



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

- Lot Summary Protocol
 Plasma Pool Certificate (if applicable)
 Certificate of Analysis of Finished Product
 Finished product test report (with raw data)

6. APPLICANT DECLARATION

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.

Remarks

Name

Signature

Date

FOR OFFICE USE ONLY

Application number:

LR documents complete?

 Yes No.

Received by, date & signature

Product under:

 Phase 1 Phase 2 Phase 3

List of pending documents:

 Lot summary protocol COA Plasma Pool Certificate (if applicable) Finished product test report

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