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NATIONAL INSTITUTE OF BIOLOGICALS NEWSLETTER



INSULIN



Issue 3, July - September, 2021

Director's Desk



NIB is continuously progressing in a highly competitive scientific arena and is coming into limelight on the national and international stage by maintaining the uniqueness in the quality control field. The institution has the social responsibility towards the public health during COVID-19 Pandemic as a part of the organizational commitment. Towards this goal, NIB has standardized the quality control evaluation of three COVID-19 vaccines.

Dr. J.P. Prasad, Deputy Director (QC) represented NIB at Global Bio Conference 2021, Korea in 6th Western Pacific Region – National Control Laboratories (WPRO-NCL) Workshop on 14th September 2021 through virtual meeting on “National Regulatory System (NRS) for Blood Products & Covid-19 Vaccine - India”.

NIB Laboratories along with QMU had successfully undergone External Audit for maintaining the continuous status of ISO 17025: 2017 accreditation via online remote audit on 7th and 8th August 2021 for an enhanced scope of various tests performed for Quality Control of Biologicals received at NIB, NOIDA.

Continuing with the tradition of Training the Trainers of the Blood Banks, NIB has trained 56 Blood Bank Officials and Technicians from the state of Haryana during this period in collaboration with Blood Cell, NHM, Ministry of Health & Family Welfare, Government of India.

I wish Good Luck to All !!

Anup Anvikar
Director

Contents in this Issue

- 03 Ensuring Quality of Insulins
- 05 First Meeting of NCET- WG On Technology Standards Development and Technology Supply Chain Security
- 06 Accreditation Of NIB Laboratories & Trainings
- 07 Publications
- 08 Hindi Pakhwada 2021

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Ensuring Quality of Insulins

Dr. Charu M Kamal, Scientist Grade - II

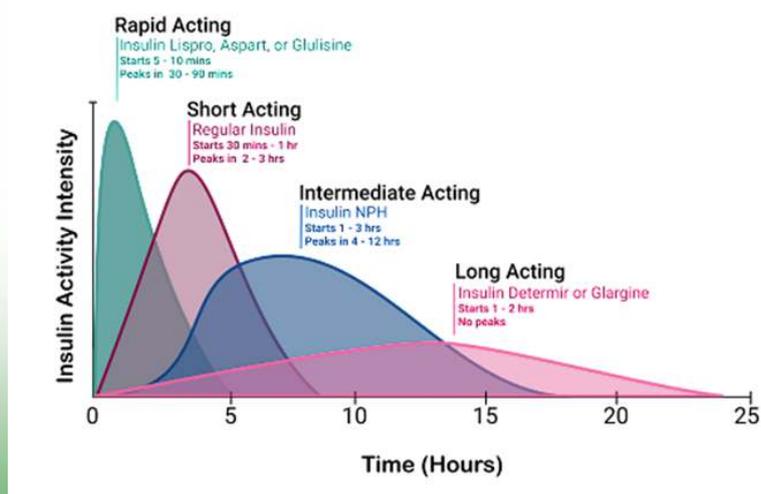
There are more than 420 million people worldwide living with diabetes. This is 6% of the world population. Diabetes is the seventh leading cause of death and a major cause of costly and debilitating complications such as heart attacks, strokes, kidney failure, blindness and lower limb amputations. Diabetes mellitus (diabetes) is a chronic and potentially life-threatening condition where the body loses its ability to produce insulin, or begins to produce or use insulin less efficiently, resulting in blood glucose levels that are too high (hyperglycaemia). There are two types of Diabetes: Type 1 and Type 2. Type 1 diabetes is a chronic condition in which the pancreas produces little or no insulin. In type 2 diabetes, pancreas doesn't produce enough insulin, and the body cells stop responding to insulin. Type 2 diabetes is the most common form of diabetes which accounts for 90-95% of diagnosed cases in adult population.

Insulin is a hormone our body makes to keep our blood glucose levels within the normal range. It is made by beta cells in the pancreas. Insulin's main job is to move glucose from our bloodstream into the body's cells to make energy. If you don't have enough insulin, the glucose builds up in your bloodstream instead of providing energy for your body. The five types of commercially available insulin and their action profiles are as follows:

- rapid-acting insulin
- short-acting insulin
- intermediate-acting insulin
- long-acting insulin
- mixed insulin



Types of Insulin



Recombinant DNA technology is used to manufacture all types of Insulins. All Insulin vials, prefilled syringes and pens look like the preceding lots once fill finished on completion of manufacturing process. It can be taken for granted that each manufacturer must have adhered to Quality Control System conscientiously and would have quarantined and not released into the market any batch of insulin that does not fulfil required specifications. It is known that manufacturing of bio-therapeutics is a highly complex process with a number of variables and each step in the manufacturing process might influence the quality attributes of the final product.

