NATIONAL INSTITUTE OF BIOLOGICALS

NEWSLETTER

Issue 3 :
July-September-2024

One day Interactive programme on "Making of Biological Reference Standards : Indian perspective" held on 24th July, 2024

Director's Desk

The third quarter of the year is highlighted by the new initiatives of the institute for improving the access to Biological Reference Standards. The one-day interactive program organized by NIB involving WHO, CDSCO, IPC industry/academia as well as experts in this field has paved way to flag certain important factors affecting Development of Biological Standards. I thank all the participants of the meet for their active participation and valuable inputs for strengthening such activities of the Institute.

As per the initiatives 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 a training programme in this quarter for Postgraduate students from various universities from Bodoland, Assam. 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, NIB has also imparted six weeks summer training to students.

NIB is climbing the ladder of success steadily in a highly competitive scientific fraternity and is coming into limelight on the national and international stage by maintaining the uniqueness in the Quality Control of Biologicals.

As Director of NIB, I envision our Institute as part of a vital strategy to invest in and promote emerging research areas for improving the quality control testing methods of various biologicals. To meet tomorrow's challenges and demand in the interest of public health, we are ready to include more and more biologicals under NIB's umbrella. Further to extend our support to indigenous manufacturers and researchers in the country, we would like to add more to the National Biological Reference Standards supplied by NIB.

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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GLP-1 DRUGS :
A BLOCKBUSTER FOR DIABETES, WEIGHT LOSS & OTHER AILMENTS

Ms. Gurminder Bindra

(Ms. Gurminder Bindra is working as Scientist Grade – III in Recombinant Product Laboratory of the organization. She holds 29 years of experience in Quality Control of various Biologicals. She is currently working on QC aspects of anti-diabetics such as Insulin and their analogs, peptides and cytokines)

The Glucagon like peptide-1 (GLP-1) drugs can be defined as the most important drug class breakthrough in medical history. They can be named as "One jab to treat them all" and have been used for decades to treat diabetes. Recently they have gained popularity for the purpose of weight loss and have been identified as multifaceted hormonal drug with broad pharmacological potential.

Glucagon like peptide-1 (GLP-1) is a 30 or 31 amino acid long peptide hormone mainly secreted by 3 tissues in the human body: enteroendocrine L cells in the distal intestine, alpha cells in the pancreas, and the central nervous system. Through its interaction with the GLP-1 receptor (GLP-1R), GLP 1 participates in the regulation of glucose homeostasis. It binds to GLP-1 receptors expressed on the pancreatic β cells and regulated the blood sugar level. In addition, glucagon like peptide-1 receptor agonists (GLP-1RAs) can be combined with GLP-1Rs, playing the same role as GLP-1. The gut derived peptides, glucagon-like peptides 1 and 2 (GLP-1 and GLP-2), are secreted intestinal L cells in response to nutrient ingestion.

GLP-1 is an incretin; thus, it has the ability to decrease blood sugar levels by enhancing the secretion of insulin. It suppresses release of glucagon which increases the blood sugar levels. They also act on the hypothalamus part of brain which controls the satiety and hunger. The pathways that modulate cravings are also controlled by GLP-1.

Studies over years have indicated that in addition to playing a role in the treatment of diabetes, GLP-1RAs can also be used in the treatment of other diseases, such as certain neurological diseases, cardiovascular diseases (CVDs), and diseases related to metabolic disorders. Many studies on the correlation between the function of GLP 1RAs and the development and progression of tumors are also underway. This can be attributed to the wide distribution of GLP-1R, GLP-1RAs also have a wide range of pharmacological effects.

As they become cheaper and easier to use, they promise to dramatically improve the lives of more than a billion people with profound consequences for industry, the economy and society. Since these anti-diabetics are expensive, this might put a burden on medical system of the country but their benefits outweigh the huge medical bill for treatment of diabetes and obesity. Obese population is also prone to many other health issues such as heart disease, a few types cancers, sleep apnea , fatty liver disease etc. Thus, weight loss can take care of such ailments and improve overall health of the individual. These medicines would make the work force healthier improving the economy of the country.

