Checklist for the grant of licence for Manufacturing Pharmaceutical Products

1. Covering letter.

2. Application Form with nonjudiciary stamp of Rs 2/
(i) For Non Biological Products*:-
Form 24/24A/24B/24C/24D/24E/24F
(ii) For Biological Products*:-
Form27/27A/27B/27D
*(Strike whichever is not Applicable)

3. Site Master File

4. Challan in original, indicating the licence fees paid.

5. Two Copies of the plan drawn to scale w.r.t Manufacturing area, Sectionwise), Quality Control (Sectionwise), Raw material store (including Thermolabile Raw Materials), Finished Product Store, Packing Material Store, Service area etc.

6. List of Machinaries installed with make and Production capacity (Sectionwise).

7. List of Instruments/Equipments in Quality Control. (Sectionwise).
Viz
(i) Instrumental & Chemical analysis.
(ii) Microbiological Analysis.
(iii) Bacterial Endotoxin Test.
(iv) Toxicity Test.

8. Names of the Competent Technical staff in
(i) Manufacturing, (Sectionwise).
(ii) Quality Control, (Sectionwise).
(iii) Quality Assurance
along with the relevant documents viz, Educational Qualifications, Experience, approval, appointment letter and acceptance letter of the candidate.etc.

9. N.O.C. from Pollution Control Board

10. List of Directors/Partners of the firm with complete residential address as on the date of application.

Contd.....2/-

11. Power of Attorney in case applicant is other than the Partner/Director.

12. Certified copy of
(i) Memorandum & Article Of Association of Limited, Private Limited company.
(ii) Certified copy of Partnership Deed.

13. Letter from Industrial Development Corpn. for allotment of Plot.

14. Copy of the documents indicating ownership, rental, lease title of the plot.

15. List of products intended to be manufactured in Triplicate section wise on the letterhead of the firm.

16. Additional Information data form for each Products applied.

17. Draft Text of the Carton/Foil/Label of each of the product applied.

18. Label text of the identical product available in the market.

19. Clearance from Drugs Controller General (India, in respect of **New Drug** as defined under Rule 122-E of the Drugs & Cosmetics Rules 1945.

20. Writeup on Water purification System.

21. Writeup on Air Handling Unit system.