

MANUFACTURING LICENCE FOR (MODERN / ALLOPATHIC MEDICINE) / HOMOEOPATHIC

A prospective manufacturer will have to first to submit a plain paper application/Project report along with a site plan of his proposed Mfg. Unit either at the District Office or at the Directorate Headquarters along with a check list to be supplied from the Directorate of Drugs Control, Govt. of West Bengal, or may be downloaded from the website www.wbhealth.gov.in

In case of loan license, the manufacturer will have to first to submit a **NO OBJECTION CERTIFICATE** from the parent concern along with their shareable capacity for the proposed category.

On receipt of the site plan an inspection of the proposed premises will be carried out by a team of officers of the Mfg, Cell of the Directorate of Drugs Control, Govt. of West Bengal, along with the area officer of the respective District. On inspection, if the premises is found suitable in respect of measurement of the area as well as surrounding suitability for the respective category of product as per Revised GMP norms, the firm then be advised to submit their layout plan (in triplicate) for final approval.

On receipt of the compliance report of the approved layout plan the firm will be finally allowed to apply in appropriate form (i.e. Form-24, 24A, 27, 27A as the case may be) with prescribed fees as well as list of their technical personnel, list proposed products, product labels and so on as prescribed in the Drugs and Cosmetics Act and Rules there under for consideration of their application towards grant of licence.

With the introduction of Revised Schedule M (2001) all manufacturers of allopathic medicines will have to comply the statutory norms in respect of their manufacturing premises. Unless & until the same is complied with no existing licenses will be liable for renewal & no new licenses will be liable for grant.

Fees for submission of application (for modern medicine) in each form is Rs. 7500/- for products not exceeding ten of each category, for each products exceeding ten @ Rs. 300/-.

Fees for submission of application (for homoeo medicine) in each form is Rs. 300/- Fees are subject to change from time to time by notification Govt. of India.

Application Forms:

A. Modern Medicine:

Form – 24 (Non Biological)

Form – 27 (Biological)

B. Homeopathic Medicine:

Form – 24C

C. Modern Medicine (Loan Licence):

Form – 24A (Non Biological)

Form – 27A (Biological)

For further details please visit www.wbhealth.gov.in