What are Biological Drugs?

According to S.R.O. 782 (I)/2000, -

'Lot Release' means an approval for the release into the market of a specific lot of a biological drug, based upon certification that the lot meets the in-process controls and control tests on final product."

'Biological drugs' means medicinal products produced by biological systems and which require standardization by biological assays and includes -

(i) blood products including Plasma, Albumin, Clotting Factors, Factors VIII, IX, Mixed Clotting Factors Tractions, Fibrinogens, Immunoglobulins.

(ii) immunological products including Antisera, Antitoxins, Monoclonal Antibodies, Specific Immunoglobulins:

(iii) *in vivo* diagnostics including Tuberculins, Lepronin, Histoplasmin, Coccidioidin, Allergens, Allergens Extracts, Antibodies conjugated with isotopes for imaging studies Antigens, Cytokines/Antibodies/Cells injected to elicta biological response;

(iv) Vaccines:- (a) **bacterial** including live, killed whole cell, protein sub unit, polysacchride or glyconjugate, toxin derivatives. rDNA.(b) **viral** including Live, Inactivated, sub-unit, rDNA:

(v) toxins and Venoms including snake venoms;

(vi) immunostimulants of biological origin including BCG vaccine for immunotherapy;

(vii) biotechnology products including rDNA products recombinant antibodies, Monoclonal Antibodies and derivatives Gene therapy Products";

"**No biological drug, whether imported or locally manufactured shall be released for sale, unless a "Lot Release Certificate" is obtained from the Federal Government Analyst, National Control Laboratory for Biologicals.**

Government of Pakistan

Cabinet Division

National Control Laboratory for Biologicals

Mailing Address:
Director
National Control Laboratory for Biologicals
Chak Shahzad, Islamabad 45500

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National Control Laboratory for Biologicals

Lot Release System applicable to Biological Drugs manufactured and imported in Pakistan.

A guide for the submission of summary Protocol for Lot Release

Tel: 051 9255263; 8312650 **Http://www.nclbmoh.gov.pk**

NCLB

Lot Release System:

Check List

Minimum requirements for submission of Lot Release request.

1. One page Lot Release Request Form addressed to Director NCLB/Federal Analyst
2. Summary Protocol of the product manufacture and Quality Control
3. Lot Release Certificate from NRA of exporting country OR Lot Release Exemption Certificate from NRA of exporting country.
4. Batch Production Record (BPR) of the products that are locally manufactured.
5. Original copy of bank challan paid in NBP/ SBP for lot release fee.
6. Copy of commercial invoice duly endorsed by the concerned ADC.
7. Copy of Registration letter issued by the Ministry of Health, Islamabad.
8. Any other document required to establish the safety and efficacy of the product as determined by the Federal Government Analyst.

Lot Release System:

Procedure

The Lot Release System is based on:

Summary Protocol Review

According to Word Health Organization (WHO) the primary responsibility of the quality of a Biological Drug rests with the manufacturer.

The national regulatory authorities of each country assures that the manufacturers are performing necessary control measures at each level of production through regular inspection, testing and batch production record review process that is applied on each lot manufactured in the country.

Importing countries thus relies on the Lot Release Certificates of the products' country of origin while going through a review process of manufacturing steps called the Summary Protocol Review. In addition random samples are to be tested at the import stage as well as a post marketing exercise.

Laboratory Testing

For countries where Biological Drugs are manufactured, the responsibility of national regulatory authorities is more stringent.

These locally manufactured biologicals could be exported based on the Lot Release Certificates. Thus WHO requires that in order to ensure consistent good quality, samples are to be tested frequently and at different stages of production. These testing could be conducted in collaboration with the manufacturer to reduce the cost and quarantine period. Thus valuable availability period is ensured.

Lot Release System:

Verification

Any consumer of the Biological Drug could verify in writing the Lot Release status of a Biological drug from NCLB.

Products going through Lot Release system are currently displayed at the website of NCLB.

Federal Inspector of Drug and Provincial Drug Inspector also can submit samples for testing of potency and safety.

Lot Release System:

Training

NCLB offers regulatory training session for new entrants in the biological manufacture industry or are engaged in the import of a biological drug.

This can save time and effort for any Biological Drug developer or Importer while knowing the roadmap before investing.

Refresher training session, special session for individual and group lectures are arranged on request.

University students and NIP internees engaged in biological drug discovery and development are encouraged in using Linux based Bioinformatics tools.