



Government of India
Ministry of Science and Technology
Department of Science and Technology
National Good Laboratory Practice (GLP) Compliance Monitoring Authority

INFORMATION BROCHURE

Document No. GLP-100
Issue No. 08
Issue Date: October 25, 2019

NATIONAL GLP COMPLIANCE MONITORING AUTHORITY
DEPARTMENT OF SCIENCE AND TECHNOLOGY
TECHNOLOGY BHAVAN, NEW MEHRAULI ROAD
NEW DELHI-110 016
<http://www.dst.gov.in/ngcma>

1. Introduction

The National Good Laboratory Practice (GLP) Compliance Monitoring Authority (NGCMA)/ GLP Authority was established by Government of India with the approval of the Cabinet under the administrative control of Department of Science and Technology (DST), Ministry of Science and Technology, in April 2002. The formation of the NGCMA was notified in the Gazette of India Part 1, Section 1 on August 31, 2002, which may be seen at **Annexure I**.

2. Background

2.1 GLP is a quality system concerned with the organizational process and the conditions under which **non-clinical health** and **environmental safety** studies are planned, performed, monitored, recorded, archived and reported. GLP applies to the non-clinical safety testing of test items contained in Industrial chemicals, Pharmaceuticals (Human and Veterinary), Agrochemicals, Cosmetics Products, Food/ Feed Additives and Medical devices. These test items are usually/ normally synthetic chemicals, may be of natural, herbal/ plant extracts or biological origin, and in some circumstances, may be living organisms.

2.2 The application of GLP principles has the following advantages:

- a) Assures the quality and integrity of data generated in GLP-certified Test Facilities (TFs).
- b) Provides confidence regarding authenticity of pre-clinical data of above-mentioned test items for hazard and risk assessment to regulatory authorities.
- c) Avoids duplicative testing
- d) Is beneficial to animal welfare
- e) Reduces time and costs for industry, government and other stakeholders
- f) Facilitates exchange of information
- g) Removes non-tariff trade barriers
- h) Contributes to the protection of human health and environment.

2.3 Considering the above benefits, Government of India, through a decision of the Cabinet, set up the NGCMA in 2002 on following lines:

2.3.1 Start the programme "National GLP Compliance Monitoring Authority" for TFs under the administrative control of the DST.

2.3.2 Constitute the Apex Body with following membership:

Chairman

Secretary
Department of Science and Technology
Ministry of Science and Technology

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trained by NGCMA or OECD for conducting GLP inspections and Study audits.

5. Nature of the National GLP Programme

- 5.1 GLP certification is voluntary and any TF in India which undertakes non-clinical health and environmental safety studies for regulatory submission will be eligible to seek GLP certification.
- 5.2 NGCMA will maintain a list of GLP-certified TFs.
- 5.3 GLP certification granted to a TF shall be valid for a period of three years. GLP-certified TFs shall be regularly monitored to ensure their compliance to OECD Principles of GLP and OECD Test Guidelines by organizing surveillance visits.
- 5.4 NGCMA would cooperate with Regulatory Authority(ies) (RAs)/ Compliance Monitoring Authorities (CMAs) of an OECD MAD adherent countries in the following ways:
 - 5.4.1 Organize a particular study audit and provide the results to the requesting RA who sought such services.
 - 5.4.2 Facilitate and conduct a Joint GLP inspection/ study audit at the request from the RAs of an OECD MAD adherent country along with their Inspectors or representative(s).

Note: Indian RAs would have a similar access in OECD MAD adherent countries

- 5.5 NGCMA has an in-built mechanism of initiating action against the GLP certified TF(s) not found to have complied with OECD Principles of GLP & OECD Test Guidelines, which might affect the validity of studies conducted in the TF. The actions would be taken by NGCMA in accordance with Document No. GLP-113 "Policies and procedures of NGCMA for taking adverse and other decisions against test facilities".

6. Scope and Extent of the National GLP Programme

- 6.1 National GLP Programme covers the application of OECD Principles of GLP and OECD Test Guidelines, where applicable, for non-clinical health and environmental safety testing of test items contained in:
 - a) Industrial chemicals
 - b) Pharmaceuticals (Human and Veterinary)
 - c) Agrochemicals
 - d) Cosmetics Products
 - e) Food/ Feed Additives

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NABL
Accreditation
Certificates



NABL

National Accreditation Board for Testing and Calibration Laboratories

Department of Science & Technology, India

CERTIFICATE OF ACCREDITATION

MGM MEDICAL COLLEGE & HOSPITAL'S CENTRAL LABORATORY

has been assessed and accredited in accordance with the standard

ISO 15189:2007

"Medical Laboratories - Particular requirements for quality and competence"

for its facilities at

Mahatma Gandhi Mission Hospital, Sector-18, Kamothe, Navi Mumbai

in the field of

MEDICAL TESTING

(To see the scope of accreditation of this laboratory, you may also visit NABL website www.nabl-india.org)

Certificate Number M-0555

Issue Date 26/04/2013



Valid Until 25/04/2015

This certificate remains valid for the Scope of Accreditation as specified in the annexure subject to continued satisfactory compliance to the above standard & the additional requirements of NABL.

