सत्यमेव जयते

Azadi Ka Amrit Mahotsav

NATIONAL INSTITUTE OF BIOLOGICALS
NEWSLETTER

First National Conference on Haemovigilance

Issue 4, October - December, 2021

Director's Desk

NIB is unceasingly booming with its aim of nurturing and promoting public health and safety by maintaining the distinctiveness in the quality control field. The institution is successfully forging ahead a fruitful scientific arena by testing biologicals and creating new opportunities for enhancement of knowledge and development of professional skills.

In December 2021, we organized the First National Conference on Haemovigilance virtually. Dr. Mansukh Mandaviya, Union Health Minister, Ministry of Health & Family Welfare, Government of India was the Chief Guest, while Shri. Rajesh Bhushan, Union Secretary Health was the Guest of Honour. Dr. Mandeep Kumar Bhandari, Joint Secretary (R), Dr. V. G. Somani, Drugs Controller General (I) and Dr. Rajeev Singh Raghuvanshi, Director, IPC, also graced the conference. The conference was attended by various experts in the field and 2763 delegates.

Continuing with the tradition of Training the Trainers of the Blood Banks, NIB has trained 36 Blood Bank Officials and Technicians from the state of Chhattisgarh during this period in collaboration with Blood Cell, NHM, Ministry of Health & Family Welfare, Government of India. Also under Pradhan Mantri Kaushal Vikas Yojana programme on National Skill Development, NIB has organized a Residential Hands-on Training programme in Quality control of Biologicals, for 14 M.Sc. Biotechnology Students from Vinoba Bhave University, Hazaribagh (Jharkhand).

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
Director

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Ms. Y. Madhu
Editor

Mr. Jaipal Meena
Associate Editor

Dr. Manjula Kiran
Associate Editor

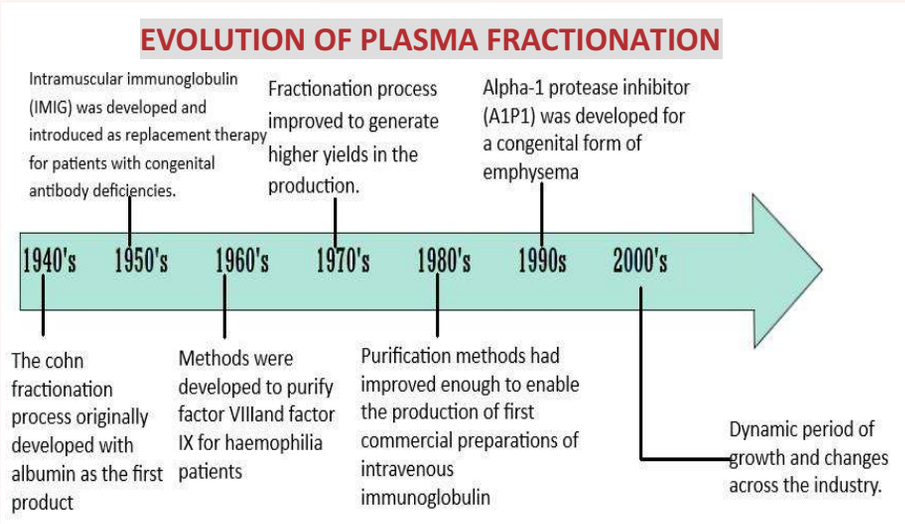
Ms. Apoorva Anand
Associate Editor

SAFETY AND QUALITY OF BLOOD PRODUCTS

Dr. Meena Kumari, Scientist-II

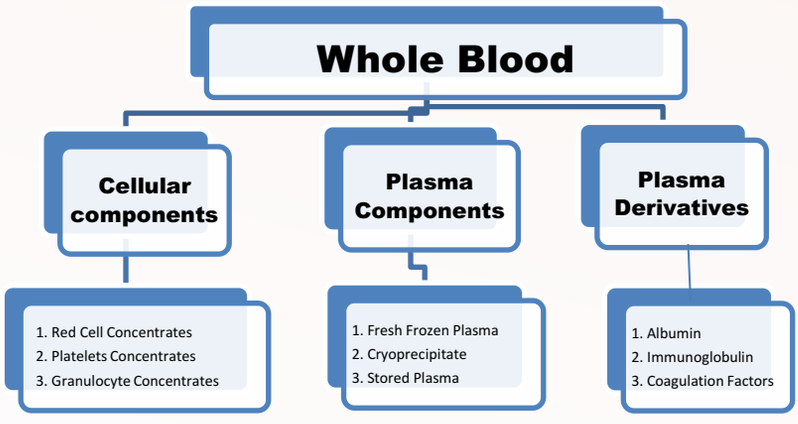
Blood is considered as river of life, Fluid of life, growth and health. Average human has 5 litres of blood i.e. 8% of total body weight. Blood is a specialized type of connective tissue in which living blood cells are suspended in a fluid matrix called plasma. It carries vital substance to all parts of body. Blood component preparation was developed in 1960 to separate blood products from one unit whole blood by a specialised equipment called as refrigerated centrifuge, which are collected from a donor for use in blood transfusion. Cohn's developed stable plasma protein solution for the treatment of battlefield injuries in the Second World War. Slowly the plasma fractionation evolve as the technology upgrade.

