GOOD LABORATORY PRACTICE COMPLIANCE PROGRAMME (GLP CP) MANUAL	Date: Issue 6, 13 March 2023
	Date of 1st Issue: 29 July 2009
	Amendment No.: --
	Date Amended: --

MINISTRY OF INTERNATIONAL TRADE AND INDUSTRY
DEPARTMENT OF STANDARDS MALAYSIA

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1.0 INTRODUCTION

The manual describes the management system of the Department of Standards Malaysia (JSM) as one of the National Compliance Monitoring Authority (CMA) for monitoring compliance to Organisation for Economic Co-operation and Development (OECD) Principles of Good Laboratory Practice (GLP). This manual is supplemented by relevant forms, OECD documents and existing procedures based on ISO/IEC 17011.

Based on Cabinet Paper dated 13 February 2008, the Cabinet has approved the following:

i) Ministry of Health Malaysia is the coordinator for Good Laboratory Practice Compliance Monitoring Programme (CMP) in Malaysia.

ii) Two Compliance Monitoring Authorities (CMAs) were appointed by the Government of Malaysia:
   (a) National Pharmaceutical Control Bureau (NPCB), Ministry of Health Malaysia and
   (b) Department of Standards Malaysia, Ministry of Science, Technology and Innovation.

2.0 OBJECTIVE

The objectives of this manual are to explain the following:

a) Policies and procedures of JSM for GLP Compliance Programme (GLP CP);

b) Mechanism for Test Facilities entering into the GLP CP;

c) Process on the conduct of Inspection on Test Facilities and Study Audit;

d) Process of exchanging information with other national CMA according to the provisions of OECD GLP and

e) Reporting of the Inspection and Study Audit.

3.0 SCOPE

GLP CP is a voluntary programme offer to test facilities conducting studies for non-clinical health and environmental safety studies, for the purpose of registering and/or licensing on test item contained in products of the following categories:

i) Industrial chemicals
ii) Pesticides
iii) Feed additives
iv) Biotechnology (non-pharmaceutical)
v) Others (such as nanomaterials, biocide, schedule waste, plant protection)

These 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 environment safety studies covered by the Principles of Good Laboratory Practice include work conducted in the laboratory, in greenhouses and in the field.

Type of studies/areas of expertise on test items subjected to JSM GLP CP are in the following categories:

1) physical-chemical testing
2) toxicity studies
3) mutagenicity studies
4) environmental toxicity studies on aquatic and terrestrial organisms
5) studies on behavior in water, soil and air; bioaccumulation
6) residue studies
7) studies on effects on mesocosms and natural ecosystems
8) analytical and clinical chemistry testing
9) other studies (Efficacy studies such as biological efficacy)

Note: Test facility conducting studies on pharmaceutical, cosmetics, veterinary, food additives and medical device products, will be inspected by the National Pharmaceutical Regulatory Agency (NPRA), Ministry of Health (https://npra.gov.my)

4.0 TERMS AND DEFINITIONS

The manual was prepared based on current documents of OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring. These documents are regularly reviewed; therefore, the user of this manual should also refer to the OECD for updated version. In cases where contradictory interpretation or elaboration arises between this manual and OECD series, the OECD series would be considered as final.

Whenever new documents are published by the OECD relevant to Good Laboratory Practice, they should be read and complied accordingly.

4.1 Good Laboratory Practice (GLP)

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.

4.2 Terms concerning the organisation of a Test Facility

a. **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 that 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 test facilities.

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

c. **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.

d. **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.

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

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

g. **Principle 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.

h. **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.

i. **Standard Operating Procedures** means documented procedures, which describes how to perform tests or activities normally not specified in detailed in the study plan of test guidelines.

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

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

a. **Non-clinical 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 safety, intended for submission to appropriate regulatory authorities.

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

**Short-term physical/chemical studies are those studies, tests, measurements or observations which are of a short duration (less than one week), employ widely used techniques and yield easily repeatable results, often expressed by simple numerical values or verbal expressions.*

Example of short-term biological studies are skin absorption tests, bacterial mutagenicity studies, acute ecotoxicological studies, in vitro and ex vivo studies and some metabolism studies.

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

d. **Study plan amendments** mean an intended change to the study after the study initiation date.

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

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

g. **Raw data** means all originally 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.

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

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

j. **Experiment completion date** means the last date on which data are collected from the study.

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

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

4.4 Terms Concerning the Test Item

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

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

c. **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.

d. **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.

e. **Software**: A program required for or developed, adapted or tailored to the test facility requirements for the purpose of controlling processes, data collection, data manipulation, data reporting and/or archiving.

f. **Source code**: An original computer program expressed in human-readable form (programming language), which must be translated into machine-readable form before it can be executed by the computer.

g. **Validation of computerised system**: Action of proving that a process leads to the expected result. Validation of a computerised system requires ensuring and demonstrating the fitness of its purpose.

4.5 Terms concerning to Compliance Programme

a. **GLP Principles:** Principles of Good Laboratory Practice that are consistent with the OECD Principles of Good Laboratory Practice

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

c. **(National) GLP Compliance Programme:** 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.

d. **(National) GLP Monitoring Authority**: 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 function 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.

