NATIONAL INSTITUTE OF BIOLOGICALS

CITIZEN CHARTER

The Institute is notified Central Drugs Laboratory and Central Medical Device Testing Laboratory under these statutory provisions. The biological products are tested as per statutory standards laid down in Indian Pharmacopoeia or relevant pharmacopoeia or International norms, in the NIB laboratories. The institute is also accredited by NABL for ISO 17025 as per the scope defined. Some of the NIB scientists have also been notified as Government Analysts and Medical Device Testing Officers for biological products as per Statutory Norms.

The scientists of the institute are committed towards their duty and follow the mandates and functions meticulously. Some of them are as hereunder:

a) to ensure quality of Biological and Biotherapeutic products, both imported and manufactured indigenously moving in the Indian market.
b) to contribute in finalizing the specifications for biological products to be incorporated in Indian Pharmacopoeia.
c) to prepare National Reference Standards for biological products.
d) to train technical personnel in the public and private sectors in the field of Quality Control of Biological products and the Haemovigilance programme
e) to collaborate with other National and International Scientific Institutions/ organizations in upgrading technologies and keeping abreast of scientific advances made in the field of quality assessment of Biological and Biotherapeutic products.
f) to extend technical expertise during joint inspections of manufacturing premises of biological products with the officers of CDSCO.
g) to implement the Haemovigilance Programme of India to promote safe blood transfusion practices.

Sample Receipt & Report Dispatch (SRRD)

It is the main interface between NIB and its stakeholders for all the products that are received in the institute. Biological samples of various categories for QC testing are forwarded to NIB from the Drug regulatory authorities of the country as part of the mandatory submission of the Performance Evaluation report required as per regulatory guidelines. Besides, samples are also accepted from several government medical organizations (medical supplies), Drug Inspectors (Survey and Samples forwarded under the Drugs & Cosmetics Act).

FLOW CHART SHOWING THE PATHWAY FROM SAMPLE RECEIPT TO CERTIFICATE OF ANALYSIS RELEASE

STEP-1 SAMPLE ACCEPTANCE

(A) Physical verification of the sample

- Recommended storage temperature
- Sample quantity
- Label Claim
- Mfg. & Exp. Date

(B) Documents verification

- Forwarding letter from authority
- Import/ Manufacturing/ Test License
- CoA from manufacturer
- Batch Release Certificate
- Pack Insert

The e-mail is sent to forwarding authority in case of any deficiency/ discrepancy.

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STEP- 2 ONLINE SAMPLE SUBMISSION

(A) Sample details as per the label claim and documents details are entered in LIMS & sample receipt register

(B) Sample acknowledgment receipt is given to the vendor and copy of the same

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STEP- 3 FORWARDING OF SAMPLE & BATCH FILE

- Sample(s) is/are forwarded to the concerned lab. The retained sample quantity is stored at appropriate temperature in SRRD Unit
- Online sample entries are verified and forwarded to concerned lab
- LIMS forwarding sample receipt form is printed
- The forwarding receipt is attached in the Batch file
- The batch file with a unique file number along with essential documents is sent to concerned lab

STEP- 4 CoA RELEASE

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- Subsequent to the QC testing of sample in the concerned lab, the CoA along with physical file is received in SRRD Unit for the release of CoA
- The report is checked and the cover letter generated is signed by Head, SRRD Unit.

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STEP- 5 DISPATCH & RECORD OF CoA

- The report along with the cover letter is sent both online and offline to drug regulatory authority (DCGI) with a copy marked to the stakeholder
- The scanned copy of released CoA is uploaded in LIMS and entry maintained in the excel sheet for records

A. **Categories of samples received under the act at NIB:**

S. No.	Category	Essential Document	Request	Reporting on	Testing Fee (Y/N)
1	Samples received from Drug Inspector for Government Analyst	Form 18 (sealed)	Form 18 (rule 57 D&C): Memorandum to Government Analyst	Form 13 (rule 46 D&C): Certificate of test or Analysis by Government Analyst Under Section 25 (1) of the D&C ACT,1940	N
2	Samples received from Medical Device Officer for Medical Device Testing Officer	Form MD-38 (sealed)	Form MD-38 (sub-rule (1) rule 78 MDR): Memorandum to Medical Device Testing Officer	Form MD-32 (sub-rule (2) of rule 68 MDR): Report of Test or Evaluation of Medical Devices by Medical Device Testing Officer	N
3	Sample Received from Magistrate for Director of CDL	Form 1 (sealed)	Form 1 (rule 4 D&C): Memorandum to the Central Drugs Laboratory	Form 2 (rule 6 D&C): Certificate of test or Analysis by the Central Drugs Laboratory (CDL)	N
4	Sample Received from Magistrate for Director of CMDTL	Form MD-30 (sealed)	Form MD-30 (sub-rule (1) of rule 67 MDR): Memorandum to the Central Medical Device Testing Laboratory (CMDTL)	Form MD-31 (sub-rule (4) of rule 67 MDR): Certificate of test or evaluation by the CMDTL by the Director of CMDTL	N

B. Categories of samples received other than under the act at NIB:

S. No.	Category	Essential Document	Request	Reporting on	Testing Fee (Y/N)
1	Samples received from Manufactures/ Importers For PER	TEST LICENSE Form 11 (rule 33, D&C): License to Import Drugs for the purposes of Examination, Test or Analysis	Manufacturer letterhead	Regular CoA (NIB)	Y
		Form MD-17 (sub-rule (1) of rule 41 MDR): License to Import Medical Devices for the Purposes of Clinical Investigations or Test or Evaluation or Demonstrations or Training	Manufacturer letterhead	Regular CoA (NIB)	Y
2	Samples received from Drug Regulatory Authority (port offices)	IMPORT LICENSE Form 10 (rule 23 and 27, D&C): License to Import Drugs (Excluding those specified in Schedule X to the Drug and Cosmetic Rules,1945	Forwarding Letter from ADCI	Regular CoA (NIB)	Y
		Form MD-15 sub-rule (1) of rule 36 MDR: License to Import Medical Device	Forwarding Letter from ADCI	Regular CoA (NIB)	Y
3	Samples received from indigenous Manufacturers If advised by Drug Regulatory Authorities	MANUFACTURING LICENSE Form 28 (rule 76) D&C License to manufacture for sale or for distribution of] drugs specified in Schedules C and C (1) 2 [excluding those specified in Schedule X]	Manufacturer letterhead	Regular CoA (NIB)	Y

S. No.	Category	Essential Document	Request	Reporting on	Testing Fee (Y/N)
	And approved by Director.	Form MD-5 (sub-rule (4) of rule 20 and sub-rule (6) of rule 20) MDR: License to Manufacture for Sale or for Distribution of Class A or Class B Medical Device.	Manufacturer letterhead	Regular CoA (NIB)	Y
		Form MD-9 (sub-rule (1) rule 25) MDR: License to Manufacture for Sale or for distribution of class C or class D	Manufacturer letterhead	Regular CoA (NIB)	Y
4	Samples received from indigenous Manufacturers For PER	Form 29 (Rule 89) D&C License to manufacture drugs for purposes of examination, test or analysis.	Manufacturer letterhead	Regular CoA (NIB)	Y
		Form MD-13 (sub-rule (3) of rule 31) MDR: License to Manufacture Medical Devices for the Purposes of Clinical Investigations or Test or Evaluation or Demonstration or Training	Manufacturer letterhead	Regular CoA (NIB)	Y
5	Samples received from Drug Inspectors as Survey Samples (field samples)	NA	Letter from Drug inspector	Regular CoA (NIB)	N
6	Samples received from Govt Medical Supply agencies	NA	Letterhead of Govt Medical supply agency	Regular CoA (NIB)	Y

C. Product-Specific requirements:

a) **Blood Products Lab- Plasma-Based products:**

1. Batch Release from the country of origin for imported samples
2. Certification of analysis with the name of pharmacopoeia complied

b) **Biochemical kit lab**

b1) Blood Glucose Test Strips:

Quantity of Sample: A total of 1200 test strips for testing by laboratory & 350 test strips as retained sample by the SRRD unit.

Sample Accessories required:

(i) Compatible 10 Nos. of Glucometers as a closed system

(ii) Normal Control Solution (3 mL x 3 Vials)

(iii) Pathological Control Solution (3 mL x 3 Vials)

b2.1) Fully automated analyzer-based Glucose Reagent- Open Ended Chemistry:

Quantity of Sample: 500 mL of Glucose reagent (sufficient to perform 1000 tests) for testing by laboratory & Nil for retained sample by the SRRD unit.

