



NATIONAL INSTITUTE OF BIOLOGICALS NEWSLETTER

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Issue #2





Director's Desk

As the year progress to the next quarter, I am happy to see more and more involvement of NIB scientists in multifaceted fields including development of Biological reference standards, extramural projects and capacity building programmes.

The second quarter of the year 2024, is highlighted with the participation of scientists in WHO SEAR Regional Hybrid workshop on improving access and building capacity on the optimal use of reference standards held on 14th-15th May, 2024. Our efforts to bring more Extramural projects related to our mandate has become fruitful with the grant of ICMR project on Advanced Center for Clinical Evaluation of Diagnostics of National Importance and NIB also filed a patent related to Omicron and Delta Variant of SARS CoV-2 in vitro diagnostics. The institute has enhanced its capacity to test newer biologicals and is using its expertise in Quality control of Biologicals for strengthening the field of biologicals in the other countries of the world.

As per the initiative of Government of India to enhance the competencies of individual officials and the Departments and organizations as a whole, Annual Capacity Building Plan for NIB has been developed and is being implemented in phased manner. Continuing with its tradition of training the students under National Skill Development and hands on Training on Quality Control of Biologicals, NIB has conducted two training programmes in this quarter for Postgraduate students from various universities from Jharkhand and Chhattisgarh. NIB has also imparted 4-6 months project work to post-graduate students with an aim to build up the 'National Talent Pool of skilled and trained manpower' and thus to facilitate Make in India by providing availability of skilled scientific manpower for industry or research endeavour in the field of biologicals.

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!!

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Antibiotics: An overview and their impact in public health

Dr. Rajesh Kumar Sharma, Scientist Grade-III, IDKL, NIB

Antibiotics are essential medications used to combat bacterial infections in humans and animals. They are among the most frequently prescribed medications in modern era. They have revolutionized medicine by saving countless lives by killing bacteria (bactericidal) or making it more difficult for bacteria to grow and multiply i.e. inhibit their growth (bacteriostatic). Here is an overview of antibiotics and their impact in public health:

How Antibiotics Work:

- **Targeting Bacterial Structures:** Antibiotics interfere with specific bacterial structures or processes. For instance:
 - **Cell Wall Synthesis Inhibitors:** Penicillins and cephalosporins prevent bacteria from building their protective cell walls.
 - **Protein Synthesis Inhibitors:** Macrolides and aminoglycosides disrupt bacterial protein production.
 - **DNA/RNA Synthesis Inhibitors:** Quinolones interfere with bacterial DNA replication.

Types of Antibiotics:

These drugs are grouped according to their antibacterial activity and chemical structure.

- **Penicillins:** Derived from *Penicillium* fungi and widely used to treat a variety of infections, including skin infections. penicillin include penicillin V, penicillin G, amoxicillin and ampicillin. Penicillin kills bacteria through binding of the beta-lactam ring to DD-transpeptidase, inhibiting its cross-linking activity and preventing new cell wall formation.
- **Cephalosporins:** They are β -lactam antimicrobials used to manage various infections caused by both gram-positive and gram-negative bacteria. antimicrobials that work via their β -lactam rings. The β -lactam rings bind to the penicillin-binding protein and inhibit its normal activity. Unable to synthesize a cell wall, the bacteria die.
- **Aminoglycosides:** They are a class of antibiotics used mainly in the treatment of aerobic gram-negative bacilli infections. aminoglycosides depends on the inhibition of polypeptide synthesis.
- **Tetracyclines:** They are classified as protein synthesis inhibitor antibiotics and are considered to be broad-spectrum. Tetracyclines specifically inhibit the 30S ribosomal subunit, hindering the binding of the aminoacyl-tRNA to the acceptor site on the mRNA-ribosome complex. When this process halts, a cell can no longer maintain proper functioning and will be unable to grow or further replicate.
- **Macrolides:** They are a class of mostly natural products with a large macrocyclic lactone ring. Macrolides are protein synthesis inhibitors.
- **Fluoroquinolones:** They are a family of broad spectrum, systemic antibacterial agents that have been used widely as powerful broad-spectrum antibiotics. Fluoroquinolones target DNA gyrase and topoisomerase IV with varying efficiency in different bacteria and inhibit their control of supercoiling within the cell.

Future Directions:

- **Phage Therapy:** Using bacteriophages to target specific bacteria.
- **Antibiotic Alternatives:** Exploring natural compounds and innovative approaches.

