



APPENDIX 10

GLP-P004
Issue 2, 13-Apr-16

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

«Name_of_TF»
«Address_1»
«Address_2»
«Address_3»
«Address_4»

(Attn:)
Tel: Fax:

Dear Sir/Madam,

GOOD LABORATORY PRACTICE COMPLIANCE PROGRAMME (GLP CP):
PRE-INSPECTION, DATE:

With reference to the above, please note that the Pre-Inspection of your test facility is scheduled on the date as confirmed.

The aim and purpose of this Pre-Inspection is to verify that the test facility has the resources to undertake GLP studies. The team will comprise the following:

	<u>Name</u>	<u>Organisation</u>
Lead Inspector: Inspector	Mr. XYZ	

You are advised to reply to Standards Malaysia 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 inspectors. We wish to draw your attention that such appeal and its resolution are provided in Standards Malaysia procedures.

Enclosed please find the Pre-Inspection plan for your kind attention. Standards Malaysia will invoice you RM 600.00 per inspector for the inspection.

Thank you.

Yours faithfully,

(FARIZA WAN ABDULLAH)
GLP CP Manager
for the Director General
Department of Standards Malaysia

c.c. All Inspectors
TF's file JSM/AD-700/01/02/04/

GLP PRE-INSPECTION PLAN

Test Facility Name :

Date of inspection:

0900 : STARTING CONFERENCE

- Introduction
- Outline of purpose and scope of the visit
- Presentation by Test Facility Management
- Designation of accompanying persons

0930 : SCOPE OF GLP ACTIVITIES

1000 –1300 : MANAGEMENT STRUCTURE OF THE TEST FACILITY

- Organisation chart
- Documentation:
 - Master Schedule
 - Study Plan
 - SOPs
 - Final Report
 - Master schedule QA programme

1300 –1400 : LUNCH

1400 : VISIT TO THE FACILITY

- Infrastructure
- Archives
- Equipment
- Test and reference substances
- Test systems

1630-1700 : EXIT CONFERENCE