These molecules act on various problems at the time making it different from other therapeutics, e.g., people with extra weight have tendency to develop diabetes, have high blood pressure, too much unhealthy fat in their blood are at risk of heart disease. GLP-1 agonist improves most of eight core defects called as 'Omnious Octet of obesity'. This includes the hypothalamus, islet cells of Langerhans, gastrointestinal tract, adipose tissue, adrenal gland, gonads, thyroid gland and the muscle.

It has also been found to reduce the outcomes of Chronic Kidney Disease (CKD) or improve liver function by reducing fat level independent of the ability to control the blood sugar level.

They also act as immune cells in body to reduce the production of the inflammatory molecules which can reduce the chance of development of some cancers, cardiovascular, autoimmune and neurodegenerative diseases. It has been shown to take care of ulcerative colitis, arthritis and in couple of certain cases post covid fog.

In a study it was found that in patients with mild Alzheimer's disease, when treated with GLP-1, showed reduction in brain shrinkage by almost 50% and cognitive decline up to 18%, thus it could be a treatment approach for neurogenerative diseases.

This drug is also being named as the most exciting drug in the upcoming times, as a recent study has shown that they work on alcohol and drug dependence related behaviour, thus will be used treating tobacco, drug and alcohol abuse.

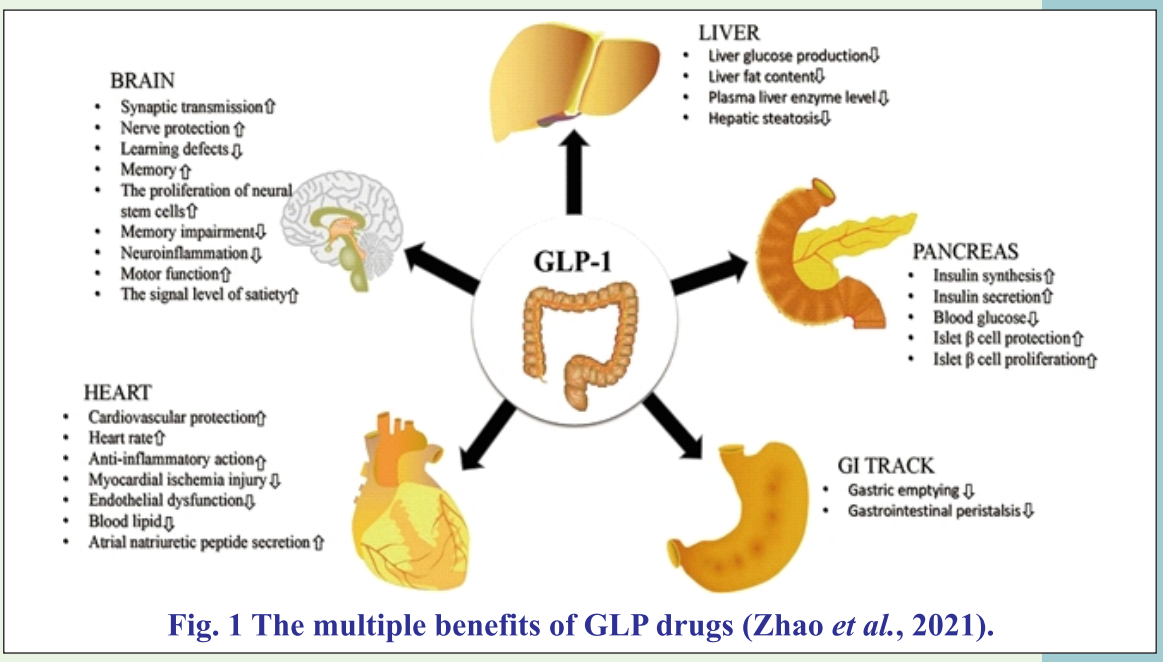

Fig. 1 The multiple benefits of GLP drugs (Zhao *et al.*, 2021).

