

**Guidelines to fill up the application form**

- 1. Before making an application to the National GLP Compliance Monitoring Authority, applicant TF should ensure that their system is being operated as per the OECD Principles of Good Laboratory Practice and OECD Test Guidelines ( Document No 1-15). Other documents which should be consulted before filing the application are Terms & Conditions of the National GLP Compliance Monitoring Authority for obtaining and maintaining GLP certification by Test Facilities (GLP-101) and the Information Brochure on the National GLP Programme (GLP-100).*
- 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. All the required information should be compiled in the Application Form itself and all the pages should be sequentially numbered. Use of Annexures should be avoided.*
- 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/she 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: 91-11-26964793**

# National GLP Compliance Monitoring Authority (INDIA)

Application for  First Certification

Re-certification

## 1. Details of the Test Facility

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)  
(For all communication in respect to GLP certification)

1.7 Tick whichever is applicable

CRO

R&D institution

University

Company / Organization

Any other (Please specify)

## 2. (a) Is the Test Facility

(i) Stand alone

(ii) Part of a parent organization

(b) If (ii) what are the decisions for which the Test Facility depends on the management of the parent organization?

2.1 Details of the Parent Organisation(if applicable)

2.2 Name \_\_\_\_\_

2.3 Address \_\_\_\_\_

2.4 Telephone \_\_\_\_\_

2.5 Fax \_\_\_\_\_

2.6 E-mail \_\_\_\_\_

2.7 Name of the contact person along with his contact details  
(Tel/Fax/e - mail) \_\_\_\_\_

2.8 Legal Status \_\_\_\_\_

## National GLP Compliance Monitoring Authority (INDIA)

3. Details of the Test Facility Management responsible for compliance of GLP principles (if different from contact person mentioned in 1.6)

3.1 Name \_\_\_\_\_

3.2 Address \_\_\_\_\_

3.3 Telephone \_\_\_\_\_

3.4 Fax \_\_\_\_\_

3.5 E mail \_\_\_\_\_

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

5. (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 behavior 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

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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. The following documents are required to be furnished:
- a) Recent Organization charts,
  - b) List of Personnel along with their qualifications and training (especially related to GLP)
  - c) Floor-plans with GLP marked-area for GLP studies
  - d) List of instrument(s)/equipment(s)/list of softwares on computerized systems for GLP studies.
  - e) Procedures being followed to maintain security and integrity of computerized data and records
  - f) Details of biological test systems (Sp, strain, whether bred in house/ purchased from outside)
  - 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
  - j) Location of the archives giving details.
9. Master schedule reflecting all ongoing studies and completed studies in the last one year in a tabular form showing the following information to be furnished:

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	Experiment Start Date	Experiment 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

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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

Monitoring Authority/ Country	Date of inspection	Result (In-compliance/ Not In-compliance/ Pending)	Scope Of Certification (Areas of Expertise)

12. Furnish details of

- (a) Working Timings
- (b) Off days

13. Declarations by the Test Facility Management :

I hereby submit this application for GLP certification under NGCMA, India. As the Test Facility Management, I undertake to ensure that the premises and the studies conducted in the facility remain in compliance with the OECD Principles of Good Laboratory Practice.

I agree to comply with the Terms and Conditions as stipulated in the document (GLP-101), NGCMA and shall pay to the necessary fees as described in the document (GLP-101).

I agree to allow NGCMA inspector (s) reasonable access to the facility premises resources, operations, procedures, records and staff so that the inspector(s) can effectively inspect the GLP system and activities of my facility. I agree to allow the inspector(s) the right to take samples, inspect records and to produce copies and photographs on site, if it is necessary for reasons of perpetuation of evidence. I understand that failure of which will lead to the removal of my facility registration in the NGCMA programme.

Note: NGCMA reserves the right to review the above terms and conditions and fees as and when necessary.

I declare that the information given in this application is correct to the best of my knowledge and belief.

Place :  
Date :

Signature  
Name  
Designation: