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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 7075Email: 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.:** |  |