PHARMACEUTICAL LICENSING

Following are the formalities under Rule 16 of the Drugs (Licensing Registering and Advertising Rules 1976).

EXTRACTS SRO 470(I)/98 DATED 15.5.1998
SCHEDULE 'B' RULE 16(a)

SECTION. 1
PREMISES

1. Location and surroundings

1.1. Location. - The premises shall be located preferably in an industrial area and in any case not in any residential or commercial area.

1.2. Surroundings. - Premises shall be situated in an environment that, when considered together with measures to protect the manufacturing processes, presents minimum risk of causing any contamination of materials or products. It shall be away from filthy surroundings and shall not be adjacent to an open sewerage, drain public lavatory or any factory which produces a disagreeable or obnoxious odor or fumes or large quantities of soot, dust or smoke which may contaminate the drugs being manufactured or adversely affect their quality. Existing units shall keep the surroundings under their control to be clean.

1.3. - The size of the plot shall not be less than 2000 square yards.

2. Building layout and its pre-approval.

The building shall be of adequate size and suitable design and construction in view of the need for drugs to be manufactured and to suit the operations to be carried out. The site and layout plan of building shall be got approved from the Central Licensing Board or person authorized by it in this behalf before starting construction of the building and any minor subsequent changes in the layout plan will be communicated as and when made with a revised updated layout plan at the time of renewal of Drug Manufacturing Licence.

The following information/documents are required for the establishment of a pharmaceutical unit:-

(i) A detailed layout plan in duplicate, for approval in terms of paragraph 2 of section 1 of Schedule-B, under the Drugs (Licensing, Registering and Advertising) Rules, 1976. the layout plan may be drawn to comply with the Good Manufacturing Practices as laid down under the aforesaid rules.

(ii) Give Schedule of Section wise covered areas.

(iii) Expected investment.

(iv) Fee @ of Rs. 1000/- per section as may be proposed in the layout plan to be deposited under the following head of account and submit original Challan:-

C-Non Tax Revenue
C02-Receipts from Civil Administration and other Functions.
C028-Social Services.
C02841-Health-Other Receipts.

(v) A list of the drugs intended to be manufactured, indicating the dosage forms and the generic names of the drugs.

(vi) Partnership deed.

FLOW CHART OF PROCEDURE FOR
'LIENCING OF PHARMACEUTICAL UNIT'
Receipt of Proposal for Drugs Manufacturing License

Site Verification through inspection for completion of the condition of ‘Schedule E’ of the Drugs (Licensing, Registering) Rules, 1976

Approval of ‘Building Layout Plan’ after examination by a Committee of Expert set up by the Central Licensing Board comprising DC, CQC, DDC (Reg-II) & DDC (L&A)

On completion of the unit and facilities a formal application in the prescribed manner for grant of License

After Rejection, the firm can make an application for Re-Inspection within 3-6 months of rejection, after removing the shortcomings

Grant of License for Drug Manufacturing is issued.

Rejection of Application.

Inspection of manufacturing facilities for Grant of license, by a panel of the Central Licensing Board comprising Member of the Board, area F.I.D, A.D.C or Provincial Inspector