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| Format: QMS/FMT/002  Revision No: 1  Effective Date: 20 June 2022 | | Department/Division/Office/Unit | Food and Drugs Inspection and Safety Monitoring/Food and Drugs Inspection and Compliance | |
| Document Type: **Form** | | | Doc. No | :FDISM/FDIC/FOM/001 |
|  | Title: **Application For Good Manufacturing Practice Inspection for Finished Pharmaceutical Products and Active Pharmaceutical Ingredient Manufacturing Facilities** | | Revision Number | : 1 |
| Revision Date: | : 03/10/2022 |
| Effective Date | : 11/10/2022 |
| Review Due Date | : 10/10/2025 |
| Ref Doc. | :FDISM/FDIC/GDL/001 |

**Applicant to fill the following sections**

1. **Particulars of the Applicant**

Name\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Physical Address\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Country\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Telephone\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

E-mail\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. **Particulars of Manufacturing Site to be Inspected**

Name of site\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Physical Address (if different from 1. above)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Country\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Tel\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

E-mail:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

***Note****: Separate application to be filled in for each individual site*

1. **Contact Person on Site**

Name of contact person\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Tel: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Fax:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

E-mail:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. **Authorized Representative/Agent in Rwanda**

Name of Local Technical Representative\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Tel: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ E-mail: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. **Type of Medicines/ Active Pharmaceutical Ingredients**

Type of medicines manufactured *(double click to check applicable box)*

Human☐ Veterinary ☐ Human & Veterinary…. Herbal

1. **Registration of Products in Rwanda**

Have you registered any products in Rwanda YES ☐ NO ☐

Have you submitted a product dossier for registration from the production line(s) applied for inspection? YES ☐ NO ☐ (If "YES", list of the products in the table below)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Trade Name (if any) | Generic Name | Dosage Form | Strength | Primary Packaging |
|  |  |  |  |  |
|  |  |  |  |  |

1. **Inspection Applied for** *(Double click to check applicable box*)

☐ First Inspection

☐ Routine Inspection (state previous inspection dates ………………*DD/MM/YYYY*)

☐ Re-inspection (after failure)

☐ Other *(please specify)* …………………………………………………………….

1. **Major Site Changes** **Since Last Inspection**

Provide summary of changes to personnel, equipment, buildings, specifications, computer systems, products (type, range or category), suppliers and contractors since last inspection, below or as an Attachment to this form.

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**Production Lines to be Inspected** *(Please tick or fill in the applicable boxes)*

