BAHAGIAN REGULATORI FARMASI NEGARA (NPRA)
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SAMPLE SUBMISSION 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	☐ Vaccine ☐ 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 ☐ Vial ☐ Ampoule ☐ Prefilled syringe ☐ 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 ☐ Ampoule ☐ Prefilled syringe ☐ Vial

4. QUANTITY, SIZE AND DOSAGE FORM (SAMPLE AND DILUENT) SUBMITTED

4.1. Sample

4.1.1 Quantity	4.1.2 Size (mL) per container	4.1.3 Dosage form ☐ Liquid/Solution ☐ Freeze Dried/Lyophilized ☐ Others: _____

4.2 Diluent

4.2.1 Quantity	4.2.2 Size (mL) per container

4.3 Testing material (To list down the reagents, standards, etc submitted for testing purpose)

No.	Item	Expiry Date	Storage Condition	Quantity

*Kindly attach a second copy if the space is insufficient

5. 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.

Remarks

Name	Signature	Date

FOR OFFICE USE ONLY	
Samples received by:	Date and time:

Application number:

Adherence to recommended storage temperature:
☐ Comply
☐ Not comply, remarks _____

Serial number (data logger/indicator for temperature sensitive items):

Mode of sample submission:
☐ Hand delivered
☐ Courier service (delivery provider and tracking number)

Sample submission status:
☐ Accept
☐ Reject