|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| |  | | --- | | **FORM NO.: BDMCA/DPS/01** |     **DEPARTMENT OF PHARMACEUTICAL SERVICES**  **MINISTRY OF HEALTH**  **BRUNEI DARUSSALAM** | | | | | | | | | | | | |
| **APPLICATION FORM FOR REGISTRATION OF MEDICINAL PRODUCTS** | | | | | | | | | | | | |
| **ADMINISTRATIVE DATA AND PRODUCT INFORMATION (PART I: SECTION 1)** | | | | | | | | | | | | |
| |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | L | O | A | - | P | / |  |  | / |  |  |  |  |  |  |  |  |   APPLICATION REFERENCE NO. (*for official use only*): | | | | | | | | | | | | |
| Instructions:   1. Applicants are advised to refer to the ‘DPS Guide to Application for Registration of Medicinal Products’ and ‘DPS Guide on How to Fill the Application Form for Registration of Medicinal Products (Part I: Section 1) for guidance before filling up the application form. 2. Only **one original copy** of the application form is required to be submitted per product. Form must be typed. 3. The completed application form should be submitted to the Drug Registration Unit, Product Regulation Section, 2nd Floor, Department of Pharmaceutical Services, Ministry of Health, Spg 433, Kg Madaras, Mukim Gadong ‘A’, Rimba Highway,BE 4710, Brunei Darussalam. 4. If space is not sufficient, please write on a separate sheet of A4 paper. | | | | | | | | | | | | |
| **1. 0** | **COMPANY PARTICULARS** | | | | | | | | | | | |
| 1.1 | Name of Company (in block letters)  *(Please enclose a copy of the Letter of Authorisation from the Product Owner under Part I: Section 2)* | | | | | | | | | | | |
| 1.2 | Address | | | |  | | | | | | | |
| 1.3 | Company Registration No.  *(Please enclose a copy of certificate)* | | | | | | 1.4 Telephone No. | | | | 1.5 Fax No. | |
| **2.0** | **APPLICANT PARTICULARS** | | | | | | | | | | | |
| 2.1 | Name (Mr/Ms/Mrs/Mdm/Dr) | | | | | | | | | | | |
| 2.2 | Designation | | | | | | | | | | | |
| 2.3 | Address | | | | | | | | | | | |
| 2.4 | Telephone No. | | | 2.5 Fax No. | | | | 2.6 Official E-mail | | | | 2.7 Passport/IC No. |
| **3. 0** | **PRODUCT PARTICULARS** | | | | | | | | | | | |
| 3.1 | Proprietary Name | | | | | | | | | | | |
| 3.2 | Dosage Form | | | | | | | | | | | |
| 3.3 | Product Description | | | | | | | | | | | |
| 3.4 | Product Formula | | | | | | | | | | | |
|  | |  |  |  | | --- | --- | --- | | **Name of Substance** | **Grade** | **Strength** | | Active Ingredient 1 |  |  | | Active Ingredient 2 |  |  | | Excipient 1 |  |  | | Excipient 2 |  |  | | Excipient 3 |  |  | | Excipient 4 |  |  |   Note : Please state roles of excipient in the respective column indicated as follows:  F – Flavouring, C – Colourant, P – Preservatives, S – Stabilisers | | | | | | | | | | | |
| 3.5 | Please indicate whether any part of the product is derived from: | | | | | | | | | | | |
|  | a) Human Blood:  □ No □ Yes (State source: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ )  b) Animal Source:  □ No □ Yes (State source: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ )  For additional data that needs to be submitted, please refer to Guide on How to Fill the Application Form for Registration of Medicinal Products (Part 1:Section 1) Item 3.5a & 3.5b | | | | | | | | | | | |
| 3.6 | Pharmacotherapeutic Group by ATC Code, if available  [WHO ATC Code for the proposed indication(s)] | | | | | | | | | | | |
| 3.7 | Route of Administration | | | | | | | | | | | |
| 3.8 | Indication | | | | | | | | | | | |
| 3.9 | Recommended Dosage | | | | | | | | | | | |
| 3.10 | Therapeutic Advantage (Please enclose Bioequivalence Studies under Part II:Section 2 - P9) | | | | | | | | | | | |
| 3.11 | a) Packaging, Shelf-life & Storage Conditions | | | | | | | | | | | |
|  | |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Container Closure System** | **Quantity/Container** | **Shelf-Life** | **Storage Conditions** | **Pack Size** | |  |  |  |  |  | |  |  |  |  |  | | | | | | | | | | | | |
|  | b) Other shelf-life information: | | | | | | | | | | | |
|  | (i) Shelf-life after first opening: \_\_\_\_\_\_\_\_\_\_\_\_\_\_(hours/days/months)  (ii) Shelf-life after reconstitution: \_\_\_\_\_\_\_\_\_\_\_\_\_\_ (hours/days/months) | | | | | | | | | | | |
| 3.12 | Forensic Classification in Brunei Darussalam:  □ Prescription Only Medicine (POM) □ Pharmacy Medicine (P) □ General Sales List Medicine (GSL) | | | | | | | | | | | |
| 3.13 | Registration Status in Other Countries (Please fill in where appropriate) | | | | | | | | | | | |