This may introduce variability leading to chances that final product does not meet the required specifications. Every manufacturer has an amount of confidentiality owing to proprietary nature of these complex molecules which limits knowledge about batch to batch variability. The variability could be in batches of a single product from a single manufacturer or between products from different manufacturers. The factors contributing to variability could be: selection of a suitable vector, choice of host, protein purification and isolation technique and differences in cold chain transportation. The product variability could affect clinical efficacy and may have serious patient safety consequences.

The option to solve this issue is Independent Evaluation of Quality. The basic requirement for this is well established fully equipped laboratories where the independent evaluation of quality attributes can be carried out.

Recombinant Product Laboratory at National Institute of Biologicals (NIB) carries out independent quality evaluation of Insulins and Insulin Analogues as per monographs in Indian Pharmacopoeia and as per manufacturer's specifications for non-pharmacopoeia products. The independent evaluation of quality at NIB:

- ✓ provides reassurance of quality attributes
- ✓ verifies the validity and accuracy of test performed by manufacturer
- ✓ ensures manufacturing consistency
- ✓ builds user confidence in the product



Each batch of Insulin is tested for its quality attributes including product attributes, product-related impurities and substances, process-related impurities, contaminants and overall safety/toxicity. The various tests carried out by the laboratory to assess the quality are

given below and accordingly, the product is declared as of Standard Quality or Not of Standard Quality.

Quality of Insulin directly impacts safety of diabetic patients. Since, there are many factors that can adversely affect Insulin's quality during manufacturing, it is imperative to carry out critical and impartial quality assurance by NIB has in-house scientific and technical expertise, calibrated specialist equipment, experienced staff trained in quality management system which ensures timely testing of



range of Insulins, including already approved and those in the process of regulatory approvals.

NIB IN THE SERVICE TO NATION DURING COVID 19 PANDEMIC:

- NIB is continuously receiving COVID-19 suspected patient samples for testing from various hospitals, and quarantine centres of Uttar Pradesh (Baghpat, Gautambudh Nagar). NIB tested about 34,142 COVID-19 suspected clinical samples during the period from July to September, 2021. And out of which only 0.06% of samples were found Positive.
- The Viral Vaccine Laboratory at NIB has established quality control testing of the Novel Corona Virus 2019-nCoV (ZyCoV-D) vaccine manufactured by Zydus Cadilla, Ahmedabad.

First Meeting Of “National Critical & Emerging Technology Sub-Working Groups” On Technology Standards Development and Technology Supply Chain Security

QUAD countries have an interest in partnering to ensure that the rules, norms and standards that govern new technologies reflect our vision of a free, open resilient and inclusive Indo-Pacific. As four of the world’s leading economies, democracies and geopolitical players, a Quad position on technology design, development and use would signal to the region our commitment to develop critical technologies based on shared values and priorities.

The first “Quad summit” of leaders from Australia, India, Japan and the USA has announced the group will create a “Critical and Emerging Technology Working Group”. QUAD countries will convene the Critical and Emerging Technology Working Group (CET WG) to develop a statement and roadmap for cooperation to shape and promote trusted, secure, competitive and diverse technologies reflective of our shared values.

NIB, NOIDA has been identified as a part of “National Critical & Emerging Technology Sub-Working Groups” by National Security Council Secretariat, Sardar Patel Bhawan, Sansad Marg, New Delhi. Dr. Harish Chander, Scientist Grade-I, NIB has represented NIB in the said meeting held on 16th July 2021 at Kautilya Conference Room, NSCS, New Delhi.

TECHNICAL EXPERT COMMITTEE MEETINGS

- Scientists of Therapeutic Antibody Laboratory, Dr. Harish Chander, Dr. Ratnesh K Sharma and Mr. Subhash Chand had attended the Meeting on discussion of Draft Monograph of Rituximab Drug Substance (DS) and Drug product (DP) through Video Conferencing held on 27th August 2021 organized by Indian Pharmacopoeia commission (IPC), Ghaziabad.
- Meeting of Equipment specifications committee held on 28th September 2021 at NIB, NOIDA.
- Dr. Harish Chander, Scientist Grade-I, NIB has been nominated as Member of Committee, constituted by the Department of Health Research, Ministry of Health & Family Welfare, Government of India, for review of Mobile testing Laboratories organized by ICMR for Covid RT-PCR tests in NCT Delhi.
- Dr. Harish Chander, Scientist Grade-I, NIB participated in Eleventh Meeting of Biological Evaluation of In-vitro Diagnostic Medical Devices Sectional Committee, MHD 19, held on 6th August 2021 via e-BIS portal.



