DEPARTMENT OF PHARMACEUTICAL SERVICES
MINISTRY OF HEALTH
BRUNEI DARUSSALAM

APPLICATION FORM FOR A LICENCE TO MANUFACTURE / ASSEMBLE MEDICINAL PRODUCTS

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

SECTION 1: INSTRUCTIONS

i) Please refer to the **'Guideline on Application for Licence to Manufacture / Assemble Medicinal Products'** before filling up the application form.
ii) Please fill out this application form in CAPITAL LETTERS.
iii) Please tick (✓) where applicable or write "N/A" for any item that is not applicable to your application.
iv) When the symbol ***** appears, please strikethrough the wording that is not applicable.
v) Only ONE ORIGINAL COPY of the completed application form with the relevant fee should be submitted to the **Product Regulation Section, 2nd Floor, Department of Pharmaceutical Services, Ministry of Health, Kg Madaras, Mukim Gadong 'A', Brunei Darussalam**.
vi) Payment of fees can be submitted either in the form of cash or cheque. Fees paid are non-refundable.

Fees for new application for a licence for:

a)	**Manufacture of external or oral preparations**	**$500**
b)	**Manufacture of external and oral preparations**	**$ 1,000**
c)	**Primary assembly**	**$350**
d)	**Secondary assembly**	**$250**

Fees for licence for:

a)	**The first year**	**No charge**
b)	**Each subsequent year for:**	
	- **A manufacturer of external or oral preparations**	**$500**
	- **A manufacturer of external and oral preparations**	**$1,000**
	- **A primary assembler**	**$350**
	- **A secondary assembler**	**$250**

vii) This application form should be submitted with the supporting documents as listed in the checklist below.
viii) Renewal Applications must be submitted 3 months prior to the expiry of the manufacturer's licence.

SECTION 2: CHECKLIST FOR SUPPORTING DOCUMENTS

i) Please tick (✓) the appropriate boxes if the documents are provided.
ii) For new applications, please proceed to Section 2A whereas for renewal applications, please proceed to Section 2B.

A) NEW APPLICATION	*Applicant*	*For official use only*
i) Organization Chart	☐	☐
ii) Site Master File	☐	☐
iii) Validation Master Plan (*applicable for manufacturing activities only*)	☐	☐
iv) Certificate of Accreditation of the contract testing laboratory, if any	☐	☐
v) List of manufacturing equipment available and their function, if applicable	☐	☐
vi) List of quality control equipment available and function of each equipment, if applicable	☐	☐
vii) List of the name and type (ie. dosage form) of product(s) manufactured / assembled	☐	☐

viii) A copy of Company / Business Certificate of Registration (Sections 16 & 17)	☐	☐
ix) A copy of Applicant's Identity Card	☐	☐
x) A copy of Importer / Wholesaler's Licence	☐	☐
xi) A copy of Annual Pharmacist Retention Certificate, if applicable	☐	☐
xii) Details of other products (non-medical) stored at the same premise, if applicable	☐	☐
B) RENEWAL APPLICATION	*Applicant*	*For official use only*
i) A copy of Company / Business Certificate of Registration (Sections 16 & 17)	☐	☐
ii) A copy of Applicant's Identity Card	☐	☐
iii) A copy of Importer / Wholesaler's Licence	☐	☐
iv) A copy of Annual Pharmacist's Retention Certificate, if applicable	☐	☐
v) A copy of previous manufacturer's licence	☐	☐

Additional documents required from applicant:

SECTION 3: DETAILS OF APPLICATION

Type(s) of Activity *(you may tick more than one box)*	☐ Manufacture ☐ Primary Assembly ☐ Secondary Assembly
Details of Previous Licence (*applicable for renewal applications only)*	Licence No. : Validity Period :
Types of Secondary Assembly Activity *Notes* *- applicable for secondary assembly only* *- you may tick more than one box*	☐ Affix / Inkjet Brunei Product Licence No. and or Approval Number (PCB ... / 20…) onto the primary / secondary packaging material ☐ Affix specific labelling requirement / country-specific requirements eg. information on animal origin (porcine / bovine) or alcohol content ☐ Include additional information as per directive issued by BDMCA ☐ Insert / attach package insert / change original package insert into / onto the unit box ☐ Attach Dear Healthcare Professional Letter onto the unit box ☐ Affix label 'Imported by (Name of company) onto the primary / secondary packaging material ☐ Repack into tertiary packaging materials without any changes to the registered finished product ☐ Shrink wrap several boxes together ☐ Others *(please specify)*: _____

