|  |  |
| --- | --- |
| 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 |
|  |
|  |  |
| **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**[ ]  **Others; please specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  |
| 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** [ ]  **Importing Packing List**[ ]  **Lot Release Certificate** [ ]  **Air Way Bill / Sea Way Bill** [ ]  **Plasma Pool Certificate (if applicable)** [ ]  **Certificate of Analysis of Finished Product** |
| 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:**[ ]  **LSP** [ ]  **LRC** [ ]  **COA**[ ]  **AWB/SWB**[ ]  **Importing Packing List****☐ Plasma Pool Certificate** |
| **Application number:** | [ ]  **VLR\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | [ ]  **PPLR\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |
| **SAB reference no.:**  | **NPRA.600-2/6/1 Jld. ( ) Bil.( )** | **Issued by, date & signature** |
| **SAB issuance date:** |  |
| **SAB Issuance amount** | **Amount:** [ ]  **RM200 (CCI Only)**[ ]  **RM300 (Monovalent V)**[ ]  **RM500 (Polyvalent V/Single PP)**[ ]  **RM800 (Complex PP)**[ ]  **RM1000 (Combination V)**[ ]  **Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |
| **Date of payment received:** |  | **Received by, date & signature** |
| **Receipt no.:** |  |