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| Hasil carian imej untuk jatanegara malaysia | BAHAGIAN REGULATORI FARMASI NEGARA (NPRA)  Ministry of Health Malaysia  Lot 36, Jalan Profesor Diraja Ungku Aziz (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 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 | | | | | | |
| 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 |