|  | |  |  |  |  | | --- | --- | --- | --- | | **Country** | **Registration Status with Details and Corresponding Dates** | **Date** | **Approved Classification of the Product** | |  |  |  |  | |  |  |  |  | |  |  |  |  |     Note: Please enclose copy of proof of registration in the relevant countries, if applicable. | | | | | | | | | | | |
| 3.14 | Product Owner Information | | | | | | | | | | | |
|  | Name | | | | | | | | | | | |
|  | Address | | | | | | | | | | | |
|  | Telephone No. | | | | | Fax No. | | | | Official E-mail | | |
| **4.0** | | | **MANUFACTURER’S PARTICULARS** | | | | | | | | | |
| **4.1** | | | **ACTIVE SUBSTANCE MANUFACTURER** | | | | | | | | | |
|  | | | |  |  |  |  |  | | --- | --- | --- | --- | --- | | **No.** | **Name of Active Substance** | **Name of Manufacturer** | **Site Address** | **Office Address** | | 1. |  |  |  |  | | 2. |  |  |  |  | | | | | | | | | | |
|  | | | Telephone No. | | | Fax No. | | | | Official E-mail | | |
| **4.2** | | | **FINISHED PRODUCT MANUFACTURER** | | | | | | | | | |
|  | | | |  |  |  |  |  | | --- | --- | --- | --- | --- | | **No.** | **Name of Manufacturer** | **Manufacturing Operation** | **Site Address** | **Office Address** | | 1. |  |  |  |  | | 2. |  |  |  |  |   Note: Please enclose letter of authorisation from product owner to manufacturer(s) and letter of acceptance from the manufacturer(s), if applicable. | | | | | | | | | |
|  | | | Telephone No. | | | Fax No. | | | | Official E-mail | | |
| **4.3** | | | **CONTRACT MANUFACTURER** *(if applicable)* | | | | | | | | | |
|  | | | |  |  |  |  |  | | --- | --- | --- | --- | --- | | **No.** | **Name of Contract Manufacturer** | **Manufacturing Operation** | **Site Address** | **Office Address** | | 1. |  |  |  |  | | 2. |  |  |  |  |   Note: Please enclose letter of authorisation from product owner to manufacturer(s) and letter of acceptance from the manufacturer(s), if applicable. | | | | | | | | | |
|  | | | Telephone No. | | | Fax No. | | | | Official E-mail | | |
| **5.0** | | **REPACKER’S PARTICULARS** *(If applicable)* | | | | | | | | | | |
|  | | |  |  |  |  |  | | --- | --- | --- | --- | --- | | **No.** | **Name of Repacker** | **Operation** | **Site Address** | **Office Address** | | 1. |  |  |  |  | | 2. |  |  |  |  |   Note: Please enclose letter of authorisation from product owner to repacker(s) and letter of acceptance from the repacker(s), if applicable. | | | | | | | | | | |
|  | | Telephone No. | | | | Fax No. | | | | Official E-mail | | |
| **6.0** | | **BATCH RELEASE PARTICULARS** | | | | | | | | | | |
| 6.1 | | Information on Company / Agency Responsible For Batch Release In The Exporting Country | | | | | | | | | | |
|  | | Name | | | | | | | | | | |
|  | | Site Address | | | | | | | Office Address | | | |
|  | | Contact Person | | | | | | | | | | |
|  | | Telephone No. | | | | Fax No. | | | | Official E-mail | | |

Note: Please enclose letter of authorisation from product owner to batch releaser and letter of acceptance from the batch releaser, if applicable

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| **7.0** | **DECLARATION** | |
| I, on behalf of the company named in Section 1.1, hereby | | |
| 7.1 | Declare that all particulars given in this application form are true | |
| 7.2 | Declare that all annexes attached to this application form are true and that all existing data, reports and information, which are relevant to the benefit/risk assessment of the medicinal product, have been supplied. | |
| 7.3 | Undertake to abide to the laws and legislations stated in the Medicines Order, 2007. | |
| 7.4 | Undertake to notify the Department of Pharmaceutical Services, Ministry of Health, Brunei Darussalam of any change in the particulars submitted in this application and of any new safety information during the course of evaluation and as long as the product remains on the market. | |
| 7.5 | Confirm that the product will be recommended for use, sold and supplied in accordance with the approved package insert and in compliance with all licence conditions, applicable legislation and guidelines. | |
| 7.6 | Undertake to notify the Department of Pharmaceutical Services, Ministry of Health, Brunei Darussalam if a product is rejected for registration in any drug regulatory authority. | |
| I understand that a wilfully false statement is an offence under the Medicines Order, 2007 and that all documents submitted for evaluation are not returnable. | | |
| Name (in block letters) | | |
| Passport/ IC No. | | |
| Designation | | |
| Signature | | Company Stamp |
| Date | | |