सत्यमेव जयते

Azadi Ka Amrit Mahotsav

राष्ट्रीय जैविक संस्थान NATIONAL INSTITUTE OF BIOLOGICALS

NATIONAL INSTITUTE OF BIOLOGICALS

NEWSLETTER

Issue 3: July-September 2023

Visit of Shri. Sudhansh Pant, IAS Secretary, Health & Family Welfare, Government of India, to NIB, on 8th September 2023.

Director's Desk

Our commitment at NIB is to provide a safe and intellectually challenging environment that will help in promoting public health by upholding the distinctiveness in the quality control field. The advancements in the area of Biologicals hold the potential for improving human health, welfare and economic development. NIB with an assemblage of dedicated well qualified and experienced staff, highly enthused research scholars and support staff, have embarked on a journey with an overall objective of using pervasive technologies in regulatory area for evaluating new products & identifying areas of technically feasible future applications.

With a great delight, NIB hosted the visit of Shri. Sudhansh Pant, IAS Secretary, Health & Family Welfare, GOI to NIB, on 8th Sept. 2023.

NIB was represented at 17th Vaccine Congress held at Glasgow, Scotland by Dr. Harish Chander, D.D. (QC) & Shri Subhash Chand, Scientist Grade III.

Continuing with the tradition, two-weeks hands-on Residential Training Programme on Quality control of Biologicals, for 16 Post Graduate Biotechnology Students and 02 Faculty members of Vinoba Bhave University, Hazaribag, Jharkhand was conducted from 21st August-2023 to 1st September-2023 at NIB Noida.

I am immensely proud of our committed staff who continues to demonstrate their resilience and agility as we move to new ways of working.

I wish Good Luck to All!!

Anup Anvikar

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Editorial Team

STERILITY TESTING, THE PARAMETER FOR SAFETY OF INJECTABLE BIOLOGICALS

Mr. Neeraj Malik,
Scientist Grade II, NIB

Microbiology plays an important role in Quality Control of pharmaceuticals and Biological Products, specifically in evaluation of raw material and end product. Sterility testing is a critical quality control parameter to ensure the product safety with respect to all injectable drugs including the Biopharmaceuticals and Biological Products. Conventional Sterility testing involves inoculation of test products in the Fluid Thioglycollate Medium (FTM) and Soyabean Casein Digest medium (SCDM) and after 14 days of incubation at specified temperature followed by visual examination of the media for any turbidity due to the microbial growth.

Sterility testing laboratory at NIB is a central testing facility; it tests a wide variety of biological samples that are submitted to NIB for Q.C. evaluation. The details are mentioned in below table;

S. No.	Biologicals category	No. of biological products in each category
1.	Blood Products Laboratory	25
2.	Recombinant Product Laboratory	34
3.	Enzymes And Hormones Laboratory	20
4.	Therapeutic Antibodies Laboratory	30
5.	Vaccine And Antisera Laboratory	14
6.	Covid Kit Testing Laboratory	1

Infrastructure required for a microbial testing laboratory :

The laboratory area is well designed to carry out the test on the work bench in a sterile environment as per schedule M, 5. Quality control area (1)

Clean room : A cleanroom is a controlled environment that filters pollutants like dust, airborne microbes, and aerosol particles to provide the cleanest area possible. Clean rooms are classified according to the cleanliness level of the air inside the controlled environment. The clean room class is the level of cleanliness the room complies with, according to the quantity and size of particles permissible per cubic meters of air. Particles limits as per ISO 14644-01:2015 mentioned below (2).

Requirements of the clean environment

- Air is highly (HEPA) filtered (99.97% @0.3µm)
- Layout should minimize particle sources in filtered air stream
- Air filter should remove most particles generated by process

	0.3µm	0.5µm	1µm	5µm
ISO Class 6	102000	35200	8320	293
ISO Class 7		352000	83200	2930
ISO Class 8		3520000	832000	29300

Microbial growth monitoring system :

According to the I.P. clean room is monitored for microbial growth in 2 ways,

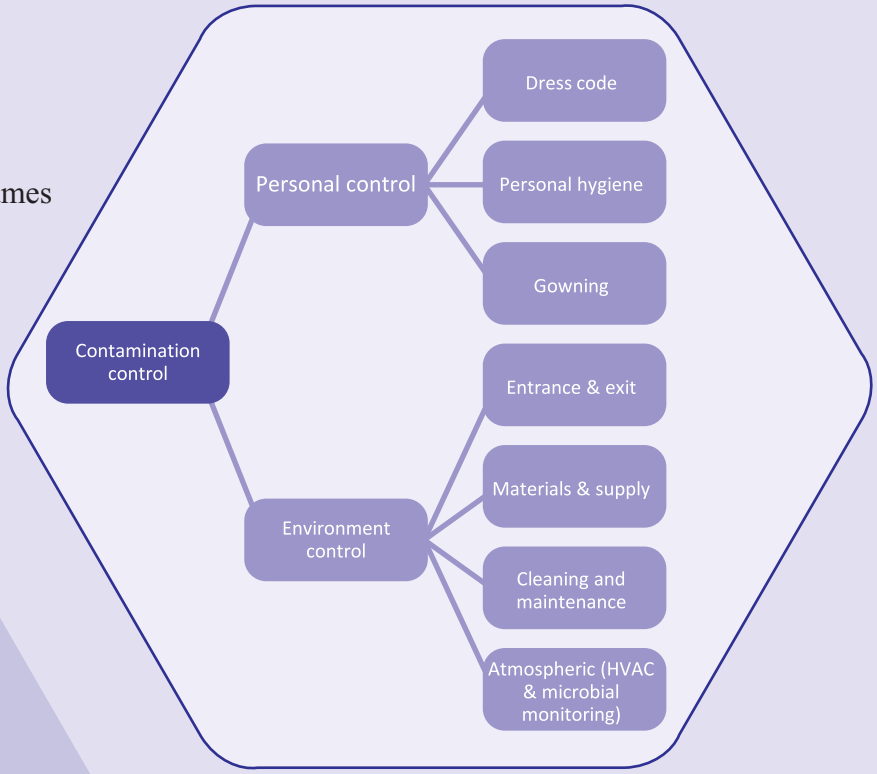
1. Personal monitoring: done during each time of testing on work bench
2. Environment monitoring: done weekly basis with both passive and active exposure of media plates.

Types of Contaminants :

Praticulate : Dust, skin, hair, Makeop

Chemicals : Oil, Grease, Metalions, Perfumes

Biologicals : Bacteria, Fungi



Contamination Sources :

- People
- Ventilation
- Room Structure
- Equipment

Good Laboratory Practice (GLP) for a Sterility Testing Laboratory :

In clean room cleanliness and tidiness should be maintained properly. Before entering to the clean room gowning should be done properly. Recommended Gowning order is mentioned below;

Gowning order

Primary Gloves → Head Gear → Coverall → Booties → Goggle → Secondary Gloves

Material And Method :

Media

I.P. describe two primary types of culture media to be used in the sterility testing of parenteral biological products. (3)

- Fluid thioglycollate media (FTM) for detection of aerobic and anaerobic bacteria
- Soyabean casean digest broth (SCDB) for detection of fungus.

Methods :

Direct transfer method: It is the most commonly followed method and carried out by transfer of the test Sample after preparation to the medium and incubate for not less than (NLT) 14 days at specified temperature.

Membrane Filtration Method :

Pre-wet the filter with peptone water → Pass the sample through it → Wash the filter thrice with peptone water → Add the required media and incubate for NLT 14 days with its specific condition

Conditions of Incubation :

S. No.	Organisms	Incubation Temperature	Incubation Time
1.	Aerobic Bacteria	30-35°C	NLT 14
2.	Anaerobic Bacteria	30-35°C	NLT 14
3.	Fungus	20-25°C	NLT 14

After incubation of 14 days with specific temperature culture media is observed visually for any growth of organisms. Positive control and negative control also run along with the samples for the test validity.

Growth Promotion Test (GPT) :

New batch of media is tested whether it is supporting the growth of the standard microbial culture or not, for this GPT is performed. According to Indian Pharmacopoeia (I.P.) seven standard cultures are used to perform the GPT with specific inoculum size.

