Version No	HISTORY OF REVISIONS		
	Prepared by	Approved by	Effective Date
1	Nur Amani Shaari Fadhilah Hasbullah	Azura Abdullah	21 April 2020
2	Fauziah Mohamed Kasim Fadhilah Hasbullah Poh Wen Tsin	Azura Abdullah	20 July 2022
3	Fauziah Mohamed Kasim Fadhilah Hasbullah	Azura Abdullah	10 January 2023
4	Fauziah Mohamed Kasim Fadhilah Hasbullah	Azura Abdullah	21 April 2023

REFERENCES	
Document No :	**Title**
-	NPRA Good Laboratory Practice Compliance Programme Manual

Amendments:

This document is a new document in line with National Pharmaceutical Regulatory Agency (NPRA) restructuring effective on 2 December 2019. The original document has been cancelled and this document is published as Version 1.

Review 1 (Version 2):

i. Annual revision of Good Laboratory Practice (GLP) procedures. The document has been revised for standardization of format and clarification of the process.

Review 2 (Version 3):

i. Annual revision of Good Laboratory Practice (GLP) procedures. The document has been revised for standardization of format and clarification of the process.

Review 3 (Version 4):

i. Annual revision of Good Laboratory Practice (GLP) procedures. The document has been revised for standardization of format and clarification of the process.

1. OBJECTIVE

To describe the procedure for application for the Good Laboratory Practice (GLP) Compliance certification.

2. SCOPE

Test facilities conducting studies for non-clinical health safety studies and for purpose of registering and/or licensing test items contained in products in the following categories:

- Pharmaceuticals products
- Cosmetics products
- Veterinary drugs and
- Food additive
- Medical devices
- Others

3. DEFINITION

NO.	ACRONYM	DEFINITION
3.1	CAPA	Corrective Actions and Preventive Actions
3.2	CCQC	Centre for Compliance and Quality Control
3.3	GLP	Good Laboratory Practice
3.4	GCP	Good Clinical Practice
3.5	SOP	Standard Operating Procedure

4. FLOW CHART

None.

5. RESPONSIBILITY

5.1 Deputy Director of Centre for Compliance and Quality Control (CCQC)
5.2 Head of GCP and GLP Section
5.3 GLP officers

6. PROCEDURE

6.1 A facility can make an application for the GLP compliance certification to the National Pharmaceutical Regulatory Agency (NPRA), Ministry of Health Malaysia.

6.2 The application can be made by completing the form *GLP Application Form* (NPRA-433-10). The form is available online and can be downloaded from the NPRA website.

Application forms should be filled in for all types of inspection (pre-inspection, inspection, surveillance inspection and extraordinary inspection).

6.3 The applicant is required to pay a processing fee and provide supportive documents as specified in the application form.

6.4 Payment shall be submitted to Finance Unit, Centre of Administration, NPRA for issuance of receipt. Official receipt of payment shall be submitted together with the application form to the GLP officer at the Centre for Compliance and Quality Control.

6.5 The applicant must submit the complete application form with the official receipt of payment to:

Deputy Director
Centre for Compliance and Quality Control,
National Pharmaceutical Regulatory Agency (NPRA),
Ministry of Health, Malaysia.
Jalan Prof Diraja Ungku Aziz
46200 Petaling Jaya, SELANGOR

6.6 GLP officers in GCP & GLP Section will review the application together with the documents. The test facility shall be informed regarding the additional documents required if necessary.

6.7 An invoice for the inspection fee will be issued to the test facility upon receiving the complete application.

6.8 Inspection fee shall be made to Finance, Account and Revenue Section, Centre of Administration, NPRA for issuance of receipt. The official receipt must be submitted to the GLP officer at the Centre for Compliance and Quality Control at least two (2) weeks before the date of inspection.

6.9 Inspection will only be conducted at to test facility once the official receipt of payment for the inspection fee has been received by Section GCP & GLP.

6.10 The inspection shall be conducted by the inspectors from NPRA who may be accompanied by experts from various fields if required. Inspection duration may vary, depending on the scope and size of the test facility.

6.11 Test facility shall be notified before the date of the inspection.

6.12 For pre-inspection, the test facility must have at least one (1) completed GLP-compliant study per area of expertise before the pre-inspection. This study will be used as the basis for the pre-inspection.

6.13 Inspection will be conducted on the test facility once the corrective actions and preventive actions (CAPA) in the pre-inspection have been addressed satisfactorily. NPRA shall issue a certificate of GLP compliance to test facilities if the facility is deemed compliant with OECD GLP Principles. The test facility shall then be included in the NPRA GLP Compliance Program.

6.14 The surveillance inspection will be conducted annually for the first two (2) years and subsequent surveillance inspections every two (2) years.

7. QUALITY RECORDS

None.

8. FORMS/ANNEX

8.1 GLP Application Form (NPRA-433-10)