**SAMPLES REPOSITORY OFFICE**

**SAMPLE SUBMISSION FORM**

**Part A: Customer Details**

1. Customer Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
2. Customer Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

1. Contact Person:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
2. Designation:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
3. Contact: Mobile No.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Telephone No.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
4. E-mail: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Part B: Product Details**

1. Product Generic Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

* 1. Brand Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
  2. Pharmacological classification (*e.g. anti-malarial*):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Manufacturer:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
   1. Manufacturer`s address:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

* 1. Date of Manufacture: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
  2. Date of Expiry:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
  3. Batch Number:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
  4. Country of Origin:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
  5. Zimbabwe Registration Number (*if any*):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Sampling Site:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
   1. State/Province/City:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
   2. Storage conditions: Temperature\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Humidity\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
   3. Sample size:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
2. Transportation conditions (*e.g. cold chain samples*):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Part C: Analysis Required**

**YES NO**

**11.0 CHEMICAL ANALYSIS**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **CUSTOMER REF NO:** | | | | |
|  | **Details of Analysis Required***(Please insert (****√ or X****) in the applicable box)* | | | | |
| **Test** | **Yes***(****√****)* **or No** *(***X***)* |  | **Test** | **Yes***(****√****)* **or No** *(***X***)* |
| a. | Appearance |  | b. | pH |  |
| c. | Identity |  | d. | Assay |  |
| e. | Uniformity of Mass |  | f. | Dissolution |  |
| g. | Disintegration |  | h. | Uniformity of Content |  |
| i. | Friability |  | j. | Heavy Metals |  |
| k. | Hardness |  | l. | Moisture Content |  |
| m. | Decomposition Products |  | n. | Related Substances |  |
| o. | Other test *(please specify)*: | | | | |

**Please note:** Tests performed, including quality performance tests (minimum test parameters), may be different from those indicated on the quotation (or on this form) depending on whether the products are USP, BP or Int'l Ph.

**12.0 Any Other Comments:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**13.0 MICROBIOLOGICALANALYSIS:**

**YES NO**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | **CUSTOMER REF NO:** | | | | | | |
|  | **Details of Analysis Required***(Please insert (****√ or X****) in the applicable box)* | | | | | | |
| **Test** | **Yes**(***√*** ) | **No***(****X***) |  | **Test** | **Yes**(***√*** ) | **No**(***X***) |
| a. | Appearance |  |  | b. | Pyrogen (LAL/BET) |  |  |
| c. | Microbial Limit (Microbiological Examination of Non-Sterile Products) |  |  | d. | Microbial Assay |  |  |
| e. | Sensitivity Test |  |  | f. | Sterility Test |  |  |
| g. | Preservative Efficacy |  |  | h. | Other Test (*please specify*) |  |  |
| i. | Other test *(please specify)*: | | | | | | |

**14.0 Any Other Comments:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**PART D: TERMS AND CONDITIONS**

1 **Privacy and Confidentiality**

1.1 The MCAZ laboratory recognizes the importance of privacy and shall be responsible for the management of all information obtained or created during the performance of laboratory activities.

1.2 The MCAZ laboratory shall hold the information disclosed to it in strict confidence and shall use the confidential information only for testing activities.

1.3 The MCAZ laboratory shall exercise reasonable care to protect your information including your test data and results from unauthorized use and disclosure.

1.4 The MCAZ Laboratory shall not, without your prior written consent, disclose your Confidential Information to any person, party or entity except to such of its representatives who need such information to perform duties connected with the testing activities, and who are bound by an obligation of confidentiality consistent with these terms and conditions.

1.5 For purposes of these terms and conditions, “Representatives” means MCAZ Laboratory’s officers, employees, partners, agents or other representatives (including, without limitation, its attorneys, accountants, auditors, assessors, consultants and financial advisers).

1.6 Exceptions: MCAZ Laboratory shall not be liable for disclosure or use of Confidential Information that:

1.6.1 at the time of disclosure was in the public domain, or subsequently became part of the public domain otherwise than by breach of these terms and conditions;

1.6.2 you authorized in writing to be disclosed; or

1.6.3 is being disclosed in compliance with a Court Order or an order of any other competent body, or as required by the Medicines and Allied Substances Control Act (*Chapter 15:03*) or any other law, provided that the MCAZ laboratory shall first give you written notice of such disclosure and further provide that the MCAZ laboratory limits the disclosure to the least that is legally required.

2 **Process requirements**

2.1 In the event that you request a statement of conformity to a specification or standard for the test (e.g. pass/fail, complies/does not comply) the MCAZ Laboratory, shall use the defined specification as stated in the method used to conduct the test. However, where a non-standard method is used, the decision rule will apply. MCAZ laboratory shall communicate to you the decision rule selected upon submission of the test results.

By signing below you agree to the terms and conditions stated above.

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Signature Printed name Date

**FOR MCAZ USE ONLY**

**Sample Received by: Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**MCAZ Ref. No: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**