GLP-1 Drugs are generally taken by a shot (injection) given daily or weekly. The various formulations available in the market are summarized in table given below:

Name of Drug	Brand Name	Dose regimen
Dulaglutide	(Trulicity)	weekly
Exenatide extended release	Bydureon	weekly
Exenatide	Byettatwice	daily
Semaglutide	Ozempic	weekly
Liraglutide	Victoza, Saxenda	daily
Lixisenatide	Adlyxin	daily
Semaglutide	Rybelsus	taken by mouth once daily

At National Institute of Biologicals (NIB), NOIDA each batch of recombinant product received for Quality Control Evaluation (QCE) is tested for its quality attributes. This ensures availability of safe, efficacious and potent biomolecule to end-users.

NIB is already carrying out QCE of all the above mentioned GLP-1 Drugs for Critical Quality Attributes in view of the public health which includes:

1. Identification
2. Potency
3. Purity
4. Physiochemical tests such as pH, Osmolality
5. Safety

As GLP-1 drugs have multiple benefits, their use may enhance the productivity leading to profound economic change that could be an initiative for elevating health levels of all.

References:

1. Glucagon-like peptides 1 and 2 in health and disease: A review. Marathe et al. Peptides 44 (2013) 75–86
2. Glucagon-like peptides 1 (GLP-1), Muller et al, Molecular Mechanism, 30 (2019), 72-130
3. GLP-1 Receptor Agonists: Beyond Their Pancreatic Effects, Zhao et al, Frontiers in Endocrinology 12 (2021)
4. The Everything drugs, The Economist, 28th October, 2024

Interactive programme on "Making of Biological Reference Standards: Indian perspective"

NIB organized one day interactive programme entitled **"Making of Biological Reference Standards - Indian perspective**" involving the representatives of WHO, CDSCO, IPC and experts from academia as well as stakeholders. The strategies to improve access to reference materials, International collaborative studies for development of National Biological Reference Standards (NBRS), Regulatory perspective and challenges in development of NBRS, as well as role of NIB in development of NBRS were discussed. The outcome of this interactive programme paved way to flag certain important factors affecting Development of Biological Standards like challenges in sourcing of candidate materials, infrastructure for lyophilization, budget allocations as well as capacity building strategies.

Quality Assurance / Quality Control of Bio-Therapeutics, Prophylactics and *In-Vitro* Diagnostics

1. Recombinant Products Laboratory (RPL) is in the process of establishing QC test parameters for a new biological Semaglutide tablet (Rybelsus), a glucagon-like peptide-1 (GLP-1) receptor agonist used for treatment of Type 2 diabetes mellitus and anti-obesity drug.

2. RPL has taken initiative towards development of First National Reference Standard of Insulin Glargine.

3. Blood Reagent laboratory has successfully 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. The results were found to be 100% satisfactory.

4. Therapeutic Antibodies Laboratory, Recombinant Products Laboratory and Enzymes and Hormones Laboratory have participated in Proficiency Testing programme Round 01 (PT/IPL/01/04/24) with Indian Pharmacopoeia Commission for Chromatographic purity by HPLC and pH. Laboratories have received Certificate of Participation with Satisfactory Performance.

Nomination/Participation in various Scientific Meetings/Workshops/Conferences/ Seminars/Trainings by NIB Scientists

1. Dr. Gauri Misra, Scientist Grade - I attended 14th, 17th and 20th Technical Advisory Committee (TAC) meeting of MedTech Mitra as an external expert on 5th July, 2024, 6th August, 2024 and 6th September, 2024 respectively at NITI Aayog, organized by ICMR, New Delhi.
2. Dr. Suresh Kumar, Scientist Grade-III attended the Institutional Animal Ethics Committee (IAEC) meeting as a CPCSEA nominee to review the research protocols on 11th July, 2024 at National Institute of Immunology, New Delhi.