Basic Concept:

Antibiotics are a boon for the world but their misuse or using them without doctor's advice can be very dangerous. In general, each time people take or give the child an antibiotic unnecessarily or improperly, mean we increase the chance of developing medicine-resistant bacteria. It is important to understand that a common misconception is that a person's body becomes resistant to specific medicines. However, it is wrong, the truth is that bacteria, not people, that become resistant to the antibiotics. Antibiotics are useless against viral and fungal infections. Doctors are the best to understand the types of diseases and their treatment, especially the use, dosage and duration of taking antibiotics.

A Global Concern:

- **Antibiotic Resistance:** Overuse and misuse of antibiotics contribute to resistance.
- **Superbugs:** Resistant bacteria (e.g., MRSA, CRE) pose serious threats.

- **Combating Resistance:** Proper antibiotic stewardship, new drug development, and infection control are crucial.

Remember, antibiotics are powerful tools, but responsible use is vital to preserve their effectiveness.

- World Health Organization (WHO). “Antibiotic Resistance.”
- News Medical life Sciences
- National Library of Medicines, National Center for Biotechnology information, National Institute of Health.
- Study.com
- Wikipedia
- Science Direct
- Medline plus
- eMedicineHealth
- Cleveland Clinic
- Medical News today
- NHS UK
- Johns Hopkins Medicine
- CDC US centers for Disease Control and Prevention

Virtual Participation of NIB Scientists in WHO-SEAR Regional Workshop on improving access and building capacity on the optimal use of reference standards held at Bangkok, Thailand, 14th & 15th May, 2024

Dr. Harish Chander DD(QC), Dr. Charu M Kamal Scientist-I, Ms. Sudha V Gopinath Scientist-II and Dr. Subhash Chand Scientist -III participated online in the **Regional hybrid workshop on improving access and building capacity on the optimal use of Reference Standards, Bangkok, Thailand, 14th–15th May, 2024** organized by WHO SEAR.

Dr. Harish Chander Presented a talk on Experiences from the region on the establishment of Biological Reference Standards.



Visit of International Delegates from Indonesia for Hands-on training on Quality Control Testing of In-vitro diagnostic kits.



02 delegates from Indonesia visited the Immunodiagnostic Kit Laboratory on 29th April, 2024. Hands-on training on quality control testing of In-vitro diagnostic kits was provided to the delegates.

Research and Development activities

EXTRAMURAL PROJECT

Dr. Gauri Misra, Scientist - I has secured the **extramural project** (funded by ICMR, New Delhi) in collaboration with various IITs, viz., IIT Kanpur, IIT Delhi, AIIMS, New Delhi, Vardhman Mahavir Safdarjung Hospital, New Delhi and various institutions of ICMR.

Project title: “Advanced Center for Clinical Evaluation of Diagnostics of National Importance” – Project ID: ICMRCAREP-2023-0000517.

Quality Assurance/Quality Control of Bio-Therapeutics, Prophylactic and In-vitro Diagnostics

- Recombinant Products Laboratory has established and standardized a new biological under the anti-diabetic category "Soliqua solostar (Fixed ratio combination of Insulin Glargine + Lixisenatide)" and released its Certificate of Analysis (CoA). This product has been received for the first time at NIB.
- Blood Reagent Laboratory participated in Proficiency Testing (PT) with Indian Red Cross Society (IRCS), New Delhi for Anti-A, Anti-B, Anti-AB, Anti-D (IgM) Anti-A1 Lectin, and Anti-H Lectin.
- Recombinant Products Laboratory, Therapeutic Antibody Laboratory & Enzymes and Hormones laboratory successfully qualified in Proficiency Testing Program on pH and for the Round-01/2024 for pH and Chromatographic purity by HPLC conducted by Indian Pharmacopoeia Commission, Ghaziabad.
- Scientists of Vaccine and antisera lab virtually attended 13th Meeting of Expert Working Group (EWG) – Vaccine & Immunoserum for Human Use held on 1st April, 2024 to discuss the proposed amendments in General Chapters and Vaccine-Specific monographs.
- A meeting with officials from Indian Pharmacopoeia Commission (IPC), Ghaziabad was held 10th April, 2024 at NIB to discuss on draft monographs of Trastuzumab DS and DP. DR. Charu Mehra Kamal, Scientist – I, Dr. Ratnesh Kumar Sharma, Scientist – II, Dr. Saurabh Sharma, Scientist – III, Dr Subhash Chand Scientist-III and Dr. Paras Jain, Junior Scientist participated in the meeting.
- Inhibition of proliferation assay for assessing biological activity of Trastuzumab was communicated to IPC for incorporation in next edition of IP monograph.
- Dr Subhash Chand, Scientist -III had been appointed as Observer by National Accreditation Board for Testing and Calibration Laboratories (NABL) for the assessment of a CAB as per ISO/IEC 17025:2017 at New Delhi on 4th and 5th May, 2024.
- Vaccine and Antisera Laboratory was audited by CDSCO officials on 9th – 10th May, 2024 to assess the testing facilities for Oral Polio Vaccine & Rabies Vaccine.



