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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**
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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** |
| **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** |