3. Ms. Sudha V. Gopinath, Scientist Grade-II, Ms. Kanchan Ahuja, Scientist Grade -II and Dr. Pankaj K. Sharma, Scientist Garde -III participated in the 1st National CME of the Indian Society of Transfusion Medicine (ISTM) organized by the Department of Transfusion Medicine, Sree Chitra Tirunal Institute for Medical Sciences and Technology, Thiruvananthapuram, Kerala from 11th – 12th July, 2024.

4. Dr. Shikha Yadav, Scientist Grade - I delivered a talk on "Perioperative Care, Anesthesia, Surgical Techniques and Analgesia and Pain: Its Causes, Category Monitoring and Distress in Laboratory Animals" in a workshop on handling and care of laboratory animals organized by School of Life Sciences, JNU from 13th to 17th July, 2024

5. Dr. Harish Chander, DD (QC), Dr. Charu Mehra Kamal, Scientist Grade - I, Ms. Sudha V. Gopinath, Scientist Grade – II and Dr. Subhash Chand, Scientist Grade-III participated in a meeting on "Biotherapeutic Products Application including Biosimilar Standards" with USP delegates at NIB on 25th July, 2024.

6. Dr. Harish Chander -DD(QC), Dr. Charu M. Kamal, Scientist Grade - I, Ms. Sudha V. Gopinath, Scientist Grade - II and Dr. Subhash Chand, Scientist Grade – III attended the first Expert Committee meeting for Biological Reference Standards organized by Reference Standard Unit at NIB on 25th July, 2024 under chairmanship of Dr. Rama S. Verma, Prof. (Retd.) IIT Madras & Director MNNIT, Allahabad.

7. Dr. ShikhaYadav, Scientist Grade-I delivered a talk on "Ethical evaluation: International Perspective and Severity Assessment" in the Federation of European Laboratory Animals Scientist's Association (FELASA) accredited course at TANUVAS, Chennai on 26th July, 2024.

8. Dr. Shikha Yadav, Scientist Grade-I delivered a lecture on "Pre-Surgery/pre-operative Preparations for Mouse Survival Procedures, Survival Surgery Standards- Postoperative Care" in the workshop titled "NeuroTech Lab: Applied Techniques in Neuroscience Research" organized by National Brain Research Centre (DBT), Manesar, Haryana on 6th August, 2024.

9. Dr. Gauri Misra, Scientist Grade-I, virtually attended workshop on 'Handling support to MedTech Innovation : Essentials of Regulation complaint Clinical Investigation' under the MedTech Mitra: A Niti Ayog-ICMR-CDSCO Initiation on 7th August, 2024.

10. Dr. Gauri Misra, Scientist Grade- I, attended MHD20 sectional Committee (BIS) virtual meeting as an external expert on 12th September, 2024.

11. Dr. Charu M. Kamal, Scientist Grade - I, Dr. Saurabh Sharma, Scientist Grade-III, Dr. Jyoti Sharma, Scientist Grade -III and Dr. Paras Jain, Junior Scientist virtually attended a meeting organized by IPC to discuss the Monographs for Trastuzumab Concentrated Solution and Injection on 19th September, 2024

12. Dr Charu M. Kamal, Scientist Grade - I, virtually attended BIS Sectional Committee Meeting MSD20-REMCO-NMC on 23rd September, 2024.

13. Ms. Kanchan Ahuja, Scientist Grade-II nominated as an Expert Principal member for MHD-19 In-vitro Diagnostic Medical Devices and Biological Evaluation of Medical Devices Sectional Committee of Bureau of Indian Standards.

14. Dr. Richa Baranwal, Scientist Grade - III, Immunodiagnostic Kit Laboratory (IDKL) virtually attended 17th meeting of MHD 19 In-vitro Diagnostic Medical Devices and Biological Evaluation of Medical Devices held on 27th September, 2024.

