**CHECK LIST FOR THE GRANT/RENWAL OF MANUFACTURING LICENCE**

| | | Remarks of the Technical Expert of Firm. | Remarks of the Inspecting Authority. |
|---|---|---|---|
| I.(1) Name and address of Manufacturing Unit. | | | |
| (2) Constitution of the firm - Proprietor/Partner/Pvt. Ltd/Ltd. | | | |
| (3) Name and address of Proprietor/ Partner/Managing Directors/Directors. | | | |
| II.(1) Whether applied in the Statutory Application Form? | Yes No N.A. | | |
| (2) Whether requisite fee is paid and Challan enclosed?_____ (Challan No._____dt._____ Rs._____) | Yes No N.A. | | |
| (3) Whether Plan/Layout of the premises submitted? | Yes No N.A. | | |
| (4) General observations | | | |
| i) Location of the factory. Whether located in a clean place remote from filthy surroundings. | Yes No N.A. | | |
| ii) Whether it is near open sewage, public lavatory? If so, what action has been taken to avoid contamination and exposure of the factory premises to such hazards. | Yes No N.A. | | |
| iii) Details of the occupier of the adjoining building. Is there any activity near by producing obnoxious odour, fume, large quantities of scot, dust smoke etc. If so, action taken to prevent contamination of the premises. | Yes No N.A. | | |
| iv) Whether any products other than drugs Manufactured in the same building. If so, is the product manufactured? In the same building or adjacent Building compatible with the drugs Manufactured by the firm. | Yes No N.A. | | |

v) Maintenance of cleanliness and Hygienic conditions — Yes No N.A.

a) Whether the factory is clean and the equipments and materials are kept in orderly manner from accumulated waste, debris etc. — Yes No N.A.

b) Compound - Whether cement/sandy/ dusty/lawn. — Yes No N.A.

c) Whether floor, walls, ceiling and table tops are smooth and easily washable. — Yes No N.A.

d) Whether electric fixtures and service lines concealed. — Yes No N.A.

e) Whether lighting and ventilation satisfactory. — Yes No N.A.

f) Whether suitable fire extinguishers are provided wherever inflammable materials are stored/handled. — Yes No N.A.

g) Whether materials necessary for manufacture are brought to the manufacturing area after removing packing materials like nay, cardboard's etc. in places away from the factory (for renewal). — Yes No N.A.

h) Whether equipment, working benches tables etc. are arranged in a manner to facilitate cleaning of the area thoroughly and easily. — Yes No N.A.

i) Whether separate sections will necessary machinery for all operations are provided for each category of drugs. — Yes No N.A.

j) Whether building is so constructed in each section to adopt uniflow system to avoid any risk of mix-up.

k) Are sufficient control measures provided -

i) to avoid cross contamination by other drugs or substances & — Yes No N.A.

ii) to avoid risk of omission. — Yes No N.A.

l) Whether doors and windows when closed have any visible gaps (Check lining) — Yes No N.A.

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| m) Whether windows and openings for exhaust system are provided with fly proof mesh. | Yes | No | N.A. |
| n) Whether drainage system is covered suitably cleaned, sprayed and provided with insect proof device. | Yes | No | N.A. |
| o) Whether surroundings are sprayed regularly with insecticides. | Yes | No | N.A. |
| 5) Whether documentary proof is furnished relating to the Ownership/rent/lease/ allotment of site and building. | Yes | No | N.A. |
| 6) Whether the declaration of the Proprietor Partners/Directors is submitted in the form of an Affidavit? | Yes | No | N.A. |
| 7) Whether copy of Ration card/Passport/ Electoral card/any other document in support of residential address is submitted. | Yes | No | N.A. |
| 8) Whether detailed list of equipment for manufacturing and for test/analysis is submitted along with copies of relevant purchase bills. | Yes | No | N.A. |
| 9) a)Whether the proposed Technical staff for Manufacturing and for Test/Analysis were earlier approved by L.A. If yes; Date of approval. | Yes | No | N.A. |
| 10)b)Whether declaring of Technical Staff are submitted. Manufacturing Unit in which he/she was approved. | Yes | No | N.A. |
| 11) Whether permission in obtain from Health Authorities, if so the date of permission. | Yes | No | N.A. |
| 12. Whether consolidated list of formu-lations applied for along with packing details is submitted. | Yes | No | N.A. |
| 13. Whether set of specimen/draft labels is submitted. | Yes | No | N.A. |
| 14. Whether copies of label of equivalent formulation presently sold in the market are enclosed. | Yes | No | N.A. |

15. Whether Method/procedure of Test/Analysis is submitted in respect of all patent and Proprietary medicines. Yes No N.A.

