



Workflow for lot release process & list of required documents with each lot for lot release process 2026

Code: EDREX.NP.Bioinn.019

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List of abbreviations:

- EDA:** Egyptian drug authority
LR: Lot release
MA: Marketing authorization
NCL: National control laboratories
NRA: National regulatory authority
OOS: Out of specification
WD: Working day

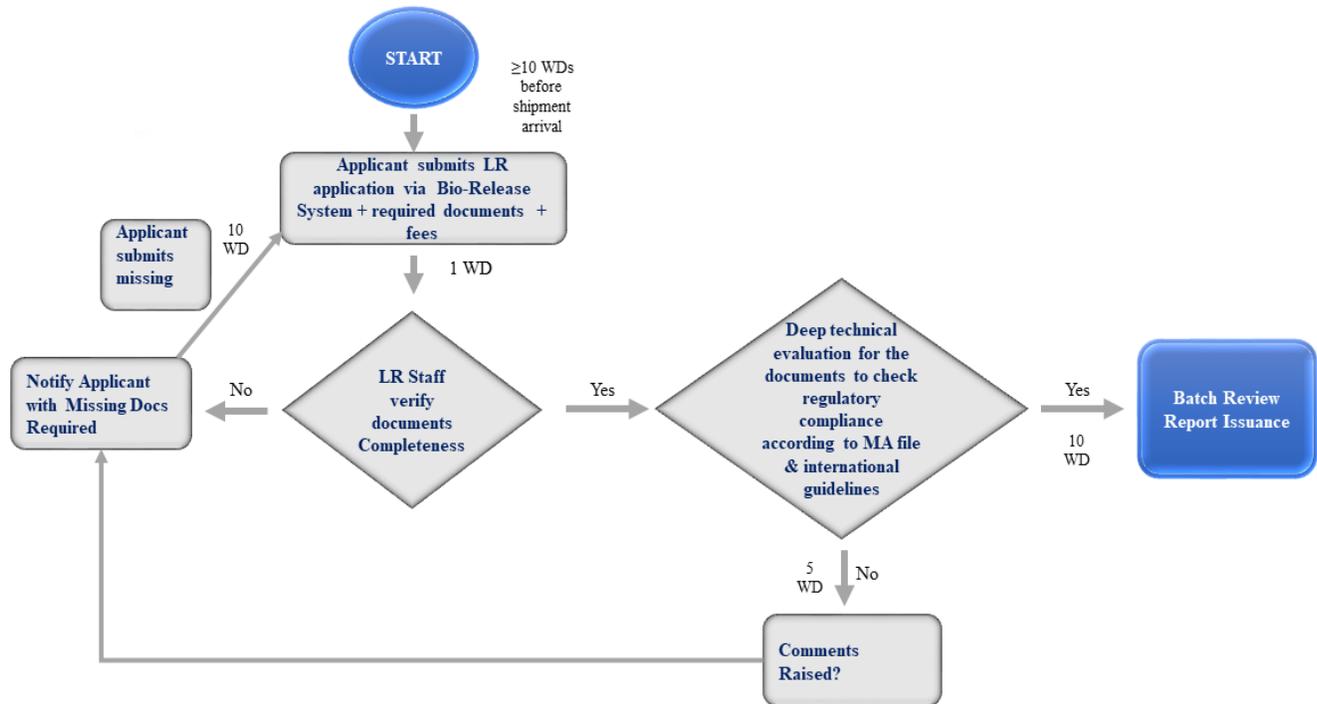
Objective:

This notice to applicants is designed to provide marketing authorization holders of biological products with a clear roadmap for the lot release approval process. It outlines an illustrative workflow and specifies the required documentation for each submitted lot.

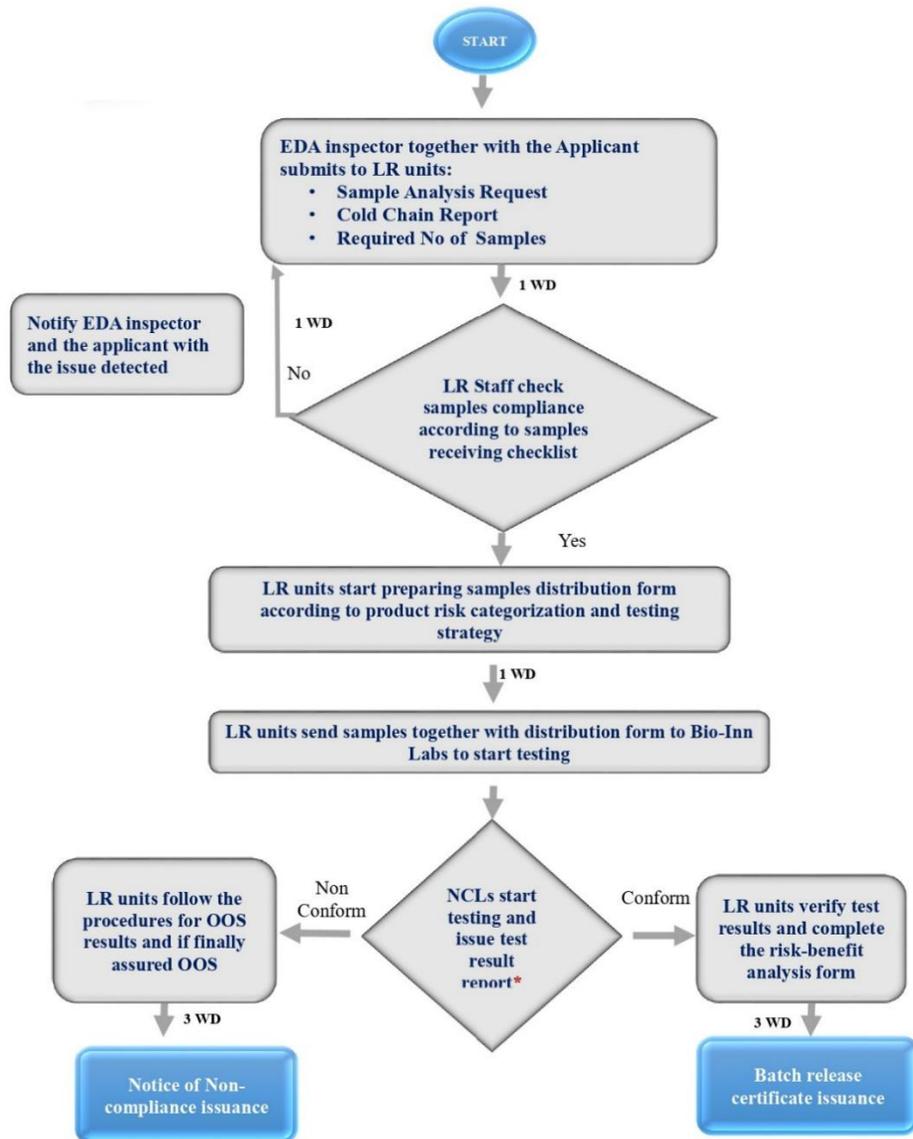
This notice to applicant has been prepared in accordance with the following EDA guideline:

