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| Hasil carian imej untuk jatanegara malaysia | **NATIONAL PHARMACEUTICAL REGULATORY AGENCY (NPRA)****Ministry of Health Malaysia**Lot 36, Jalan Universiti (Jalan Profesor Diraja Ungku Aziz), 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**
 |  |
| * 1. **Name & address of**

**manufacturer** |  |
| * 1. **Name and address of other 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** |
| **Application no.:** |  |
| **Datalogger serial no.:** |  |
| **Datalogger expiry/next calibration date:** |  |
| **Adherence to registered storage temperature:** | **☐ Comply****☐ Not comply, remarks :****\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |
| **Mode of sample submission:** | **☐ Hand delivered****☐ Courier service (delivery provider and tracking number)** |
| **Sample submission status:** | **☐ Approved****☐ Reject, remarks :****\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |
| **Samples received date & time:** |  |
| **Sample received by:** |  |