FORM NO.: BDMCA/DPS/MLV/14

DEPARTMENT OF PHARMACEUTICAL SERVICES
MINISTRY OF HEALTH
BRUNEI DARUSSALAM

APPLICATION TO AMEND MANUFACTURING LICENCE OF MEDICINAL PRODUCTS

APPLICATION REFERENCE NO. *(For Official Use only):*

SECTION 1: INSTRUCTIONS

i) Please refer to the **'Guideline on Application to Amend Manufacturing Licence of Medicinal Products'** before filling up application form.

ii) Please fill up this application form in CAPITAL LETTERS.

iii) Please tick ☑ the appropriate boxes, where applicable.

iv) Only ONE ORIGINAL COPY of the completed application form is required to be submitted to the **Product Regulation Section, 2nd Floor, Department of Pharmaceutical Services, Ministry of Health, Kg Madaras, Mukim Gadong A', Brunei Darussalam.**

v) Payment of fees can be made in the form of cash or cheque. Fees paid are NON-REFUNDABLE.

Fees for application to amend a licence:

a) with site inspection (for manufacturer)	**$100**
b) with site inspection (for assembler)	**$50**
c) without site inspection	**$25**

vi) This application form should be submitted with the supporting documents as listed in the checklist below.

vii) Only completed application form with payment will be processed.

SECTION 2: CHECKLIST FOR SUPPORTING DOCUMENTS

i) This checklist is to be filled in by the applicant.
ii) The application form should be submitted with the listed supporting documents, if applicable.
iii) Please tick ☑ the appropriate boxes if the documents are attached.

List of Supporting Documents	*Applicant*	*For Official Use Only*
i) A copy of Company / Business Certificate of Registration (Section 16 & 17)	☐	☐
ii) A copy of manufacturer's licence	☐	☐
iii) List of manufacturing equipment available and their function, if applicable	☐	☐
iv) A copy of Product Licence and/or Letter of Approval for Variations to a Registered Medicinal Product	☐	☐
v) Revised Site Master File	☐	☐
vi) List of manufacturing equipment available and their function, if applicable.	☐	☐
vii) Letter of authorisation from company	☐	☐

SECTION 3: DETAILS OF COMPANY			
Name of Company		Company Registration No.	
Address of Business			
Telephone No.		Fax No.	
E-Mail Address			
Address of Manufacturing / Assembly Site *(if different from above)*			

SECTION 4: DETAILS OF APPLICANT			
Title	☐ Dr ☐ Mr ☐ Mdm ☐ Ms ☐ Mrs		
Name			
Designation			
Address			
Telephone No. (Office)		Mobile No.	
E-mail		Passport / I.C. No. & Colour	
Importer / Wholesaler's Licence No.			

SECTION 5: DETAILS OF AMENDMENT

i) For amendments of a licence to manufacture medicinal products, please complete **Section 5.1(a)** Details of the Amendment to the Licence.

ii) For amendments of list of medicinal products, please complete **Section 5.2 (a)** Details of the Amendment on the List of Medicinal Products.

SECTION 6: DECLARATION OF APPLICANT

I, on behalf of the company named in Section 4, hereby declare that:

i) There are no other changes than those proposed on this application form;
ii) All the conditions for the proposed changes are fulfilled;
iii) The supporting documents required for the proposed changes have been submitted;
iv) All particulars given in this application form and the supporting documents attached to this form are true
v) I understand and undertake to comply with all the provisions of Medicines Order, 2007 and its related regulations.
vi) I understand that a wilfully false statement is an offence under the Medicines Order, 2007 and that all documents submitted for evaluation are non-returnable.

Name of Applicant Signature Date

SECTION 7: CERTIFICATION BY COMPANY		
I confirm that i) The applicant is an employee / owner of the above-mentioned company; ii) The amendment applied is only for the purpose of business of the above-mentioned company; and iii) All the information provided is true and complete. Name of *Company Owner/Manager/Director	Signature	Date & Company's Stamp

FOR OFFICIAL USE ONLY: APPLICATION FEE DETAILS	
Receipt No.	Name & Signature of Officer receiving the Application Fee
Amount Paid	
Name of Payee	Received Date
Notes	

Section 5.1 (a): DETAILS OF AMENDMENT TO THE MANUFACTURING LICENCE						
No.	**Type of Amendment**	**Current Details**	**Proposed Change (s)**	**Reasons for Change**	**Expected Effective Date**	**Document Attached**

Note:

Please attach additional pages if the space provided is insufficient.

Section 5.2 (a): DETAILS OF AMENDMENTS ON THE LIST OF MEDICINAL PRODUCTS					
No.	**Product Name (including dosage form)**	**Active ingredient and strength**	**Pack Size**	**Product Licence Number (if applicable)**	**Validity Period**

Note:

Please attach additional pages if the space provided is insufficient.