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PHARMACEUTICAL QUALITY ASSURANCE

UNIT 1

TOPIC :

- **NABL accreditation : Principles and procedures**



NABL (National Accreditation Board for Testing and Calibration Laboratories)

- NABL stands for National Accreditation Board for Testing and Calibration Laboratories.
- It is an autonomous accreditation body operating under the Quality Council of India that provides accreditation to testing, calibration, medical, and other laboratories in India.
- NABL ensures that laboratories perform testing, calibration, and diagnostic activities according to internationally accepted standards of quality, competence, and reliability.
- Accreditation by NABL demonstrates that a laboratory is technically competent, follows validated procedures, and generates accurate, reliable, and traceable results.

Historical Background

- NABL was established in **1992** under the Department of Science and Technology (DST), Government of India.
- Later, NABL became a constituent board of the Quality Council of India (QCI).
- NABL operates according to international accreditation standards.

NABL is a signatory to:

- Asia Pacific Accreditation Cooperation Mutual Recognition Arrangement (MRA)
- International Laboratory Accreditation Cooperation Mutual Recognition Arrangement (MRA)

These agreements make NABL-accredited laboratory reports widely accepted internationally.

Objectives of NABL

1. Provide formal recognition to competent laboratories.
2. Promote quality assurance in laboratory operations.
3. Ensure technical competence in testing and calibration.
4. Maintain data integrity and traceability.
5. Improve reliability of laboratory results.
6. Enhance global acceptance of Indian laboratory reports.
7. Facilitate compliance with regulatory requirements.
8. Encourage continual improvement in laboratories.

Need for NABL Accreditation

- To ensure accuracy of laboratory results.
- To improve confidence in test reports.
- To meet national and international standards.
- To support pharmaceutical quality control.
- To reduce testing errors.
- To enhance laboratory credibility.
- To facilitate international trade and exports.

Scope of NABL Accreditation

NABL provides accreditation to:

1. Testing Laboratories

- Chemical testing
- Biological testing
- Pharmaceutical testing
- Environmental testing

2. Calibration Laboratories

- Mechanical calibration
- Electrical calibration
- Thermal calibration
- Dimensional calibration

3. Medical Laboratories

- Clinical pathology
- Biochemistry
- Microbiology
- Hematology

Standards Used by NABL

Laboratory Type	Standard
Testing & Calibration Laboratories	ISO/IEC 17025
Medical Laboratories	ISO 15189
Proficiency Testing Providers	ISO/IEC 17043
Reference Material Producers	ISO 17034

NABL Accreditation Process

Step 1: Application

Laboratory submits application to NABL along with required documents.



Step 2: Application Review

NABL secretariat reviews application and supporting documents.



Step 3: Quality System Assessment

Evaluation of:

- Quality Manual
 - SOPs
 - Records
- Technical competence



Step 4: Pre-Assessment Visit

Lead assessor evaluates laboratory preparedness.



Step 5: Final Assessment

Assessment team conducts detailed evaluation.



Step 6: Assessment Report Review

NABL reviews findings and recommendations.



Step 7: Accreditation Committee Review

Committee examines assessment results.



Step 8: Approval by NABL Authority

Final approval granted by competent authority.



Step 9: Issue of Accreditation Certificate

NABL issues accreditation certificate.



Step 10: Surveillance and Reassessment

Periodic audits ensure continued compliance.

Requirements for NABL Accreditation

Management Requirements

- Quality management system
- Document control
- Internal audits
- Corrective actions
- Management review

Technical Requirements

- Qualified personnel
- Validated methods
- Calibrated equipment
- Measurement traceability
- Quality control procedures

Role of NABL in Pharmaceutical Industry

→ NABL plays a crucial role in ensuring quality and reliability of pharmaceutical testing laboratories.

Areas of Application

Raw Material Testing

- Ensures quality of active pharmaceutical ingredients and excipients.

In-Process Quality Control

- Monitors manufacturing quality during production.

Finished Product Testing

- Confirms safety, purity, potency, and efficacy.

Stability Testing

- Determines shelf life and storage conditions.

Microbiological Testing

- Ensures products are free from harmful microorganisms.

Calibration Services

- Maintains accuracy of laboratory instruments.

Benefits of NABL Accreditation

For Laboratories

1. Recognition of technical competence.
2. Improved laboratory performance.
3. Better quality management.
4. Enhanced credibility.

For Customers

1. Confidence in test results.
2. Reliable and accurate reports.
3. Reduced risk of incorrect decisions.

For Industry

1. Regulatory compliance.
2. Reduced need for retesting.
3. International acceptance of reports.
4. Improved product quality.

Importance of NABL in Pharmaceutical Industry

1. Ensures compliance with GMP requirements.
2. Supports Quality Assurance and Quality Control.
3. Improves reliability of analytical results.
4. Ensures traceability of measurements.
5. Facilitates regulatory inspections.
6. Enhances patient safety.
7. Supports export of pharmaceutical products.
8. Promotes continual quality improvement.