16. Whether copies of monographs of the drugs which are not official in I.P. but applied for are enclosed. Yes No N.A.

17. Is the application is for the Manufacturing of Bulk Drugs. If so a) Whether permission/ clearance from A.P. Pollution Control Board is obtained (State the Number and date). Yes No N.A.

b) Whether Manufacturing process in brief along with Flow Chat and consumption co-efficient, effluents generated and their treatment is submitted. Yes No N.A.

c) Whether the protocols of standards and the matters of Test/Analysis is submitted in respect of Bulk Drugs which are not Official in any Pharmacopoeia. Yes No N.A.

d) Whether copies of Monographs of drugs of drugs applied for which are not official in I.P. but official in other Pharmacopoeia. Yes No N.A.

e) Whether employees including temporary employees who come into direct contact with products and raw materials are medically examined at the time of recruitment and thereafter yearly.

d) Whether records of medical examination maintained. (records should indicate clearly that the workers have been examined for freedom from skin diseases, infections and contagious diseases. Reports of examination of blood, urine stools and sputum and X-ray/screening of chest obtained at the time of employment should be checked). Yes No N.A.

e) Is there any visible sign of employees suffering from infectious/contiguous diseases. Yes No N.A.

f) Whether services of qualified physician for assessing health status of personnel employed in the factory, availed. Yes No N.A.

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| g) Whether washing facilities for workers are provided adjoining working area before entry. (Washing room should be provided with soap, clean towel, hand scrubbing brushes etc.) The area should be provided for each sex. | Yes | No | N.A. |
| h) Whether workers are provided with enough clean uniforms including headgear's, foot wear, masks and hand gloves etc. | Yes | No | N.A. |
| i) Do employees wear necessary uniforms at the time of work. | | | |
| j) Whether employees are provided with protective uniforms during manufacture of sex hormones, corticosteroids, psychotropic substances and other hazardous substances. (collect details of uniforms provided for this purpose). | Yes | No | N.A. |
| k) Are the employees insisted upon to maintain a good degree of personnel hygiene (written instructions in this regard should be kept at strategic points). | Yes | No | N.A. |
| l) Is there any evidence of any unhygienic practices in the mfg. area like eating, chewing, smoking found. | Yes | No | N.A. |
| m) Note the cleaning agent and disinfectant used for cleaning equipment and premises. | Yes | No | N.A. |
| n) Whether rooms are cleaned daily and in between batch operations, if necessary. | Yes | No | N.A. |
| o) Whether all equipment's cleaned immediately after batch operation. (for Renewal). | Yes | No | N.A. |
| p) Whether mfg. area is used for general through fare for personnel or for storage of materials other than materials being processed. (for Renewal). | Yes | No | N.A. |

q) Whether water storage tank, if any cleaned properly and frequently. ( for Renewal ). Yes No N.A.

r) Whether written cleaning schedule for premises, equipment etc. is maintained, and followed scrupulously under supervision of a responsible staff member. The sanitation programme record details should be collected and adequacy checked. ( for Renewal ).

18. Water supply

a) Whether own or municipal supply. Yes No N.A.

b) If own, whether treated before use. Yes No N.A.

c) Whether distilled water or purified water used for manufacture is free from pathogenic organisms. Yes No N.A.

d) If demonized water is used, whether conductivity is tested for checking efficiency of demonizing resin. (for renewal ) Yes No N.A.

e) Whether resin in the demonizing plant replaced and regenerated periodically. Yes No N.A.

f) Whether resin are treated with formaldehyde vapour to prevent contamination. Yes No N.A.

g) Whether waste water and other residue from Lab., prejudicial to public health are disposed after suitable treatment (details should be recorded). Yes No N.A.

