MINISTRY OF HEALTH MALAYSIA
NATIONAL PHARMACEUTICAL REGULATORY AGENCY

MALAYSIAN GUIDELINE FOR NATIONAL PHARMACEUTICAL REGULATORY AGENCY (NPRA) GOOD LABORATORY PRACTICE (GLP)

COMPLIANCE PROGRAMME

FIRST EDITION (2026)

MALAYSIAN GUIDELINE FOR NATIONAL PHARMACEUTICAL REGULATORY AGENCY (NPRA) GOOD LABORATORY PRACTICE (GLP) COMPLIANCE PROGRAMME

National Pharmaceutical Regulatory Agency (NPRA)

Ministry of Health Malaysia

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THIS GUIDELINE IS ISSUED BY

THE DIRECTOR OF PHARMACEUTICAL SERVICES

UNDER REGULATION 29,

CONTROL OF DRUGS AND COSMETICS REGULATIONS 1984.

THE DIRECTOR RESERVES THE RIGHT TO AMEND ANY PART OF THE GUIDELINE AT THEIR DISCRETION.

Published by:
National Pharmaceutical Regulatory Agency (NPRA)
Ministry of Health
Lot 36, Jalan Prof Diraja Ungku Aziz,
46200 Petaling Jaya,
Selangor Darul Ehsan

Telephone: +603-7883 5400
Homepage: www.npra.gov.my

Cataloguing-in-Publication Data

Perpustakaan Negara Malaysia

A catalogue record for this book is available from the National Library of Malaysia

eISBN 978-629-99329-4-9

The quality system governing the National Pharmaceutical Regulatory Agency (NPRA) Good Laboratory Practice (GLP) Compliance Programme was previously set out in the GLP Compliance Programme Manual, which outlined NPRA's function as Malaysia's national Compliance Monitoring Authority (CMA) for the Organisation for Economic Co-operation and Development (OECD) Principles of GLP.

The GLP Compliance Programme Manual was first published in 2009 as part of Malaysia's preparation to become an adherent country to the OECD Mutual Acceptance of Data (MAD) system. Following Malaysia's recognition as an OECD MAD-adherent country in 2013, the Manual was updated periodically until 2015, resulting in Edition 5. In 2016, in line with the renaming of the National Pharmaceutical Control Bureau (NPCB) to NPRA and the requirements of the MS ISO 9001 quality management system, the GLP Manual was revised and updated, and subsequently republished as Edition 1 (November 2016). The Manual has since undergone regular updates, with the latest edition published in March 2023 (Edition 5), which serves as the current reference document.

In line with the requirements for information transparency and the harmonisation of practices and reference documents at the international level, the Manual has been improved and rebranded as the Malaysian Guideline for the NPRA Good Laboratory Practice (GLP) Compliance Programme.

This Guideline is adapted from the OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring. The OECD documents listed below were referred to in its development. As these documents are revised periodically, it is the responsibility of test facilities and relevant stakeholders to refer to the OECD for the most current versions. Any new OECD publications relevant to Good Laboratory Practice shall be reviewed and implemented in full, where applicable.

- No. 1: OECD Principles of Good Laboratory Practice (as revised in 1997)
- No. 2: Revised Guides for Compliance Monitoring Procedures for Good Laboratory Practice (1995)
- No. 3: Revised Guidance for the Conduct of Laboratory Inspections and Study Audits (1995)
- No. 5: Compliance of Laboratory Suppliers with GLP Principles (as revised in 1999)
- No. 6: The Application of the GLP Principles to Field Studies (as revised in 1999)
- No. 7: The Application of the GLP Principles to Short-Term Studies (as revised in 1999)
- No. 8: The Role and Responsibilities of the Study Director in GLP Studies (as revised in 1999)
- No. 9: Guidance for the Preparation of GLP Inspection Reports (1995)
- No. 11: The Role and Responsibilities of the Sponsor in the Application of the Principles of GLP (1998)

- No. 12: Requesting and Carrying Out Inspections and Study Audits in Another Country (2000)
- No. 13: The Application of the OECD Principles of GLP to the Organisation and Management of Multi-Site Studies (2002)
- No. 14: The Application of the Principles of GLP to in vitro studies (2004)
- No. 15: Establishment and Control of Archives that Operate in Compliance with the Principles of GLP (2007)
- No. 16: Guidance on the GLP Requirements for Peer Review of Histopathology (2014)
- No. 17: The Application of GLP Principles to Computerised Systems (2016)
- No 17 Supplement 1: Advisory Document on GLP & Cloud Computing (2023)
- No. 18: OECD Position Paper Regarding the Relationship between the OECD Principles of GLP and ISO/IEC 17025 (2016)
- No. 19: The Management, Characterisation and Use of Test Items (2018)
- No. 20: Guidance Document for Receiving Authorities on the Review of the GLP Status of Non-Clinical Safety Studies (2019)
- No. 21: OECD Position Paper Regarding Possible Influence of Sponsors on Conclusions of GLP Studies (2020)
- No. 22: GLP Data Integrity (2021)
- No. 23: Quality Assurance and GLP (2022)
- No. 24: Position Paper on Quality Improvement Tools and GLP (2022)
- No. 25: OECD Position Paper on Good Laboratory Practice and IT Security (2024)
- The Use of Laboratory Accreditation with reference to GLP Compliance Monitoring (1994)
- Position Paper on 'Outsourcing' of Inspection Functions by GLP Compliance Monitoring Authorities (2006)

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Special thanks to the stakeholders for their contributions and assistance during the public consultation via the UPC system.

Contents

1. ABBREVIATIONS

CAPA	Corrective and Preventive Action
CMA	Compliance Monitoring Authority
DSM	Department of Standards Malaysia
GLP	Good Laboratory Practice
JKPPPK	*Mesyuarat Jawatankuasa Penilaian Pemeriksaan Premis dan Kajian*
MAD	Mutual Acceptance of Data
MITI	Ministry of Investment, Trade and Industry, Malaysia.
MOH	Ministry of Health, Malaysia
NIC	Not in Compliance
NPRA	National Pharmaceutical Regulatory Agency
OECD	The Organisation for Economic Co-operation and Development
RA	Regulatory Authority
SOP	Standard Operating Procedures
TF	Test Facility
TFM	Test Facility Management

2. DEFINITIONS OF TERMS

2.1 Good Laboratory Practice

Good Laboratory Practice (GLP) is a quality system concerned with the organisational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported.

2.2 Terms Concerning the Organisation of a Test Facility

Test facility means the persons, premises and operational unit(s) that are necessary for conducting the non-clinical health and environmental safety study. For multi-site studies, those which are conducted at more than one site, the test facility comprises the site at which the Study Director is located and all individual test sites, which individually or collectively can be considered to be test facilities.

Test site means the location(s) at which a phase(s) of a study is conducted.

Test facility management means the person(s) who has the authority and formal responsibility for the organisation and functioning of the test facility according to these Principles of Good Laboratory Practice.

Test site management (if appointed) means the person(s) responsible for ensuring that the phase(s) of the study, for which he is responsible, are conducted according to these Principles of Good Laboratory Practice.

Sponsor means an entity which commissions, supports and/or submits a non-clinical health and environmental safety study.

Study Director means the individual responsible for the overall conduct of the non-clinical health and environmental safety study.

Principal Investigator means an individual who, for a multi-site study, acts on behalf of the Study Director and has defined responsibility for delegated phases of the study. The Study Director's responsibility for the overall conduct of the study cannot be delegated to the Principal Investigator(s); this includes approval of the study plan and its amendments, approval of the final report, and ensuring that all applicable Principles of Good Laboratory Practice are followed.

