Board.

2. Brief Manufacturing procedure and flow chart along with consumption co-efficient Effluents generated and their treatment for the drugs applied for along with the Methods/procedure of Test/Analysis.