* An application form for the purpose of **obtaining** a licence **or renewing/amending** a licence in terms of the provisions of Section 22C(1)(b) and Section 22D of the Medicines and Related Substance Act 101 of 1965 as amended, read together with Regulations 23 and 24 of the General Regulations to the Medicines Act as the case may be.

Select the type of activity being applied for:

|  |  |
| --- | --- |
| **Manufacturer: Medicinal Product** |  |
| **Manufacturer: API (including cannabis extraction)** |  |
| **Importer: API** |  |
| **Exporter: API** |  |
| **Contract Laboratory** |  |
| **Packer only** |  |
| **HCR Importer** |  |
| **HCR Exporter** |  |
| **HCR Local 3rd Party Manufacturer** |  |

**API—Active Pharmaceutical Ingredient HCR—Holder of the Certificate of Registration**

* This form should be completed by or for each manufacturer of medicines or scheduled substances who is not exempted from the requirement to hold a licence and who wishes to manufacture, import or export medicine or who wishes to renew or amend their existing manufacture licence to manufacture, import or export medicines and scheduled substances.
* Incomplete forms may be rejected. Please type or print in black ink. Any alterations must be initialled and dated. All required copies of certificates should be certified.
* The application will only be recognised if accompanied by the prescribed application fee for a licence. For the amount, refer to the summary of fees and charges available on the SAHPRA website: <https://www.sahpra.org.za/document/regulations-regarding-fees-payable-in-terms-of-the-provisions-of-the-medicines-and-related-substances-act-1965-act-no-101-of-1965/>
* The completed form and supporting documents should be emailed to: [gmplicensing@sahpra.org.za](mailto:gmplicensing@sahpra.org.za)
* The licence is the property of South African Health Products Regulatory Authority and must be returned upon demand. The licence remains valid for the period of five years from the date of issue unless otherwise suspended or revoked by South African Health Products Regulatory Authority.
* Licensing guidelines are available at the SAHPRA website: <https://www.sahpra.org.za/inspectorate-and-regulatory-compliance/>
* **Application for renewal of the licence must be submitted at least 180 days before expiry of the existing licence**.

**Guidance notes & General information**

**Name of the proposed license holder**

Full, legal name of licence applicant or owner of the business who wishes to manufacture, import or export medicine (must be full, *legally identifiable name* e.g. ‘ABC Pty Ltd’, ‘Newcorp Ltd’ trading as XYZ’, ‘Gillian Linda Smith trading as MNR). Spaces are provided for the following options. Please insert as applicable.

a) Name if sole individual trader

The individual's full name if trading as an individual trader

b) Name of corporation or company

If a corporation or company, the name of the registered corporation or company under the Companies Act and the **registration number** allocated by the Registrar of Companies.

c) Name if trading under other business name

The business name, or name under which you propose to trade for purposes of the Act

[if different from (a) or (b)]

**Declaration**

This declaration seeks assurances that the requirements of Section 22C and 22D and Regulation 23 and 24 of the General Regulations to the Medicines Act, as the case may be, have been satisfied and that the information provided in the application is current and correct at the time it was signed by the manufacturer, importer or exporter. The declaration in A (iii) is intended to establish whether a manufacturer has received a notice that its manufacturing operations do not comply with current acceptable quality assurance principles and good manufacturing practices as determined by South African Health Products Regulatory Authority. A penalty applies for false and misleading statements made in relation to this application.

**Persons signing the declaration**

Persons signing the declaration should be the manufacturer, or the manufacturer's duly appointed designee who is responsible to South African Health Products Regulatory Authority for compliance with the Act – refer Regulation 23(2)(b).

Name Full name

Position The role in the organization e.g. Owner, Designee.

**Site Master File**

Part of the reporting aspects of the audit can be addressed by receiving information on related company details, e.g. details of the company's facilities, personnel structure and operating procedures including manufacturing activities, prior to audit.