1. Guideline for Lot Release of Biological Products in Egypt (Code: EDREX.GL.BioInn.003)

A. LR- Document review phase workflow:

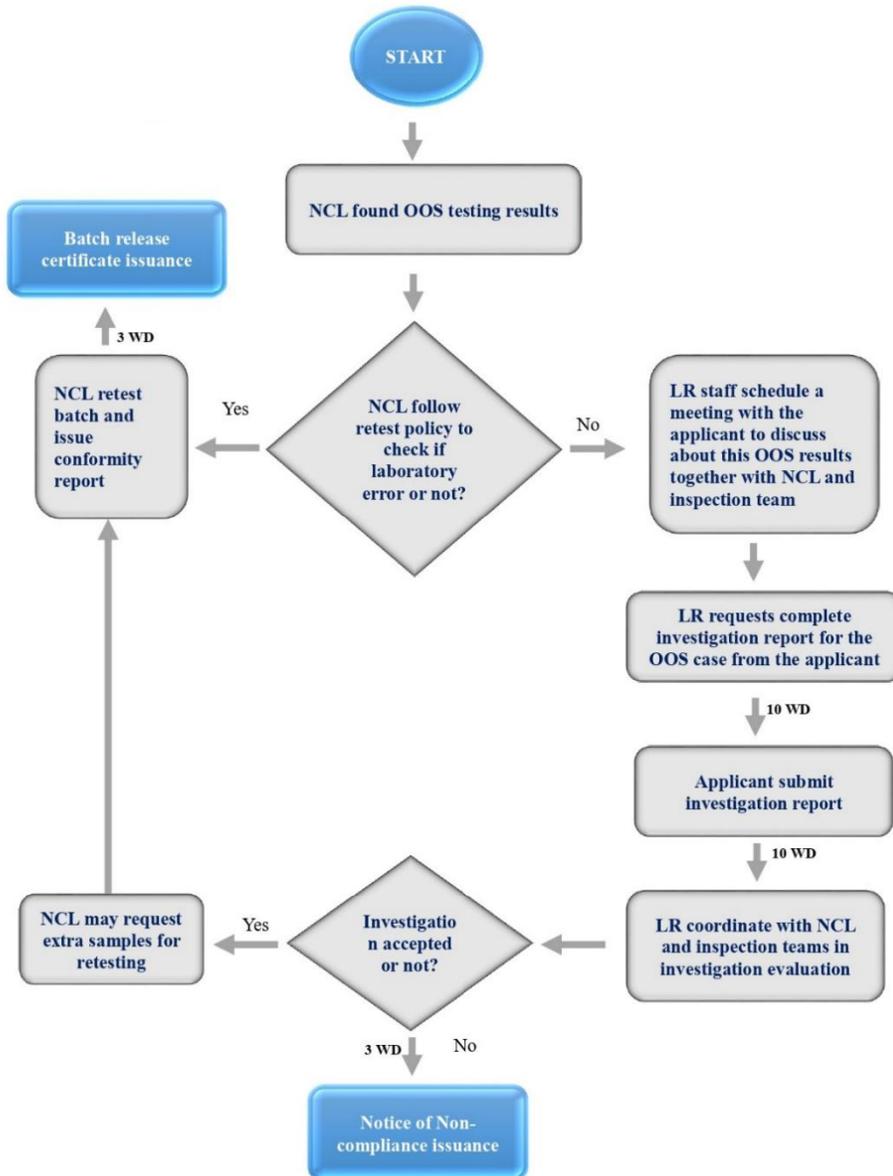


B. LR – Sample analysis phase workflow:



Samples testing timeline acc.to product risk categorization level and release pathway and tests performed.

C. LR – Testing non-conformity workflow:



D. List of Documents required to be submitted with each lot for lot release approval

1. Document must be submitted with each batch:

<u>Vaccines</u>
<ol style="list-style-type: none">1. Complete summary protocol2. Certificate of analysis of finished product3. Certificate of analysis of solvent (if applicable)4. Batch release certificate of finished product from National Regulatory Authority of country of origin (NRA certificate)5. <u>In case of using human albumin as stabilizers the following documents are required.</u><ol style="list-style-type: none">5.1- Certificate of analysis of albumin batch used as stabilizer/ Summary protocol.5.2- Batch release of albumin from NRA of Country of origin5.3- Link between finished product batch and the albumin batch used as stabilizer
<u>Antisera of animal origin</u>
<ol style="list-style-type: none">1. Complete summary protocol2. Certificate of analysis of finished product3. Certificate of analysis of solvent (if applicable)
<u>Plasma derived medicinal products</u>
<ol style="list-style-type: none">1. Complete Summary protocol.2. Certificate analysis of finished product.3. Certificate of analysis of solvent (if applicable)4. Batch release certificate of finished product from National Regulatory Authority of country of origin (NRA certificate)5. Batch release certificate of plasma pool from National Regulatory Authority of country of origin (NRA certificate)6. Plasma quality certificate7. Viral inactivation declaration (if applicable)8. TSE Declaration (if applicable)

<u>Products prepared by recombinant DNA technology</u>
<ol style="list-style-type: none">1. Certificate of analysis of finished product2. Certificate of analysis of active pharmaceutical ingredients3. Certificate of analysis of solvent (if applicable)4. <u>In case of the biological product using human albumin as stabilizer the following documents are required.</u><ol style="list-style-type: none">4.1- Certificate of analysis of albumin batch used as stabilizer/ Summary protocol.4.2- Batch release of albumin from NRA of Country of origin.4.3- Link between finished product batch and the albumin batch used as stabilizer.
<u>Extractable products</u>
<ol style="list-style-type: none">1. Certificate of analysis of finished product2. Certificate of analysis of active pharmaceutical ingredients3. Certificate of analysis of solvent (if applicable)4. TSE Declaration (if applicable)

2. Document must be submitted annually or when required:

2.1 GMP certificates for all manufacturing sites

2.2 Yearly Biological Product Report (YBPR) / Annual product quality review (APQR)



History table

Version No.	Issue date	Summary of changes
1	18/3/2026	Initial issue