1st meeting of advisory committee for setting up BSL-3 facility at NIB held on 14th September 2021

INVITED TALKS

- Dr. Shikha Yadav, Scientist-II, Animal facility, NIB has been invited as a speaker for the 3rd workshop on “Basic Training in Animal handling & Experimentation” organized by Institute of Liver & Biliary Sciences, Delhi held from 26th - 29th July 2021, and delivered a lecture on “Pain Assessment and Management in Laboratory Rodents” on 29th July 2021.
- Dr. Harish Chander, Scientist Grade-I, NIB has been invited as a Guest Speaker for online Webinar on “Monoclonal Antibodies and Vaccination to Curb Covid-19 Pandemic”, held at Amity Institute of Pharmacy, Amity University, Madhya Pradesh on 17th August 2021 via zoom webinar.

ACCREDITATION OF NIB LABORATORIES

- NIB Laboratories and Quality Management Unit had successfully undergone NABL online remote audit on 7-8 August 2021 for renewal of accreditation as per ISO 17025: 2017 for the various biologicals tested at NIB under the Biological & Chemical testing disciplines. NIB received Accreditation certificate for the same with new validity, post assessment by NABL.



Team – Quality Management Unit

PROFICIENCY TESTING (PT)/ EXTERNAL QUALITY ASSURANCE SCHEME (EQAS)/ BIOLOGICAL STANDARDISATION PROGRAMME (BSP)

- 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 on 05.07.2021, 02.08.2021 & 01.09.2021 and the generated results were uploaded on CMC-EQAS website.
- COVID-19 Kit testing laboratory participated in SARS CoV-2 Proficiency Testing (PT) of National Institute of Virology, Pune for coded positive and negative samples and results were found to be 100% concordant/satisfactory.
- Molecular Diagnostic Laboratory has participated in NRL, Australia External Quality Assessment Scheme Event-3 in September 2021 for 04 programs.

TRAININGS

- NIB imparted Training/ Project Work in Quality Control of Biologicals to Post Graduate Students of various Universities. The training on various analytical platforms and cell & animal-based bioassays help

them for their future research endeavours. Five (05) students enrolled for Project work have completed training in the month of July, 2021. A total 10 students (selected by Sub-Committee on 22nd July 2021) from various Universities have joined NIB for Six Weeks Summer Training scheduled from 9th August - 17th September 2021. NIB will impart Training in Quality Control of Biologicals including hands- on training on various analytical platforms and cell & animal-based bioassays.

- NIB in collaboration with Blood Cell NHM, Ministry of Health & Family Welfare, Government of India, framed training programme on “Training of Trainers for Strengthening of Blood Services” for 56 Blood Bank officials of Haryana state at NIB, Noida for the period July to September 2021.



PUBLICATIONS:

- Sujithra Shankar, Sushmita G.Shah, Shikha Yadav, Archana Chugh. Novel corneal targeting cell penetrating peptide as an efficient nanocarrier with an effective antimicrobial activity. *European Journal of Pharmaceutics and Biopharmaceutics*. 2021;116: 216-226. (Published online; ISSN: 0939-6411, Impact Factor 5.571).
- Bharti Gupta*, Anoop Kumar, Parikipandla Sridevi, A Comprehensive in Silico Analysis for Identification of Immunotherapeutic Epitopes of HPV-18, *Int J Pept Res Ther*. 2021 Sep 20: 1–10. doi:10.1007/s10989-021-10285-x

APPRECIATION

The collaborative study with IIT, Delhi under the project titled “Corneal delivery of antifungal-peptide conjugate encapsulated nanoparticle formulation in an experimental animal model of *Fusarium solani*” wherein the in-vivo studies in mice and rabbits had been done at Animal Facility of NIB has been highly appreciated by press in digital as well as print media and covered by several national newspapers like Indian Express, Hindustan Times, Times of India etc. and also covered by Rajya Sabha TV (RSTV) on 14th July 2021 in their program Gyan Vigyan and also by NDTV.



HINDI PAKHWADA 2021



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