S. No.	Name of the Organism (Positive Cultures)	ATCC No.
1.	Clostridium sporogenes	19404
2.	Pseudomonas aerugenosa	9027
3.	Streptococcus aureus	6538
4.	Bacillus subtilis	6633
5.	Candida albicans	10231
6.	Aspergillus brasiliensis	16404
7.	Bacteroides vulgatus	8482

Rapid Microbial Method (RMM) :

Rapid microbial methods supposed to be rapid, accurate and cost effective. RMM should be either equivalent or better than the existing conventional method. It is desirable to have a rapid method that can detect viable as well as non-culturable microbes (3, 4-7). Sterility testing laboratory, NIB has initiated the study on alternative RMM viz ATP Bioluminescence based kit method to detect contaminants in less time in comparison to the conventional method. ATP bioluminescence technique is one of the methods, in which contaminants can be detected based on ATP production. Further other rapid alternative methods for sterility testing are like:

- **i.** ATP Bioluminescence based automated system
- **ii.** CO_2 production based detection
- **iii.** Detection of live cells through FACS or any other suitable method.

References :

1. Drugs and cosmetics rules, 1945, schedule M, 5. Quality control area, 376
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VISITS :

- **Shri. Sudhansh Pant,** IAS Secretary, Ministry of Health & Family Welfare, Government of India visited NIB on 8th September 2023 along with Dr. Kiran, DS, MOHFW. He interacted with Scientists of NIB and discussed the significance of Quality Control of Biologicals in the interest of public health.

- **Dr. Dilip Kumar Panda,** Technical officer, Central Drugs Laboratory, Kolkata visited Enzymes and Hormones Laboratory on 21st & 22nd September - 2023 to discuss technical issues related to the Quality Control testing of various Enzymes and Hormones.

PROFICIENCY TESTING (PT) / EXTERNAL QUALITY ASSURANCE SCHEME (EQAS)

- Biochemical Kit Laboratory is enrolled into the Association of Clinical Biochemists of India/ Christian Medical College (ACBI/CMC) External Quality Assessment Scheme (EQAS) - 2023 for Chemistry II (Glucose, Cholesterol, Triglyceride, Creatinine, Uric acid & Albumin), conducted by the Department of Clinical Biochemistry, Christian Medical College, Vellore. The test was put up on 06.07.2023, 04.08.2023 & 05.09.2023 for Chemistry II and the generated results were uploaded on the CMC-EQAS website.
- Immunodiagnostic Kit Laboratory has participated in the 2nd Round of EQAS 2023 organized by NRL, Australia for the Multi-marker Blood Screening Serology Programme.
- The Molecular Diagnostics Laboratory has participated in EQAS conducted by NRL-Australia for Event-3 2023 NAT Proficiency Testing. The lab put-up the tests for viral load monitoring of HBV, HCV, HIV and Qualitative Multi-marker blood donor screening.

TECHNICAL EXPERT COMMITTEE MEETINGS :

- Dr. Gauri Misra, Head, CKTL - MDL & SRRDU attended the First Hub meeting by BIRAC virtually on 07.07.2023 and 04.08.2023 for addressing queries of innovators as an external expert

- Dr. Meena Kumari, Head, BPL, Ms. Kanchan Ahuja, Head, BRL, Ms. Y. Madhu, Scientist Grade-III, Dr. Manoj Kumar, Scientist Grade-III & Sh. Tara Chand, Scientist Grade-III attended "8th Meeting of the Expert Working Group-Blood and Blood-related Products" at Indian Pharmacopoeia Commission, Ghaziabad on 25.09.2023.

WORKSHOPS/ CONFERENCES/ SEMINARS :

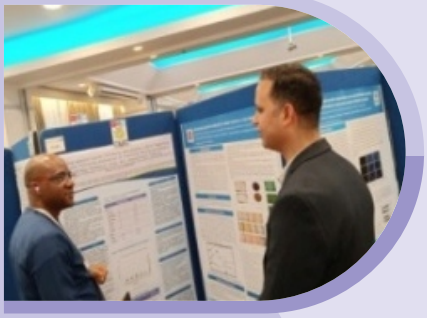
- Dr. Charu M Kamal, Head, RPL & EHL, Ms Y. Madhu Scientist Grade-III, Mr. N Nanda Gopal Scientist Grade-III, Dr. Sanjay Mendiratta Scientist Grade-III, Mr. Anoop, Junior Scientist, Mr Mohitlal, Lab Technician attended a One-day seminar on Insights into Recombinant LAL and automation in BET on 18.07.2023 organized by Charles River Laboratories in New Delhi.

