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மருத்துவ ஆராய்ச்சி நிறுவனம்
MEDICAL RESEARCH INSTITUTE
NATIONAL CONTROL LABORATORY
SRI LANKA



Application Form for Lot Release Certificate for Vaccines & Sera

Office use only

Ref No:

1. Applicant's information		
1.1 Name		
1.2 Address		
1.3 Contact person in Sri Lanka		
1.4 Contact details	Phone: email:	
2. 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:	
2.11 Number of doses per container:	<input type="checkbox"/> Vial <input type="checkbox"/> Ampoule <input type="checkbox"/> Prefilled syringe	
2.12 Quantity of vaccine/serum imported:	2.13 No. of vials sent to NCL:	
3. Diluent information (if any)		
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:	
	<input type="checkbox"/> Vial <input type="checkbox"/> Ampoule <input type="checkbox"/> Prefilled syringe	
4. Documentation		
4.1 Documents submitted:		
<input type="checkbox"/> Summary lot protocols	<input type="checkbox"/> Lot release certificate from NRA/NCL	
<input type="checkbox"/> Package insert leaflet	<input type="checkbox"/> Certificate of analysis of finished product	
<input type="checkbox"/> Certificate of analysis of diluent	<input type="checkbox"/> Temperature monitoring data during transportation	
<input type="checkbox"/> Airway bill & importing packing list	<input type="checkbox"/> Registration certificate issued by NMRA	
5. Applicant's declaration		
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 misrepresenting I may be held liable for it, this application will be rejected. Any payments made will not be refunded.		
Name & Designation	Signature	Date