Form: **V-PAR**
Regulation Section: **35 & 38**

APPLICATION FORM FOR ABRIDGE REGISTRATION OF MEDICINES

I/we ……hereby apply for abridge registration of the product specified below for sale/distribution in Bhutan as per the Product Registration guideline.

The product that has been approved by the following referenced drug regulatory agency or agencies (*Circle the appropriate agencies*);

i. Australia Therapeutic Goods Administration (TGA);
ii. Health Canada (HC);
iii. US Food and Drug Administration (FDA);
iv. European Medicines Agency (EMA)
v. UK Medicines and Healthcare Products Regulatory Agency (UK MHRA)
vi. Japan DRA
vii. Health Science Authority of Singapore (HSA)
viii. Drug Control Authority of Malaysia (BPFK)
ix. Thai FDA
x. WHO / OIE / other UN recognized international agencies

Details of Medicinal Product (*Use one application per product*)

Product	Pack	Composition (With Strength)	Manufacturer

Name of the Market Authorization Holder:
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: ……

Date: …….....

Address: ……