It is expected that a Site Master File be prepared and submitted to the Inspectorate that should be in line with the guidelines on the preparation of a Site Master File, which can be obtained from the office of the Chief Executive Officer or the SAHPRA website at: <https://www.sahpra.org.za/inspectorate-and-regulatory-compliance/>

**Date of audit**

Before a licence may be issued or renewed, the Inspectorate may have to conduct an audit of the company's manufacturing operations to assess conformity with the Good Manufacturing Principles as determined by South African Health Products Regulatory Authority. In order to schedule an audit, the applicant should indicate an approximate date by which they will be ready for an audit. If this date changes after the application is submitted the Inspectorate should be notified as soon as possible. The inspector assigned to undertake the audit will advise the manufacturer of the actual date of the audit in advance in order to accommodate the necessary logistics.

**Good Manufacturing Practices**

Pursuant to the current GMP Guidelines, SAHPRA may determine written principles to be observed by a manufacturer of medicines or scheduled substances. These principles will primarily comprise the Guidelines on Good Manufacturing Practice (GMP). A copy of the current guidelines on GMP may be obtained by the manufacturer of medicines and scheduled substances from the SAHPRA website:[[https://www.sahpra.org.za/inspectorate-and-regulatory-compliance/](mailto:www.sahpra.org.za)](https://www.sahpra.org.za/inspectorate-and-regulatory-compliance/)

**Note: If any of the details contained in this Application Form should change after this document has been signed, the Applicant will be obliged to submit an updated application form within 30 days, otherwise the Licence will automatically become null and void.**

|  |
| --- |
| **GENERAL INFORMATION** |

**1.1 NAME OF PROPOSED LICENCE HOLDER**

|  |
| --- |
|  |

**NOTE:** Manufacturers’ Licences are granted to persons who, in the course of a business, manufacture, test and/or pack, import or export medicine or scheduled substances. This can include:

(i) A natural person, or

(ii) A legal person

**1.2 PROPOSED LICENCE HOLDER BUSINESS DETAILS**

|  |  |
| --- | --- |
| Name of business owner |  |
| Registered company name if Corporation |  |
| Name if trading under other business name |  |
| Company or Corporation Registration number issued by the registrar of Companies |  |

**1.3 SITE/PHYSICAL ADDRESS**

|  |  |
| --- | --- |
|  | |
|  | |
|  | |
| **Town/City** | **Postal Code** |
| **Province** | |

**1.4 ADDRESS FOR COMMUNICATIONS (IF DIFFERENT FROM PHYSICAL ADDRESS)**

|  |  |
| --- | --- |
|  | |
|  | |
|  | |
| **Town/City** | **Postal Code** |
| **Province** | |

**1.5 LICENCE HOLDER CONTACT**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Surname** |  | **Initials** |  | **Title** |  |

|  |  |
| --- | --- |
| **Telephone number** |  |
| **Fax number** |  |
| **E-mail address** |  |

**1.6 HAS THE SITE previously held A SAHPRA licence? If YES, PROVIDE THE LICENCE NUMBER**

|  |
| --- |
|  |

**1.7 IS YOUR BUSINESS REGISTERED WITH THE SOUTH AFRICAN PHARMACY COUNCIL AS A MANUFACTURING PHARMACY?**

|  |  |
| --- | --- |
| **YES** | **NO** |

**If yes, supply the Y registration number and copy of certificate of recording**

|  |
| --- |
| **Y** |

**1.8 SUPPLY REGISTRATION NUMBER AND COPY OF CERTIFICATE OF RECORDING OF PHARMACY OWNER WITH PHARMACY COUNCIL**

|  |
| --- |
|  |

|  |
| --- |
| **SITE INFORMATION** |

**2.1 SITE MASTER FILE (Tick the appropriate block)**

**Enclosed Submitted before 20**

**Note:** Before a licence audit is conducted manufacturers are required to submit a Site Master File. SMF previously submitted must not be older than **2 years**.