|  | | Yes | No | Building Block name/ number | Number of production lines | Non  β-lactam | β-lactam | |  | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Penicillin | Cephalosporin | Cytotoxic | Hormones | Human | Veterinary |
| **1. MANUFACTURING OPERATIONS** | | | | | | | | |  | |  |  |
| **1.1 Sterile products** | | | | | | | | |  | |  |  |
| a | Aseptically prepared (list of dosage forms) |  |  |  |  |  |  |  |  |  |  |  |
|  | Large volume liquids |  |  |  |  |  |  |  |  |  |  |  |
|  | Lyophilisates |  |  |  |  |  |  |  |  |  |  |  |
|  | Semi-solids |  |  |  |  |  |  |  |  |  |  |  |
|  | Small volume liquids |  |  |  |  |  |  |  |  |  |  |  |
|  | Solids and implants |  |  |  |  |  |  |  |  |  |  |  |
|  | Other aseptically prepared products  (e.g. eye drops, prefilled syringes) |  |  |  |  |  |  |  |  |  |  |  |
|  | Terminally sterilized (list of dosage forms) |  |  |  |  |  |  |  |  |  |  |  |
|  | Large volume liquids |  |  |  |  |  |  |  |  |  |  |  |
|  | Semi-solids |  |  |  |  |  |  |  |  |  |  |  |
|  | Small volume liquids |  |  |  |  |  |  |  |  |  |  |  |
|  | Solids and implants |  |  |  |  |  |  |  |  |  |  |  |
|  | Other terminally sterilised prepared products |  |  |  |  |  |  |  |  |  |  |  |
| **1.2 Non-sterile products (list of dosage forms)** | | | | | | | | |  | |  |  |
| 1. a | Capsules, hard shell |  |  |  |  |  |  |  |  |  |  |  |
|  | Capsules, soft shell |  |  |  |  |  |  |  |  |  |  |  |
|  | Impregnated matrices |  |  |  |  |  |  |  |  |  |  |  |
|  | Liquids for external use |  |  |  |  |  |  |  |  |  |  |  |
|  | Liquids for internal use |  |  |  |  |  |  |  |  |  |  |  |
|  | Dry powders for oral suspension |  |  |  |  |  |  |  |  |  |  |  |
|  | Medicated lozenges |  |  |  |  |  |  |  |  |  |  |  |
|  | Powders/granules in sachets |  |  |  |  |  |  |  |  |  |  |  |
|  | Medicinal gases |  |  |  |  |  |  |  |  |  |  |  |
|  | Other solid dosage forms (please specify) |  |  |  |  |  |  |  |  |  |  |  |
|  | Pressurised preparations |  |  |  |  |  |  |  |  |  |  |  |
|  | Radionuclide generators |  |  |  |  |  |  |  |  |  |  |  |
|  | Semi-solids |  |  |  |  |  |  |  |  |  |  |  |
|  | Suppositories |  |  |  |  |  |  |  |  |  |  |  |
|  | Tablets |  |  |  |  |  |  |  |  |  |  |  |
|  | Transdermal patches |  |  |  |  |  |  |  |  |  |  |  |
| 1. a | Intraruminal devices |  |  |  |  |  |  |  |  |  |  |  |
|  | Veterinary premixes |  |  |  |  |  |  |  |  |  |  |  |
|  | Other non-sterile medicinal products |  |  |  |  |  |  |  |  |  |  |  |
|  | | | |  |  |  |  |  |  |  |  |  |
| **1.3** | **Biological medicinal products** | | | | | | | |  | |  |  |
|  | Blood products |  |  |  |  |  |  |  |  |  |  |  |
|  | **Immunological products** |  |  |  |  |  |  |  |  |  |  |  |
| 1. Vaccines |  |  |  |  |  |  |  |  |  |  |  |
| 1. Sera |  |  |  |  |  |  |  |  |  |  |  |
| 1. Other immunological products |  |  |  |  |  |  |  |  |  |  |  |
|  | Cell therapy products |  |  |  |  |  |  |  |  |  |  |  |
|  | Gene therapy products |  |  |  |  |  |  |  |  |  |  |  |
|  | Biotechnology products |  |  |  |  |  |  |  |  |  |  |  |
|  | Human or animal extracted products |  |  |  |  |  |  |  |  |  |  |  |
|  | Biosimilar products |  |  |  |  |  |  |  |  |  |  |  |
|  | Other |  |  |  |  |  |  |  |  |  |  |  |
| **1.4 Other products or manufacturing activity** | | | | |  |  |  |  |  |  |  |  |
|  | **Manufacture of:** |  |  |  |  |  |  |  |  |  |  |  |
| 1. a | Herbal products |  |  |  |  |  |  |  |  |  |  |  |
|  | Homoeopathic products |  |  |  |  |  |  |  |  |  |  |  |
|  | Biological active starting materials |  |  |  |  |  |  |  |  |  |  |  |
|  | Active pharmaceutical ingredients (chemical) |  |  |  |  |  |  |  |  |  |  |  |
|  | Other |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
| **2.0**  **Sterilisation of active substance/excipients/finished product:** | | | | | | | | |  | |  |  |
|  | Filtration |  |  |  |  |  |  |  |  |  |  |  |
|  | Dry heat |  |  |  |  |  |  |  |  |  |  |  |
|  | Moist heat (steam, superheated water) |  |  |  |  |  |  |  |  |  |  |  |
|  | Chemical (ethylene oxide, ozone |  |  |  |  |  |  |  |  |  |  |  |
|  | Gamma irradiation |  |  |  |  |  |  |  |  |  |  |  |
|  | Electric beam |  |  |  |  |  |  |  |  |  |  |  |
|  | Other |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
| **3.0 Quality control testing** | | | | | |  |  |  |  |  |  |  |
|  | Microbiological: sterility |  |  |  |  |  |  |  |  |  |  |  |
|  | Microbiological: non-sterility |  |  |  |  |  |  |  |  |  |  |  |
|  | Chemical/Physical |  |  |  |  |  |  |  |  |  |  |  |
|  | Biological |  |  |  |  |  |  |  |  |  |  |  |
|  | Animal |  |  |  |  |  |  |  |  |  |  |  |
|  | Stability |  |  |  |  |  |  |  |  |  |  |  |

1. **Declaration**

*I hereby certify that the above information is correct and apply for Good Manufacturing Practice inspection of the above-named site(s).* *I also commit to welcome the Rwanda FDA GMP inspectors for the inspection.*

Signature of applicant……………………………. Date……………………………

Name……………………………………….. Designation..............................

***Notes****:*

*1. Please submit a copy of the current Site Master File together with this application (refer to Guideline on preparation of a Site Master File)*

*2. Submit the completed application together with proof of payment of the appropriate fees, to the Director General Rwanda Food and Drugs Authority.*

|  |  |  |
| --- | --- | --- |
| *This box is to be completed by Rwanda FDA official only* | | |
| **Inspection Reference Number**: | | |
| *Assigned to:* | *Lead GMP Inspector* | *Team GMP Inspector(s)* |
| *Name* |  |  |
| *Assigned by :*  *Name* | *Title: signature: Date:* | |