Quality Assurance Programme means a defined system, including personnel, which is independent of study conduct and is designed to assure test facility management of compliance with these Principles of Good Laboratory Practice.

Standard Operating Procedures (SOPs) means documented procedures which describe how to perform tests or activities normally not specified in detail in study plans or test guidelines.

Master Schedule means a compilation of information to assist in the assessment of workload and for the tracking of studies at a test facility.

2.3 Terms Concerning the Non-Clinical Health and Environment Safety Study

Non-clinical health and environmental safety study, henceforth referred to simply as "study", means an experiment or set of experiments in which a test item is examined under laboratory conditions or in the environment to obtain data on its properties and/or its safety, intended for submission to appropriate regulatory authorities.

Short-term study means a study of short duration with widely used, routine techniques.

Study plan means a document which defines the objectives and experimental design for the conduct of the study, and includes any amendments.

Study plan amendment means an intended change to the study plan after the study initiation date.

Study plan deviation means an unintended departure from the study plan after the study initiation date.

Test system means any biological, chemical or physical system or a combination thereof used in a study.

Raw data means all original test facility records and documentation, or verified copies thereof, which are the result of the original observations and activities in a study. Raw data also may include, for example, photographs, microfilm or microfiche copies, computer readable media, dictated observations, recorded data from automated instruments, or any other data storage medium that has

been recognised as capable of providing secure storage of information for a time period.

Specimen means any material derived from a test system for examination, analysis, or retention.

Experimental starting date means the date on which the first study specific data are collected.

Experimental completion date means the last date on which data are collected from the study.

Study initiation date means the date the Study Director signs the study plan.

Study completion date means the date the Study Director signs the final report.

2.4 Terms Concerning the Test Item

Test item means an article that is the subject of a study.

Reference item ("control item") means any article used to provide a basis for comparison with the test item.

Batch means a specific quantity or lot of a test item or reference item produced during a defined cycle of manufacture in such a way that it could be expected to be of a uniform character and should be designated as such.

Vehicle means any agent which serves as a carrier used to mix, disperse, or solubilise the test item or reference item to facilitate the administration/application to the test system.

2.5 Terms Concerning the Compliance Programme

GLP Principles means Principles of Good Laboratory Practice that is consistent with the OECD Principles of Good Laboratory Practice.

GLP Compliance Monitoring means the periodic inspection of test facilities and/or auditing of studies for the purpose of verifying adherence to GLP Principles.

(National) GLP Compliance Programme means the particular scheme established by a member country to monitor good laboratory practice compliance by test facilities within its territories, by means of inspections and study audits.

(National) GLP Monitoring Authority means a body established within a Member country with responsibility for monitoring the good laboratory practice compliance of test facilities within its territories and for discharging other such functions related to the good laboratory practice as may be nationally determined. It is understood that more than one such body may be established in a member country.

Test Facility Inspection means an on-site examination of the test facility's procedures and practices to assess the degree of compliance with GLP Principles. During the inspection, the management structures and operational procedures of the test facility are examined, the key technical personnel are interviewed, and the quality and integrity of data generated by the test facility are assessed and reported.

Study Audit means a comparison of raw data and associated records with the interim or final report in order to determine whether the raw data have been accurately reported, determine whether testing was carried out in accordance with the study plan and standard operating procedures, to obtain additional information not provided in the report, and to established whether practices were employed in the development of data that would impair their validity.

Observation means a condition, practice, or piece of information noted by inspectors during an inspection, based on direct evidence or discussion. An observation represents what was seen or identified at the time of inspection and may or may not lead to a finding upon further classification.

Finding means a failure to meet specifications, requirements or expected functionalities, as documented in the inspection report. In this document, the term *Non-conformance* is used interchangeably with *Finding*.

Non-conformance is used interchangeably with *Finding* in this document. See *Finding* for the definition.

Deviation means non-conformance where an unintended departure from the study plan (after the study initiation date), the GLP Principles, or from an SOP occurs.

Corrective Action and Preventive Action (CAPA) means the collective term used for corrective and preventive actions. The term CAPA system is often used to describe the processes used for managing corrective and preventive actions within a test facility.

Inspector means a person who performs test facility inspection and study audits on behalf of NPRA.

Lead Inspector means a suitably qualified and authorised individual who leads and is responsible for the planning, coordination, execution and final reporting of a GLP inspection or study audit of a test facility.

Expert means a person who has knowledge in their specified area i.e. computerised system, toxicology, etc.

GLP Compliance Status means the level of adherence of a test facility to the GLP Principles as assessed by the (National) GLP Monitoring Authority.

In Compliance means the GLP CMA confirms that the test facility/test site operates in compliance with GLP. Studies may be accepted by the regulatory authorities in support of a product registration or other application for which GLP compliance is required.

Not in Compliance means the GLP CMA considers the test facility/test site not to operate in accordance with GLP. Studies conducted at the test facility/test site cannot be regarded as GLP-compliant. Study reports may not be used for regulatory purposes. If a test facility has passed an inspection at an earlier stage, GLP claims for studies completed since the last 'successful' inspection should not be accepted. The NIC status also applies to studies audited as part of the inspection. If issues are identified that render the study non-compliant with GLP, the study reports cannot be considered as GLP-compliant and may not be used for regulatory purposes.

Regulatory Authority means a national body with legal responsibility for the registration or licensing of pharmaceutical products, cosmetic products, veterinary drugs, food additives, feed additives, pesticide products, medical devices, and industrial chemicals.

OECD GLP Secretariat refers to the Secretariat of the OECD, operating under the OECD Environment Directorate. The Secretariat supports the OECD Working Party on Good Laboratory Practice (WP-GLP) and facilitates coordination, communication, and documentation related to the implementation of the OECD Principles of GLP. The OECD GLP Secretariat does not conduct inspections or determine compliance status, which remain the responsibility of respective national GLP monitoring authorities.

3. INTRODUCTION

In the Cabinet Paper of 13 February 2008, the Government of Malaysia, through the Cabinet, granted approval for the following:

i) The Ministry of Health Malaysia as the coordinator for the OECD GLP Compliance Monitoring Programme in Malaysia.
ii) The two (2) Compliance Monitoring Authorities (CMAs):

- National Pharmaceutical Regulatory Agency (NPRA), Ministry of Health (formerly known as National Pharmaceutical Control Bureau, NPCB)
- Department of Standards Malaysia (DSM), Ministry of Investment, Trade and Industry

4. OBJECTIVES

The objectives of this guideline are to provide clear direction and understanding regarding the implementation and operation of the NPRA GLP Compliance Programme. Specifically, this guideline aims to:

- Outline the policies, roles, and responsibilities of NPRA in its capacity as the national CMA for overseeing GLP compliance in Malaysia.

- Describe the mechanism and criteria for the listing and recognition of test facilities under the NPRA GLP Compliance Programme.

- Define the procedures for the conduct of inspections of test facilities and study audits, including preparation, execution, and follow-up actions.

- Establish the requirements for reporting the outcomes of inspections and study audits to relevant stakeholders.

- Facilitate the exchange of information with other national CMAs in accordance with the OECD Principles of GLP and the Mutual Acceptance of Data (MAD) framework.

- Promote continuous compliance with OECD Principles of GLP, support international data acceptance, and enhance the integrity and quality of non-clinical health and environmental safety studies conducted in Malaysia.