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

f. **Study Audit**: 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, to 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.

g. **Lead Inspector**: A person who has been trained on OECD Principles of GLP, to lead and responsible for the inspection conducted.

h. **Inspector**: A person who performs the Test Facility Inspections and Study Audits on behalf of JSM.

i. **Expert**: A person who has knowledge in their specified area i.e computerised system, toxicology etc

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

k. **Regulatory Authority**: A national body with legal responsibility for aspects of the control of chemicals.

5.0 GLP COMPLIANCE MONITORING AUTHORITY (CMA)

JSM is one of the CMAs appointed by the Government of Malaysia on 13 February 2008 for the products as mentioned in the scope. The Director General of JSM is responsible for GLP CP and its GLP Unit under Accreditation Division carries out the daily operations.

5.1 Administration

JSM was set up by the Government of Malaysia on 28 August 1996 under an Act of Parliament, the Standards of Malaysia Act 1996 (Act 549) and Amendment 2012 (Act A1425). It was placed under the Ministry of Science, Technology and Innovation (MOSTI) until 16 October 2018 and transferred to Ministry of International Trade and Industry (MITI) since then. JSM is a government funded agency, operates as the sole national accreditation body in the country for conformity assessment activities. Details on the establishment of JSM, its roles and objectives as an independent body, including its advisory council and committees are described in the document RoP-MSAC and other related documentations.

The office address and further information on JSM GLP CP can be obtained from:

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Website: http://www.jsm.gov.my

As GLP CMA, JSM has adopted the OECD Principles GLP in its structure, policies and procedures to ensure implementation of GLP CP is administered in an independent and impartial manner.

Cooperation with other GLP CMA may include, carrying out inspections of test facility/study audit on the request of local/international Regulatory Authority and foreign GLP CMA.

JSM is directly responsible for an adequate team of inspectors having the necessary technical/scientific expertise or is ultimately responsible for such a "team". Details are described in the personnel and training section of the manual.

5.1.1 Structure of Organisation

Director General of JSM as the head of department who is appointed in accordance with Section 9 and responsible to oversee the overall operation and executive functions of the department as stipulated in Subsection 10 of the Act 549 and reports to the Minister of MITI through the Secretary General of the Ministry. In performing his duties, he is assisted by one (1) Senior Director and three (3) Directors.

The Director of Accreditation is responsible for overseeing the operation of all accreditation and GLP CP including regional and international accreditation / compliance matters. The organisation chart of the Accreditation Division and GLP Unit are as shown in (Appendix 1) and (Appendix 2) respectively.

5.1.2 Malaysian Standards and Accreditation Council

The Malaysian Standards and Accreditation Council (MSAC or the Council) is an independent advisory council who advises the Minister and approves all accreditation schemes, criteria and programmes. The terms of reference, memberships and rules of procedure of MSAC are described in document RoP-MSAC.

5.1.3 National Accreditation Committee (NAC)

The NAC is established by the MSAC and has been delegated by the MSAC to perform specific functions relating to accreditation and GLP compliance, and to make recommendations on specific matters to the MSAC. The terms of reference, memberships and rules of procedure of NAC are described in the document RoP-NAC.

5.2 Confidentiality

JSM procedures provide adequate arrangement consistent with the laws of Malaysia, to safeguard confidentiality of the information obtained during its compliance monitoring activities at all levels within the organisation. This arrangement is to safeguard confidentiality which all members of the MSAC, NAC, Inspectors/Experts, Appeal Panels, Technical Working Groups and individuals acting on behalf of JSM.

During an inspection, JSM inspectors/experts would have access to confidential information relating to individual test facilities activities and practices. Except where required by law or permitted by contractual arrangements, the findings of any inspection must be treated as confidential.

Inspectors/experts, observers, staff and individual acting on behalf of JSM and members of the MSAC, NAC, Inspectors/Experts, Appeal Panels, TWG and all to whom that have access to JSM files or test facility files, shall be required to sign an Undertaking for Maintaining Confidentiality, Impartiality and Declaration of No Conflict of Interest. In addition, all inspectors/experts shall abide by the GLP-R005: Code of Ethics for Inspectors (Appendix 4) that includes the upholding of confidentiality requirements.

Information about a test facility shall not be disclosed to a third party without written consent of the test facility in question. Where the law requires information to be disclosed to a third party, the test facility shall be informed accordingly subject to the advice of JSM or Regulatory Authority where applicable. However, JSM shall be required to inform OECD on the GLP status of test facilities and any non-compliant GLP studies. In such cases the written consent of the test facilities shall not be required. This applies to study audit /facilities inspection conducted on the request of national/international authority.

The Government General Orders and the Official Secret Act provide that any person found contravening the above requirements is guilty of an offense and on conviction is liable to a fine, or to imprisonment or to both.

During the Inspections and Study Audits, the inspectors may have access to highly confidential and commercially valuable information. To ensure that maximum confidentiality is maintained:

- JSM has to communicate with the test facility at least two weeks before the start of the inspection/study audit. The observers are required to sign and date a form, GLP-R004: Undertaking of Confidentiality (Appendix 5). Test facility may object to the use of any inspector/expert or observers with valid reasons. The reason for objection should be communicated to JSM.

- Information about the JSM GLP CP and Directory of GLP compliant test facilities are available on the website www.jsm.gov.my. Confidential information such as inspection reports, questions and replies, minutes of internal meetings, etc., which are available on paper or electronic, can only be accessed by JSM officers, inspectors/experts and Regulatory Authorities concerned.