Whole blood is now rarely used for transfusion. Blood component therapy makes clinical sense as most patients require a specific element of blood, such as red cells or platelets, and the dose can then be optimised. Each component is stored under ideal conditions and the use of precious blood donations becomes more efficient. The current intention of transfusion medicine is to improve the quality of blood components in response to the clinical requirements.



A constituent of blood (erythrocytes, leukocytes, platelets, cryoprecipitate and plasma) that can be prepared by various separation methods and under such conditions that it can be used either directly for therapeutic purposes or for further processing/manufacturing. Blood Products are classified as blood components prepared in the blood transfusion centre or plasma derivatives manufactured from pooled plasma donations in plasma fractionation centres (such as albumin, coagulation factors and immunoglobulins).

Quality control (QC) is required testing to ensure that products or processes are meeting standards. Quality control is that part of Good Manufacturing Practice (GMP) which is concerned with specifications, sampling and testing. Quality control is also concerned with the organization, documentation and release procedures which ensure that the necessary and relevant tests are carried out. Regulatory guidelines for Quality Control testing of Blood Products is given in various Pharmacopoeia viz. Indian Pharmacopoeia , European Pharmacopoeia and British Pharmacopoeia .Various methods for testing of plasma derived products as per Indian Pharmacopoeia are as mentioned below:



S. No.	Test Parameters	Methods
1.	Identification	Double Immuno Diffusion Immuno-electrophoresis ; Gel Electrophoresis ; Assay
2.	Purity	HPLC (Related Protein & High Molecular Weight Protein; SEC) Protein composition (Horizontal electrophoresis)
3.	Impurities	Anti-A, Anti-B Haemagglutinins & Anti-D Antibody Haem & Pre Kallikrein Activity Immunoglobulin A & Anti-Complementary Activity
4.	Potency	Factor VIII, Factor IX, Fibrinogen, Thrombin, Etc. Specific potency assay IgG & Total protein content
5.	General Safety	Sterility & Bacterial Endotoxin Test Pyrogen & Abnormal toxicity
6.	General Test	pH / Osmolality / Moisture content
7.	Test for Limits	Sodium & Potassium Activated coagulation factors & Heparin & HBsAg Titre
8.	Viral Markers	HIV 1& 2 Ab / Anti-HCV Ab / HBsAg

The quality control of blood products ensures the timely availability of a blood component of high quality with maximum efficacy and minimal risk to potential recipients. To achieve the highest level of accuracy and reliability, standard QC/QA testing procedures and conditions must be practiced in laboratories on an everyday basis.

According to WHO Guidelines for national regulatory authorities (NRA) on quality assurance of biological products, NRAs have the duty to ensure that available biological products, whether imported or manufactured locally, are of good quality, safe and efficacious, and should thus ensure that manufacturers adhere to approved standards of quality assurance and good manufacturing practice. NRA responsibilities should also include the enforcement and implementation of effective national regulations, standard settings and controls. The evaluation and control of the quality, safety and consistency of production of blood products involve the evaluation of the starting material, production processes and test methods to characterize batches of the product. This requires specialized expertise by the NRA.

In August 2020, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for convalescent plasma for the treatment of hospitalized patients with COVID-19. On February 4, 2021, the FDA revised the convalescent plasma EUA to limit the authorization to high-titer COVID-19 convalescent plasma.

Having said that, it is anybody's guess, we can't live without blood. Without blood, we couldn't keep warm or cool off, we couldn't fight infections, and we couldn't get rid of our own waste products. Blood, therefore, is a vital body fluid – lifeline of a body that performs many important functions.

NIB IN THE SERVICE TO NATION DURING COVID 19 PANDEMIC:

- NIB is engaged in testing the COVID-19 suspected patient samples receiving from various hospitals, and quarantine centres of Uttar Pradesh (Baghpat, Gautambudh Nagar). During the period from October to December 2021, NIB has tested about 42527 COVID-19 suspected clinical samples. Out of which only 24 samples were found positive, indicating a significantly low positive rate of infection.

