

Form: XI-PAM
Regulation Section: 94 & 103

**APPLICATION TO SET UP A MANUFACTURING PLANT FOR
MEDICINAL PRODUCTS**

I/weof.....
hereby apply for the grant/renewal of a provisional authorization to set up a
manufacturing plant for medicinal products, and I have attached the following
documents

- a. *Location of the proposed site with pictorial presentation or sketch map of the proposed factory site plan,*
- b. *Memorandum of Association or Article of Incorporations of the firm including organizational chart,*
- c. *Graphic Layout of the premise detailing on the intended production facilities and traffic routes for material and personnel,*
- d. *Description of the layout of the premise,*
- e. *List of key technical personnel (Production head, Quality Control, Store In-charge),*
- f. *List of Medicinal Products indicating the formulation, composition, strength, pharmacopeial specifications intended to be manufactured,*
- g. *List of equipments and machinery to be employed for manufacture and testing, and*
- h. *Waste management plan(Effluent Treatment Plant)*

The Plant is expected to be operation with effect from.....

Application fee has been deposited to the Royal Government of Bhutan vide Revenue Receipt no (*Attach copy*)

Declaration (please tick the boxes):

I hereby declare that the documents submitted above/all information provided is true to my knowledge and will be liable for any consequences if any information provided is proved to be false or misleading.

If my application is granted, I shall abide by the Medicines Act and Medicines Regulations and any other standards set by the Authority.

Signature of applicant:
Name & address:

Date: