|  |  |  |
| --- | --- | --- |
|  |  | **(For Official use only)** |
|  | **L.R No.** |  |
|  | **Date of Receipt** |  |
|  |  |  |

The Federal Government Analyst, Reference No. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

National Control Laboratory for Biologicals, Dated:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Drug Regulatory Authority of Pakistan,

Ministry of National Health Services, Regulations and Coordination,

Prime Minister’s National Health Complex,

Park Road, Chak Shahzad,

**Islamabad.**

Please issue the lot release certificate in respect of the biological product as detailed below. All the required documents are enclosed along with one unit commercial pack as per requirement of storage conditions of the applied product. The sample of the product for testing will be provided, if required:-

|  |  |
| --- | --- |
| **Importer/ Manufacturer Details** | |
| Name and address of the Importer/manufacturer |  |
|  |  |
| Commercial Invoice No. |  |
| Invoice Date |  |
| Date of Receipt of Shipment |  |
| Date of Endorsement of Invoice |  |
| Mode of Shipment |  |
| Port of Receipt of Shipment |  |
| Name and Address of the Indent Holder (if applicable) |  |
| **Product details** | |
| Name of Product |  |
| Generic Name of Product |  |
| Registration No. |  |
| Lot No. |  |
| Manufacturing Date (dd/mm/yyyy) |  |
| Expiry Date (dd/mm/yyyy) |  |
| Storage Temp |  |
| Transportation Temp. |  |
| Name and address of Manufacturer |  |
| Pharmaceutical form |  |
| Type of Container |  |
| Number of Doses per container |  |
| Volume per container |  |
| Strength |  |
| Transportation/Storage data evidence |  |
| Total Quantity applied for Lot Release |  |
| **Solvent/ Diluent Details (in case of Freeze Dried Product)** | |
| Solvent/ Diluent Name |  |
| Lot No. |  |
| Type of container |  |
| Volume per container |  |
| Registration No. |  |
| Mfg. Date |  |
| Exp. Date |  |
| Name & address of Manufacturer |  |
| **Details of Fee Deposited** | |
| Bank Name |  |
| Bank Code |  |
| Deposit Date |  |
| Deposit Slip No. |  |
| Amount Deposited |  |
| Endorsement from DRAP | □ Yes |
| **Lot Release Requested By Authorized Person** | |
| Name |  |
| Designation |  |
| Signature |  |
| Date |  |
| Telephone No. |  |
| Cell No. |  |
| Name of Firm/ Pharmaceutical Company |  |
| Complete Address |  |
| Official Stamp |  |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **For Official Use only:** | | | | | | | |
| 1. | Summary Protocol Received | | | | | □ Yes |  |
| 2. | Lot release certificate from NRA of exporting country received (in case of imported products) | | | | | □ Yes | □ Exemption Certificate |
| 3. | Batch Production Record received (for locally manufactured products). | | | | | □ Yes | □ No |
| 4. | Copy of the Registration Letter received. | | | | | □ Yes |  |
| 5. | Copy of the paid bank challan received. | | | | | □ Yes |  |
| 6. | Copy of Invoice/Clearance certificate received. | | | | | □ Yes |  |
| Date of Receipt | |  | | Received By (sig) | | |  |
| Application accepted | | □ Yes | | Name | | |  |
| If rejected (reason) | |  | | Designation | | |  |
|  | |  | |  | | |  |
| Assessment required | | | □ Summary protocol review | | | | □ Laboratory Access |
| Assigned reviewer | | |  | | | |  |
| Deadline for assessment | | |  | | | |  |
|  | | |  | | | |  |
|  | | |  | |  | |  |
|  | | |  | | Federal Government Analyst | | |