**2.2 SITE MASTER FILE NUMBER**

|  |
| --- |
|  |

**Note:** If not known, request a Site Master File Number from [smf@sahpra.org.za](mailto:smf@sahpra.org.za)

**2.3 SUPPLY LICENCE NUMBER AND COPY OF LICENCE FOR THE PREMISES OBTAINED FROM THE DEPARTMENT OF HEALTH**

|  |
| --- |
|  |

**2.4 SITE CONTACT (RESPONSIBLE PHARMACIST)**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Surname** |  | **Initials** |  | **Title** |  |

|  |  |
| --- | --- |
| **Telephone number** |  |
| **Fax number** |  |
| **E-mail address** |  |

**2.5 ACTIVITIES AT SITE**

If the Licence is for Packaging **only**, go to section 2.6.

Filling of sterile products is classified as manufacture not as packaging.

Please tick **MP** (Manufacture, Testing and Packaging) or **M** (Manufacture and Testing only) as appropriate for each category of production.

**2.5.1 STERILE PRODUCTS**

|  |  |  |  |
| --- | --- | --- | --- |
| **A.1** | **Large volume (100 ml or more) sterile liquid** dosage forms (including large volume parenteral and irrigation solutions): |  |  |
|  |  | **MP** | **M** |
| A.1.1 | Aseptically prepared |  |  |
| A.1.2 | Terminally sterilised products |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **A.2** | **Small volume (<100 ml) sterile liquid** dosage forms (including small volume parenterals and eye drops): |  |  |
|  |  | **MP** | **M** |
| A.2.1 | Aseptically prepared |  |  |
| A.2.2 | Terminally sterilised |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **A.3** | **Semi-solid sterile** dosage forms including creams and ointments: |  |  |
|  |  | **MP** | **M** |
| A.3.1 | Aseptically prepared |  |  |
|  | Specify dosage form(s) below: |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  | **MP** | **M** |
| A.3.2 | Terminally sterilised |  |  |
|  | Specify dosage form(s) and sterilisation method below: |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
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| --- | --- | --- | --- |
| **A.4** | **Solid sterile dosage forms:** |  |  |
|  |  | **MP** | **M** |
| A.4.1 | Solid fill (including powders for reconstitution) |  |  |
| A.4.2 | Freeze-dried (lyophilised) |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
|  |  | **MP** | **M** |
| **A.5** | **Other sterile products:** |  |  |
|  | Specify dosage form and sterilisation method: |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**2.5.2 NON-STERILE PRODUCTS**

|  |  |  |  |
| --- | --- | --- | --- |
| **B.1** | **Unit and multi-dose non-sterile liquids:** |  |  |
|  |  | **MP** | **M** |
| B.1.1 | Internal |  |  |
| B.1.2 | External |  |  |
| B.1.3 | Aerosols (pressurised) |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **B.2** | **Semi-solid and other liquid non-sterile dosage forms:** |  |  |
|  | Please specify below: |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **B.3** | **Solid non-sterile dosage forms:** |  |  |
|  |  | **MP** | **M** |
| B.3.1 | Unit-dose forms: tablets |  |  |
|  | capsules, hard gelatin |  |  |
|  | capsules, soft gelatin |  |  |
|  | suppositories/pessaries |  |  |
| B.3.2 | Multi-dose forms (including powders and granules) |  |  |
| B.3.3 | Other solid non-sterile dosage forms: |  |  |
|  | Specify below: |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
|  |  | **MP** | **M** |
| **B.4** | **Medical Gases** |  |  |

**2.5.3 BIOLOGICALS**

produced or handled and appearing in the finished product

|  |  |  |  |
| --- | --- | --- | --- |
|  |  | **MP** | **M** |
| C.1 | Vaccines |  |  |
| C.2 | Sera and other immunologicals |  |  |
| C.3 | Blood and other blood products |  |  |
| C.4 | Other biologicals, please specify below: |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**2.5.4 OTHER ACTIVE INGREDIENTS**

appearing in the finished product

|  |  |  |  |
| --- | --- | --- | --- |
| **2.5.4.1** | **Potentially hazardous** | **MP** | **M** |
| D.1 | Penicillins |  |  |
| D.2 | Cephalosporins |  |  |
| D.3 | Hormones |  |  |
| D.4 | Cytostatics / cytotoxics |  |  |
| D.5 | Others, please specify below: |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **2.5.4.2** | **Miscellaneous** | **MP** | **M** |
| D.6 | Radio-active materials |  |  |
| D.7 | Complementary medicines |  |  |

**2.6 PACKAGING ONLY**

Filling of sterile products is classified as manufacture, not as packaging.