5. SCOPE

The NPRA GLP Compliance Programme is a voluntary programme open to test facilities conducting non-clinical health and environmental safety studies. It is applicable to studies conducted for the purpose of registration and/or licensing of test items contained in products within the following categories:

- Pharmaceutical products
- Cosmetics products
- Veterinary drugs
- Food additives
- Medical Devices

For chemicals such as pesticides, feed additives, industrial chemicals, and non-pharmaceutical biotechnology products, the responsibility for inspection and GLP compliance monitoring lies with the Department of Standards Malaysia (*Jabatan Standard Malaysia*) under the Ministry of Investment, Trade and Industry (MITI), Malaysia (http://www.jsm.gov.my).

There is close collaboration between NPRA and the Department of Standards Malaysia to ensure harmonisation in the implementation of the OECD Principles of GLP. A mutual cooperation agreement has been established and signed by both CMAs, reinforcing coordination in activities related to GLP inspections, information exchange, and adherence to OECD requirements.

Annex 1: Mutual Cooperation

The test items are frequently synthetic chemicals but may be of natural or biological origin and, in some circumstances, may be living organisms. The purpose of the non-clinical safety testing of test items is to obtain data on their properties and/or their safety with respect to human health and the environment. Non-clinical health and environmental safety studies covered by the OECD Principles of GLP include work conducted in the laboratory and in the field.

Type of studies/area of expertise on test item subjected to NPRA GLP Compliance Programme:

- Physical-chemical testing
- Toxicity studies
- Mutagenicity studies
- Analytical and clinical chemistry testing
- Other studies (test facility to specify)

6. GLP COMPLIANCE MONITORING AUTHORITY (CMA)

6.1 Administration

NPRA, formerly known as the National Pharmaceutical Control Bureau (NPCB), was officially appointed as one of Malaysia's Compliance Monitoring Authorities (CMAs) by the Cabinet of Malaysia on 13 February 2008. This appointment applies to all non-clinical health and environmental safety studies within the scope of this guideline. The appointment was subsequently enforced through a Directive issued on 1 June 2009 by the Senior Director of Pharmaceutical Services under Regulation 29 of the Control of Drugs and Cosmetics Regulations 1984 (Amendment) 2006.

NPRA operates as one of the five (5) divisions under the Pharmaceutical Services Programme of the Ministry of Health Malaysia and is responsible for overseeing the NPRA GLP Compliance Programme. The Good Clinical Practice and Good Laboratory Practice (GCPGLP) Section, under the Centre of Compliance and Quality Control, NPRA, is tasked with the day-to-day management and implementation of the NPRA GLP Compliance Programme.

Annex 2: Organogram - National Pharmaceutical Regulatory Agency (NPRA)

Further information on the NPRA GLP Compliance Programme can be obtained from:

NPRA GLP Compliance Programme page:
www.npra.gov.my/index.php/en/gcpglp.html

As one of the designated GLP CMAs for Malaysia, NPRA has formally adopted the OECD Principles of GLP. The structure, policies, and procedures under which NPRA operates are clearly defined and documented to ensure that all compliance activities are conducted in an independent, impartial, and consistent manner.

To support the effective implementation and administration of the GLP Compliance Programme, NPRA has established a comprehensive quality management system. This system is documented, implemented, and maintained in accordance with international standards to provide assurance in NPRA's capability to carry out compliance monitoring activities reliably, transparently, and efficiently.

6.2 Appointment of inspectors

NPRA is directly responsible for maintaining an adequate and qualified team of inspectors with the necessary technical and scientific expertise to conduct GLP inspections and study audits. NPRA may also engage additional experts where necessary but retains full responsibility for the inspection team's conduct and competency. The procedures for the appointment, qualification, and training of inspectors are clearly defined in internal NPRA documentation.

For each inspection, NPRA shall appoint an inspection team. The names of the inspectors, along with any observers and/or external experts (if applicable), shall be communicated to the test facility at least one (1) week prior to the commencement of the inspection. The inclusion of observers and/or external experts shall be determined by the Deputy Director, Centre of Compliance and Quality Control, where appropriate and in accordance with the specific requirements of the inspection.

Test facilities have the right to submit a written objection to the participation of a particular observers and/or external experts, provided that the objection is supported by valid and clearly stated reasons. Such objections shall be submitted to the NPRA within three (3) working days from the date of notification of the observer's and/or external expert's participation. The final decision on the matter shall rest solely with the NPRA.

6.3 Confidentiality

NPRA has established and implemented procedures to ensure appropriate measures are in place to safeguard the confidentiality of information obtained during the course of GLP compliance monitoring activities.

During inspections, NPRA inspectors and any appointed observers and/or external experts may have access to confidential and proprietary information pertaining to the operations, data, and practices of test facilities. Except where disclosure is required by law or permitted under contractual arrangements, all such information and inspection findings shall be treated as strictly confidential.

All inspectors, experts, observers, staff, and any other individuals acting on behalf of NPRA who may have access to sensitive or proprietary information are required to sign a formal agreement on

statement of confidentiality, declaration for conflict of interest, and adherence to the code of ethics.

These measures are intended to protect the intellectual property, data integrity, and commercial interests of the test facilities, while upholding the trust and transparency necessary for the proper functioning of the NPRA GLP Compliance Programme.

While a directory of GLP-compliant test facilities is made publicly available via the NPRA website, confidential materials such as inspection reports, internal correspondence, and meeting minutes, are securely stored and accessible only to authorised NPRA personnel.

Information specific to a test facility shall not be disclosed to any third party without the written consent of the test facility. However, in accordance with Malaysia's obligation under the OECD GLP framework, NPRA is required to report the GLP compliance status of test facilities and any confirmed non-compliant studies to the OECD GLP Secretariat, and, where applicable, to relevant national or international CMA and/or regulatory authorities. In such cases, prior consent from the test facility is not required.

NPRA reserves the right to overrule a facility's request to classify information as sensitive, if doing so is necessary to comply with regulatory or legal obligations.

6.4 Personnel and Training

NPRA is responsible for ensuring that each inspector and expert involved in the NPRA GLP Compliance Programme is appropriately qualified, trained, and competent to perform their duties prior to participating in any inspection or study audit.

New inspectors shall undergo structured training covering the OECD Principles of GLP, NPRA inspection procedures, and inspection skills. They are required to participate in supervised inspections and undergo competency assessments before being qualified as independent inspectors. Inspectors must possess a relevant scientific or technical background with appropriate experience in laboratory or quality management systems. All inspectors shall participate in regular refresher training and workshops to maintain and enhance their knowledge and competency.

NPRA actively engages in the exchange of information and consultation with personnel from other GLP CMAs. This practice

promotes harmonisation in the interpretation and application of the OECD Principles of GLP, as well as in the oversight of compliance with those principles.

In this context, should inspectors from foreign GLP CMAs express interest in participating as observers during NPRA-led inspections, NPRA will seek prior written consent from the test facility before permitting such participation.

Prior to the conduct of an inspection, the inspector shall present official identification issued by NPRA to the test facility as proof of their authorisation.

GLP inspectors and experts may be:

- on the permanent staff of NPRA;
- on the permanent staff of a body independent from NPRA;
- individuals employed on contract by NPRA to perform test facility inspections or study audits, subject to compliance with NPRA's requirements for qualification, training, and impartiality.

These provisions ensure that the NPRA inspection team maintains the highest standards of professionalism, technical expertise, and ethical conduct in carrying out its mandate under the GLP Compliance Programme.

7. NPRA GLP COMPLIANCE PROGRAMME

7.1 General

The NPRA GLP Compliance Programme is implemented to verify that test facilities have effectively applied the requirements set forth in the OECD Series on Principles of GLP and Compliance Monitoring, in alignment with the Malaysian legal and regulatory framework. This includes the planning, conduct, and documentation of inspections to verify that test facilities consistently comply with GLP requirements.

