APPENDIX 14

GOOD LABORATORY PRACTICE COMPLIANCE PROGRAMME

DEPARTMENT OF STANDARDS MALAYSIA

REPORT ON INSPECTION FOR COMPLIANCE WITH THE OECD PRINCIPLES OF GOOD LABORATORY PRACTICE

TEST FACILITY:	
ADDRESS:	
FILE NO:	JSM/AD-700/01/02/04/XXX
DATE OF INSPECTION:	
TYPE OF INSPECTION:	
TEST FACILITY MANAGEMENT:	
LEAD INSPECTOR:	
INSPECTOR:	i) ii) iii)

Classification used in this report:

Obs - For Inspection, it is recommendation or suggestion for improvement.

For Surveillance, it is recommendation or a reminder for follow-up/review at next

Minor - For Inspection, the applicant shall submit the evidence of corrective action within 3 months from the last date of inspection.

For Surveillance, Test Facility shall submit the evidence of corrective action within 3 months from the last date of inspection or JSM may consider removing Test Facility from the programme.

Major - For Inspection, the applicant shall submit the evidence of corrective action within 1 month from the last date of inspection.

For Surveillance, Test Facility shall submit the evidence of corrective action within 1 month from the last date of inspection or JSM may consider removing Test Facility from the programme.

INSPECTION SCOPE:

The test facility was assessed for compliance with the OECD Principles of Good Laboratory Practice.

PREVIOUS INSPECTION: << Pre-inspection / Inspection / Surveillance Inspection / Extra-ordinary Inspection >>

Pre-inspection of the test facility was conducted on XX Month YYYY. Findings and evidence of corrective actions were reviewed and accepted.

OBSERVATIONS AND ACTIVITIES:

The three days inspection was conducted based on OECD Principles of Good Laboratory Practice, OECD Series No. 3 & 9 and also JSM GLP CP Manual. This inspection cover both test inspection and study audit.

STUDIES AUDITED:
Both completed and on-going studies were inspected as the details below:

Completed study no.:

On-going study no.:

Type of studies observed:

SUMMARY:

Generally the quality system implemented in test facility found to be compliance with the OECD Principles of GLP and Department of Standards Malaysia requirements except for findings raised in this inspection report. Although most of findings does not affect the integrity of the study, the test facility must take appropriate action within the stipulated time frame.

Recommendation for granting/continuity OECD GLP compliance status will be made subject to action taken being satisfactorily accepted.

Clause No.	**Classification** (Major/Minor/ Observation)	**Inspection Findings**	**Action taken by facility** (with reference to supporting documentation)	**Inspection Team review**
1. Test Facility Organisation and Personnel				
2. Quality Assurance Programme				
3. Facilities				
4. Apparatus, Material and Reagents				
5. Test System				

Clause No.	**Classification** (Major/Minor/ Observation)	**Inspection Findings**	**Action taken by facility** (with reference to supporting documentation)	**Inspection Team review**
6. Test and Reference Items				
7. Standards Operating Procedures				
8. Performance of the Study				
9. Reporting of study results				
10. Storage and Retention of Records and Materials				
NOTE: It must be emphasised that because the inspection did not cover every aspect of the test facility's work/activities, it does not follow that no non-compliance exist in areas where none have been reported.				

CONCLUSION (to be completed by Lead Inspector)

Summary of GLP deviation:

Major ☐ Minor ☐ Observation ☐

Additional information where necessary (e.g. as required by local/international Regulatory Authority or CMA):
List of on-going study(ies) inspected:
List of completed study(ies) inspected:

Conclusion by Lead Inspector on the compliance of test facility

I hereby, confirm the test facility / study audit inspected is in compliance / not in compliance * to the OECD Principles of GLP and JSM GLP CP subject to satisfactorily corrective action taken.

If not in compliance, please explain:

Name: _____ Signature: _____
(Lead Inspector)
Date:

Acknowledgement by test facility:

Name: Signature: _____

Date:

Reviewed by GLP Manager:

Result of review: *Satisfactory / Unsatisfactory

Comments:

Name: Signature: _____

Date:

Authorised by Director of Accreditation:

***Approved / Not Approved**

Comments:

Name: Signature: _____

Date: