FREQUENTLY ASKED QUESTIONS (FAQs)

Q.1 What are the requirements for sample submission?
Ans. Requirement of sample submission are as follows:

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	Manufacture r 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	Manufacture r 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]	Manufacture r 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.	Manufacture r 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	Manufacture r 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.	Manufacture r 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	Manufacture r 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

Q.2 What are the requirements for sample testing and testing fee towards quality control evaluation?
Ans. The requirements for sample testing and testing fee towards quality control evaluation can be checked from the Institute's website i.e., https://www.nib.gov.in/Testing_fees.aspx.

Q.3 What is the product specific requirement?
Ans. Product specific requirement with respect to Blood Products and Biochemical Kits are detailed below:

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- b a s e d 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.

Q.4 What are the different type of products tested at NIB?
Ans. NIB performs quality control evaluation of biological products. Details can be checked from the Institute's website i.e., https://www.nib.gov.in/Testing_fees.aspx.

Q.5 How do we submit testing fees for quality control of our products?
Ans. Testing fees can be deposited through Bank transfer as per details as under:

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

Q.6 What if the sample does not pertain in NIB list of testing?
Ans. If sample does not pertain to NIB document list of testing, stakeholder has to send a query through email to NIB at the email id i.e., info@nib.gov.in and NIB will provide the appropriate response in this regard addressing the feasibility.

Q.7 What is the mode of sample submission?
Ans. Samples are submitted by Speed Post / Couriers or submitted by company representative with essential documents as per checklist and recommended storage conditions.

Q.8 What is the checklist for sample submission?
Ans. Kindly refer to the Answer to the Question No.1.

Q.9 Is information under the Citizen Charter available on the Institute's website?
Ans. Yes. Details can be checked from the Institute's website: https://www.nib.gov.in/media/Citizen_Charter.pdf.