NATIONAL GOOD LABORATORY PRACTICE (GLP) COMPLIANCE MONITORING AUTHORITY

APPLICATION FORM

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NATIONAL GLP COMPLIANCE MONITORING AUTHORITY
DEPARTMENT OF SCIENCE AND TECHNOLOGY
TECHNOLOGY BHAWAN
NEW MEHRAULI ROAD NEW DELHI-110 016

Guidelines to fill up the application form

1. ***Organisation for Economic Co-operation and Development (OECD)*** *Principles of Good Laboratory Practice, Terms & Conditions of the* ***National GLP Compliance Monitoring Authority*** *and the Brochure on the* ***GLP Programme*** *should be fully read and understood by the applicant. Before making an application to the National GLP Compliance Monitoring Authority, applicant test facility should ensure that their system is being operated as per the OECD Principles of Good Laboratory Practice and OECD Test Guidelines.*

2. ***National GLP Compliance Monitoring Authority*** *has given the sequence number for each information it needs in its application form. For each point, please use as many sheets as required, in continuation.*

3. *For each sequence number of the application form, all information should be compiled in one go and all the pages should be sequentially numbered so that Annexures are not used.*

4. *At the end of the application, the competent authority of the laboratory should sign as a token of commitment to ensure that all furnished information is correct and the management of the test facility fully understands its responsibilities and commitment to National GLP Compliance Monitoring Authority.*

5. *The competent authority is required to furnish his full name and the position which he holds.*

6. *Please submit* ***7 sets*** *of applications along with the application fee of Rs.10,000/- by way of Demand Draft, drawn in favour of Drawing and Disbursing Officer, DST and payable at New Delhi, to :*

Head
National GLP-Programme
National GLP Compliance Monitoring Authority
Department of Science & Technology
Technology Bhavan New Mehrauli Road
New Delhi-110 016
Telefax: 26964793

NATIONAL GLP COMPLIANCE MONITORING AUTHORITY

Application for ☐ First Certification

☐ Re-certification

1. Details of the applicant

1.1 Name_____
1.2 Address_____
1.3 Telephone_____
1.4 Fax_____
1.5 e-mail_____
1.6 Name of the contact person along with his contact details (Tel/Fax/e-mail)
1.7 Legal Status
1.8 Please tick whichever is applicable

Company ☐

Test facility ☐

R& D Laboratory ☐

University ☐

Any other (Please specify) ☐

2. Details of the test facility

2.1 Name_____
2.2 Address_____
2.3 Telephone_____
2.4 Fax_____
2.5 E mail_____
2.6 Name of the contact person with contact details (Tel/Fax/e-mail)
2.7 Legal Status

3. (a) Is the test facility totally autonomous?

Yes ☐

No ☐

(b) If no, what are the decisions for which the test facility depends on the management of the company/ university / R&D laboratory?

4. Date of implementation of OECD Principles of GLP in the test facility :

5. Type of facilities offered :

(a) Tick-mark the category of chemicals being tested:

Type of chemical	
Industrial chemicals	
Pharmaceuticals	
Veterinary drugs	
Pesticides	
Cosmetic products/Food additives/ Feed additives, etc. (specify)	

b) Tick mark the area of expertise for which GLP compliance is being sought

Areas of expertise	
physical-chemical testing	
toxicity studies	
mutagenicity studies	
environmental toxicity studies on aquatic and terrestrial organisms	
studies on behaviour in water, soil and air; bioaccumulation	
residue studies	
studies on effects on mesocosms and natural ecosystems	
analytical and clinical chemistry testing	
other studies, specify	

Note: GLP Certificate will include the areas of expertise

6. (a) Is the test facility also engaged in non-GLP testing and studies?

Yes ☐

No ☐

(b) If yes, please specify the nature of testing and areas of expertise. How frequently does it perform non-GLP studies and tests?

7. Are there other test sites, subcontractors and/or external scientists being involved in the conduct of GLP studies? If yes, please give details

8. Furnish the following documents:

a) Recent Organization charts,

b) List of Personnel along with their qualifications and training (especially GLP)

c) Floor-plans with GLP marked-area

d) List of instrument(s)/equipment(s) including number of computers

e) Procedures being followed to maintain security and integrity of computerized data and records

f) Details of test systems

g) List of Standard Operating Procedures (SOPs)

h) SOPs of general procedures for drafting, authorizing, modifying, distributing and archiving SOPs

i) Brief description of the working of the Quality Assurance Unit with list of SOPs for this purpose

9. Furnish master schedule reflecting all ongoing studies and completed studies in the last one year in a tabular form showing the following information:

Study No.	***GLP / Non-GLP***	***Name of Study (Short Title- Test System/ Method or Description of Study)***	***Test Item /Substance* (category, Code/ Description)***	***Name of Study Director***	***Study Initiation Date***	***Exp. Start Date***	***Exp. Completion Date***	***Study Completion Date***	***Date of Archiving***	***Study status/ Remarks*****

*** Use code numbers, if there is a secrecy agreement with the sponsor**

**** Use OG for on-going studies, C for completed studies, CAN for cancelled studies and ARC for studies which have been archived after completion**

Note For cancelled studies or studies terminated before completion, please provide details including reasons for cancellation or termination

10. Do you submit studies directly or through a sponsor to a regulatory authority? Please provide details including study number, brief description of the study, name of regulatory authority along with the address, status of acceptance.

S.No.	Study No.	GLP/Non-GLP	Title of study	Test item	Name & address of Regulatory Authority	Date of submission	Status (Pending/accepted/ Rejected)

11. Furnish the details of GLP inspections of the test facility conducted by the national or any foreign GLP Compliance Monitoring Authority

Details of inspections

Monitoring Authority/ Country	Date of inspection	Result (In-compliance/ Not In-compliance/ Pending)

12. Declarations by the Test Facility Management:

- I have read and understood the GLP Principles as enunciated in OECD Principles of GLP, Document numbers 1-14.
- I, hereby, give my consent on behalf of the management of the test facility to abide by the Terms & Conditions (GLP-101) of the National GLP Compliance Monitoring Authority.
- I declare that the information furnished above is correct.
- I am fully aware that this programme involves international commitment by the National GLP Compliance Monitoring Authority, and to this effect, I commit that the applicant test facility would abide by all those norms which may be stipulated by OECD from time to time.

Place :
Date :

Signature
Name
Designation: