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| Hasil carian imej untuk jatanegara malaysia | BAHAGIAN REGULATORI FARMASI NEGARA (NPRA)Lot 36, Jalan Profesor Diraja Ungku Aziz (Jalan Universiti), 46200 Petaling Jaya, SelangorTel: 03-7883 5400Fax: 03-7956 7075Phase 1 Email: vaccinecqc@npra.gov.myPhase 2 & 3 Email: biotesting@npra.gov.my |
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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. |  |
| 1. PRODUCT INFORMATION
 |
| * 1. Category
 | ☐ Vaccine ☐ Plasma product   |
| * 1. Name of product as registered in Quest3+
 |  |
| * 1. 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 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  |
| 1. 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 |
| 1. 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)**

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| No. | Item | Expiry Date | Storage Condition | Quantity |
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\*Kindly attach a second copy if the space is insufficient  |
| 1. 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 Reasons: |