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| **PLASMA PRODUCT 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. **PLASMA PRODUCT INFORMATION** | | | | | | | | |
| * 1. **Name of plasma product**   **(as registered in Quest system)** | |  | | | | | | |
| **2.2 Ingredients & strength** | |  | | | | | | |
| **2.3 Name of manufacturer** | |  | | | | | | |
| **2.4 Name of other manufacturer (If any)** | |  | | | | | | |
| **2.5 MAL no.** | | | | | | **2.6 Lot no. of plasma product** | | |
| **2.7 Date of manufacture** | | | | | | **2.8 Expiry date** | | |
| **2.9 Storage condition** | | | | | | **2.10 Types of final container plasma product**  **☐ Vial☐ Prefilled syringe**  **☐ Ampoule**  **☐ Others; please specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | | |
| 1. **DILUENT INFORMATION (IF ANY)** | | | | | | | | |
| **3.1 Name of diluent** | | | | | | **3.2Lot no. of diluent** | | |
| **3.3 Date of manufacture** | | | | | | **3.4 Expiry date** | | |
| **3.5 Storage condition** | | | | | | **3.6 Types of final container for diluent**  **☐ Ampoule**  **☐ Prefilled syringe** | | |
| 1. **QUANTITY OF PLASMA PRODUCT IMPORTED** | | | | | | | | |
| **4.1 Quantity in primary packaging** | | | | **4.2 Quantity in secondary packaging** | | | | **4.3 Total no. of doses per shipment** |
| 1. **TRANSPORTATION OF PLASMA PRODUCT** | | | | | | | | |
| **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**  **☐ Certificate of Analysis of Finished Product**  **☐ Importing Packing List**  **☐ Air Way Bill / Sea Way Bill** | | | | | | | |
| 1. **REDRESSING / REPACKING/RELABELLINGINFORMATION**   **(ONLY APPLICABLE FOR MAL NO. WITHOUT SUFFIX -R)** | | | | | | | | |
| **7.1 Do these product require redressing/repacking/ relabelling?**  **☐ Yes. Refer to 7.2**  **☐ No** | | | | | | **7.2 Have you submitted a request letter to conduct ANY redressing/repacking for these products to the Regulatory Coordination Section, Centre for Product Registration (SKR PPP)?**  **☐ Yes. Submission date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **☐ No** | | |
| **The Malaysian Drug Registration Guidance Document defines redressing, repacking and relabelling as a manufacturing activity. Manufacturing of products without a valid manufacturing license is an offense under**  **Control of Drugs and Cosmetics Regulations 1984 [Regulation 12(1)]** | | | | | | | | |
| 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** | | | | | | | | |
| **PPLR Documents complete?** | | | **☐ YES** | | | | **Received by, date & signature** | |
| **☐ NO. List of pending documents:**  **☐ LRC ☐ COA ☐ AWB/SWB**  **☐ Importing Packing List** | | | |
| **SAB Reference No.:**  Bil( ) BPFK/PKK/16/04 | | | **Amount:**  **☐RM200**  **☐RM500**  **☐RM800** | | | | **Issued by, date & signature** | |
| **Date of issuance:** | | |
| **Date of payment received:** | | | **Receipt no.:** | | | | **Received by, date & signature** | |