The programme covers various types of inspections, including

- Pre-inspection
- Full inspection
- Surveillance inspection
- Extraordinary inspections

To support national oversight and contribute to international transparency, NPRA shall establish and maintain a register of all inspected test facilities. This register shall include, at a minimum, the following information:

- Name of the test facility
- Date of inspection
- Area(s) of expertise
- Type/nature of inspection (e.g., routine, surveillance, etc.)
- GLP compliance status
- Relevant remarks or follow-up actions

This register is updated regularly and submitted annually to the OECD GLP Secretariat, in accordance with Malaysia's obligations under the OECD Mutual Acceptance of Data (MAD) system.

7.2 Application and procedures to enter the programme

Test facilities that intend to participate in the NPRA GLP Compliance Programme shall adhere to the established application procedures.

Application procedures and relevant forms can be downloaded from the NPRA GLP Compliance Programme webpage at www.npra.gov.my/index.php/en/gcpglp.html. Test facilities are advised to review the requirements thoroughly before submission.

The applicant shall first submit an email to NPRA (sgcpglp@npra.gov.my) to express their interest in joining the

programme. An invoice for the processing fee will then be issued to the applicant. The applicant shall complete the application form and submit it via email, together with the payment receipt and all required documents specified in the form. Incomplete applications or submissions without payment will not be processed.

Upon receipt and review of the application, NPRA will issue an invoice for the inspection fee, which must be paid in full by the applicant.

Once payment is confirmed, NPRA will issue an official announcement letter of inspection, and the inspection date will be coordinated and communicated to the applicant.

Test facilities are expected to fully cooperate in the scheduling and preparation for the inspection. Acceptance into the NPRA GLP Compliance Programme is contingent upon the successful completion of the inspection and fulfilment of all applicable compliance requirements.

NPRA GLP Compliance Programme applies only to test facilities located within Malaysia. Foreign test facilities are not eligible for inclusion in the programme. However, NPRA may conduct study-specific inspections at foreign test facilities upon request from the Centre of Product and Cosmetics Evaluation, NPRA, for the purpose of supporting product registration in Malaysia.

Annex 3: Flow Chart of GLP Inspection

7.3 Fee

Fee shall be imposed for all activities conducted under the NPRA GLP Compliance Programme, as detailed in the table below:

Activity	Fee
Processing	RM 2,000 per application
Document assessment*	RM 2,000 per application
Inspection [Pre-inspection / Full Inspection / Extraordinary Inspection / Surveillance Inspection]	RM 2,000 per working day per inspector
Technical Expert Fee	RM 2,000 per working day per expert
GLP certificate	RM 2,000

*Document assessment includes evaluation of documentation prior to inspection, as well as Corrective and Preventive Action (CAPA) documents submitted post-inspection.

Notes:

- Government-owned test facilities, excluding those under the Ministry of Health Malaysia, are eligible for a 50% reduction of the fees listed above.
- Non-clinical test facilities under the Ministry of Health (MOH) are fully exempted from these fees.
- The maximum total fee for each inspection (including processing, document assessment, inspection days, and GLP certificate) shall be capped at RM 10,000.

Payment Terms:

- Fees shall be paid using the acceptable payment methods as specified in the invoice issued by NPRA.
- The accepted payment methods are subject to the requirements and instructions of the Finance, Accounts and Revenue Section, NPRA as stated in the invoice, and may be revised from time to time without prior notification.
- As at the time of publication of this Guideline, fees are payable via Bank Draft or Money Order, made payable to: "*Bahagian Regulatori Farmasi Negara*".
- Payment by credit card and debit card is also accepted; however, such payments must be made at the NPRA payment counter, as online payment facilities are not available.
- Cash / Foreign currency payments are not accepted.
- Failure to make timely payment may result in postponement or cancellation of the inspection.

8. GLP INSPECTION

8.1 Categories of GLP Inspection

All GLP inspections conducted under the NPRA GLP Compliance Programme, as outlined in the categories below, are generally conducted as announced inspections to ensure adequate preparation and effective assessment of compliance. However, under specific circumstances, extraordinary inspections may be conducted without prior notice, in accordance with the provisions described in Section 8.1.4. The descriptions of each inspection category are detailed in the subsections below.

8.1.1 Pre-inspection

A pre-inspection is conducted for test facilities applying for the first time to be listed under the NPRA GLP Compliance Programme. The purpose of the pre-inspection is to:

- Verify the readiness of the facility to conduct studies in compliance with GLP requirements.
- Assess whether the facility has the necessary resources, management structure, infrastructure, documentation, and quality systems in place.

During the pre-inspection:

- The inspectors will assess the physical layout of the buildings, including the segregation of activities, environmental conditions, and storage / identification of:
    - Apparatus and equipment
    - Test and reference items
    - Test systems
    - Archival facilities, etc.

- An overview of activities will be obtained for each declared area of expertise.

- The facility must present at least one (1) completed study for each declared area of expertise, for inspection purposes.

Following the pre-inspection:

- A full inspection shall be scheduled within six (6) months, provided that all corrective actions from the pre-inspection findings have been satisfactorily addressed.
- If the test facility fails to implement satisfactory corrective actions within this six-month period, the facility must submit a new application.

8.1.2 Full Inspection

A full inspection is a comprehensive assessment conducted by NPRA that includes both test facility inspection and study audits. The objective of this inspection is to verify the test facility's compliance with the OECD Principles of GLP and the specific requirements of the NPRA GLP Compliance Programme.

As part of the inspection process:

- The study audit will cover both completed and ongoing studies (where applicable), selected on a sampling basis.
- The audit is intended to evaluate the integrity, reliability, traceability, and reproducibility of data generated under GLP conditions.

To facilitate the inspection, the test facility shall:

- Submit an updated *Master Schedule* of all completed and ongoing studies, including both GLP and non-GLP studies, and
- Provide any additional relevant documentation as requested by NPRA prior to the inspection.

The selection of studies for audit will be based primarily on the information provided in the *Master Schedule*. NPRA may also consider factors such as study type, sponsor, and study phase when selecting studies for inspection.

8.1.3 Surveillance Inspection

A surveillance inspection is conducted to ensure that test facilities maintain ongoing compliance with the OECD Principles of GLP and the requirements of the NPRA GLP Compliance Programme following initial certification.

The surveillance inspection schedule is as follows:

- Annually for the first two (2) years after GLP compliance certification.
- Every two (2) years thereafter, provided the facility demonstrates consistent compliance.

To remain eligible for continued listing in the NPRA GLP Compliance Programme, the test facility must have:

- A minimum of one (1) completed study per area of expertise per year, or
- At least two (2) completed studies per area of expertise within a two-year period
- In certain cases, a test facility may experience difficulties in securing study sponsors and conducting GLP studies. If no GLP study has been conducted within two (2) years since the last inspection, the test facility shall inform NPRA as soon as possible. The inactivity of the facility will be reviewed and discussed during the technical and approval committee meetings. If it is determined that the facility no longer conducts GLP studies and continued participation in the programme is not justified, the facility may be removed from the NPRA GLP Compliance Programme.

The approach and methodology used for surveillance inspections are generally consistent with those described under Section 8.1.2 – Full Inspection.

8.1.4 Extraordinary inspection

An extraordinary inspection is conducted under circumstances not covered by the routine inspections described in Sections 8.1.1 (Pre-inspection), 8.1.2 (Full Inspection), or 8.1.3 (Surveillance Inspection).

Such inspections may be initiated for various reasons, including but not limited to:

- Study audit or facility inspection at the request of foreign CMAs or local/international Regulatory Authorities (RAs).
- Verification of the implementation of corrective and preventive actions (CAPA)
- Extension of scope or addition of new areas of expertise
- Significant changes to the test facility, such as:
    - Change of address
    - Major renovations or structural changes
- Complaints or concerns received by NPRA regarding GLP non-compliance
- Other circumstances deemed necessary by NPRA

Extraordinary inspections may be conducted on an announced or unannounced basis, depending on the nature and urgency of the situation.

