



BAHAGIAN REGULATORI FARMASI NEGARA (NPRA)
Ministry of Health Malaysia
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LOT RELEASE APPLICATION FORM FOR BIOLOGICAL PRODUCTS MANUFACTURED IN MALAYSIA

1. APPLICANT INFORMATION

1.1 Name & Address of Product Registration Holder	
1.2 Contact Person	
1.3 Contact no.	

2. PRODUCT INFORMATION

2.1 Category	<input type="checkbox"/> Vaccine <input type="checkbox"/> Plasma product	
2.2 Name of product as registered in Quest3+		
2.3 Ingredients & strength		
2.4 Name of manufacturer		
2.5 Address of manufacturer		
2.6 MAL no.		2.7 Lot no. of product
2.8 Date of manufacture		2.9 Expiry date
2.10 Storage condition	2.11 Type of final container for product <input type="checkbox"/> Vial <input type="checkbox"/> Ampoule <input type="checkbox"/> Prefilled syringe <input type="checkbox"/> Others; please specify _____	

3. DILUENT INFORMATION (IF ANY)

3.1 Name of diluent	3.2 Lot no. of diluent
3.3 Date of manufacture	3.4 Expiry date
3.5 Storage condition(s)	3.6 Types of final container for diluent <input type="checkbox"/> Ampoule <input type="checkbox"/> Prefilled syringe <input type="checkbox"/> Vial

4. QUANTITY MANUFACTURED		
4.1 Total final containers manufactured	4.2 Total dose of production	
5. DOCUMENTATION		
5.1 Documents submitted	<input type="checkbox"/> Lot Summary Protocol <input type="checkbox"/> Plasma Pool Certificate (if applicable) <input type="checkbox"/> Certificate of Analysis of Finished Product <input type="checkbox"/> Finished product test report (with raw data)	
6. APPLICANT DECLARATION		
<p>I hereby certify that the above information given are true and correct as 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 am aware that I may be held liable for it, this application will be rejected and any payments made will not be refunded.</p>		
Remarks		
Name	Signature	Date
FOR OFFICE USE ONLY		
Application number:	LR documents complete? <input type="checkbox"/> Yes <input type="checkbox"/> No.	Received by, date & signature
Product under: <input type="checkbox"/> Phase 1 <input type="checkbox"/> Phase 2 <input type="checkbox"/> Phase 3	List of pending documents: <input type="checkbox"/> Lot summary protocol <input type="checkbox"/> COA <input type="checkbox"/> Plasma Pool Certificate (if applicable) <input type="checkbox"/> Finished product test report	Received by, date & signature
SAB reference no.: NPRA.600-2/6/1 Jld. (3) Bil.()	Date of issuance:	Issued by, date & signature
Date of payment received:	Receipt no.:	Received by, date & signature