



Ref. File no.: JSM/AD-700/01/02/04/

Date: dd-mm-yyyy

GLP-P008

Issue 3, 21-March-23

APPENDIX 12

<name of test facility>

<address>

(Attn: Mr.)

Tel:

Fax:

Dear Sir/Madam,

GOOD LABORATORY PRACTICE COMPLIANCE PROGRAMME (GLP CP): INSPECTION / SURVEILLANCE INSPECTION / EXTRA ORDINARY INSPECTION, DATE: <dd-mm-yyyy>

With reference to the above, please note that the above inspection of your test facility is scheduled on the date as confirmed. The purpose of this inspection/surveillance inspection is to verify compliance to the OECD Principles of GLP and Department of Standards Malaysia GLP CP requirements.

The inspection team will comprise the following:

| | <u>Name</u> | <u>Organisation</u> |
|---------------------|-------------|---------------------|
| Lead Inspector: | | |
| Inspector/ Experts: | | |

You are advised to reply to JSM on the acceptance of the above inspector/s.

Kindly inform us in writing, with valid reason/s should you wish to appeal against the use of any of the above inspector/s. We wish to draw your attention that such appeal and its resolution are provided in JSM procedures.

As for preparation of this inspection, you are advised to submit the latest version of the following documents:

- a) Master schedule
- b) Master List of Standard Operating Procedures (SOP)
- c) Floor plan with GLP marked-area
- d) Organisational Chart
- e) Schedule of Quality Assurance Programme
- f) List of GLP equipment

Please be informed that it is desirable for your top management representative to be present at both the starting and closing conference. Inspection findings and provisional report will be presented at the closing conference.

Enclosed please find the inspection plan for your kind attention. JSM will invoice you in accordance to Standards Malaysia (Fees) Regulation 2018 for this inspection.

Thank you.

Yours faithfully,

(FARIZA WAN ABDULLAH)

GLP Manager

for the Director General

Department of Standards Malaysia

c.c. All Inspectors

INSPECTION PLAN

Test Facility Name :
Type of Inspection :
Date of inspection :

FIRST DAY

0900 : STARTING CONFERENCE

- Introduction
- Outline of purpose and scope of visit
- Approval of inspection/study audit programme
- Designation of accompanying persons

0930 : INSPECTION AND STUDY AUDITS

- Organisation and personnel
- Documentation
- QA program
- Archives
- Internal Discussion Inspection Team

1300-1400 : LUNCH

1400 : INSPECTION AND STUDY AUDITS (continue)

- Facilities
- Equipment
- Test and Reference substances
- Test system
- Performance
- Internal Discussion Inspection Team

1630-1700 : INTERIM CLOSING CONFERENCE MANAGEMENT (if necessary)

INSPECTION PLAN

SECOND AND FOLLOWING DAYS

0900-1300 : INSPECTION AND STUDY AUDIT (continue)

1300-1400 : LUNCH

INSPECTION AND STUDY AUDIT (continue)

1630-1700 : INTERIM CLOSING CONFERENCE WITH MANAGEMENT
(if necessary)

LAST DAY

0900-1300 : PREPARATION OF THE GLP INSPECTION REPORT

1300-1400 : LUNCH

1400 : PREPARATION OF THE GLP INSPECTION REPORT

1630-1700 : FINAL CLOSING CONFERENCE WITH MANAGEMENT