- Dr Harish Chander (DDQC), Dr Subhash Chand Scientist -III and Mr. Ajay Ade Junior Scientist visited NIMHANS Bengaluru (WHO collaborative center for Rabies) for Rabies CVS adaptation to cell culture and standardization of Rapid Fluorescent Focus Inhibition Test (RFFIT) for estimation of rabies immunoglobulins from 24th June, 2024 – 28th June, 2024.

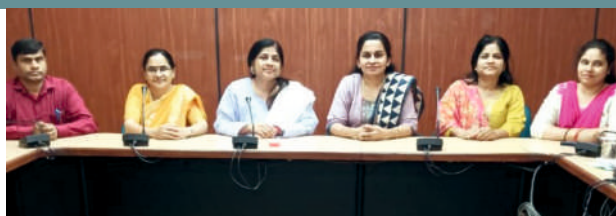
Nomination/participation of NIB scientists in various meetings/ workshops/ conferences/ seminars

- Dr. Gauri Misra, Scientist -II virtually attended the FIRST HUB meeting (special session) of DBT-BIRAC on 5th April, 2024 for addressing queries of innovators.
- Dr. Gauri Misra, Scientist - II virtually attended as an external expert the 'Technical cum Purchase Committee' meeting of NIMR on 5th April, 2024 and 15th-16th April, 2024.
- Dr. Gauri Misra, Scientist- I, has virtually attended 12th Technical Advisory Committee (TAC) meeting of MedTech Mitra on 8th-10th April, 2024 and 15th April, 2024.
- Ms. Kanchan Ahuja, Scientist Grade-II attended a CME cum workshop on “Advanced ABO blood grouping and Rh phenotyping” on 9th & 10th April, 2024 at Institute of Liver and Biliary

Sciences (ILBS) Vasant Kunj, New Delhi.



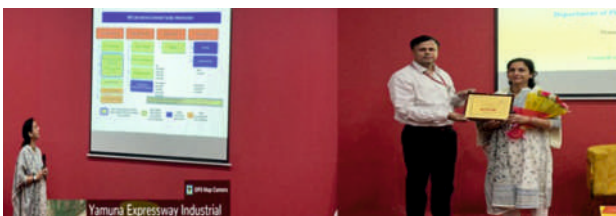
- Dr. Meena Kumari, Scientist -II, Ms Kanchan Ahuja, Scientist II, Ms. Y. Madhu, Scientist Grade-III and Mr. Tara Chand, Scientist -III attended 9th meeting of Expert Working Group-Blood and Blood Related Products at Indian Pharmacopoeia Commission, Ghaziabad on 12th April, 2024.



- Dr. Gauri Misra, Scientist-II has been appointed as an Interview Board member for the post of Examiner of Patents and Design by National Testing Agency (NTA) from 19th – 25th April, 2024.
- Dr. Shikha Yadav, Scientist-I delivered a talk on “Post-Operative Care” on 26th April, 2024 in the Rodent Surgery Workshop organized by Institute of Liver and Biliary Sciences (ILBS), Delhi.



- Dr. Gauri Misra, Scientist -I delivered keynote address on 'Fostering Indian Pharmaceutical Industries and Challenges in Sustainable Environment Development' from 27th – 28th April, 2024 at Galgotias University, Greater Noida, UP.



- Dr. Harish Chander DDQC & Dr. Paras Jain, Junior Scientist attended a summit organized by Economic times on 27th April, 2024 at Mumbai



- Ms. Rashmi Srivastava, Scientist-III attended Technical Evaluation and Negotiation committee meeting of ICMR- NICPR, NOIDA as an External expert & Chair on 1st May, 2024.
- Dr. Gauri Misra, Scientist -I, virtually attended committee meeting on 8th May, 2024 regarding online application in form MD-28 for granting permission of new in vitro diagnostics medical device for the detection of Covid-19 organized by CDSCO, New Delhi.
- Ms. Rashmi Srivastava, Scientist-III attended

Meeting on 13th May, 2024 with representatives from ICWAI and ICMR regarding Cost fixation for IVD testing by ICMR at ICMR HQ, New Delhi.