Please tick the boxes as appropriate.

|  |  |  |
| --- | --- | --- |
| **2.6.1** | **Packaging activities** | **P** |
| E.1 | Filling of primary containers |  |
| E.2 | Labelling of primary containers |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **2.6.2** | **Dosage forms packed** | | **P** |
| E.3 | Liquid dosage forms | |  |
| E.4 | Semi-solid dosage forms (including creams and ointments) | |  |
| E.5 | Solid dosage forms (including tablets and powders) | |  |
| E.6 | Medical gases | |  |
| E.7 | Other dosage forms, please specify below: | |  |
|  |  | |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**2.6.3 OTHER DOSAGE FORMS MANUFACTURED AND/OR PACKED**

|  |  |  |  |
| --- | --- | --- | --- |
|  |  | **MP** | **M** |
| F.1 | Veterinary premixes / feed mills |  |  |
| F.2 | Registerable wound dressings |  |  |
| F.3 | Registerable medical devices (e.g. intra-uterine device) |  |  |
| F.4 | Any other medicinal products not listed elsewhere in this application |  |  |
|  | Please specify below: |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**2.6.4 OTHER SPECIFIC PROCESSES / ACTIVITIES**

|  |  |  |
| --- | --- | --- |
| G.1 | Form / fill / seal processes |  |
| G.2 | Strip and / or blister packing |  |
| G.3 | Packaging of parallel-imported products |  |
| G.4 | Manufacture and / or packaging for export |  |
| G.5 | Manufacturer as Sole Importer |  |
| G.6 | Sterilisation processes used (for products or components): |  |
| G.6.1 | Steam or steam / air |  |
| G.6.2 | Dry heat |  |
| G.6.3 | Irradiation / electron beam |  |
| G.6.4 | Biocidal gas / chemical |  |

**2.7 ANALYTICAL TESTING/SITES**

This refers to the site(s) at which analysis or testing of starting materials, packaging materials, intermediate, bulk and finished products takes place. This may also include one or more of the sites where manufacture and/or packaging also takes place.

**2.7.1 Site Name (if testing is contracted to a third party SAHPRA licenced testing laboratory)**

|  |
| --- |
|  |

**2.7.2 Site Address (if testing is contracted to a third party SAHPRA licenced testing laboratory)**

|  |  |
| --- | --- |
|  | |
|  | |
|  | |
| **Town** | **Postal code** |

**2.7.3 Testing activities at this site**

|  |  |  |
| --- | --- | --- |
| H.1 | Chemical / physical |  |
| H.2 | Microbiological / sterility / environmental / LAL |  |
| H.3 | Pyrogens (rabbit test method) |  |
| H.4 | Bioassay |  |
| H.5 | Stability testing |  |
| H.6 | Other, please specify: |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

**2.8 STORAGE AND HANDLING OF MATERIALS**

|  |
| --- |
| **Please complete separate forms for each site from which storage, distribution or other activities take place** |

**2.8.1 Site Name (if storage and handling of materials is contracted to a third party SAHPRA licenced facility)**

|  |
| --- |
|  |

**2.8.2 Site Address (if storage and handling of materials is contracted to a third party SAHPRA licenced facility)**

|  |  |
| --- | --- |
|  | |
|  | |
|  | |
| **Town** | **Postal code** |

**2.8.3 Site Contact**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Surname** |  | **Initials** |  | **Title** |  |

|  |  |
| --- | --- |
| **Telephone number** |  |
| **Fax number** |  |
| **E-mail address** |  |

