FORM NO.: BDMCA/DPS/MLV/14

DEPARTMENT OF PHARMACEUTICAL SERVICES
MINISTRY OF HEALTH
BRUNEI DARUSSALAM

MEDICINES ORDER, 2007 [SECTION 15(3)]

APPLICATION TO AMEND MANUFACTURING LICENCE OF MEDICINAL PRODUCTS

For Official Use only

Application No. :												

Date Received:			-			-					

SECTION 1: INSTRUCTIONS

1. Applicants are advised to refer to the ***'Guideline on Application to Amend Manufacturing Licence of Medicinal Products'*** for guidance before filling up application form.
2. Only **ONE ORIGINAL COPY** of the completed application form is required to be submitted. Form must be **typed.**
3. Please tick ☑ the appropriate boxes, where applicable.
4. The completed application form should be submitted to the Drug Administration Section, Department of Pharmaceutical Services, Ministry of Health, Kampong Madaras, Simpang 433, Lebuhraya Rimba, Brunei Darussalam.
5. Payment of fees can be made in the form of **CASH** or **CHEQUE** only. Payment made is **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
6. This application form should be submitted with the supporting documents as listed in the checklist below.
7. Only completed application form with payment will be processed.

SECTION 2: CHECKLIST FOR SUPPORTING DOCUMENTS

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

List of Supporting Documents		For Official Use Only
a. A copy of Company / Business Certificate of Registration (Section 16 & 17)	☐	☐
b. A copy of manufacturer's licence	☐	☐
c. List of manufacturing equipment available and their function, if applicable	☐	☐
d. A copy of Product Licence and/or Letter of Approval for Variations to a Registered Medicinal Product	☐	☐
e. Revised Site Master File	☐	☐
f. List of manufacturing equipments available and their function, if applicable.	☐	☐

SECTION 3: COMPANY PARTICULARS	
3.1 Company Name	
3.2 Company / Business Registration no.	
3.3 Company Business Address	
3.4 Telephone No.	
3.5 Fax No.	
3.6 E-Mail Address	
3.7 Correspondence Address *(if different from above)*	

SECTION 4: APPLICANT PARTICULARS			
4.1 Title	☐ Dr ☐ Mr ☐ Mdm ☐ Ms ☐ Mrs		
4.2 Name			
4.3 I.C. No & colour		☐ Yellow ☐ Red ☐ Green	
4.4 Designation			
4.5 Telephone No.	Mobile:	Office:	
4.6 E-mail address			

SECTION 5: DETAILS OF AMENDMENT
5.1 For amendments of a licence to manufacture medicinal products, please complete **Section 5.1(a)** on details of the amendment to the licence.
5.2 For amendments of list of medicinal products, please complete **Section 5.2 (a)** on details of the amendment.

SECTION 6: DECLARATION OF APPLICANT

I, on behalf of the company named in Section 4.0, hereby declare that:

6.1 There are no other changes than those proposed on this application form;

6.2 All the conditions for the proposed changes are fulfilled;

6.3 The supporting documents required for the proposed changes have been submitted; and

6.4 All particulars given in this application form and the supporting documents attached to this form are true.

I understand and undertake to comply with all the provisions of Medicines Order, 2007 and its related regulations.

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.

Company's Stamp

Name:

Signature:

Date:

SECTION 7: CERTIFICATION (COMPANY / ESTABLISHMENT)

I confirm that

6.1 The applicant is an employee / owner of the above-mentioned company;

6.2 The amendment applied is only for the purpose of business of the above-mentioned company; and

6.3 All the information provided is true and complete.

Company's Stamp

Company's Owner/ Manager/ Director

Name:

Signature:

Date:

For Official Use Only	
FEE DETAILS	
Receipt No.	Amount Paid:
Name of Payee:	
Officer receiving the fees Name: Signature:	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.