

Form: XII-FAM
Regulation Section: 104 & 110

**APPLICATION FOR TECHNICAL AUTHORIZATION FOR
MANUFACTURE OF MEDICINAL PRODUCTS**

I/weof.....
hereby apply for the grant/renewal of authorization to manufacture the medicinal products as the following firm is ready for production;

Name of the firm:
Location/ Address of the firm:

Provisional Authorization no. :
(As issued by DRA)
Expected dated of Operation:
(If different from what was indicated on the Provisional Authorization application):

Name of the Proposed Competent Person(s):
Production Manager:
Quality Assurance Manager:
Store In charge:

List of standards or Operating procedures:
(Please use additional sheet)

The prescribed fee been deposited to the Royal Government of Bhutan vide Revenue Receipt No..... (Please 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: