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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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| **LOT RELEASE APPLICATION 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 & address of other**   **manufacturer (if any)** |  | | | | | |
| **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**  **Others; please specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | |
| 1. **QUANTITY MANUFACTURED** | | | | | | |
| **4.1 Total final containers manufactured** | | | | **4.2 Total dose of production** | | |
| 1. **DOCUMENTATION** | | | | | | |
| **5.1 Documents submitted** | | **Lot Summary Protocol**  **Plasma Pool Certificate (if applicable)**  **Certificate of Analysis of Finished Product**  **Finished product test report (with raw data)** | | | | |
| 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 and any payments made will not be refunded.** | | | | | | |
| **Remarks** | | | | | | |
| **Name** | **Signature** | | | | | **Date** |
| **FOR OFFICE USE ONLY** | | | | | | |
| **LR documents complete?** | **YES** | | | | | **Received by, date & signature:** |
| **NO. List of pending documents:**  **LSP  COA**  **Plasma Pool Certificate (if**  **applicable)**  **☐ Fisnihed product test report** | | | | |
| **Application number:** | **VLR\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | | | | | **PPLR\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |
| **LR documents complete?** | **Yes** | | | | | **Received by, date & signature** |
| **No.**  **List of pending documents:**  **Lot summary protocol**  **COA**  **Plasma Pool Certificate (if**  **applicable)**  **Finished product test report** | | | | |
| **Product assigned under:** | **Phase 1  Phase 2  Phase 3** | | | | |
| **SAB reference no.:** | **NPRA.600-2/6/1 Jld. ( ) Bil.( )** | | | | | **Issued by, date & signature** |
| **SAB Issuance date:** |  | | | | |
| **SAB Issuance amount:** |  | | | | |
| **Date of payment received:** |  | | | | | **Received by, date & signature** |
| **Receipt no.:** |  | | | | |