**2.8.4 Site Usage**

|  |  |  |
| --- | --- | --- |
| Is this site used for distribution only (i.e. onward dispatch of ready packed orders) | **YES** | **NO** |
| or is this site used for other purposes | **YES** | **NO** |
| Please specify these other purposes (e.g. order receipt, invoicing, picking of orders, handling of goods returned from customers): | | |
|  | | |
|  | | |
|  | | |

**2.8.5 Facilities on site**

|  |  |  |
| --- | --- | --- |
| Is the description of the facilities available for the storage and distribution of medicinal products detailed in the Site Master File? | **YES** | **NO** |
| If not, please provide a brief description (approximately 500 words) of the facilities available for the storage and distribution of medicinal products on a separate sheet of paper. | | |

**2.8.6 Equipment on site**

|  |  |  |
| --- | --- | --- |
| Is a description of the major items of equipment other than transport available for the storage and distribution of medicinal products detailed in the Site Master File? | **YES** | **NO** |
| If not, please provide a brief description (approximately 500 words) of the equipment available for the storage and distribution of medicinal products on a separate sheet of paper. In particular please provide details of any refrigeration equipment available. | | |

**2.9 Activities of site relating to Import or Export**

|  |  |  |
| --- | --- | --- |
| Are medicines Imported by the Applicant? | **YES** | **NO** |
| Are medicines Exported by the Applicant? | **YES** | **NO** |
| If yes, please provide a list of products being exported. | | |

**2.10 SITE USAGE**

Describe below all other activities on this site.

|  |
| --- |
|  |

**3 LIST OF ACTIVITIES**

|  |  |  |  |
| --- | --- | --- | --- |
| **PLEASE SPECIFY THE ACTIVITIES TO BE PERFORMED AT THIS SITE IN ACCORDANCE WITH THE FOLLOWING MATRIX (Note: The entire matrix will be included on annexure of the actual license that will be granted, however only the activities as approved by the inspection resolution will be authorized. Certain activities will be denied as outlined in the conditions of the licence)** | | | |
| **3.1 MANUFACTURING ACTIVITIES** | | **YES** | **NO** |
| **Sterile, Non-biological Manufacture (includes filling, but not cartoning or labelling)** | |  |  |
| Large volume parenteral products | |  |  |
| Small volume parenteral products | |  |  |
| Other sterile dosage forms (please specify) | |  |  |
| **Non-sterile Manufacture** | |  |  |
| Tablets | |  |  |
| Capsules | |  |  |
| Liquids | |  |  |
| Semi-solids | |  |  |
| Suppositories | |  |  |
| Other non-sterile dosage forms (please specify) | |  |  |
| **Biological Manufacture** | |  |  |
| Vaccines | |  |  |
| Sera and other immunologicals | |  |  |
| Blood and other blood products | |  |  |
| Other biological products (please specify) | |  |  |
| **Medical Gas Manufacture** | |  |  |
| **Radioactive Medicines Manufacture** | |  |  |
| **Complementary Medicines Manufacture** | |  |  |
| **3.2 PACKAGING ACTIVITIES** | |  |  |
| Packaging of bulk product and labelling | |  |  |
| Re-labelling or redressing | |  |  |
| Cartoning or secondary packaging | |  |  |
| **3.3 TESTING ACTIVITIES** | |  |  |
| Analytical | |  |  |
| Microbiological | |  |  |
| Sterility | |  |  |
| Stability | |  |  |
| Animal | |  |  |
| Other (please specify) | |  |  |
| **3.4 DISTRIBUTION ACTIVITIES (excluding wholesaling of other manufacturer’s products)** | |  |  |
| Bulk distribution to wholesale pharmacies | |  |  |
| Fine distribution to retail pharmacies and other clients | |  |  |
| **3.5 Import of medicines and scheduled substances (as per Product Certificate of Registration)** | |  |  |
| Medicines and Scheduled Substances: S0 to S4 | |  |  |
| Medicines and Scheduled Substances: S5 and S6 (note: an additional import permit will be required) | |  |  |
| **3.6 Export OF MEDICINES AND SCHEDULED SUBSTANCES** **(as per Product Certificate of Registration. Please specify products exported on a separate list)** | |  |  |
| Medicines and Scheduled Substances: S0 to S4 | |  |  |
| Medicines and Scheduled Substances: S5 and S6 (note: an additional export permit will be required) | |  |  |
| **3.7 MATERIALS HANDLED OR STORED AT THIS SITE** | | **YES** | **NO** |
| Penicillins | |  |  |
| Cephalosporins | |  |  |
| Hormones | |  |  |
| Cytostatics/Cytotoxics | |  |  |
| Bulk Pesticides, Herbicides or Rodenticides | |  |  |
| Potent Steroids | |  |  |
| Other potent, toxic, sensitising or hazardous materials (please specify) | |  |  |

