NPRA	QUALITY PROCEDURE	Document No : PKPB/200/103
	APPLICATION FOR GOOD LABORATORY PRACTICE (GLP) CERTIFICATION	Version : 3
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Version No	HISTORY OF REVISIONS		
	Prepared by	Approved by	Effective Date
1	Dr. Hasenah Ali	Dr. Kamaruzaman Saleh	15 November 2016
2	Nur Amani Shaari	Dr. Noraida Mohamad Zainoor	14 August 2017
3	Poh Wen Tsin	Dr. Noraida Mohamad Zainoor	1 November 2017

REFERENCES	
Document No :	**Title**
NPRA/GLP/100	NPRA Good Laboratory Practice Compliance Program Manual

Amendments:

This procedure is a new document in line with efforts towards upgrading the institution's certification to the ISO 9001: 2015 version and the renaming of the institution from National Pharmaceutical Control Bureau (NPCB) to National Pharmaceutical Regulatory Agency (NPRA). Therefore, the original document has been cancelled and this document is published as Version 1.

Revision 1 (Version 2):

i. Amendments in the version 2 include the new procedure for method of payment for processing fee and inspection fee.

Revision 2 (Version 3):

i. Format of the quality procedure has been standardised.

1. OBJECTIVE

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

2. SCOPE

To Test Facilities conducting studies for non-clinical health safety studies and for purpose of registering and/or licensing on test item contain in product in the following categories:

- Pharmaceuticals products
- Cosmetics products
- Veterinary drugs and
- Food additive
- Medical Devices

3. RESPONSIBILITY

3.1 Head of GLP Compliance Section
3.2 Officers in the GLP Compliance Section

4. PROCEDURE

4.1 A facility can make an application for the GLP compliance certification to the *Bahagian Regulatory Farmasi Negara* (NPRA), Ministry of Health Malaysia.

4.2 The application can be made by completing the Application Form (PKPB/300/101). The form is available online and can be downloaded from our website.

4.3 The applicant has to pay a processing fee and provide supportive documents as specified in the Application Form.

4.4 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 officer at Centre for Investigational New Product.

4.5 The applicant must submit the complete Application Form (together with official receipt
of payment for processing fee and documents) to:

Deputy Director
Centre for Investigational New Product,
***Bahagian Regulatori Farmasi Negara* (NPRA),**

Ministry of Health, Malaysia.
Jalan Universiti
46200 Petaling Jaya, SELANGOR

4.6 NPRA will review the application together with the documents. The test facility shall be informed regarding the additional documents required if necessary.

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

4.8 Inspection fee shall be made to Finance Unit, Centre of Administration, NPRA for issuance of receipt. The official receipt must be submitted to officer at Centre for Investigational New Product at least 2 weeks before date of Pre-Inspection.

4.9 Pre-inspection will only be conducted on Test Facilities once the official receipt of payment for inspection fee is received.

4.10 The Pre-inspection shall be conducted by the inspector(s) from NPRA who may be accompanied by experts from various fields. Inspection duration may vary, depending on the scope and size of the test facility.

4.11 Test Facility shall be notified prior to the date of the Pre-inspection.

4.12 The Test Facility must have at least one completed GLP-compliant study per area of expertise before the Pre-inspection. This study will be used as the basis for the Pre-inspection.

4.13 Inspection will be conducted on Test Facilities once the corrective actions in the Pre-Inspection have been addressed satisfactorily. NPRA shall issue Certificate of GLP Compliance to Test Facilities if it has satisfied OECD GLP Principles. The Test Facilities shall then be included in the NPRA GLP Compliance Monitoring Program. The Surveillance inspection will be conducted annually for the first two years and subsequent surveillance inspections in every two years, at least 4 months from the date of compliance certificate expires.

5. QUALITY RECORDS

5.1 Application Form (PKPB/300/101)