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| Hasil carian imej untuk jatanegara malaysia | **NATIONAL PHARMACEUTICAL REGULATORY AGENCY (NPRA)**  **Ministry of Health Malaysia**  Lot 36, Jalan Universiti, 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** | | | | | | | |
| 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+** |  | | | | | | |
| **2.3 Ingredients & strength** |  | | | | | | |
| **2.4 Name of manufacturer** |  | | | | | | |
| **2.5 Name 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** | | |
| 1. **QUANTITY IMPORTED** | | | | | | | |
| **4.1 Quantity in primary packaging** | | | **4.2 Quantity in secondary packaging** | | | **4.3 Total no. of units per shipment *(Specify no. of doses for vaccines)*** | |
| 1. **TRANSPORTATION** | | | | | | | |
| **5.1 Arrival date** | | | | | **5.2 Transit point (if any)** | | |
| **5.3 Route of transportation**  **Air**  **Ocean** | | | | | **5.4 Mode of transportation**  **Active system**  **Passive system** | | |
| 1. **DOCUMENTATION** | | | | | | | |
| **6.1 Documents submitted** | | **Lot Summary Protocol**  **Lot Release Certificate**  **Plasma Pool Certificate (if applicable)**  **Certificate of Analysis of Finished Product**  **Importing Packing List**  **Air Way Bill / Sea Way Bill** | | | | | |
| 1. **REDRESSING / REPACKING/RELABELLING INFORMATION**   **(ONLY APPLICABLE FOR MAL NO. WITHOUT SUFFIX -R)** | | | | | | | |
| **7.1 Does this product require redressing/repacking/ relabelling?**  **Yes. Refer to 7.2**  **No** | | | | | **7.2 Have you obtained approval to conduct ANY redressing/repacking for the product from NPRA?**  **Yes. Approval date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **No** | | |
| 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:**  **LRC  COA  AWB/SWB**  **Importing Packing List**  **☐ Plasma Pool Certificate** | | | | | |
| **SAB reference no.:**  **NPRA.600-2/6/1 Bil.( )** | **Amount:**  **RM200 (CCI Only)**  **RM300 (Monovalent V)**  **RM500 (Polyvalent V/Single PP)**  **RM800 (Complex PP)**  **RM1000 (Combination V)**  **Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | | | | | | **Issued by, date & signature** |
| **Date of issuance:** |
| **Date of payment received:** | **Receipt no.:** | | | | | | **Received by, date & signature** |