|  |
| --- |
| **PERSONNEL INFORMATION** |

**Guidance notes on nomination of personnel having control (refer to SA Guide to GMP)**

**The Medicines and Related Substance Act, 1965**

The Act requires that the applicant shall identify the persons who will have and maintain control of the manufacture of medicine and scheduled substances. The Regulations to the Act require that changes be notified promptly to South African Health Products Regulatory

**Relevant Qualifications**

Relevant qualifications are those relevant to the manufacture of medicines and scheduled substances including those in related sciences and management.

**Relevant Experience**

Relevant experience is that relevant to the manufacture (including quality management) of medicines and scheduled substances involving comparable good manufacturing practice or experience, which the applicant believes should be taken into consideration as relevant.

All applications should include a relevant CV and each pharmacist nomination shall include a letter of appointment by the licence holder and a letter of acceptance.

**4 THE RESPONSIBLE PHARMACIST (NOT APPLICABLE FOR CONTRACT TESTING LABORATORIES)**

Please give the following details of the pharmacist who is to control the manufacture, import or export of medicines or scheduled substances in terms of the provisions of Regulation 23(2)(a) of the General Regulations to the Medicines Act.

**4.1 Personal information**

|  |  |  |  |
| --- | --- | --- | --- |
| Surname | Given names | Position in Company | Pharmacy Council registration number |
|  |  |  |  |

**4.2 Relevant qualifications**

|  |  |  |  |
| --- | --- | --- | --- |
| Degree/Diploma | Field of Study | Institution | Year Graduated |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**4.3 Relevant experience (last job first)**

|  |  |  |
| --- | --- | --- |
| Number of Years | Employer | Position Held |
|  |  |  |
|  |  |  |

**4.4 Business Address and Phone number**

|  |
| --- |
| **Tel. no.** |

Please submit a certified copy of the candidate's Registration Certificate from the SA Pharmacy Council with this application.

I confirm that the above particulars are to the best of my knowledge and belief accurate and true.

I agree to be nominated as the Pharmacist responsible for the manufacture, import or export of medicines or scheduled substances as detailed in this licence application.

Signed (responsible pharmacist): Date:

Signed (business owner/designee): Date:

**5** **NOMINATION OF PERSON WHO WILL HAVE CONTROL OF PRODUCTION** **12**

**5.1 Personal information**

|  |  |  |
| --- | --- | --- |
| Surname | Given names | Position in Company |
|  |  |  |

**5.2** **Relevant qualifications**

|  |  |  |  |
| --- | --- | --- | --- |
| Degree/Diploma | Field of Study | Institution | Year Graduated |
|  |  |  |  |
|  |  |  |  |

**5.3** **Relevant experience (last job first)**

|  |  |  |
| --- | --- | --- |
| Number of Years | Employer | Position Held |
|  |  |  |
|  |  |  |
|  |  |  |

**6 PERSON WHO WILL HAVE CONTROL OF QUALITY CONTROL / ASSURANCE**

**(MANDATORY FOR CONTRACT TESTING LABORATORIES)**

**6.1 Personal information** **15**

|  |  |  |
| --- | --- | --- |
| Surname | Given names | Position in Company |
|  |  |  |

**6.2** **Relevant qualifications**

|  |  |  |  |
| --- | --- | --- | --- |
| Degree/Diploma | Field of Study | Institution | Year Graduated |
|  |  |  |  |
|  |  |  |  |