The inspection methodology will be similar to that described in Section 8.1.2 – Full Inspection, involving a facility inspection and/or, study audit.

8.1.5 An Inspection Performed at the Request of other CMA / RA

Inspections or study audits may also be conducted at the request of foreign CMAs or local/international Regulatory Authorities (RAs). These requests are typically for:

- Specific study audits, and/or
- Test facility inspections related to regulatory submissions or international collaboration

It is the responsibility of the requesting authority (RA or foreign CMA) to:

- Clearly identify the test facility or study of interest
- Justify the need for the inspection or audit

Upon receipt of such request, NPRA will invite the concerned test facility to submit a formal application for inspection/study audit.

These inspections shall be managed as extraordinary inspections as outlined in Section 8.1.4, and will follow similar

procedures to those described under Section 8.1.2 – Full Inspection, involving a facility inspection and/or study audit.

8.1.6 Joint Inspection by NPRA and DSM

Test facilities conducting GLP studies under the scope of NPRA and DSM may formally request a joint inspection by both CMAs. A formal written request shall be submitted separately to each CMA, together with the prescribed inspection fees and all required documents in accordance with the respective requirements of each CMA.

No additional fees are imposed for a joint inspection. Each CMA shall apply its standard inspection fees as prescribed under its respective fee structure. For inspections conducted by NPRA, the applicable fees are as specified in Section 7.3 (Fees), while fees applicable to inspections conducted by DSM shall be in accordance with DSM's prevailing requirements.

Acceptance of a joint inspection request is subject to mutual agreement between both CMAs. The joint inspection will only be conducted if both CMAs determine that it is feasible and appropriate.

The test facility shall ensure that sufficient resources, including qualified personnel, working space, and operational support, are available to accommodate both inspection teams simultaneously.

During the joint inspection, each CMA shall conduct the inspection according to its own standard operating procedures and regulatory requirements. Compliance evaluation will be performed independently by each CMA, and the final inspection outcomes will be determined separately based on their respective assessments.

The resulting compliance status will be recorded in the respective GLP compliance registers of each CMA in accordance with their procedures.

8.2 Conduct of GLP Inspection

All inspections under the NPRA GLP Compliance Programme shall be conducted based on a structured and pre-established inspection plan. This plan will be customised to the type and scope of the inspection (e.g., pre-inspection, full inspection, surveillance, or extraordinary inspection).

Notification of Inspection:

Inspections under the NPRA GLP Compliance Programme are generally conducted on an announced basis, whereby preparatory communication between NPRA and the test facility is carried out in advance to facilitate inspection planning. However, NPRA may conduct unannounced inspections when warranted, particularly in the case of extraordinary inspections (refer to Section 8.1.4).

An official inspection announcement letter will be issued to the test facility. This letter will include the following information:

- Date of the inspection
- Objective and scope of the inspection
- Duration of the inspection
- Names of the assigned inspectors and any observers/external experts (if applicable)
- Inspection schedule
- A list of pre-inspection documents to be submitted to NPRA

Under normal circumstances, the test facility is required to submit all requested pre-inspection documents within the timeline specified in the inspection announcement letter. Failure to do so may affect the scheduling or progress of the inspection.

Opening meeting:

Each inspection shall begin with an opening meeting between the inspection team and the test facility’s designated representatives.

During the opening meeting, the lead inspector shall outline the following:

- Introduction of the inspectors and any observers/external experts present
- Overview of the scope and objectives of the inspection
- Explanation of the regulatory framework under which the inspection is conducted

- Description of the inspection methods and procedures
- Confirmation of the availability of necessary resources, documents, personnel, and facilities
- Confirmation of the date and time for the closing meeting and any interim meetings, if applicable

Following the opening remarks, the test facility representative shall deliver a presentation which should cover:

- Current activities of the test facility
- Changes in the organisational structure, facilities, equipment, procedures, and other GLP relevant aspects since the previous inspection, if applicable
- Workload and study portfolio
- Functions of relevant departments involved in the conduct of GLP studies

An attendance record for the opening meeting must be maintained by the test facility.

Conduct of Inspection:

The inspection will generally follow the detailed agenda provided together with the inspection announcement letter. However, adjustments may be made based on the availability or reasonable requests of the test facility. The inspector(s) reserve the final right to modify the agenda as needed to ensure that all inspection objectives are met.

Documents or records may be requested, copied as evidence, and provided to the inspection team in a secure electronic format.

The test facility shall ensure that its management and key personnel are available throughout the inspection to provide clarification or additional information, if requested.

The test facility shall also provide appropriate support to facilitate the inspection process, including:

- Provide a designated room or suitable workspace for inspectors to review documents and records.
- Assist in inspection-related activities, including retrieving documents and arranging site access as required.
- Provide direct access to all relevant documents, including electronic records and raw data, as required.

Inspectors will not assess on the scientific design of the study or the interpretation of the findings of studies with respect to risks for human health or the environment. These aspects are the responsibility of those Regulatory Authorities to which the data are submitted for regulatory purposes.

Closing meeting:

At the conclusion of the inspection, a closing meeting shall be held between the inspection team and the representatives of the test facility.

During this meeting:

- The inspection team will present all observations identified during the inspection. These observations will be shared verbally and discussed in a constructive manner. The observations will later be reviewed and classified during a technical meeting, as described in Section 8.3.

- Unauthorised recording of the closing meeting is not permitted.

- The representatives of the test facility will be given the opportunity to seek clarification and provide responses or justifications regarding the observations raised.

- The test facility is responsible for maintaining an attendance record of the closing meeting and for documenting a list of evidence requested during the inspection.

8.3 Classification of Findings

During the course of an inspection, the inspection team may observe practices that are not in compliance with the OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring and the requirements of the NPRA GLP Compliance Monitoring Programme.

All observations will be presented for classification during the technical meeting, which is chaired by the Deputy Director of the Centre of Compliance and Quality Control, NPRA. The meeting quorum comprises experienced and impartial NPRA inspectors who were not involved in the inspection, together with GLP-trained and qualified inspectors.

Observations presented and agreed upon during the meeting shall be recorded as official findings and reported in the inspection report.

These findings are classified into two (2) categories based on their potential impact:

8.3.1 Major findings

These are deviations that:

- Directly compromise the integrity of the test facility's quality system, and/or
- Affect the reliability and validity of the study data generated.

Such findings indicate significant weaknesses in GLP implementation.

8.3.2 Minor findings:

These refer to less critical deviations that:

- Do not directly impact the quality system or the integrity of the study data, and
- Mainly isolated incidents or procedural lapses.

While considered less severe, minor findings must still be addressed by the test facility through corrective and preventive actions to ensure full compliance.

8.4 Inspection report and CAPA

All findings will be documented in a formal written inspection report.

- The inspection report will be issued to the test facility within 30 working days from the last date of inspection.

- The report will clearly outline the findings, including their classification (major or minor).

The test facility is required to:

- Submit a written corrective and preventive action (CAPA) response addressing all written findings within 30 working days from the date of the inspection report received.

- Each CAPA must outline specific corrective measures, preventive strategies, and timelines for implementation.

If the submitted CAPA is found to be unsatisfactory, the test facility will be requested to revise and resubmit the CAPA within a further 30 working days. Subsequent CAPA responses shall also be submitted within 30 working days. A maximum of three (3) CAPA correspondences is allowed.