- Commercially sensitive information and about the inspections/Study Audits undertaken in test facilities can be requested by other local/international national Compliance Monitoring Authority and Regulatory Authority. However, paper or electronic information is only available on request and with the permission of the test facility.

- Copies of any documents taken from the test facility before, during and after the inspections are uniquely marked. These documents should be listed, signed and dated by inspector and test facility representative in standard form, GLP-P016: List of Evidence Document (Appendix 6) and retained by test facility and CMA. The list must be verified and dated by lead inspector/inspector.

All the original and electronic documents of the JSM GLP CP are stored and retained separately from other documents. Only the respective personnel mentioned above have access to the documents maintained in JSM archive.

JSM would always ensure that sensitive business information shall never be disclosed to any third party. It is also ensure that, commercially sensitive and confidential information will be excised from test facility inspection and study audit reports, before made available to Regulatory Authority and where appropriate to the test facility inspected or concerned with study audit and/or to study sponsors.

5.3 Personnel and Training

5.3.1 JSM should ensure that an adequate number of competent inspectors are appointed to carry out Inspections and Study Audits. The inspection will be led by a Lead inspector that is responsible for the conduct of inspection, starting conference, report findings and exit conference. Inspectors/experts assigned will perform Test Facility Inspections and Study Audits wherever necessary. The names of the inspectors/experts and their organisation will be maintained in the JSM inspector database.

5.3.2 The competence of an inspector is determined based on tertiary education in a recognised academic institution with relevant working experience and training in GLP inspection. In addition, the candidate shall have working experience in the field of science relevant under the GLP Compliance Programme. The candidate shall be appointed as a Trainee Inspector by the Director of Accreditation based on recommendation by the GLP Manager upon satisfactory evidence provided to show fulfillment of the education and working experience requirements.

5.3.3 The Trainee Inspector is to undergo a GLP Inspector training programme. The first part of the training programme includes at least one GLP course or workshop organised by OECD or national/international GLP Compliance Monitoring Authority. The aim is to equip the Trainee Inspector with adequate knowledge of the requirements and implementation as described in the OECD GLP document series, inclusive of the principles, guidance, consensus and test guidelines.

5.3.4 The second aim of the GLP Inspector training programme, is to equip the Trainee Inspector with appropriate skills and attributes for conduct of GLP inspection. The training shall be in the form of observation and/or performing inspection. A Trainee Inspector shall be considered for appointment as a GLP Inspector after completing at least one (1) inspection of observation and one (1) supervised inspections/ or study audits.

5.3.5 GLP Inspector can be appointed as GLP Lead Inspector if he/she has good managerial and leadership skills in communication, planning, organising, conducting and reporting of the inspection/study audit including dealing with conflicts and decision-making. A GLP Inspector shall be considered for appointment as GLP Lead Inspector, after completing at least five (5) inspections.

5.3.6 JSM can appoint a person to the position of GLP Inspector or GLP Lead Inspector, without the person going through the GLP Inspector programmes as described in respective sections above, if the person has already obtained the necessary pre-requisites, i.e. tertiary education, relevant working experience, comprehensive knowledge in GLP documents, trained in GLP inspection/study audit, managerial and leadership skills in auditing.

5.3.7 GLP Inspector or GLP Lead Inspector candidate to be evaluated during the first inspection by using GLP-R008 Evaluation Report of Inspector (Appendix 7).

5.3.8 A person is authorized to carry-out the job function of a JSM GLP Inspector or GLP Lead Inspector only after the appointment letter has been signed by the GLP CP Manager.

5.3.9 The GLP Inspectors shall participate in seminars, courses, workshops, attachments, observations etc. for continuous improvement of their knowledge and skill related to the inspection/study audits techniques and scientific knowledge of area of expertise of test facilities.

6.0 GLP COMPLIANCE PROGRAMME (GLP CP)

6.1 General

JSM GLP Compliance Programme is intended to ascertain whether Test Facilities have implemented requirements as described in documents of OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring according to the Malaysian legal framework. The GLP CP includes Pre-Inspection, Inspection, Surveillance Inspection and Extraordinary Inspections (where applicable). The inspection process is demonstrated in the flow chart as in (Appendix 3).

JSM will conduct Test Facilities Inspections/Study Audit for compliant Test Facilities annually for the first two years and continue Surveillance Inspection every two years in accordance with the GLP-R001: Master Register of GLP Compliance Programme (Appendix 8).

If no GLP study has been conducted within two years since the last inspection by the compliant Test Facilty, a suspension status for maximum twelve (12) months will be given. If there is no action taken by the test facility, JSM will remove the test facilities from GLP CP. Test Facility should advise JSM as soon as possible, if there is GLP study to be performed. Hence, JSM will conduct a Test Facility Inspection/Study Audit in order to reinstate the suspension status.

JSM may also remove test facilities from the GLP CP in the light of:

i) Failure to comply with GLP CP requirements as stated in this manual;
ii) Failure to provide cooperation or facilities for JSM, its inspectors and/or its authorised representatives to discharge their official duties;
iii) Fraudulent practices, which include but not limited to; deception of claims and alteration of GLP certificate;
iv) An individual or sole proprietorship test facilities is declared bankrupt or enter into composition with his creditors; or
v) Compliant test facilities, being a company, enters into liquidation, whether compulsory or voluntary (but not including liquidation for the purposes of reconstruction) or enters into receivership.