19. Heating system:
(firewood and coal should not be used for heating purpose in the mfg. premises)

20. Raw materials.

a) Source of procurement indigenous/imported.

b) Whether procurements are made from bonafied dealers against valid purchase vouchers and bills etc. (for renewal).

c) Whether proper stock and issue registers are maintained with details. (for renewal).

d) Whether physical stocks tally with stocks register (random check may be made) ( for renewal ).

e) Whether containers of raw materials received are examined for damage and recorded. ( for renewal ).

f) Are separate storage facilities for raw materials approved, rejected and those under quarantine (note the conditions of storage - whether on the floors, racks etc. - whether containers are properly closed.

g) Are approved raw materials arranged in such manner in the shelf that the older stocks are approached first for consumption. ( for renewal ).

h) Are they properly and boldly labelled to avoid any mixup. ( for renewal ).

i) Are they labelled as to whether they are under test/approved/rejected with respective control numbers. (for renewal).

j) What action has been taken on the rejected raw materials.

k) Whether separate storage facilities available for inflammable, poisonous and narcotic drugs.

l) Are packing materials stored separately.

m) Whether raw materials are sampled personally by the quality control personnel ( for renewal).

n) Whether cool/cold storage facilities required. If so, whether provided.

21. Labelling and packing:

i) Whether separate packing and labelling section is provided.

ii) Whether labels are kept underlock & key or in a place having very restricted entries (pigeon-hole steel almirah) (for renewal).

iii) Whether labels & cartons are scrutinized to see that they conform to labeling provisions of D&C Act and Rules and the internal standards are released by quality control personnel under written order (one set of labels/strips/inserts to be obtained.)

iv) Whether printing, issue, use and destruction of labels are properly accounted for and records maintained thereof.

22. Storage facilities for finished/semi finished products:

a) Whether storage facilities for finished goods are proper & adequate.

b) Whether each product stored, conspicuously labelled and identified to avoid mix-up. (for renewal).

c) Whether adequate and suitable containers with conspicuous label and lids are provided for storage of semi-finished goods and finished goods awaiting packing.

23. Records:

i) Whether all records are in accordance with those specified in Schedule U. (for renewal).

ii) Whether finished products, simi finished products, raw materials are released under release order signed by quality control personnel. (for renewal).

iii) Whether master formula records with required details are maintained for product. (for renewal).

iv) Whether mfg. records are maintained with required details. (for renewal).

v) Whether records of distribution of their products with details like name, address to whom the drugs were distributed, dt. of distribution, quantity distributed and details of B.No. and transfer documents are maintained. (for renewal).

24. Manufacturing operation and controls

a) Name, qualification and experience of technical personnel employed and the section in which they are working.

b) Whether critical steps of manufacturing operation are done under direct supervision of approved mfg. chemist. (for renewal).

c) Whether non sterile products (like tabs. capsules, oral liquids etc.) are checked for freedom from pathogens like Salmonella E.coli, Pyocyanea etc. or whether suitable measures have been taken ot keep the products free from pathogens. (for renewal)

d) Whether each manufacturing equipment, vessels and containers used in the manufacture and storage are conspicuously labelled with names of products and batch Nos.

e) Whether weighing and measuring equipment's are periodically checked and records maintained.

25. Precautions against contamination and mix-up:

i) (a) Whether separate confined areas with exclusive machineries for operations are provided for sex hormones, corti costeroids, B.Lactum antibiotics, antineoplastic drugs.

(b) Whether suitable pressue differential and exhaust system are provided in the mfg. area.

(c) Whether separate laminar airflow system provided for sterile products.

ii) Whether actual yield against theoretical yield is checked in each product & recorded. (for renewal).

iii) Whether visual checking device with black and white background fitted with diffused light provided wherever necessary.

iv) Whether process controls as required under master formula checked and recorded. (for renewal).

v) (a) details of not of standard quality report on the products of the firm received after last inspection and action by Licensing Authority.