- Dr. Charu M Kamal, Head, RPL & EHL, Ms Rashmi Srivastava, Scientist Grade-III and Sri. Q.W.Zaheeruddin, Senior Administrative Officer (P) attended Workshop on "Prevention of Sexual Harassment of Women at Workplace" held from 24.9.2023 to 27.09.2023 organized by National Academy of Human Resources and Development (NAHRD) at Goa

TRAININGS :

- Dr. Meena Kumari, Head, BPL, Ms. Y. Madhu, Scientist Grade-III, Mr. Anoop, Junior Scientist, Mr Mohitlal, Lab Technician and Mr. Reetesh, Lab Technician attended a One-day Hands-on training on various methods of BET on 01.09.2023 organized by Charles River Laboratories in New Delhi.

- Dr. Harish Chander, Deputy Director (QC) & Shri Subhash Chand, Scientist Grade III participated in the 17th Vaccine Congress held at Glasgow, Scotland, from 24th -27th September 2023. They also visited The National Institute for Biological Standards and Control (NIBSC) UK, on 28.09.2023 for a scientific interaction with NIBSC, UK Scientists.



- Five days "**Short -Term Training Course** comprising of demonstration and Hands-on practice **on RT-PCR including RNA extraction"** held from 03rd - 07th July, 2023 organized in CKTL & MDL.

- Five days structured training entitled **"Quality Control of Blood Products using Atomic Absorption Spectrometry (AAS)"** comprising of demonstration and Hands-on practice held from 07th-11th August 2023**,** in Blood Products Laboratory.

- Five days structured trainings entitled **"Cell Culture based Techniques for evaluation of Biologicals and Vaccines"** conducted from 21st-25th August 2023 and 18th - 22nd September 2023, in Vaccine and Antisera Laboratory. Total nine participants attended this course.

- Five days structured training entitled **"Internal Quality Control and method validation Basics"** conducted from 18th-22nd Sept.2023 in Biochemical Kit Laboratory. Total 05 participants attended this training course.

- Two-Weeks Hands-on Residential Training Programme on Quality control of Biologicals, for 16 Post Graduate Biotechnology Students of Vinoba Bhave University, Hazaribag, Jharkhand has been conducted from 21st August-2023 to 1st September-2023 at NIB Noida.

AWARDS :

- Dr. Shikha Yadav, Head, *In-Vivo* Bioassay Laboratory & Animal Facility had been selected by the AAALAC International Council on Accreditation as an Ad hoc Specialist for the period 2023 to 2026.
- Dr. Gauri Misra, Head. SRRDU, Molecular Diagnostic & COVID kit testing Laboratories has been awarded 'InRes C V Raman Prize 2023' and 'InRes Research Excellence Award 2023' by the Ministry of MSME and Ministry of Corporate Affairs, Government of India.
- Ms. Gurminder Bindra, Scientist Grade-III secured second Protsahan prize in Ashu Bhashan Pratiyogita organized by Nagar Rajbhasha Karyanvayan Samiti, NOIDA on 09.08.2023.

ACCREDITATION : NIB received its accreditation renewal validity for ISO/IEC 17025:2017 till 15 August 2025 with the enhanced scope of tests in the field of Biological and Chemical testing.

HINDI PAKHWADA 2023 : NIB celebrated Hindi Diwas and Hindi Pakhwad from 14.09.2023 to 29.09.2023 with high spirit and enthusiasm. Several competitions have been organised to encourage the use of Hindi language in regular office work among staff.

SUPERANNUATION :
Shri. Pradeep Kumar, Administrative Assistant, retired from his services on 30.09.2023.
NIB wishes him a happy and healthy retired life.

KNOWLEDGEMENT : Newsletter Editorial Team acknowledges the contribution of all the staff members of NIB.

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