

Form: BMRR IV-FAM

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

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

Name of the firm:

Location/Address of the firm:

Provisional Authorization no (as issued by MPD):

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:*

List of Products intended for manufacture:

*(Please use additional sheet)*

List of standard operating procedures

*(Please use additional sheet)*

The prescribed fee has been deposited to the Royal Government of Bhutan *(Please submit a copy)*

***Declaration (please tick the boxes)***

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

☐ I declare that I have read the regulation and I am fully aware that my application may be rejected if I do not fulfill the conditions or contravenes the provisions of the Act and Regulations thereunder.

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

Signature of Applicant:

Name, Address, Contact No:

Date:.....