(b) has the firm reprocessed any batch of their products. If so, have they been authority and recorded. (for renewal)

(c) Whether any investigation carried out into causes of defects and appropriate corrective measures incorporated in their master formula records. (for renewal).

vi) (a) What types of containers and closures used in their products. (products vis-a-vis container used to be records.) (for renewal).

(b) do they comply with the product used.

26.Other remarks:

TESTING

1.Whether the firm has testing facilities of their own. Are the available facilities adequate for all the tests required for their preparations (if getting tested from approved lab., the name may be noted.)

2.Whether all raw materials (including Pharmaceutic al aids) and finished pro-ducts are tested prior to use and before release for sale respectively. (for renewal).

3.Are the raw materials which deteriorate at faster rate on storage re-tested six months time. (for renewal).

4.Are the Pharmacopoeial raw materials and formulations subjected to all prescribed tests (random check may be made) (for renewal).

5.Are adequate house specifications laid down for non-pharmacopoeial raw materials and formulations.

6.Does the firm manufacturing ophthalmic and parenteral products have facilities to carry out the following tests.

i) Sterility test and adequate facilities to monitor the bacterial contamination of the premises etc.

ii) Fungus test

iii) Pyrogen test.

7.For sterility testing whether prescribed quantities of samples are collected and tested (check the details of method used for various products) (for renewal).

8.Whether the chemist in-charge of biological testing section has adequate experience in a recognized lab. carrying out such tests.

9.Whether bulk solution to be filled aseptically is tested for sterility.

10.Is the animal house and its maintenance satisfactory and adequate.

11.Whether samples are collected independently by the quality control department (for renewal).

12.Are the apparatus available properly calibrated.

13.How often the standard solutions are checked for correctness of normality, strength etc. (for renewal).

14.Is there a proper place to store the control samples and are they checked and tested periodically.

15.Are the batches recalled from the market whenever the control samples show any deterioration or other visible changes.

16.In parenteral preparations, whether particulate matter identified. (for renewal).

17.Check whether `House specifications' for container and closures are maintained and followed. (for renewal).

18.Whether stability studies are conducted for formulations having a life period (note the system of assigning date of expiry to products having a shelf life) (for renewal).

19.Whether the technical persons employed are competent (names, qualifications and experience of chemists).

III.It the proposed Technical staff were not earlier approved by L.A.

1.Whether Attested two copies of academic qualification are submitted. Yes No N.A.

2.Whether attested true copies of experience certificates are enclosed. Yes No N.A.

3.Whether attested latest Photographs and application submitted by the Manufacturer. Yes No N.A.

IV.If the application is for the grant of Loan License.

1.Whether consent letter of the parent firm is enclosed. Yes No N.A.

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|---|---|
| 2.Whether the number of Loan license already granted exceed the optimum number of 10 loan license. | Yes No N.A. |
| V. If the application for Renewal of the existing license. | |
| 1. Whether the previous license and list of products approved by L.A.are submitted in original. | Yes No N.A. |
| 2.Whether set of printed labels are submitted. | Yes NO N.A. |
| VI.If the application is for grant of additional products. | |
| 1.Whether requisite fee is paid for additional products taking under License in Form-28. (Challan No..... dt.....Rs.....) | Yes No N.A. |
| 2.Whether the additional product applied for is a New Drug. | Yes No N.A. |
| If yes, whether necessary clearance is obtained from Drugs Controller General (India), (Letter No..... dated.....) | Yes No N.A. |
| 3.Whether a consolidated list of all the additional products applied for is submitted along with the formulae. | Yes No N.A. |
| 4.Whether the method of Test/Analysis is submitted in respect of Patent and proprietory medicines. | Yes No N.A. |

Signature of the Technical Expert of the firm

Specific Recommendation of the Inspecting Authority. Recommended / Not Recommended

Date: Signature of the Inspecting Authority.

Remarks of the Licensing Authority. Accepted / Rejected.

Date: Signature of Licensing Authority.