JSM shall establish and maintain a Master Register which contains information on the name of the test facility, the date of inspection, scope, the area of studies/expertise, compliance status and remarks.

The GLP CP documents are prepared, reviewed and approved as table below:

Type of document	Prepared	Reviewed	Approved
Manual GLP CP	GLP Personnel	Director of Accreditation	Director General
Forms	GLP Personnel	GLP Manager	Director of Accreditation

JSM may conduct internal audit and management review as and when necessary together with other schemes under Accreditation Division, with the view to ensure compliance of GLP CP with OECD requirements.

6.2 Mechanism of entering the programme

In Malaysia, GLP CP is a voluntary programme. There are two mechanisms by which a test facility may enter the programme:

1. By submitting application (GLP-P001) to JSM; or

2. Through request of inspection from the national or international authority.

The test facility is required to submit detailed information through JSM's application form (GLP-P001).

In both cases the test facility details shall be registered in JSM Master Register.

Note: GLP-P001 Application form as in Appendix 9.

6.3 Categories of Test Facility Inspections/Study Audits

Description of each type of inspections are as follows:

6.3.1 Pre-Inspection

Pre-inspection will be conducted within 60 days upon receiving completed application documents including information on:

- the type, size and layout of the test facility;
- the master schedule;
- the management structure of the test facility including CVs, job description of key personnel; and
- at least one study plan/protocol for completed study

This pre-inspection is normally carried out within one day to familiarise and to verify that the test facility has the resources to undertake GLP studies in respect of management structure, physical layout of buildings and type of studies.

GLP-P004: Notification of Pre-Inspection (Appendix 10) will be sent to the test facility before the date of inspection. This notification contains inspection plan, name of team members, date and time of Inspector's arrival, the objective of their visit and inspection duration. This shall allow the test facility to ensure that the appropriate personnel and documentation are available.

In cases where particular documents or records are to be examined, it shall be communicated to the test facility in advance of the visit so that they will be immediately available during the Pre-Inspection. It is recommended that Test Facility Management or its representative, Study Director, Archivist and QA Staff be present at the Pre-Inspection.

Some areas of the test facility will be visited, where the overview of activities such as the type and separation of activities, the environmental conditions and the identification and storage of apparatus, test systems, test and reference items and archives are observed. During this visit, the normal work could be slightly disturbed, documents and records may be asked and copied for inspection.

The result arising from the Pre-Inspection shall be presented in a report via e-accreditation system or GLP-P005: Pre-Inspection Report (Appendix 11). The report highlighting the gaps will be submitted to the test facility for necessary corrective actions. The test facility is required to submit evidence of corrective actions and accepted by the Lead Inspector before the proposed date of Inspection.

Inspection is scheduled within 6 months from completion of Pre-Inspection's report. If the test facility is still not ready for the Inspection, JSM will consider performing a new Pre-Inspection or be removed from the programme.

6.3.2 Inspection

The inspection shall be a full inspection that involves both Test Facility Inspection and Study Audit of one or more of both on-going and completed studies on a sampling basis. This inspection would normally be conducted at least two days depending on the number of studies conducted by the test facility. The purpose of this inspection is to verify compliance to the Principles of GLP and JSM GLP CP requirements.

For the purpose of this inspection, the test facility is required to submit an updated Master Schedule of all completed and on-going studies of both GLP and non-GLP and other relevant documents to JSM (where appropriate). Preparation for inspection will focus on the information on the Master Schedule for selection of the studies to be inspected.

JSM shall notify the test facility the inspection team that has been assigned by using GLP-P008: Notification of Inspection/Surveillance Inspection/Extraordinary Inspection (Appendix 12) which normally will be sent to the test facility before the date of inspection. This notification contains inspection plan, name of team members, date and time of Inspector's arrival, the objective of their visit and inspection duration.

It is absolutely necessary that Test Facility Management or its representative, Study Director and QA staff are present at the starting conference and exit conference. During the inspection it is desirable that a member of the QA unit accompany the inspectors. As far as possible, the lead inspector inspects the general operation of the test facility whereas the Study Audit is conducted by the inspector. During the inspections, inspectors may interview Study Director/s, study personnel and archivist of the test facility. In some particular cases, documents or records may be asked and copied for evidence. Test facility shall make available a room for examination documents and other activities during the inspection.

At the starting conference, the lead inspector will introduce the inspection team, inform the purpose, outline the scope of inspection to the Test Facility Management and its personnel including selection of one or more on-going and completed studies for inspection.

The inspection team will not be concerned with the scientific design of the study, or the interpretation of the findings of the studies, with respect to risk for human health or the environment. These aspects are the responsibility of those Regulatory Authorities to which the data are submitted for registration/ licensing purposes.

The inspections shall be carried out in accordance with OECD No. 3 Guidance for the conduct of Laboratory Inspections and Study Audits and recorded in GLP-P013 Inspector Notes (Appendix 17) or GLP-P015: GLP Inspection Checklist (Appendix 13). The criteria described in the OECD Consensus and Advisory Documents shall also be taken into consideration during the Test Facility Inspections and/or Study Audits, where appropriate.

During the exit conference on the last day of the inspection, the lead inspector will present the findings in e-accreditation system or an inspection report GLP-P009: Test Facility Inspection Report (Appendix 14) to the Test Facility personnel and acknowledged by Test Facility Management.

