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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, Selangor  Tel: 03-7883 5400  Fax: 03-7956 7075  Email: [vaccinecqc@npra.gov.my](mailto:vaccinecqc@npra.gov.my) | | | | | | | |
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| **SAMPLE SUBMISSION FORM FOR IMPORTED BIOLOGICAL PRODUCTS** | | | | | | | | |
| 1. **APPLICANT INFORMATION** | | | | | | | | |
| **1.1 Name & Address of**  **Product Registration Holder** |  | | | | | | | |
| **1.2 Name & Address of**  **Importer** |  | | | | | | | |
| **1.3 Name & Address of**  **Warehouse** |  | | | | | | | |
| **1.4 Contact Person** |  | | | | | | | |
| **1.5 Contact no.** |  | | | | | | | |
| 1. **PRODUCT INFORMATION** | | | | | | | | |
| * 1. **Category** | **☐ Vaccine** | | | | | **☐ Plasma product** | | |
| * 1. **Name of product as registered in Quest3+** |  | | | | | | | |
| * 1. **Ingredients & strength** |  | | | | | | | |
| **2.4 Name and address of**  **manufacturer** |  | | | | | | | |
| **2.5 MAL no.** | | | | **2.6 Lot no. of product** | | | | |
| **2.7 Date of manufacture** | | | | **2.8 Expiry date** | | | | |
| **2.9 Storage condition** | | | | **2.10 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** | | | |
| 1. **TRANSPORTATION AND COLD CHAIN INSPECTION (CCI)** | | | | | | | | |
| **5.1 Arrival date (at warehouse)** | |  | | | | | | |
| **5.2 Date of CCI** | |  | | | | | | |
| 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** | | | | | | | | |
| **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)** | | | | | | | |
| **Samples received date & time:** |  | | | | | | | |
| **Sample received by:** |  | | | | | | | |