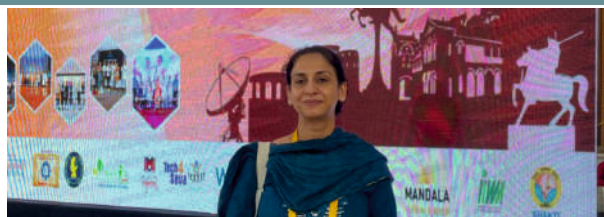
- Dr. Gauri Misra, Scientist- I, virtually attended as an expert in the National Level Malaria Working Group meeting organized by ICMR headquarters on 15th & 16th May, 2024.
- Mr. Anoop Kumar, Jr. Scientist & Mr. Reetesh Kumar Prajapati, Laboratory Technician attended a seminar on “Advanced Analytical Solutions in Ion Chromatography” on 22th May, 2024 at Delhi.
- Dr. Akanksha Bisht, Scientist-I attended 32nd GB meeting of National Blood Transfusion Council (NBTC) under the Chairmanship of (Prof.) Dr. Atul Goel, DGHS on 29th May, 2024 at 4:00 p.m. at Nirman Bhawan, New Delhi.
- Reference Standard Unit Organized a meeting with WHO SEAR officials Dr. Adrien Inoubli and Dr. Ani Chawla to discuss on Role of NIB in Improving access to Biological Standards in SEAR. Dr. Harish Chander DDQC, Dr. Charu M Kamal Scientist-I, Ms. Sudha V. Gopinath Scientist-II and Dr. Subhash Chand, Scientist - III participated in the online meeting held on 31st May, 2024.
- Dr. Suresh Kumar, Scientist -III attended the Institutional Animal Ethics Committee (IAEC) meeting as a CCSEA nominee “Link Nominee” to review the research protocols at Dhiti Life Sciences, New Delhi on 1st June, 2024.
- Dr. Gauri Misra, Scientist - I, has virtually attended the MHD 20 - Medical Biotechnology and Medical Nanotechnology organized by BIS HQ held on 6th June, 2024.
- Ms. Shalini Tewari, Scientist-III and Ms Rashmi Srivastava, Scientist-III virtually Attended the Sixteenth meeting of the Medical Biotechnology and Medical Nanotechnology Sectional Committee (MHD 20) of the Bureau of Indian Standards (BIS) on 6th June, 2024 as an alternate member from NIB.
- Ms. Rashmi Srivastava Scientist -III delivered Lecture as an Expert on CMDTL requirements at CDSCO- NABL ICMR Joint program for IVD testing laboratories as CMDTL/ MDTL regarding regulatory and accreditation requirements at ICMR HQ, New Delhi and ICMR-NIE, Chennai on 7th June, 2024.



- Dr. Akanksha Bisht, Head - IDKL and HvPI and Dr. Rajesh Kumar Sharma, Scientist – III participated in 2.0 km Walkathon (in morning) and candle lighting (in evening) for celebrating World Blood Donor Day organized by NIB on 14th June, 2024.



- Dr. Rajesh Kumar Sharma, Scientist -III, attended meeting under Chairmanship of Prof. (Dr.) Atul Goel, DGHS on 15th June, 2024 at Nirman Bhawan, New Delhi.
- Dr. Gauri Misra, Scientist - I, has attended 6th Vigyan Bharti Adhiveshan on 22nd-23rd June, 2024 at Pune, Maharashtra.



- Dr. Shikha Yadav, Scientist-I delivered lecture on “Ethical Evaluation– An International Perspective and Severity Classification” in FELASA (Federation of European Laboratory Animal Scientists Association) at Tamil Nadu Veterinary and Animal Sciences University (TANUVAS), Chennai on 24th June, 2024.
- Dr. Shikha Yadav, Scientist-I attended the Institutional Animal Ethics Committee (IAEC) meeting of Bio-Med Pvt Ltd, Ghaziabad as the main Nominee of CCSEA on 26th June, 2024 to review their research protocols for ethical approval.

TRAININGS

- Two weeks residential NSDT programme on “Quality Control of Biologicals” with total 36 participants (35 M.Sc. Biotechnology Students + 01 Faculty member) from Guru Ghasidas Vishwavidyalaya, Bilaspur, Chhattisgarh) was conducted from 22nd April to 3rd May, 2024.



- NIB organized a Training cum-Orientation Programme on “Building Effective Teams” and Motivation' for research scholars, held on 29th April, 2024 imparted by Symbiosis Centre for Management Studies SCMS Noida.