6.3.3 Surveillance Inspections

First and second surveillance inspection will be conducted annually for the first two years after the date of granting. The next surveillance inspection will be conducted every two (2) years based on the granting date. The process used for the surveillance inspection is similar to what has been described under inspection 6.3.2.

6.3.4 Extra Ordinary Inspections

Extra ordinary inspection shall be carried out in situations not covered under 6.3.1, 6.3.2 and 6.3.3.

The examples of such inspections are as listed below but not limited to:

- conduct of Inspection or Study Audits on the request of national or international authority
- verification on the implementation of the corrective actions
- extension of new area of expertise
- significant changes in the test facility (e.g. changes of address, relocation, renovation etc.)
- others where necessary.

The process used for the Extra Ordinary Inspection as described under Inspection 6.3.2.

6.3.5 Inspection conducted on the request of other authorities

Specific Study Audits may also be requested by a foreign CMA or local/international Regulatory Authorities. Such requests may sometimes involve Test Facility Inspections. However, it is the responsibility of the Regulatory Authority or the foreign CMA to identify and justify the need of such Inspections and Study Audits.

In cases where local/international Regulatory Authorities and/or foreign CMA request for Study Audit, Standards Malaysia will invite the concerned test facility to submit an application for inspection/study audit using the GLP-P001: GLP CP Application Form (Appendix 9). The request for such audits shall be handled as Extra Ordinary Inspection according to 6.3.4.

Test facilities should allow JSM inspector/s access to the test facility to specify area, resources, operations, procedures, records and staff so that the inspector/s can effectively inspect the GLP system and activities of the test facility. Detailed report of the findings will be given to the Regulatory Authority which requested the Study Audit.

6.4 Fees

The following fees are payable by the Test Facility Management according to Department of Standards Malaysia Fee Regulation 2018.

Application	RM 2000
Type of Inspections: i) Pre-Inspection ii) Inspection iii) Surveillance Inspection iv) Extra Ordinary Inspection	Lead Inspector: RM 1000/ man day Inspector/Expert: RM 800/ man day
Annual renewal fee	RM 1000
Annual branch fee	RM 500
Appeal	RM 1500
Inspector/Expert from other countries or inspection requested by Regulatory Authority or foreign CMA.	Inspection fee, travel cost and accommodation are borne by the test facility

7.0 FOLLOW UP TO TEST FACILITY INSPECTIONS AND STUDY AUDITS

7.1 Inspection Report

The inspection team will prepare a written report including inspection findings via e-accreditation system or GLP-P009: Test Facility Inspection Report (Appendix 14) and submit to the test facility after the exit conference.

7.2 Classification of Deviation

During the inspection, the inspection team may come across areas/issues which are not in compliance with the OECD Principles of GLP, JSM GLP CP and Test Facility's procedure. Such deviations are classified into following categories.

(A) **Major deviation:**

Major deviation is defined as deviation from the GLP Principles, JSM GLP CP and Test Facility's procedure that threatens the integrity of the management system and/or study data.

i) When major deviation is observed during Inspection, appropriate corrective action shall be taken by the applicant. The corrective action period shall not exceed one (1) month from the last date of inspection, but another delay of one (1) month can be permitted if the test facility can justify the delay. The applicant shall not receive a compliance certificate until corrective action has been handled satisfactorily and accepted by the inspection team. In case if the test facility fails to take satisfactory actions within the specified time, JSM may consider verification inspection or removal from the programme.

ii) When major deviation is observed during Surveillance Inspection, the test facility would be given an opportunity to make appropriate measures within a specified time frame of one (1) month, to resolve the issues. If corrective action is not submitted within the time frame, the lead inspector will make a recommendation to the Director General whether part or entire part of the test facility or part or entire part of study is declared as non-compliant and removed from the program.

iii) The test facility is given 14 working days to respond to the Director of Accreditation. Once the test facility is removed from the programme, OECD GLP secretariat will be informed about this decision according to existing provisions of OECD and if the test facility wishes to re-enter into the programme, the test facility needs to submit a new application. JSM will consider whether it is necessary to conduct Pre-Inspection or an Inspection can be conducted directly.

(B) **Minor deviations:**

During the Inspection and/or Study Audit, the inspector may come across deviations that have significant impact to the quality of GLP system or to integrity of raw data. Such deviations are normally observed in isolated areas.

i) When minor deviation is observed during Inspection, appropriate corrective action shall be taken by the applicant. The corrective action period shall not exceed 3 months from the date of last inspection. The applicant shall not receive a compliance certificate until corrective action has been handled satisfactorily and accepted by the inspection team.

ii) During the Surveillance Inspection, the test facility will be given 3 months to take action of such deviations. However, if the test facility fails to take satisfactory action within the duration mentioned, then JSM may consider removing it from the programme.

(C) **Observation:**

During the inspection and surveillance inspection, observations may be raised as an opportunity for the test facility to consider possible improvement.

7.3 Final approval of inspection reports

The inspection team will review and accept the corrective action submitted by the test facility. The inspection/study audit report will be authorised by the GLP CP Manager/GLP Senior Officer and/or it will be approved by the Director of Accreditation. For test facility found to be in compliance, the Director General of JSM will grant/continue GLP compliance GLP-P012: Certificate of Compliance to OECD GLP (Appendix 15) and a notification GLP-P010: Letter of Statement of Compliance (Appendix 16) will be issued to the test facility.

