**FORM NO.: BDMCA/DPS/03**

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

## MEDICINES ORDER, 2007 [SECTION 10(1)]

## APPLICATION FOR A LICENCE TO MANUFACTURE / ASSEMBLE MEDICINAL PRODUCTS

| | |
|---|---|
| APPLICATION NO. (*for DAS use only*): | |
| DATE RECEIVED (*for DAS use only*): | - - |
| DETAILS OF PREVIOUS LICENCE (*If renewal*) | Licence No. ……<br>Validity period …… |

**INSTRUCTION:**

1. Please fill in this application form in **CAPITAL LETTERS** in 1 original copy. Form must be typed.
2. Please tick ☑ the appropriate boxes.
3. If space is not sufficient please write on a separate sheet of A4 paper.
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. Fee for application for a manufacturer's licence and renewal should be submitted either in the form of cheque made payable to the **Government of Brunei Darussalam** or in the form of 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 |

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.

8. Application for renewal must be submitted 3 months prior to the expiry of the manufacturer's licence.

**CHECKLIST FOR SUPPORTING DOCUMENTS:**

1. This checklist is to be filled in by the applicant.

2. Please tick ☑ the appropriate boxes if the documents are attached. Note: Section A below is for new application whereas Section B is for renewal application.

**A) NEW APPLICATION:**

| | | |
|---|---|---|
| i. | Organization Chart | ☐ |
| ii. | Site Master File | ☐ |
| iii. | Validation Master Plan | ☐ |
| 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 (i.e. dosage form) of products manufactured / assembled | ☐ |
| viii. | A copy of Company / Business Certificate of Registration (Section 16 & 17) | ☐ |
| ix. | A copy of Applicant's Identity Card | ☐ |
| x. | Poison Licence, if applicable | ☐ |
| xi. | A copy of Annual Pharmacist Retention Certificate, if applicable | ☐ |
| xii. | Details of other products (Non-medicinal) stored at the same premise, if applicable. | ☐ |

**B) RENEWAL APPLICATION:**

| | | |
|---|---|---|
| i. | A copy of Business Licence (Business Premise and Store if any) | ☐ |
| ii. | A copy of Applicant's Identity Card | ☐ |
| iii. | Poison Licence, if applicable | ☐ |
| iv. | A copy of Annual Pharmacist Retention Certificate, if applicable | ☐ |
| v. | A copy of previous manufacturer's licence | ☐ |

| | | |
|---|---|---|
| **1. 0** | **COMPANY PARTICULARS** | |
| 1.1 | Company Name | |
| 1.2 | Company Business Address | |
| 1.3 | Company / Business Registration no. | Telephone no. |
| 1.4 | Fax no. | E-Mail |
| **2.0** | **APPLICANT PARTICULARS** | |
| 2.1 | Name (Mr/Ms/Mrs/Mdm/Dr) | |

| | | | | |
|---|---|---|---|---|
| 2.2 | Designation | | | |
| 2.3 | Address | | | |
| 2.4 | Telephone no.<br><br>(O) (M) | Fax no. | E-mail | Passport/IC no. |
| 2.5 | Annual Retention Certificate No. (if applicable) | | | |
| 2.6 | Poison Licence no. | | | |

**3.0 PRODUCT DETAILS**

3.1 Product type:
☐ Non-sterile ☐ Sterile

3.2 Product classification:
☐ Poison ☐ Non-poison ☐ Traditional Medicine & Health Supplement Product (TMHS)
☐ Others: Pls specify:……

3.3 Class of medicinal product:
☐ Cephalosporin / Penicillin group ☐ Hormone ☐ Anti-infective ☐ Anti-neoplastic
☐ Vaccine ☐ Biotechnology ☐ Blood products ☐ Steroids
☐ Others: Pls specify: ……

3.4 Dosage form (s):

☐ **Oral preparation:**
- ☐ Tablet
- ☐ Capsule
- ☐ Lozenges
- ☐ Syrup / Liquid / Mixture
- ☐ Powder / Granules
- ☐ Others: pls specify……

☐ **External preparation**
- ☐ Cream / Lotion / Ointment / Gel
- ☐ Liquid
- ☐ Suppository / pessary
- ☐ Others: pls specify……

☐ **Other preparation**
- ☐ Aerosol
- ☐ Eye Drop/Nasal Drop/Ear Drop
- ☐ Injectable
- ☐ Others: pls specify……

3.5 Activity:
☐ Manufacture ☐ Primary Assembly ☐ Secondary Assembly

**4.0 STORE / WAREHOUSE ADDRESS**

4.1 Store / Warehouse Address: *(addresses of all the sites where the materials used for manufacturing and the medicinal products would be stored if different from the above)*

4.2 Storage condition of the warehouse: (*please provide the optimized warehouse temperature and relative humidity):*

**5.0 MANUFACTURING / ASSEMBLY PARTICULARS**

5.1 Manufacturing / Assembly Addresses *(addresses of all the sites where the medicinal products would be manufactured or assembled)*

| 6.0 | CONTRACT TESTING LABORATORIES (if applicable) |
|---|---|
| 6.1 | Name |
| 6.2 | Address |
| 6.3 | Type of analytical test performed by the laboratory based on your contract. |
| 6.4 | Accreditation of the laboratory to international quality system standards<br>☐ Yes, *Please specify scope of accreditation* ☐ No<br>…….. |
| 7.0 | **PERSONNEL PARTICULARS** |
| 7.1 | Name of Head of Production: (Mr/Ms/Mrs/Mdm/Dr) |
| | Designation |
| | Passport/IC no. |
| | Experience *(if not stated in the Site Master File)* |
| 7.2 | Name of Head of Quality Control: (Mr/Ms/Mrs/Mdm/Dr) |
| | Designation |
| | Passport/IC no. |
| | Experience *(if not stated in the Site Master File)* |

| 8.0 | DECLARATION OF APPLICANT |
|---|---|
| I, on behalf of the company named in Section 1.1, hereby declare that | |
| 8.1 | all particulars given in this application form and attachment are true and complete |
| 8.2 | I will comply with all the provisions of Medicines Order, 2007 and its related regulations. |
| 8.3 | I will comply with the principles of the current Good Manufacturing Practice or / and Good Distribution Practice or / and Good Storage Practice |

Signature

Date

Name

| 9.0 | CERTIFICATION (COMPANY / ESTABLISHMENT) |
|---|---|

I confirm that

9.1 The applicant is an employee of the above-mentioned company
9.2 The licence applied is only for the purpose of business of the above-mentioned company
9.3 All the information provided is true and complete

Signature of Company's Owner / Manager / Director & Company's Stamp

Date

Name

**FOR OFFICIAL USE**

**FEE DETAILS**

Receipt No: ……..  Amount Paid: …….

Name of Payee: ……

| **Name & Signature of officer receiving the Fees:** | **Received date:** |
|---|---|
| …… | …… |

**Notes:**