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| Hasil carian imej untuk jatanegara malaysia | BAHAGIAN REGULATORI FARMASI NEGARA (NPRA)Ministry of Health MalaysiaLot 36, Jalan Profesor Diraja Ungku Aziz (Jalan Universiti), 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+
 |  |
| 2.3 Ingredients & strength |  |
| 2.4 Name of manufacturer |  |
| 2.5 Address of 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 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
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| 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 |
| Application number: |  LR documents complete?[ ] Yes[ ] No. List of pending documents:[ ] Lot summary protocol[ ] COA [ ]  Plasma Pool Certificate (if applicable)[ ] Finished product test report | Received by, date & signature |
|  Product under:[ ] Phase 1[ ] Phase 2[ ] Phase 3 |
| SAB reference no.: NPRA.600-2/6/1 Jld. (3) Bil.( )  | Date of issuance: | Issued by, date & signature |
| Date of payment received: | Receipt no.: | Received by, date & signature |