For final report of specific Study Audit, a detailed report GLP-P009: Test Facility Inspection Report (Appendix 14) approved by the Director of Accreditation and will be provided to the requested CMA/RA, where applicable.

7.4 Status of GLP Compliance

There will be two categories of compliance status given to test facilities namely;
(i) in compliance [ic] and
(ii) not in compliance [nic]

JSM will issue a certificate with statement of GLP compliance to show the test facility has been inspected and found to be operating in compliance with Principles of GLP and JSM GLP CP requirements.

If, a test facility has been removed from the programme, it shall not make any claim on GLP compliant.

8.0 GLP COMPLIANT SYMBOL

8.1 Any usage of this symbol or references to GLP compliant shall refer and comply with the requirements stipulated in Accreditation Policy 1 (AP 1) – Policy on the Use of Accreditation Symbol and Reference to Accreditation. Test facility may use JSM accreditation symbol or make references to GLP compliant on promotional material (e.g. letterhead, quotations, brochures, banners, signboards) or other items related to the test facility GLP activity.

8.2 The symbol shall only be displayed in the appropriate form, size and colour as detailed below:

(a) The symbol is to be displayed in colour as shown in Figure 1 or in black and white as in Figure 2.

Figure 1: Symbol in colour

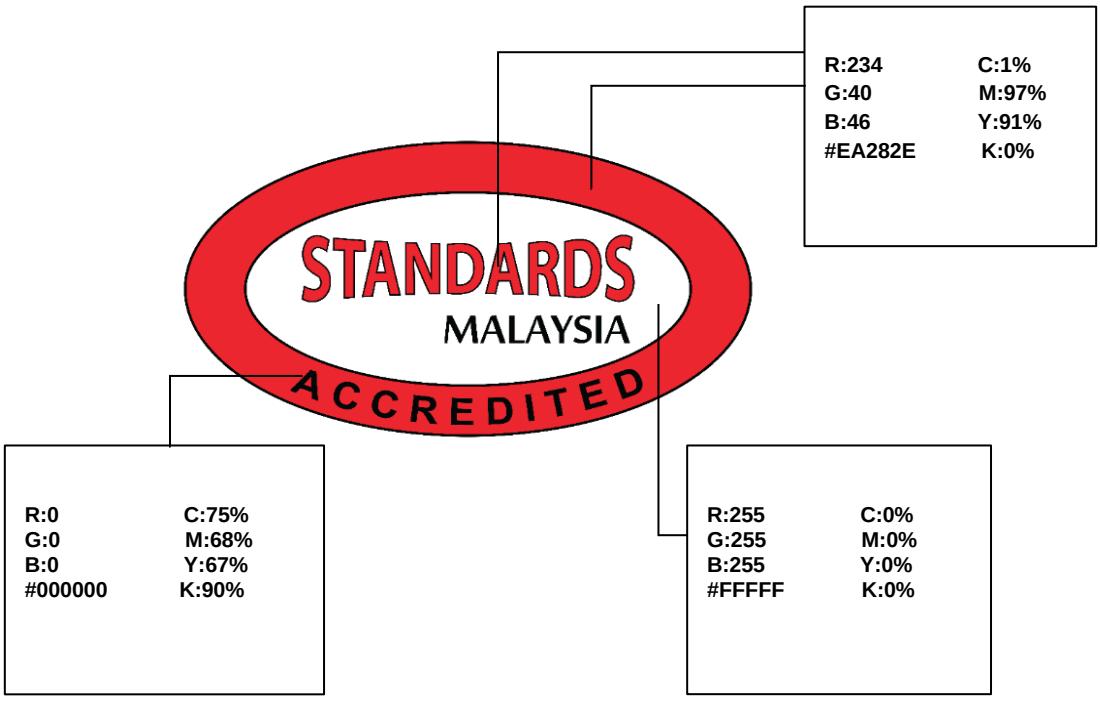
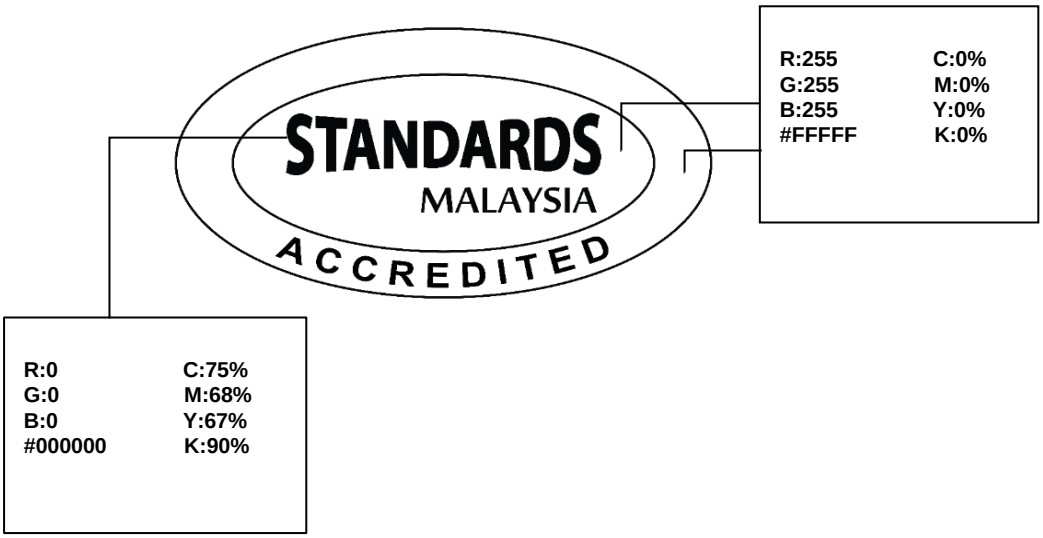


Figure 2: Symbol in Black and White



(b) The GLP unique number is displayed beneath the symbol at all times as shown in Figure 3. The words accompanying the symbol is Arial font and bold. The size of the words is legible and proportionate to the size and symbol.

