Agensi Regulatori Farmasi Negara (NPRA)
Kementerian Kesihatan Malaysia
Lot 36, Jalan Universiti, 46200 Petaling Jaya, Selangor
No. Tel. : 03-78835400
No. Faks: 03-79567075
Laman Web: http://npra.moh.gov.my
Emel Unit Kawalan Kualiti Produk Darah: pplr@npra.gov.my
Emel Pemeriksa Rangkaian Sejuk : cc@npra.gov.my

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.	

2. PLASMA PRODUCT INFORMATION

2.1 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 _____

3. 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

4. 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**

5. TRANSPORTATION OF PLASMA PRODUCT

5.1 Arrival date	5.2 Transit point (if any)

5.3 Route of transportation	5.4 Mode of transportation
☐ Air ☐ Ocean	☐ Active system ☐ Passive system

6. 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

7. 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)]

8. 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 Date of issuance:	Amount: ☐RM200 ☐RM500 ☐RM800	Issued by, date & signature
Date of payment received:	Receipt no.:	Received by, date & signature