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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  Phase 1 Email: [vaccinecqc@npra.gov.my](mailto:vaccinecqc@npra.gov.my)  Phase 2 & 3 Email: [biotesting@npra.gov.my](mailto: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)**   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **No.** | **Item** | **Expiry Date** | **Storage Condition** | **Quantity** | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  |   **\*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:** | | |  | | | |