SECTION 4: DETAILS OF COMPANY

Name of Company				Company Registration No.	
Address of Business					
Telephone No.		Fax No.		E-mail	
Address of Store / Warehouse *(if different from above)*					
Address of Manufacturing / Assembly Site *(if different from above)*					

SECTION 5: DETAILS OF APPLICANT			
Title	☐ Dr ☐ Mr ☐ Mrs ☐ Ms ☐ Miss		
Name			
Designation			
Address			
Telephone No. (Office)		Mobile No.	
E-mail		Passport / I.C. No. & Colour	
Annual Retention Certificate No. *(if applicable)*			
Importer / Wholesaler's Licence No.			

SECTION 6: DETAILS OF KEY PERSONNEL / RESPONSIBLE PERSON

For applications involving manufacturing activities, please proceed to Section 6A whereas for applications involving secondary assembly activities, please proceed to Section 6B.

A) MANUFACTURING ACTIVITIES

Title	☐ Dr ☐ Mr ☐ Mrs ☐ Ms ☐ Miss	Title	☐ Dr ☐ Mr ☐ Mrs ☐ Ms ☐ Miss
Name of Head of Production		Name of Head of Quality Control	
Passport / I.C. No.		Passport / I.C. No.	
Designation		Designation	
Telephone No. (Office)		Telephone No. (Office)	
Mobile No.		Mobile No.	
E-mail		E-mail	

B) SECONDARY ASSEMBLY ACTIVITIES

Title	☐ Dr ☐ Mr ☐ Mrs ☐ Ms ☐ Miss	Title	☐ Dr ☐ Mr ☐ Mrs ☐ Ms ☐ Miss
Name		Name	
Passport / I.C. No.		Passport / I.C. No.	
Designation		Designation	
Telephone No. (Office)		Telephone No. (Office)	
Mobile No.		Mobile No.	
E-mail		E-mail	

SECTION 7: DETAILS OF PRODUCT	
Product Type	☐ Non-Sterile ☐ Sterile
Product Classification	☐ Poison ☐ Non-Poison ☐ Others (*please specify):* _____
Class of Medicinal Product	☐ Cephalosporin / Penicillin Group ☐ Anti-Infective ☐ Vaccine ☐ Blood Products ☐ Others (*please specify):* ☐ Hormone ☐ Anti-Neoplastic ☐ Biotechnology ☐ Steroids
Dosage Form(s)	**Oral Preparation** ☐ Tablet ☐ Capsule ☐ Lozenges ☐ Syrup / Liquid / Mixture ☐ Powder / Granules ☐ Others (*please specify):* _____ **External Preparation** ☐ Cream / Lotion / Ointment / Gel ☐ Liquid ☐ Suppository / Pessary ☐ Others (*please specify):* _____ **Other Preparation** ☐ Aerosol ☐ Eye Drop / Nasal Drop / Ear Drop ☐ Injectable ☐ Others (*please specify):* _____

SECTION 8: CONTRACT TESTING LABORATORIES *(if applicable)*	
Name	
Address	
Type of analytical test performed by the laboratory based on your contract	
Accreditation of the laboratory to international quality system standards	☐ Yes, *Please specify scope of accreditation* _____ ☐ No

SECTION 9: DECLARATION OF APPLICANT

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

i) All particulars given in this application form and true and that the documents enclosed are authentic and true.
ii) I understand and undertake to comply with all the provisions of the Medicines Order, 2007 and its related regulations.
iii) I will comply with the principles of the current Good Manufacturing Practice and/or Good Distribution Practice and/or Good Storage Practice.
iv) I undertake to notify the Department of Pharmaceutical Services, Ministry of Health, Brunei Darussalam of any change in the particulars submitted in/with this application form.

Name of Applicant Signature Date

SECTION 10: CERTIFICATION BY COMPANY

I hereby declare that

i) The applicant is an *employee/owner of the above-mentioned company.
ii) The Licence applied is only for the purpose of business of the above-mentioned company.
iii) All of the information provided is true and complete.

Name of *Company Owner / Manager / Director Signature Date & Company 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:
Additional Notes	