APPENDIX 9

GOOD LABORATORY PRACTICE COMPLIANCE PROGRAMME

APPLICATION FORM

1. ORGANISATION DETAILS

Name:……
(Indicate exactly how the name of the organisation is to appear on the certificate)

Address:……

……

……

Tel. no.:…… Fax. No.:……..

Website: …… E-mail: ……

Contact person:…… Designation:……

2. TEST FACILITY DETAILS

(If different from above)

Name:……
(Indicate exactly how the name of the laboratory is to appear on the certificate)

Address: ……

……..

……..

Tel. No.: …… Fax. No.: ……..

Website: …… E-mail:……...

Contact person:…… Designation:……

Date of establishment : ……...

Registration number : ……
(a copy of ROC to be attached)

Legal status : ……
(e.g. Govt. Dept., Pte/Ltd, etc)

APPENDIX 9

3. CATEGORY OF TEST ITEM

Industrial chemical	
Pesticide	
Feed Additive	
Biotechnology (Non-Pharmaceutical)	
Others, please state:	

4. AREAS OF STUDIES/ EXPERTISE

(Please indicate the studies conducted in the test facility for last 2 years)

i) Physical-Chemical Testing ☐

ii) Toxicity Studies ☐

iii) Mutagenicity studies ☐

iv) Environment toxicity studies on aquatic and terrestrial organisms ☐

v) Studies on behaviour in water, soil and air, bioaccumulation ☐

vi) Residue Studies ☐

vii) Studies on effects on mesocosms and natural ecosystems ☐

viii) Analytical and clinical chemistry associated with non-clinical studies ☐

ix) Others: Please specify ☐

a)…….

b)…….

c)…….

APPENDIX 9

5. LIST OF KEY PERSONNEL

(Please attach CV, qualifications, further training especially GLP and provide details of the office bearers below and please use extra sheet if necessary)

Total number of relevant test facility staff:……

No.	Designation	Name
i.	Test Facility Management(s) (TFM):	
iii.	Quality Assurance Personnel (QA):	
iv.	Study Director(s) (SD):	
v.	Archivist (s):	

6. SUBMISSION OF DOCUMENTS

We enclosed herewith a copy each of the following for your examination:

a)	Recent organisation charts	
b)	Floor-plans with GLP marked-area	
c)	List of instrument / equipment	
d)	List of Test Systems used in GLP studies	
e)	List of Standard Operating Procedures (SOPs)	
f)	SOPs of general procedures (e.g SOP for preparation of Study Plan, Final Report, Handling of Test Item/Reference Item, Handling of Test System, Archive etc)	
g)	Copy of at least one Study Plan and Final Report	
h)	Schedule of Quality Assurance Programme	
i)	Master Schedule of all planned (completed) and on-going studies, as well as all studies completed within the last two years: GLP/non-GLP, study code/identification, type of study, test system, test item, study initiation/completion date, study director, status, sponsor	

APPENDIX 9

7. DECLARATION

- I have read, understood and will comply with GLP Principles as published in OECD series of Principles of GLP and Compliance Monitoring, Document No. 1-24

- I hereby, give my consent on behalf of the test facility to abide by the Department of Standards Malaysia GLP CP Manual and requirements.

- I hereby, declare that the information furnished above is correct.

- I have to pay all fees and costs connected with the inspection process irrespective of the eventual granting of GLP compliance.

- I will provide access to those documents that provide insight into the level of independence and impartiality of the test facility from its related bodies, where applicable; and;

- I agree to allow JSM inspector/s access to the test facility specify area, resources, operations, procedures, records and staff so that the inspector/s can effectively inspect the GLP system and activities of my test facility. I understand that the failure to allow the above access will lead to the removal of my test facility application in the JSM GLP CP.

Signature: ……. Date:……

Name of test facility
Representative:…….…… Organisation's Stamp / Seal:

Please return completed forms to:

Director General
Department of Standards Malaysia,
Menara Cyber Axis,
Level 4, 5, 6 & 7 Tower 2,
Cyber 6, Jalan Impact
63000 Cyberjaya, Malaysia
Attention: Director of Accreditation
Tel : +(603) 8008 2819/ 2776/ 2818
Fax : +(603) 8008 2901

Acknowledgement Receipt

To: …….
…….
…….
…….

I, ……. hereby confirmed that we have received your application form and will proceed to further action i.e. to assign Lead Inspector, issuing inspection notification, plan etc.
Name & Designation: ……..…… Signature:..……

Date: …….