Sample Accessories required:
(i) Calibrator
(ii) Normal Control
(iii) Pathological Control
(iv) Machine protocol

Materials at (i), (ii) and (iii) to be submitted in quantity enough to last over 25 days of QC protocol execution – keeping in view the shelf life of the respective preparations.

b2.2) Fully automated analyzer based Glucose Reagent- Closed Chemistry System:

Quantity of Sample: Glucose Reagents/ Test Cartridges/ Modules/ Slides/ Cassettes/ Packs/ Bottles/ Dry-chemistry Cards should be in sufficient quantity to be used for 25 working days for QC protocol execution/ 1000 tests (whichever applicable), irrespective of number of tests possible from each unit/pack/cartridge, keeping in view the on-board shelf life of the respective preparations & Nil for retained.
Sample Accessories required:
(i) Temporary installation of the Automated Analyzer
(ii) 'Calibrator' preparation
(iii) 'Normal' control preparation
(iv) 'Pathological' control preparation
(v) Equipment related consumables- sample cups/ printer paper/ maintenance reagents/ solutions.
(vi) Service/ technological/ training support with respect to the use of the equipment.

Materials at (ii), (iii), (iv) and (v) to be submitted in quantity enough to last over 25 days of QC protocol execution – keeping in view the on-board shelf life of the respective preparations.

b3) Glucometer Device:
Quantity of Sample: Glucometer Devices 10 Nos. required for testing by laboratory and 2 Nos. shall be kept for taking care of exigencies as malfunction etc. to be retained in SRRD Unit.

Sample Accessories required:

(i) Specific Blood Glucose Test Strips as accessory 1200 Strips

(ii) Level 1 (Normal) Control solution 3ml x 3 vials per model

(iii) Level 2 (Pathological) Control Solution 3ml x 3 vials per model.

D. **Testing fee requirements:**
Testing Fee Details Click Here

E. Payment modes:
1. FOR PAYMENT/DEPOSIT OF TESTING FEE THROUGH BANK TRANSFER

NAME OF BANK	**:**	BANK OF BARODA, SECTOR-29, NOIDA (U.P.)
NAME OF ACCOUNT	**:**	NATIONAL INSTITUTE OF BIOLOGICALS
S.B. ACCOUNT	**:**	26290100001774
IFSC CODE	:	BARB0NOIDAX
SWIFT CODE	:	BARBINBBNOI
MICR CODE NO.	:	110012066
PAN	:	AAATN5228R
GSTIN	:	09AAATN5228R1ZX
ST No.	:	AAATN5228RST001
TIN	:	09466201769

Note:
a) TESTING FEES IS REQUIRED TO BE SUBMITTED IN ADVANCE ALONG WITH THE RESPECTIVE BATCH SENT TO THE INSTITUTE FOR TESTING

b) Testing Fees once submitted at NIB for Samples forwarded through Zonal / Sub-zonal/ Port Offices of CDSCO which can be tested at NIB cannot be refunded.

c) Testing Fees submitted at NIB for Samples which cannot be tested at NIB can be refunded or adjusted against other samples within a month of submission of the testing fee.

d) **Testing Fees submitted Online should also be intimated to the Institute through email (1) srrd[at]nib[dot]gov[dot]in (2) finance[at]nib[dot]gov[dot]in**

F. Turnaround Time (TAT) for release of the report of Test or Analysis of samples received at NIB:

S. No.	Type of Samples	Turn Around Time
1.	Samples received under the ACT (Form 1, Form 18, Form MD-30, Form MD-38)	Within 60 days
2.	Biological Samples requiring cell culture-based *in-vitro* testing	60 days
3.	Biological Samples requiring animal-based (except for abnormal toxicity, Pyrogen test & Virus inactivation)	90- 120 days
4.	Any other Samples	42 days

G. **Surveillance:**
Institute is under CCTV Surveillance for necessary security and maintenance of samples and records.

H. **Customer feedback:** is always acknowledged. Submission of feedback should be marked at srrd[at]nib[dot]gov[dot]in. Further, a Suggestions / Complaints / Feedback Register is also placed in the Unit for necessary redressal.

I. RIGHT TO INFORMATION?

A person who wants to get any additional information may apply under RTI Act, 2005 (details on the website)

J. All relevant information regarding the institute is available on the institute's website