1.4 Norms for discharge of functions [Section 4(1)(b)(iv)]

1.4.4 Time Limit for Achieving the Targets:

Turnaround Time 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

The Flow Chart given on the page 2 is indicating the process by which the quality control evaluation of biological products services can be accessed by stakeholders.

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.

01

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 is placed in batch file

02

03

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

04

- 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.

05

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