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| Hasil carian imej untuk jatanegara malaysia | BAHAGIAN REGULATORI FARMASI NEGARA (NPRA)  Lot 36, Jalan Profesor Diraja Ungku Aziz (Jalan Universiti), 46200 Petaling Jaya, Selangor  Tel: 03-7883 5400  Fax: 03-7956 7075  Phase 1 Email: [vaccinecqc@npra.gov.my](mailto:vaccinecqc@npra.gov.my)  Phase 2 & 3 Email: [biotesting@npra.gov.my](mailto:biotesting@npra.gov.my) | | | |
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| **SAMPLE SUBMISSION 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 |  | | | |
| 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, SIZE AND DOSAGE FORM (SAMPLE AND DILUENT) SUBMITTED | | | | |
| **4.1. Sample** | | | | |
| 4.1.1 Quantity | | 4.1.2 Size (mL) per container | | 4.1.3 Dosage form  ☐ Liquid/Solution  ☐ Freeze Dried/Lyophilized  Others: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **4.2 Diluent** | | | | |
| 4.2.1 Quantity | | | 4.2.2 Size (mL) per container | |
| **4.3 Testing material (To list down the reagents, standards, etc submitted for testing purpose)**   |  |  |  |  |  | | --- | --- | --- | --- | --- | | No. | Item | Expiry Date | Storage Condition | Quantity | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  |   \*Kindly attach a second copy if the space is insufficient | | | | |
| 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. | | | | |
| Remarks | | | | |
| Name | | Signature | | Date |
| FOR OFFICE USE ONLY | | | | |
| Samples received by: | | | Date and time: | |
| Application number:  Adherence to recommended storage temperature:  ☐ Comply  ☐ Not comply, remarks \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Serial number (data logger/indicator for temperature sensitive items):  Mode of sample submission:  ☐ Hand delivered  ☐ Courier service (delivery provider and tracking number)  Sample submission status:  Accept  Reject  Reasons: | | | | |