

**DEPARTMENT OF PHARMACEUTICAL SERVICES
MINISTRY OF HEALTH
BRUNEI DARUSSALAM**

**GUIDE TO APPLICATION FOR A LICENCE TO MANUFACTURE / ASSEMBLE MEDICINAL
PRODUCTS**

1. In line with Section 15 (1) of the Medicine Order, 2007, all manufacturing facilities engaged in the manufacture of medicinal products will be subjected to an inspection before a manufacturer's licence can be issued. A manufacturer's licence would only be granted when the manufacturing facilities is found to comply with the current international Good Manufacturing Practice (GMP) standard i.e. the Pharmaceutical Inspection Convention (PIC)/Pharmaceutical Inspection Co-operation Scheme (PIC/S) Guide to GMP for Medicinal Products as stipulated under Regulations 4b of the Fourth Schedule of Medicines (Licensing, Standard Provisions and Fees) Regulations, 2010.
2. Application for a Manufacturer's License shall be submitted by filling in form: BDMCA/DPS/03 – Application for a licence to manufacture / assemble medicinal products.
3. All sections of the application form must be completed. Please indicate N.A. (Not applicable) in those sections that are not relevant to the application.
4. Application form must be submitted with the following supporting documents:
 - I) **For New Application:**
 - a) Company's Organization Chart.
 - b) Site Master File.
 - c) Validation Master Plan.
 - d) Certificate of Accreditation of the contract testing laboratory, if any.
 - e) List of manufacturing equipment available and their function, if applicable.
 - f) List of quality control equipment available and function of each equipment, if applicable.
 - g) List of name (including active ingredients, strength and Brunei product licence no., if applicable) and type (i.e. dosage form) of products manufactured / assembled.
 - h) A copy of Company / Business Certificate of Registration (Section 16 & 17).
 - i) A copy of Applicant's Identity Card.
 - j) Poison Licence, if applicable.
 - k) A copy of Annual Pharmacist Retention Certificate, if applicable.
 - l) Details of other products (Non-medicinal) stored at the same premise, if applicable.
 - II) **For Renewal Application:**
 - a) A copy of Company / Business Certificate of Registration (Section 16 & 17).
 - b) A copy of Applicant's Identity Card.
 - c) Poison Licence, if applicable.
 - d) A copy of Annual Pharmacist Retention Certificate, if applicable.
 - e) A copy of previous manufacturer's licence
5. Only completed application form with fee payment will be processed.

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6. Application fees for a manufacturer's licence and renewal shall not be refundable. The payment can either be in the form of cheque made payable to the **Government of Brunei Darussalam** or by cash.

Fee 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

Fee 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

7. Inspection of the manufacturing facilities will be conducted upon receiving letter of application / request for an inspection by the applicant.
8. Each license is valid for **one (1) year**.
9. Application Form:

Part 1.0 – Company Particulars

The company named in this section should be based and registered in Brunei Darussalam. For every successful application for a licence to manufacture / assemble medicinal products, a manufacturer's licence will be issued in the name of the company.

Part 2.0 – Applicant Particulars

The person named in this section should be based in Brunei Darussalam and be contactable at all times. The company shall authorize /certify the applicant that he/she is an employee of the company under Part 9.0 of the application form. The Department of Pharmaceutical Services (DPS) will only liaise with this person pertaining to the application and inspection arrangements.

It should be noted that the applicant and the person who authorize the applicant bear full responsibilities for ensuring that all available and relevant information submitted to support the application is true and complete.

Part 3.0 - Product Details

This section requires the applicant to provide information on the product type, product classification, class of medicinal product, dosage form (s) and activity the company is dealing with. All products manufactured at the facilities must be registered or notified with the Ministry of Health, Brunei Darussalam.

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Part 4.0 – Store / Warehouse Address

Addresses of all the store / warehouse sites where the materials used for manufacturing and the products would be stored must be provided if they are different from the company address. The optimized warehouse temperature and relative humidity must also be provided under this section.

Part 5.0 – Manufacturing / Assembly Particulars

This section requires the applicant to provide information on the manufacturing / assembly addresses of all the sites where the medicinal products would be manufactured or assembled.

Part 6.0 – Contract Testing Laboratories

This section is applicable only if the company is engaging a contract testing laboratory to conduct laboratory tests. Name and address of the contract testing laboratory and type of analytical test performed by the laboratory based on the contract must be provided. If the contract testing laboratory is accredited to any international quality system standards, a copy of the certificate of Accreditation must be provided.

Part 7.0 – Personnel Particulars

This section required applicant to provide particulars of Head of Production/Assembly and Quality Control.

Part 8.0 – Declaration of Applicant

Application form must be declared and signed by the applicant.

Part 9.0 – Certification

This section must be filled in by the Company's Owner / Manager / Director.

10. For any enquiries related to the application please contact:

Drug Administration Section,
Department of Pharmaceutical Services,
Ministry of Health, Kampong Madaras,
Simpang 433, Lebuhraya Rimba,
Brunei Darussalam.
Tel: +673 2393298 / 2393301 Ext 223 or 222
Fax: +673 393297