**6.3** **Relevant experience (last job first)**

|  |  |  |
| --- | --- | --- |
| Number of Years | Employer | Position Held |
|  |  |  |
|  |  |  |
|  |  |  |

**7 PERSON(S) RESPONSIBLE FOR LIVING TISSUE CULTURES**

**7.1 Personal information**

|  |  |  |
| --- | --- | --- |
| Surname | Given names | Position in Company |
|  |  |  |

**7.2** **Relevant qualifications**

|  |  |  |  |
| --- | --- | --- | --- |
| Degree/Diploma | Field of Study | Institution | Year Graduated |
|  |  |  |  |
|  |  |  |  |

**7.3** **Relevant experience (last job first)**

|  |  |  |
| --- | --- | --- |
| Number of Years | Employer | Position Held |
|  |  |  |
|  |  |  |
|  |  |  |

**7.4 Name and function of the person to whom he/she reports**

|  |
| --- |
|  |

**8 PROPOSED DATE OF AUDIT**

Approximate date when ready for audit

|  |
| --- |
|  |

**9 list of supporting documents to be submitted**

|  |  |  |
| --- | --- | --- |
|  | **Yes** | **No** |
| Proof Of Payment |  |  |
| Existing SAHPRA Licence for Renewal and Amendment Applications |  |  |
| Cover Letter |  |  |
| Site Master File |  |  |
| Signed Declaration |  |  |
| Sahpra Inspection Resolution |  |  |
| CIPC/CIPRO/DTI Certificate (Docs) |  |  |
| NDOH Premises Licence |  |  |
| Registration of Responsible Pharmacist |  |  |
| SAPC Record of a Pharmacy |  |  |
| SAPC Record of a Pharmacy Owner |  |  |
| Municipal Approval/Zoning Certificate |  |  |

|  |
| --- |
| **DECLARATION** |

*Applicants should note that in terms of the provisions of the Medicines and Related Substance Act, 1965 it is an offence to make false and misleading statements in connection with an application for a licence to manufacture, import or export medicine or scheduled substances.*

|  |  |  |
| --- | --- | --- |
|  | *Tick () one box only in each case* | |
| A. I declare that: | Yes | No |
| (i) The manufacturer had a licence revoked after being granted such a licence. |  |  |
| (ii) The manufacturer has been convicted of an offence against the Medicines and Related Substance Act, 1965 or a law of a state or territory relating to medicines or scheduled substances. |  |  |
| (iii) The manufacturer has received notification from SAHPRA on more than one occasion that the manufacturer has failed to observe Good Manufacturing Practices in connection with the manufacture of medicines or scheduled substances. |  |  |
| (iv) The information provided in this application is current and correct. |  |  |

If parts (i), (ii) or (iii) of the declaration were answered in the affirmative, details should be provided on additional pages.

**Delete part (iii) of the declaration if it is not applicable.**

B. I / We apply for the **granting of the new/ renewed/ amended** (*indicate by crossing out the non-applicable section*) Manufacturer's Licence to the proposed holder named in this application form in respect of the activities to which the application refers.

1. The licence to be subject to all the Standard Provisions applicable to Manufacturer's Licences under regulations for the time being in force under Section 22C of the Medicines and Related Substance Act, 1965.

2. The manufacturing operations are conducted only in accordance with the information set out in the application or furnished in connection with it.

3. I / We declare that we hold the relevant product registrations or are named on the relevant product registrations as manufacturers and / or packaging relating to the medicinal products we wish to manufacture and / or pack pursuant to this application.

4. To the best of my / our knowledge and belief the particulars I / we have given in this form are correct and complete.

**The above declaration must be signed:**

* in the case of a corporation or company by the designee / natural person who shall be responsible to SAHPRA for compliance with the Act.
* in the case of other enterprises by the owner.

|  |  |
| --- | --- |
| Name |  |
| Signature |  |
| Position within Organization |  |
| Date |  |

**Note: This is a legal document. Any changes to the application once submitted must be made in writing detailing the requested variation and be signed by the authorized person above.**