Figure 3: Accreditation symbol with GLP number

GLP Compliant TF
GLP XXX

9.0 RIGHTS AND DUTIES

It is in the interest of the test facility to comply with the requirements of Principles of GLP and to produce data of adequate quality for inspection and decision-making by Regulatory Authorities. Failure to do so may lead to non-acceptance of safety data by Regulatory Authorities.

If the Test Facility Management, QA Staff, Study Director/s, personnel and infrastructure of the test facility, or the types of studies conducted is significantly extended or changed, the test facility is required to inform these changes within two weeks to JSM.

The acceptability of safety data is decided by the responsible local/international Regulatory Authority and not by JSM. If a study/test facility has not been performed or operating in accordance with Principles of GLP and GLP CP requirements, JSM will inform the OECD Secretariat through Malaysia's coordinator (NPRA), relevant local/international Regulatory Authority and/or foreign CMA of the receiving country.

In order to facilitate the communication between sponsors, test facility, local/ international Regulatory Authority, OECD Secretatriat and Compliance Monitoring Authority, JSM will provide information on inspections to interested parties in the following formats:

i. The conclusions of an inspection and a statement of GLP Compliance where the inspection reveals adequate compliance with GLP are given to the test facility. This information will also be made available on request to the local/international Regulatory Authority concerned;

ii. Directory of GLP Compliant Test Facility is available in our website (http://www.jsm.gov.my);

iii. List of test facilities under JSM GLP CP, GLP-R001: Master Register of GLP Compliance Program (Appendix 8); and

iv. OECD Annual Overview of Test Facilities Inspected which includes the test facilities inspected and their GLP compliance status shall be submitted to the OECD Secretariat annually.

10.0 COMPLAINT/APPEAL PROCEDURES

Any disagreement or difference of opinion between the inspection team and Test Facility Management arising from the inspection process, will normally be resolved during the inspection or at the exit conference. However, where problems persist and agreement on differences cannot be reached during the inspection process, Test Facility Management may appeal/s against the findings.

Such appeal/s against those findings must be addressed, in writing, to the Director General of JSM within 30 days after inspection. The Director General of JSM will then take appropriate steps to achieve a mutually acceptable resolution. Therefore, he/she may ask for advice from independent internal or external experts or NAC members. Based on this advice, the Director General will make his/her final decision. As and when required, an independent and impartial panel is established for each appeal to be heard.

JSM policies and procedures for the resolution of complaints, appeals and disputes received from customers or related matters are covered by documents QP 110 Handling of Complaints, CAB 3 - Appeals (RoP-AP) and CAB 2 - Complaints and other related procedures.

11.0 ARCHIVES

There are two types of documents that shall be archived:

1. Documents related to JSM GLP CP

    - The manual of JSM GLP CP and forms
    - Inspector records (such as training records, CV etc.)
    - Other GLP documents, if appropriate.

JSM retains the above records at a designated area for at least ten (10) years.

2. GLP Test Facility documents such as:
    - test facility application records;
    - test facility inspection records; and
    - documents of correspondence with local/international Regulatory Authority or CMA including the inspection reports etc.

All documents related to GLP test facilities are stored and retained separately from other documents. These documents shall be retained for at least 10 years. Authorised personnel will have access to the documents maintained in JSM locked archive.

Test facility is recommended to retain all documents and records related to GLP Compliance for at least 10 years. Before disposing or discarding the records or documents after 10 years, communication with the sponsor needs to be recorded.

12.0 REFERENCES

(1) Doc No. 1, OECD Principles on Good Laboratory Practice, 1997

(2) Doc No. 2, Guidance for GLP Monitoring Authorities Procedures for GLP, 1995

(3) Doc No. 3, Guidance for the Conduct of Laboratory Inspections and Study Audit, 1995

(4) Doc No. 4, Quality Assurance and GLP, 1999 *(withdrawn)*

(5) Doc No. 5, Compliance of Laboratory Suppliers with GLP Principles, 2000

(6) Doc No. 6, The Application of the GLP Principles to Field Studies, 1999

(7) Doc No. 7, The Application of the GLP Principles to Short Term Studies, 1999

(8) Doc No. 8, The Role and Responsibility of the Study Director in GLP Studies, 1999

(9) Doc No. 9, Guidance for the Preparation of GLP Inspection Reports, 1995

(10) Doc No. 10, The Application of the Principles of GLP to Computerised Systems, 1995 *(withdrawn)*

(11) Doc No. 11, Advisory Document of the Panel on GLP: The Role and Responsibilities of the Sponsor in the Application of the Principles of GLP, 1998

(12) Doc No. 12, Advisory Document of the Working Group on GLP: Requesting and Carrying out Inspections and Study Audits in Another Country, 2002