- Government of India in public interest so as to meet the requirements of emergency which have arisen due to COVID-19 pandemic has notified NIB- Noida, vide Gazette notification CG-DL-E-13122021-231820 dated 13th December, 2021 in addition to its existing functions to perform the function of Central Drugs Laboratory as an additional facility in respect of COVID-19 vaccine via official gazette. The notification shall remain into force for a period up to 30th November, 2022.

FIRST NATIONAL CONFERENCE ON HAEMOVIGILANCE:

Haemovigilance Programme of India entered into 10th year on 10th December, 2021 and on this occasion the First National Conference on Haemovigilance via online mode was organized by NIB for 3 days from 9th - 11th December, 2021. Dr. Mansukh Mandaviya, Union Health Minister, Ministry of Health & Family Welfare, Government of India was the chief guest for the conference and addressed the fraternity about utmost significance of Haemovigilance Program. The other guests who were the part of the inaugural ceremony and addressed the gathering were Shri. Rajesh Bhushan, Secretary, Ministry of Health & Family Welfare, Government of India; Dr. Mandeep Kumar Bhandari, Joint Secretary (R), Ministry of Health & Family Welfare, Government of India; Dr. V. G. Somani, Drugs Controller General (I), CDSCO, New Delhi and Dr. Rajeev Singh Raghuvanshi , Secretary-cum-Scientific Director, IPC, Ghaziabad. Dr. Anup Anvikar, Director NIB welcomed the dignitaries & the participants. About 2763 number of registrations were done for the conference and about 70 abstracts were submitted for the conference. Apart from online platform many participants participated the conference through the live streaming on you tube channel of the First National Conference on Haemovigilance.

FIRST DAY (09th Dec., 2021)

SECOND DAY (10th Dec., 2021)

THIRD DAY (11th Dec., 2021)

A glance from the First National Conference on Haemovigilance showing various Chairpersons, Speakers

COLLABORATION(S)/PROFICIENCY TESTING (PT)/ EXTERNAL QUALITY ASSURANCE SCHEME (EQAS):

- Therapeutic Antibody Laboratory has participated in the International Collaborative study by The National Institute for Biological Standards and Control (NIBSC), U.K for development of 1st WHO International standard for the biological activities of Cetuximab.

- Vaccine & Antisera Laboratory has participated in International Collaborative study (BSP-148) for the standardization of an in vitro assay for the potency control of human rabies vaccine by ELISA, conducted by department of Biological standardization, OMCL Network & Healthcare, EDQM, Council of Europe.

- Therapeutic Antibody Laboratory has participated in Proficiency Testing for bioassay (FACS based) of Anti D immunoglobulin organized by EDQM, France.

- Biochemical Kit laboratory is presently enrolled into the ACBI/CMC External Quality Assessment Scheme (EQAS) - 2021 for Chemistry II (Glucose, Cholesterol & Triglycerides), conducted by the Department of Clinical Biochemistry, Christian Medical College, Vellore. The laboratory put-up the test for Chemistry II for the month of October, November & December 2021 and the generated results were uploaded on CMC-EQAS website.

TECHNICAL EXPERT COMMITTEE MEETINGS:

- Scientists of Enzyme and Hormone Laboratory attended virtual Meeting of experts and stakeholders organized by Indian Pharmacopeia Commission (IPC), Ghaziabad on 08th October 2021, to review the existing Monograph for Heparin sodium injection in IP 2018.

- Scientists of Therapeutic Antibody Laboratory attended the 1st meeting of the Joint Working Group Biologicals held on 13th October 2021 organized by Indian Pharmacopeia Commission (IPC), Ghaziabad through video conferencing.

- Sri. Subhash Chand, Scientist Grade – III, Therapeutic Antibody Laboratory participated in virtual meeting on 'Malaria Monoclonal antibodies for malaria prevention: Preferred Product Characteristics and Clinical Development held on 3rd and 11th November 2021.

- Dr. Shikha Yadav, Scientist Grade-II & Head, Animal facility attended online conference on 3R's Research & Progress "Advances in Animal Models and Cutting-Edge Research in Alternatives" organized by University of Hyderabad, Hyderabad held on 18th & 19th November 2021.

- Dr. Ratnesh, Scientist Grade-II & Head, Therapeutic Antibody Laboratory participated in NABL's accreditation committee meeting held online on 24th November 2021 for rendering recommendation on the scope of accreditation and the accreditation scheme as a technical expert for Recombinant Proteins, Antibodies, Peptide, Vaccines and Hormones.

