**Application Form for Lot Release Certificate for Vaccines & Sera**

 Office use only

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| --- | --- |
| Ref No: |  |
| 1. **Applicant’s information**
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| 1.1 Name  |  |
| 1.2 Address |  |
| 1.3 Contact person in Sri Lanka |  |
| 1.4 Contact details | Phone: email: |
| 1. **Vaccine/Serum information**
 |
| 2.1 Name of the vaccine/serum |  |
| 2.2 Trade name |  |
| 2.3 Name of manufacturer |  |
| 2.4 Address of manufacturer |  |
| 2.5 Marketing Authorization Registration No: | 2.6 Lot No: |
| 2.7 Date of manufacture: | 2.8 Expiry date: |
| 2.9 Storage condition:  | 2.10 Type of container: Vial Ampoule Prefilled syringe  |
| 2.11 Number of doses per container: |
| 2.12 Quantity of vaccine/serum imported: | 2.13 No. of vials sent to NCL:  |
| 1. **Diluent information (if any)**
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| 3.1 Name of diluent: | 3.2 Manufacture same/different. If so name and address of the manufacturer:  |
| 3.3 Lot No: |
| 3.4 Manufacturing date: | 3.5 Expiry date: |
| 3.6 Storage condition: | 3.7 Type of container: Vial Ampoule Prefilled syringe  |
| 1. **Documentation**
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| 4.1 Documents submitted:   Summary lot protocols Lot release certificate from NRA/NCL  Package insert leaflet Certificate of analysis of finished product    Certificate of analysis of diluent Temperature monitoring data during transportation    Airway bill & importing packing list Registration certificate issued by NMRA  |
| 1. **Applicant’s declaration**
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| I hereby certify that the above information is true and correct to the best of my knowledge. I understand that if any of the above information is found to be false or untrue or misleading or mispresenting I may be held liable for it, this application will be rejected. Any payments made will not be refunded. |
| Name & Designation  | Signature | Date |