(13) Doc No. 13, Consensus Document of the Working Group on GLP: The Application of the OECD Principles of GLP to the Organisation and Management of Multi-Site Studies, 2002

(14) Doc No. 14, Advisory Document of the Working Group on GLP: The Application of the Principles of GLP to in-vitro Studies, 2004

(15) Doc No. 15, Advisory Document of the Working Group on GLP: Establishment and Control of Archives that Operate in Compliance with the Principles of GLP, 2007

(16) Doc No. 16, Advisory Document of the Working Group on GLP: Guidance on the GLP Requirements for Peer Review of Histopathology, 2014

(17) Doc No. 17, Advisory Document of the Working Group on GLP: Application of GLP Principles to Computerised Systems, 2016

(18) Doc No. 18, OECD Position Paper Regarding the Relationship between the OECD Principles of GLP and ISO/IEC 17025, 2016

(19) Doc No. 19, Advisory Document of the Working Group on GLP: Management, Characterisation and Use of Test Items, 2018

(20) Doc No. 20, Guidance Document for Receiving Authorities on the Review of the GLP Status of Non-Clinical Safety Studies, 2019

(21) Doc. No. 21, OECD Position Paper Regarding Possible Influence of Sponsors on Conclusions of GLP Studies, 2020

(22) Doc. No. 22, Advisory document of the Working Group on GLP: Data Integrity, 2021

(23) Doc. No. 23, Advisory document of the Working Group on GLP: Quality Assurance and GLP, 2022

(24) Doc. No. 24, OECD Position Paper on Quality Improvement Tools and GLP, 2022

(25) Rules of Procedure for The Malaysian Standards and Accreditation Council (RoP-MSAC)

(26) Rules of Procedure for National Accreditation Committee (RoP-NAC)

(27) Rules of Procedure for Appeals Panel (RoP-AP)

(28) CAB 1 – Confidentiality

(29) CAB 2 – Complaints

(30) CAB 3 – Appeals

(31) Accreditation Policy 1 (AP1) - Policy on the Use of Accreditation Symbol and Reference to Accreditation

13.0 LIST OF APPENDIXES

[1] Appendix 1: JSM & Accreditation Division Organisation Chart

[2] Appendix 2: GLP Unit Organisation Structure

[3] Appendix 3: Inspection Process

[4] Appendix 4: GLP-R005: Code of Ethics for Inspectors

[5] Appendix 5: GLP-R004: Undertaking of Confidentiality

[6] Appendix 6: GLP-P016: List of Evidence Document

[7] Appendix 7: GLP-R008: Evaluation Report of Inspector

[8] Appendix 8: GLP-R001: Master Register of GLP Compliance Programme

[9] Appendix 9: GLP-P001: Application form

[10] Appendix 10: GLP-P004: Notification of Pre-Inspection

[11] Appendix 11: GLP-P005: Pre-Inspection Report

[12] Appendix 12: GLP-P008: Notification of Inspection/Surveillance Inspection/Extraordinary Inspection

[13] Appendix 13: GLP-P015: GLP Inspection Checklist

[14] Appendix 14: GLP-P009: Test Facility Inspection Report

[15] Appendix 15: GLP-P012: Certificate of Compliance to OECD GLP

[16] Appendix 16: GLP-P010: Letter of GLP Statement of Compliance

[17] Appendix 17: GLP-P013: Inspector Notes

14.0 LIST OF FORMS

Document GLP-PXXX (P series):

1) GLP-P001: Application form
2) GLP-P002: Dossier for Undertaking Test Facility
3) GLP-P003: Letter of Participation in National GLP CP
4) GLP-P004: Notification of Pre-Inspection
5) GLP-P005: GLP Pre-Inspection Report
6) GLP-P006: Letter of Confirmation of GLP Activities
7) GLP-P008: Notification of Inspection/ Surveillance Inspection/ Extraordinary Inspection
8) GLP-P009: Test Facility Inspection Report
9) GLP-P010: Letter of GLP Statement of Compliance
10) GLP-P011: Memo for Approval
11) GLP-P012: Certificate of Compliance to OECD GLP
12) GLP-P013: Inspector's Note
13) GLP-P014: Attendance List
14) GLP-P015: GLP Inspection Checklist
15) GLP-P016: List of Evidence Document
16) GLP-P017: Acceptance as Inspector
17) GLP-P018: Letter of Removal
18) GLP-P019: Checklist Remote Inspection

Document GLP-RXXX (R Series):

1) GLP-R001: Master Register GLP Compliance Programme
2) GLP-R004: Undertaking of Confidentiality
3) GLP-R005: Code of Ethics for Inspectors
4) GLP-R006: Inspector Registration Form
5) GLP-R008: Evaluation of Inspector
6) GLP-R009: Master List of Manual and Forms
7) GLP-R010: Checklist of GLP Inspector
8) GLP-R011: Appointment letter as GLP Inspector

15.0 ACRONYM

CAB	– Conformity Assessment Body
CMA	– Compliance Monitoring Authority
GLP	– Good Laboratory Practice
GLP CP	– Good Laboratory Practice Compliance Programme
JSM	– Department of Standards Malaysia
ic	– In Compliance
MoH	– Ministry of Health
NAC	– National Accreditation Committee
NPRA	– National Pharmaceutical Regulatory Agency
nic	– Not In Compliance
OECD	– Organisation for E
	conomic Co-operation and Development