THIS IS COLOUR XEROX

Signed for and on behalf of NABL


Soma Nath
Convener


Anil Relia
Director


Dr T. Ramasami
Chairman



NABL

National Accreditation Board for Testing and Calibration Laboratories

(An Autonomous Body under Department of Science & Technology, Govt. of India)

CERTIFICATE OF ACCREDITATION

MGM MEDICAL COLLEGE & HOSPITAL'S CENTRAL LABORATORY

has been assessed and accredited in accordance with the standard

ISO 15189:2012

"Medical laboratories - Requirements for quality and competence"

for its facilities at

Plot No. 1 & 2, NH-4 Junction, Sion Panvel Junction, Express Highway, Sector 1, Kamothe, Navi Mumbai, Maharashtra

in the field of

MEDICAL TESTING

(To see the scope of accreditation of this laboratory, you may also visit NABL website www.nabl-india.org)

Certificate Number M-0555

Issue Date 26/04/2015



Valid Until 25/04/2017

This certificate remains valid for the Scope of Accreditation as specified in the annexure subject to continued satisfactory compliance to the above standard & the additional requirements of NABL.

Signed for and on behalf of NABL

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Dr. Vandana Jain
Program Manager

Anil Rella

Anil Rella
Director

Prof. Ashutosh Sharma

Prof. Ashutosh Sharma
Chairman



**National Accreditation Board for
Testing and Calibration Laboratories**

(A Constituent Board of Quality Council of India)



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MGM MEDICAL COLLEGE & HOSPITAL'S CENTRAL LABORATORY

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for its facilities at

Plot No. 1 & 2, NH-4 Junction, Sion Panvel Express Highway, Sector 1, Kamothe, Navi Mumbai, Maharashtra

in the field of

MEDICAL TESTING

Certificate Number MC-2166 (in lieu of M-0555)

Issue Date 26/04/2017



Valid Until 25/04/2019

This certificate remains valid for the Scope of Accreditation as specified in the annexure subject to continued satisfactory compliance to the above standard & the relevant requirements of NABL.

(To see the scope of accreditation of this laboratory, you may also visit NABL website www.nabl-india.org)

Signed for and on behalf of NABL

[Signature]

Dr. Vandana Jain
Program Director

[Signature]
Anil Relia
Chief Executive Officer



NABL

National Accreditation Board for Testing and Calibration Laboratories

(An Autonomous Body under Department of Science & Technology, Govt. of India)

CERTIFICATE OF ACCREDITATION

MGM'S CENTRAL PATHOLOGY LABORATORY

has been assessed and accredited in accordance with the standard

ISO 15189:2012

"Medical laboratories - Requirements for quality and competence"

for its facilities at

Mahatma Gandhi Mission Hospital, N-6, CIDCO, Aurangabad, Maharashtra

in the field of

MEDICAL TESTING

(To see the scope of accreditation of this laboratory, you may also visit NABL website www.nabl-india.org)

Certificate Number M-0692

Issue Date 03/06/2016



Valid Until 02/06/2018

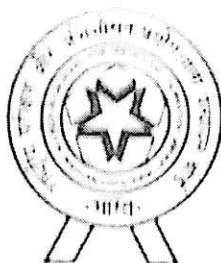
This certificate remains valid for the Scope of Accreditation as specified in the annexure subject to continued satisfactory compliance to the above standard & the additional requirements of NABL.

Signed for and on behalf of NABL

Dr. Vandana Jain
Program Manager

Anil Relia
Director

Prof. S.K. Joshi
Chairman



NABL

National Accreditation Board for Testing and Calibration Laboratories

(An Autonomous Body under Department of Science & Technology, Govt. of India)

CERTIFICATE OF ACCREDITATION

CENTRAL LABORATORY, MGM'S MEDICAL COLLEGE AND HOSPITAL

has been assessed and accredited in accordance with the standard

ISO 15189:2012

"Medical laboratories - Requirements for quality and competence"

for its facilities at

N-6, CIDCO, Aurangabad, Maharashtra

in the field of

MEDICAL TESTING

(To see the scope of accreditation of this laboratory, you may also visit NABL website www.nabl-india.org)

Certificate Number M-0692

Issue Date 28/05/2015



Valid Until 02/06/2016

This certificate remains valid for the Scope of Accreditation as specified in the annexure subject to continued satisfactory compliance to the above standard & the additional requirements of NABL.

Signed for and on behalf of NABL

Dr. Vandana Jain
Program Manager

Anil Relia
Director

Prof. Ashutosh Sharma
Chairman