The inspection team, in consultation with the Head of the GCP and GLP Section may consider a fourth (4^{th}) CAPA only on a case-by-case basis. The proposed fourth CAPA will be presented at the technical meeting and JKPPPK meetings for approval.

Failure to provide acceptable CAPA responses may affect the compliance status of the test facility and/or studies audited.

8.5 Power of inspectors

The inspectors shall be granted full and unrestricted access to all areas of the test facility, as well as to all relevant documentation, records, data, personnel, and study-related materials, necessary to conduct any type of GLP inspection.

This access is essential to enable inspectors to verify compliance with the OECD Principles of GLP and the requirements of the NPRA GLP Compliance Programme.

Failure by a test facility to provide such access may result in:

- Refusal to issue or renew GLP compliance status
- Removal of the test facility from the NPRA GLP Compliance Programme

Test facilities seeking recognition under the NPRA GLP Compliance Programme must fully cooperate with NPRA inspectors and acknowledge their authority to perform compliance-related activities in accordance with applicable regulations and procedures.

9. OUTCOMES OF GLP INSPECTION

Upon receiving the CAPA from the test facility, the inspection team will review the adequacy and effectiveness of the CAPA. The inspection team will present their final recommendations regarding the GLP compliance status of the test facility to the technical meeting.

Following the committee's review, the proposed compliance status shall be presented to the Director of NPRA for final decision during the approval meeting, *Mesyuarat Jawatankuasa Penilaian Pemeriksaan Premis dan Kajian* (JKPPPK). The quorum of this meeting consists of Deputy Directors, Section Heads, other evaluators, experienced and impartial NPRA inspectors who were not involved in the inspection, together with GLP-trained and qualified inspectors.

Upon approval meeting's endorsement, NPRA will issue an official closing letter to the test facility, thereby concluding the inspection process. The letter will state the outcomes, which include:

- GLP Compliance Status of the Test Facility – Based on the facility's overall compliance with the OECD Principles of GLP and NPRA GLP Compliance Programme requirements.
- GLP Compliance Status of the GLP Studies Audited – Based on the compliance of individual audited studies conducted by the test facility.

9.1 GLP Compliance Status of the Test Facility

For new or existing test facilities that are found to be in compliance with the OECD Principles of GLP and NPRA GLP Compliance Programme requirements, a GLP Compliance Certificate will be issued.

For new test facilities (not yet listed under the NPRA GLP Compliance Programme) that are found not in compliance with the OECD Principles of GLP and NPRA GLP Compliance Programme requirements, an official letter will be issued to formally notify the facility of the rejection of its application for listing.

- The said new test facility may reapply for inclusion by submitting a new application in accordance with current requirements. Upon receipt of the application, NPRA will assess whether a pre-inspection is required or if the facility may be exempted and allowed to proceed directly to a full GLP inspection.

For existing test facilities listed under the NPRA GLP Compliance Programme, if found not in compliance, a letter of removal from the programme will be issued by the Director of NPRA. The test facility will then be removed from the *List of GLP Compliant Test Facilities* on the NPRA website, and the OECD GLP Secretariat will be informed accordingly.

9.2 GLP Compliance Status of the GLP Studies Audited

Studies found to be in compliance with the OECD Principles of GLP shall be acceptable to the regulatory authorities of OECD member countries and other countries adhering to the Mutual Acceptance of Data (MAD) system to support product/test item registration/licensing.

Conversely, if the audited study is found to be not in compliance with the OECD Principles of GLP, it will be reported as not in compliance.

9.3 Reporting of Not in Compliance (NIC) to OECD

In line with Malaysia's obligations under the OECD GLP framework, NPRA shall report the following to the OECD GLP Secretariat:

- Test facilities removed from the NPRA GLP Compliance Programme.
- GLP studies confirmed to be non-compliant with the OECD Principles of GLP.

9.4 Validity of the GLP Compliance Certificate

The validity of the GLP Compliance Certificate is linked to the inspection cycle as follows:

- Annually for the first two (2) years following the initial GLP compliance certification.
- Every two (2) years thereafter, provided the test facility demonstrates consistent compliance with the OECD Principles of GLP and NPRA GLP Compliance Programme requirements.

A surveillance inspection shall be conducted before the expiry of the current GLP compliance certificate.

It is the responsibility of the test facility to apply for a surveillance inspection at least twelve (12) months before the expiry date of the certificate to allow sufficient time for NPRA to plan and conduct the inspection.

If the application for a surveillance inspection is received less than twelve (12) months before the certificate expiry date, NPRA will make reasonable efforts to schedule and conduct the inspection based on the availability of resources and inspection slots. However, the test facility should note that late submissions may delay inspection processes. Consequently, there may be a gap between the expiry of the existing certificate and the issuance of a new one, during which the facility cannot claim GLP compliance status for any studies initiated or conducted.

For test facilities that remain listed in the programme and are found to be in compliance, the validity of the GLP certificate will be extended from the expiry date of the previous certificate.

If the certificate validity cannot be extended from the previous expiry date due to circumstances such as non-compliance issues, or other factors, a new validity date will be proposed during the technical meeting and approval meeting, and will be subject to the final decision of the committee.

9.5 Removal of Test Facilities

A test facility may be removed from the NPRA GLP Compliance Programme under the following circumstances:

- Significant non-compliance is identified during a GLP inspection, and the decision for removal has been endorsed by the technical and approval committees.

- Closure of the company, formation of a new entity, or other structural changes. The test facility must notify NPRA of such changes.

NPRA will issue an official letter of removal to the test facility. The OECD GLP Secretariat will be informed of the removal of the test facility, in accordance with current OECD requirements.

A test facility that has been removed from the NPRA GLP Compliance Programme may reapply for inclusion by submitting a new application in accordance with current requirements. Upon receipt of the application, NPRA will assess whether a pre-inspection is required or if the facility may be exempted and proceed directly to a full GLP inspection.

10. RIGHTS AND DUTIES

Test facilities are responsible for ensuring full compliance with the Principles of GLP and for generating high-quality, reliable data to support regulatory assessments. Non-compliance may result in the rejection of submitted safety data by regulatory authorities.

If there are significant changes or extensions involving the Test Facility Management, Quality Assurance personnel, Study Director(s), facility infrastructure, or the types of studies conducted, the test facility is required to notify NPRA accordingly.

It is important to note that the acceptability of non-clinical health and environmental safety studies is determined by the relevant local or international regulatory authority, not by the GLP CMA. However, if a study is found to be not in compliance with the Principles of GLP, or if the test facility is operating outside the scope of the NPRA GLP Compliance Programme, NPRA (as the GLP CMA) will notify the concerned local/international regulatory authorities and/or the foreign CMA of the receiving country.

To facilitate transparent communication between sponsors, test facilities, regulatory authorities, and CMAs, NPRA will provide inspection-related information to interested parties in the following formats:

- A statement of GLP compliance and the conclusions of the inspection will be provided to the test facility if compliance is confirmed. This information will also be made available to relevant local/international regulatory authorities upon request and published on the NPRA GLP Compliance Programme webpage.
- An *Annual Overview*, listing all test facilities inspected along with their GLP compliance status, will be submitted to the OECD GLP Secretariat, in accordance with the details required.

11. APPEALS

All appeals must be submitted in writing to the Director of NPRA. Upon receipt, the Director will initiate appropriate steps to investigate and resolve the matter in a fair and transparent manner. Where necessary, independent internal and/or external experts may be consulted to support the evaluation process.

Types of Appeals:

- Appeals regarding findings from GLP inspections
- Appeals against the Not In Compliance (NIC) status of a test facility or GLP study

Appeals under this section must be submitted within fourteen (14) calendar days from the issuance date of the inspection report or the official closing letter.

All appeals will be presented for review during the technical meeting and subsequently at the approval meeting. The final outcome will be communicated to the appellant through an official letter.

12. COMPLAINTS

Complaints related to the NPRA GLP Compliance Programme shall be submitted in writing and will be handled objectively, confidentially, and in accordance with established NPRA procedures. Where necessary, independent internal and/or external expertise may be sought to support the review process.

Complaints may generally be categorised as follows:

- **Complaints concerning test facilities**
  Complaints related to test facilities listed under the NPRA GLP Compliance Programme shall be submitted in writing to the Director of NPRA. Such complaints will be subject to formal review and deliberation during the technical meeting and subsequently at the approval meeting, as applicable. The outcome of the review will be communicated to the complainant through an official NPRA letter.

- **Complaints related to administrative or publication matters**
  Complaints concerning administrative, clerical, or publication errors, including inaccuracies in GLP Compliance Certificates or information published on the NPRA website, may be submitted via the NPRA Helpdesk or directly to the GCPGLP Section. These complaints may be managed and resolved administratively and do not require deliberation at the technical or approval meeting level.

13. STORAGE AND RETENTION OF RECORDS

NPRA shall maintain comprehensive records of all test facilities inspected, including their GLP compliance status, as well as details of studies audited, to serve both national and international reporting obligations in alignment with OECD requirements.

NPRA has established internal procedures for the proper archiving of all documents related to GLP inspections of test facilities, as well as documents associated with NPRA's quality management system.

Sponsors are responsible for ensuring the appropriate retention and storage of all records and materials related to a study. The required retention period is typically defined by the relevant regulatory (receiving) authorities. This period represents the minimum duration that study data must be preserved and available for review, especially if safety studies are used to support the registration of products and may be subject to regulatory audits.

It is strongly recommended that all records and supporting materials related to such safety studies be retained for as long as they may be requested by regulatory authorities for GLP verification purposes. In Malaysia, test facilities are advised to retain these records and materials for a minimum of ten (10) years, to ensure they remain accessible for inspection and verification of compliance with the OECD Principles of GLP.

14. ANNEXES

Annex 1: Mutual Cooperation
Annex 2: Organogram of National Pharmaceutical Regulatory Agency (NPRA)
Annex 3: Flow Chart of GLP Inspection

Annex 1: Mutual Cooperation

MUTUAL COOPERATION

BETWEEN

NATIONAL PHARMACEUTICAL CONTROL BUREAU (NPCB)
MINISTRY OF HEALTH MALAYSIA

AND

DEPARTMENT OF STANDARDS MALAYSIA
MINISTRY OF SCIENCE, TECHNOLOGY AND INNOVATION
MALAYSIA

ON

IMPLEMENTATION OF ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT (OECD) GOOD LABORATORY PRACTICE (GLP) IN MALAYSIA

Objective: To ensure that harmonized practices are used in Malaysia with regards to implementation of Organisation for Economic Co-operation and Development (OECD) guidelines on Good Laboratory Practice (GLP) Inspection.

We hereby agree that:

1. National Pharmaceutical Control Bureau (NPCB) as a focal point shall be responsible for organising meetings of the two Compliance Monitoring Authorities (CMAs) and will record the minutes of the meetings.
2. The frequency of the meeting shall be at least once a year.
3. As part of the inspectors training program, inspectors from NPCB may participate as an observer in STANDARDS MALAYSIA inspections, vice versa.
4. If a Test Facility conducts studies that fall under the scope of NPCB and STANDARDS MALAYSIA, the Test Facility may request a joint inspection by both CMAs by submitting a parallel application to both CMAs for GLP certification. Joint inspections of Test Facilities will be carried out together at the request/agreement of Test Facilities (on a same date basis only).
5. Both CMAs shall exchange views on non-compliant GLP issues.
6. Both CMAs shall discuss issues of mutual interest related to GLP.

SELVARAJA SEERANGAM
Director
National Pharmaceutical Control Bureau
Ministry of Health Malaysia

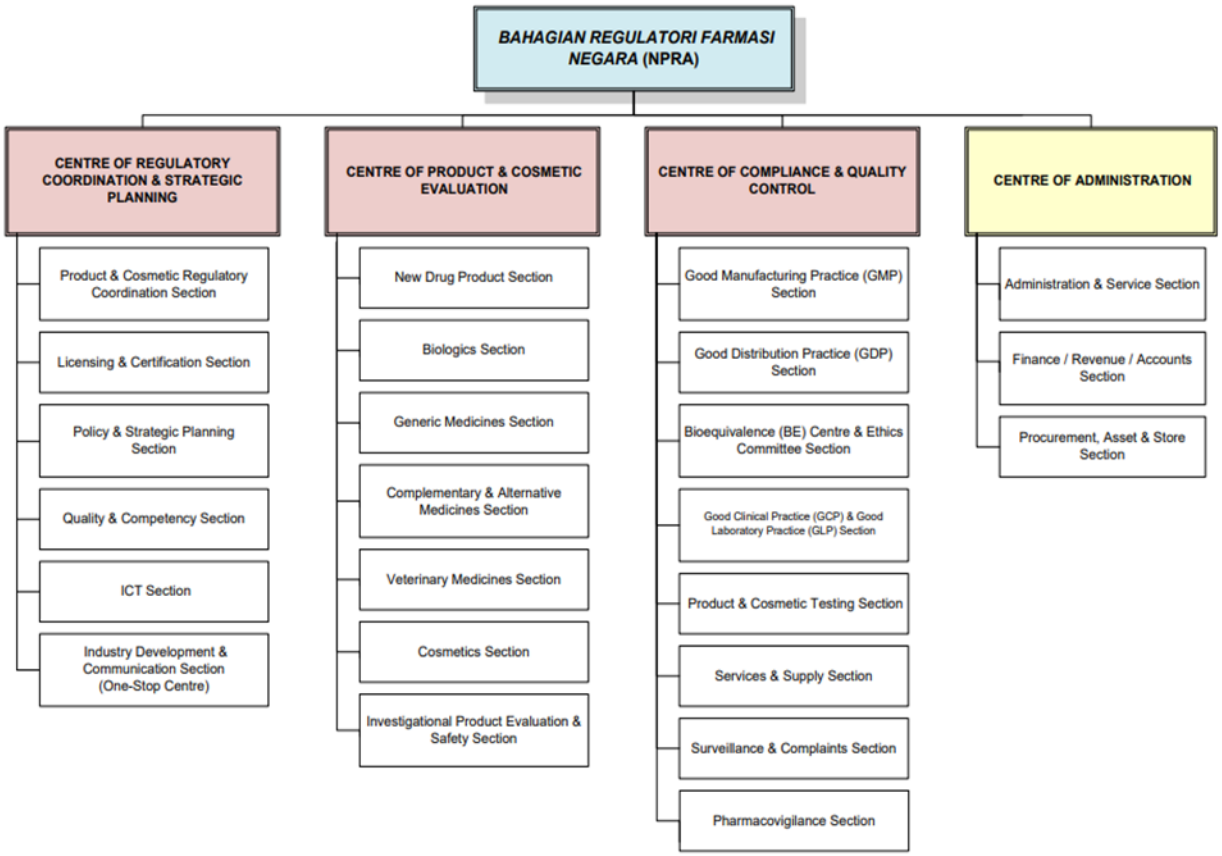
Date: 2 October 2010

SHAHARUL SADRI BIN ALWI
Director of Accreditation
Department of Standards Malaysia
Ministry of Science, Technology and Innovation