- Dr. Gauri Misra, Scientist Grade-II & Head, COVID Kit Testing Laboratory and Molecular Diagnostic Laboratory virtually participated as a technical expert in a meeting held on 29th November 2021 to examine the specifications formulated by IRCS, NHQ and to assist in processing of the bids to be invited for purchasing / hire the NAT equipment for IRCS, NHQ Blood Centre.

- Dr. Gauri Misra, Scientist Grade-II & Head, COVID Kit Testing Laboratory attended AcSIR meeting virtually on 15th December 2021.

- A meeting has been organized by NIB with DPSRU, Delhi at NIB, NOIDA on 29th December, 2021 for designing a DPSRU-NIB Joint Certificate Course on Quality Control of Biopharmaceutical & Biologicals.

INVITED TALKS/ LECTURES DELIVERED

- Dr. Gauri Misra, Scientist Grade-II & Head, COVID Kit Testing Laboratory and Molecular Diagnostic Laboratory delivered a talk on "Structure Based Approaches for Drug-Discovery" in series of webinar Genomics4Health- "Genomics in Drug Discovery" on virtual platform held on 23rd October 2021 organized by ICMR, (National Institute of Research in Tribal Health), Jabalpur.

- Dr. Gauri Misra, Scientist Grade-II & Head, COVID Kit Testing Laboratory and Molecular Diagnostic Laboratory delivered a talk on Regulatory aspects on Medical Diagnostic Kits/ Therapeutics at Kalinga Institute of Industrial Technology, Bhubaneswar, Odisha on 29th November 2021.

- Dr. Shikha Yadav, Scientist Grade-II & Head, Animal Facility delivered a talk on "Ethics and Regulations for Humane Care and Use of Animals in India" on 23rd December 2021 in a 3-days HYBRID Workshop on "In vivo Preclinical Imaging and Drug Discovery" organized by Advanced Centre for Treatment, Research & Education in Cancer (ACTREC), Tata Memorial Center, Mumbai from 21st-23rd December 2021.

TRAININGS

- NIB in coordination with Blood Cell, NHM, Ministry of Health & Family Welfare, Government of India organised Training program for 36 Blood Bank Officials from Chhattisgarh State in the month of October and November in two batches.

- NIB in line with ongoing Pradhan Mantri Kaushal Vikas Yojana programme on National Skill Development organized a two weeks Residential Hands-on Training programme on Quality control of Biologicals, from 22nd Nov. to 3rd Dec., 2021 at NIB for 14 M.Sc. Biotechnology Students from Vinoba Bhave University, Hazaribagh (Jharkhand).




सैंतीसवाँ त्रिदिवसीय अखिल भारतीय राजभाषा प्रशिक्षण शिविर एवं सम्मेलन

संस्थान ने दिनांक 18–11–2021 से 20–11–2021 तक भारतीय भाषा एवं संस्कृति केंद्र द्वारा आयोजित सैंतीसवाँ त्रिदिवसीय अखिल भारतीय राजभाषा प्रशिक्षण शिविर एवं सम्मेलन, नैनीताल में सहभागिता ली, जिसमें संस्थान को राजभाषा कार्यान्वयन उत्कृष्ट पुरस्कार प्रदत्त से सम्मान्नित किया गया



SWATCH BHARAT ABHIYAN 2021

NIB has observed Swatch Bharat Abhiyan 2021. As a part of this programme, during the period 01.10.2021 to 31.10.2021, in addition to routine practice, all departments of the Institute have maintained the best cleaning of their premises and clearing of unwanted stuff present in their departments.

AWARDS

- Best paper presentation award received for: Shankar S, Shah S.G, Yadav S, and Chugh A (2021) Novel Corneal Targeting Cell Penetrating Peptide for Management of Corneal Diseases and Disorders. In: 27th Annual Meeting of the Indian Eye Research Group (IERG or ARVO, India Chapter), held from 7th October to 10th October 2021.

SUPERANNUATION

Dr. J.P Prasad, Deputy Director (QC), superannuated from his services on 31st December, 2021 after rendering 26 years of service since 1995. NIB will always be indebted for his untired service to the organization and scientific contributions. NIB wishes him a happy and healthy life.

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National Institute of Biologicals
A-32, Sector-62, NOIDA - 201309, Uttar Pradesh
NIB website: http://nib.gov.in, Email: info@nib.gov.in
Tel: 0120-2400072, 2400022, Fax: 0120-2403014

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For any other Information/ Suggestions/ Queries related to Newsletter kindly contact: Dr. Manjula Kiran, Associate Editor, Email: mkiran@nib.gov.in. Please feel free to share your valuable thoughts & feedback for the betterment of the edition. We look forward to hear from you!!!