TRAININGS IMPARTED TO STUDENTS/ MEDICAL PROFESSIONALS/ RESEARCHERS AND INDUSTRY PERSONNELS

1. National Skill development and Training (NSDT) programme on "Quality Control of Biologicals" for 31 M.Sc. Biotechnology Students from Bodoland University, Kokrajhar, Assam from 27th August - 6th September, 2024.
2. Six-weeks Summer Training from 10th June – 19th July, 2024 for 19 students from various universities.
3. Five-days training on RT-PCR including RNA extraction held from 08th - 12th July, 2024 in COVID Kit Testing Laboratory & Molecular Diagnostic Kit Laboratory.
4. Five-days training on "Quality Control of Blood Products using Atomic Absorption Spectrometry (AAS)" held from 5th - 9th August, 2024 at Blood Products Laboratory.
5. Five-days training on "Ethical use & care of Laboratory Animals in Research and Regulatory Testing" held from 2nd to 6th September, 2024 at In-Vivo Bioassay Laboratory & Animal Facility.
6. Two-days training on "Fundamentals of Laboratory Quality Management System (ISO/IEC 17025: 2017)" held from 24th to 25th September, 2024 at Quality Management Unit (QMU).

Events organized under "Annual Capacity Building Plan 2024-25" for NIB Officials

1. Scientific staff attended the lecture session on "Intellectual Property Rights IPR" delivered by Dr. Vivek Kashyap (Associate Director)-Patents, Roche Products (India) Pvt. Ltd. on 2nd July 2024.
2. Scientific staff attended the lecture session on "Biosafety Regulations and best practices – Laboratory Biosafety Management" delivered by Sh. N. Nanda Gopal, Scientist Grade - III on 30th July, 2024.
3. Dr. Jyoti Sharma, Scientist Grade - III, Mr. Brij Bahadur, Junior Scientist, Dr. Priya Sharma, Junior Scientist, Mr. Mohit Lal, Lab. Technician, Dr. Mohammad Imran, Lab. Technician and Mr. Lakhan, Lab. Technician participated in the training course on "Laboratory Quality Management System and Internal Audit as per ISO/IEC 17025:2017", held at National Institute of Training for Standardization (NITS) Noida, from 6th to 9th August, 2024.

4. Ms. Sudha V. Gopinath, Scientist Grade - II and Ms. Shalini Tewari, Scientist Grade - III participated in One-Day workshop on Mission Karmayogi - Content Creator for the IGOT platform held on 13th August, 2024 at National Institute of Health and Family Welfare (NIHFW) Ministry of Health and Family Welfare, Govt. of India.

5. Organized visit of M.Sc. Clinical Research students from DBT-Translational Health Science and Technology Institute (THSTI) Faridabad Haryana, to NIB on 30th August, 2024.

6. Ms. Suchitra, Junior Scientist, Ms. Poonam, Junior Scientist, Mr. Prem Prasad, Lab. Technician, Mr. Himanshu Shukla, Lab. Technician and Mr Lakhan, Lab. Technician participated in the training course on "Laboratory Quality Management System and Internal Audit as per ISO/IEC 17025:2017", held at National Institute of Training for Standardization (NITS) NOIDA, from 9th to 12th September, 2024.

PUBLICATIONS

1. Conference Paper presented by co -author in the 37th European Peptide Symposium (EPS) & 14th International Peptide Symposium held in Florence, Italy from 25th to 29th August, 2024. "Application of membrane-active peptide-based therapeutics in the management of stromal melts associated with microbial keratitis"; Jyoti Sood, Sujithra Shankar, Sushmita G. Shah, Shikha Yadav, Archana Chugh (https://doi.org/10.17952/37EPS.2024.P1136)

2. Patent ID 202311077789 filed for "A novel formulation for breast cancer and process thereof" with Mr. Harit Kasana, Scientist Grade - II and Dr. Manjula Kiran, Scientist Grade – III as external co-inventors.

3. Manuscript entitled "Effect of amino acid addition as stabilizers on total protein content of intravenous therapeutic human normal immunoglobulin" published in Asian Journal of Pharmaceutical and Clinical Research, vol. 17, issue no. 7 in July, 2024.

4. Manuscript entitled "Validation of GF-AAS Method for the Determination of Aluminium Content in Human Albumin Finished Product" published in Current Pharmaceutical Analysis, Volume 20, September 2024.

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

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