- Mr. Sanjeev, S.O. Finance, participated in Two-Days Online “Workshop on Income Tax” from 13th - 14th May, 2024 organized by Institute of Secretariat Training and Management (ISTM, Delhi).
- Two weeks residential NSDT programme on “Quality Control of Biologicals” involving total

30 participants (29 M.Sc. Biotechnology Students + 01 Faculty member) from Vinoba Bhawe University Hazaribagh, (Jharkhand) conducted from 3rd – 14th June, 2024 at NIB Noida



- Five-days training course entitled as “Cell Culture based Techniques for evaluation of Biologicals and Vaccines” conducted from 24th – 28th June, 2024 in Vaccine and Antisera



Laboratory.

- Ms. Sudha V. Gopinath Scientist -II participated in Two Days Online Training Workshop on “Inter Laboratory Comparison, Proficiency Testing & Evaluation of Scores (ILC-PT)”, held on 24th - 25th June 2024, organized by National Institute of Training for Standardization NITS-Noida.

PUBLICATIONS

- Kasana H, Ade AK, Meena J, Sayal A, Sheikh F, Anvikar AR, Chander H. SARS-CoV-2 spike protein expression as an identification in quality control testing for Adenovector based COVID-19 vaccine. Journal of Immunological Methods. 2024 Jun 1; 529: 113680. Impact Factor 5.3].
- Harsha Rohira, Sujithra Shankar, Shikha Yadav, Priyanka P. Srivastava, Shilpi Minocha, Pravin K. Vaddavalli, Sushmita G. Shah, Archana Chugh, RiTe conjugate mediated corneal collagen crosslinking, a novel therapeutic intervention for keratoconus – in vitro and in vivo study. International Journal of Pharmaceutics, 2024 Volume 656, 124092. <https://doi.org/10.1016/j.ijpharm.2024.124092> [ISSN- 0378-5173 (print); 1873-3476 (web),
- Dr. Gauri Misra, Scientist Gr. I, and Head has published a patent title “Allele Specific Primer-Probe Sets Based Kit for the Rapid and Accurate Diagnosis and Differentiation of Omicron and Delta Variant of SARS CoV-2” in the Name of National Institute of Biologicals (NIB), Patent Application No. 202411038068.
- Dr. Gauri Misra, S-I and Head has published the following International Book-
“Quality Control and Regulatory Aspects for Biologicals: Regulations and Best Practices”, 2024, Taylor & Francis, CRC Press, Boca Raton. *eBook ISBN: 9781032697444*-
- Anoop Kumar, Gauri Misra *et al.*, (2024) Multi-epitope vaccine design using in silico analysis of glycoprotein and nucleocapsid of NIPAH virus. Plos One, 19(5):e0300507. doi: 10.1371/journal.pone.0300507
- Kumar, S., Atul, P.K. (2024). Animal Models for Gut Microbiome Research. In: Vijayakumar Sreelatha, H., Patel, S., Nagarajan, P. (eds) Animal Models in Research. Springer, Singapore. https://doi.org/10.1007/978-981-97-0048-6_10.
- Satyajeet Singh, Manika P Sharma and Gauri Misra, 'Regulatory Bodies: European Medicines Agency (EMA) and Pharmaceutical Inspection Co-operation Scheme (PIC/S)' in Quality Control and Regulatory Aspects for Biologicals: Regulations and Best Practices”, 2024, Ed. Gauri Misra, Taylor & Francis, CRC Press, Boca Raton.
- Bhartendu Sharma, Priyanshi Singh, Supriya Shukla and Gauri Misra, 'Good Manufacturing Practices In Quality Control' in “Quality Control and Regulatory Aspects for Biologicals: Regulations and Best Practices”, 2024, Ed. Gauri Misra, Taylor & Francis, CRC Press, Boca Raton.
- Ashwini Kumar Dubey and Mahima Gupta, 'Importance of Quality Control in Biologicals' in “Quality Control and Regulatory Aspects for Biologicals: Regulations and Best Practices”, 2024, Ed. Gauri Misra, Taylor & Francis, CRC Press, Boca Raton.
- Tara Chand and Ashwini Kumar Dubey, 'Quality control considerations specific to the development and production of gene and cell therapies' in “Quality Control and Regulatory Aspects for Biologicals: Regulations and Best Practices”, 2024
- Anoop Kumar, 'Animal-Based Testing Methods and Their Alternatives In Quality Control Evaluation Of Biologicals' in “Quality Control and Regulatory Aspects for Biologicals: Regulations and Best Practices”, 2024, Ed. Gauri Misra, Taylor & Francis, CRC Press, Boca Raton.

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