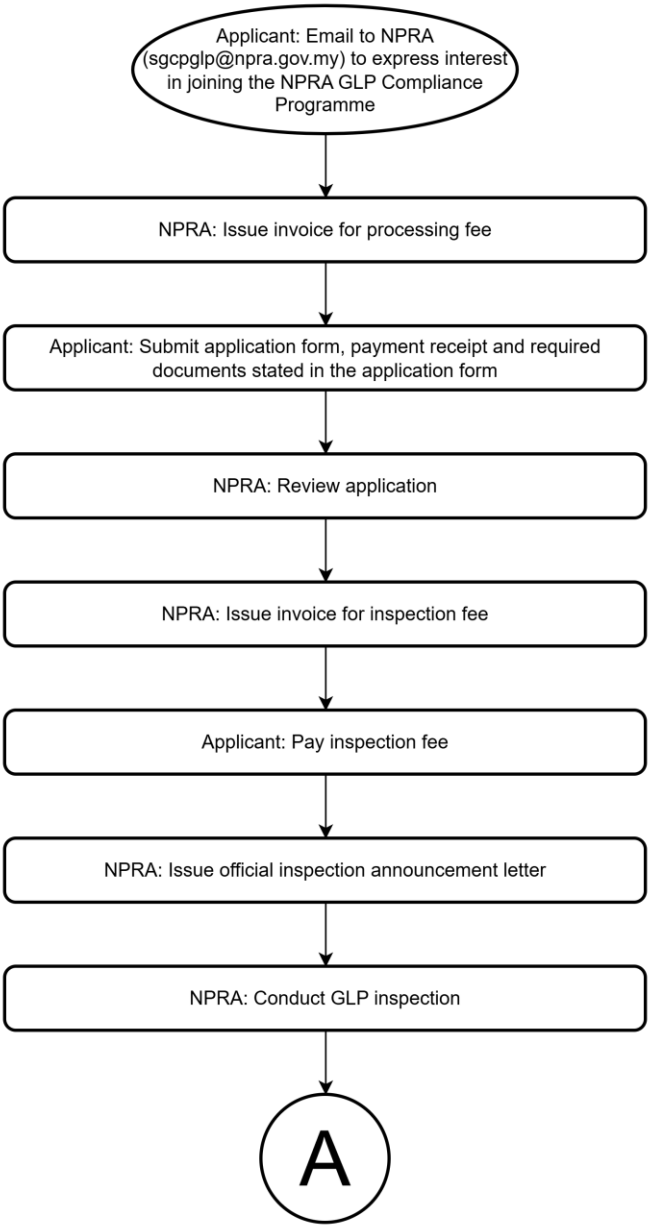
Date: 2 October 2010

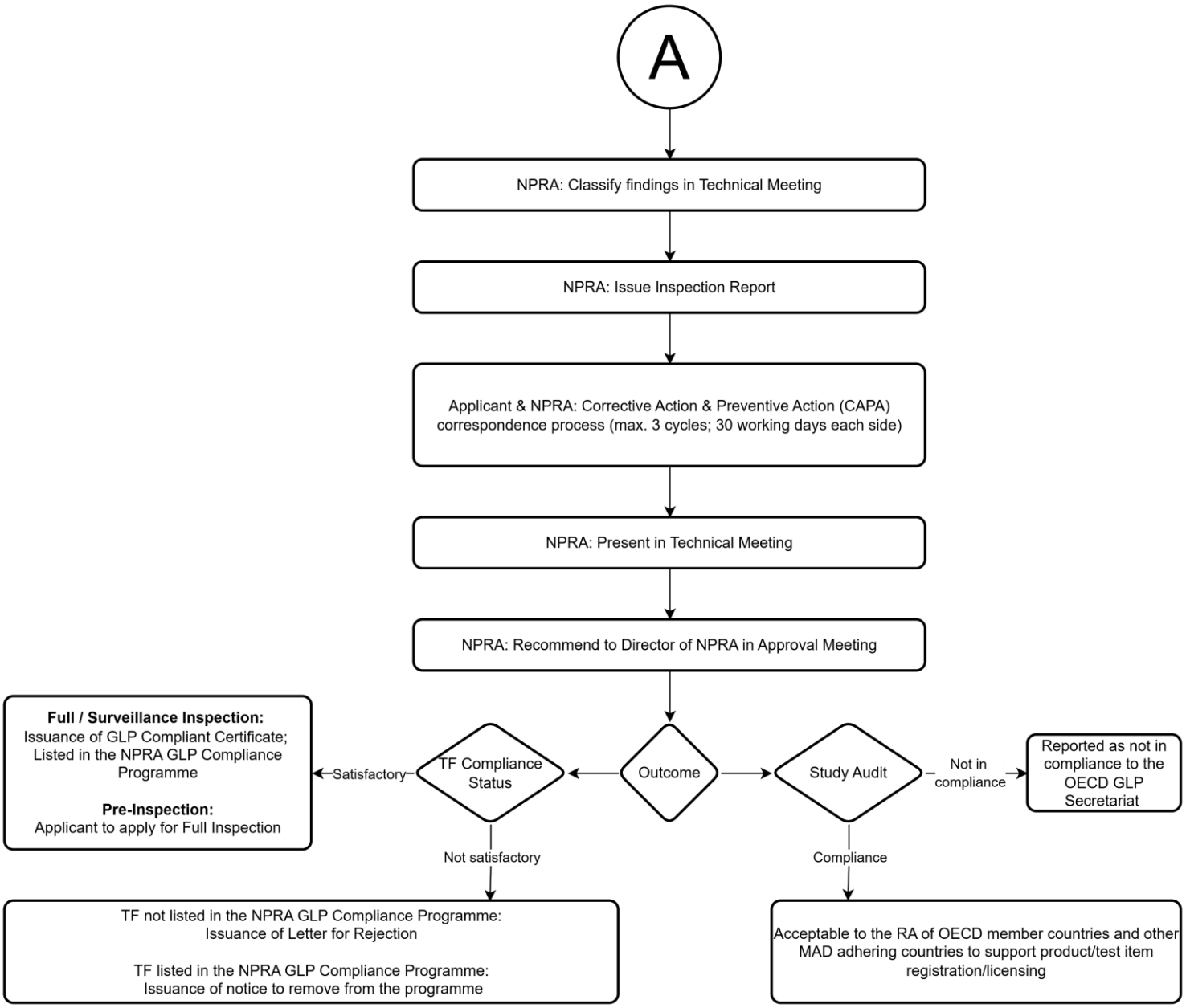
NPCB/GLP/200/001
Version : 1
Date : 1 October 2010

Annex 2: Organogram of National Pharmaceutical Regulatory Agency (NPRA)



Annex 3: Flow Chart of GLP Inspection




A
NPRA: Classify findings in Technical Meeting
NPRA: Issue Inspection Report
Applicant & NPRA: Corrective Action & Preventive Action (CAPA) correspondence process (max. 3 cycles; 30 working days each side)
NPRA: Present in Technical Meeting
NPRA: Recommend to Director of NPRA in Approval Meeting
Outcome
TF Compliance Status
Satisfactory
Full / Surveillance Inspection:
Issuance of GLP Compliant Certificate; Listed in the NPRA GLP Compliance Programme
Pre-Inspection:
Applicant to apply for Full Inspection
Not satisfactory
TF not listed in the NPRA GLP Compliance Programme:
Issuance of Letter for Rejection
TF listed in the NPRA GLP Compliance Programme:
Issuance of notice to remove from the programme
Study Audit
Not in compliance
Reported as not in compliance to the OECD GLP Secretariat
Compliance
Acceptable to the RA of OECD member countries and other MAD adhering countries to support product/test item registration/licensing

-End-

eISBN 978-629-99329-4-9