

Frequently Asked Questions (FAQs)

Q1 . What are the requirements for sample submission?

Ans. Requirements of Sample submission are as follows:

Essential Documents

- a) Forwarding Letter from Drug Regulatory Authority or any other statutory authority of the country which has been marked to NIB for testing/evaluation purpose.
- b) Copy of Import License/Test License issued by Govt. of India
 - i. Form -11 (Copy of Import License for Testing purpose)
 - ii. Form -10 (Copy of Import License for Commercial purpose)
 - iii. Form MD-15 (Copy of License to Import Medical Device)
 - iv. Form MD-17 (License to Import Medical Devices for the purpose of Evaluation)
 - v. Form MD-13 (License to Manufacture Medical Devices for the purpose of Testing)
- c) Copy of Manufacturing License Issued by Govt. of India (In case of Indigenous Product) Form 25/28/29.
- d) Certificate of Analysis from Manufacturer in respect of the lot submitted for evaluation.
- e) Batch Release Certificate (BRC) from Manufacturer/NCA/NCL of the Country of origin for the lot submitted for evaluation.
- f) Pack insert and label Claim of the Product.

Q2. What are the requirements for sample testing & fee towards Quality control evaluation?

Ans. Kindly check the link <http://www.nib.gov.in/Testing%20Fees.pdf> for sample quantity & testing fee related query.

Q3 . What is the product specific requirement?

Ans. Queries related to Blood Products Lab & Biochemical kit lab retrieval from <http://www.nib.gov.in/SRRDP.html>

Q4. What is the different type of products tested in NIB?

Ans. NIB performs quality control evaluation of Biologicals. Details can be checked from the website link <http://www.nib.gov.in/Testing%20Fees.pdf>

Q5. How do we submit fees for quality control of our products?

Ans. Kindly check the link <http://www.nib.gov.in/SRRDP.html>

Q6. What if sample dose not pertain in NIB List of Testing?

Ans. If sample does not pertain to NIB Document List of testing, stakeholder has to send an query email to NIB at the email id info@nib.gov.in and NIB will provide the appropriate response in this regard addressing the feasibility.

Q7. What is the mode of samples submission?

Ans. Sample are Submitted by Speed Post/ Couriers or Submitted manually by company representative with essential documents as per checklist and recommended storage conditions.

Q8. What is the Checklist for sample submission?

Ans. Kindly refer to the Answer to the Question No. 1.