الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Guideline on the Scientific Data Requirements for Plasma Master File (PMF)

Adopted from European Medicines Agency (EMA)

Version 1.3

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Saudi Food & Drug Authority

Drug Sector

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Saudi Food and Drug Authority

Vision and Mission

Vision

To be a leading international science-based regulator to protect and promote public health

Mission

Protecting the community through regulations and effective controls to ensure the safety of food, drugs, medical devices, cosmetics, pesticides and feed

Document Control

Version	Adopted by	Date	Comments
1.0	13/03/2010	Executive Directorate of Product Evaluation	Published for comments
1.1	31/08/2010	Executive Directorate of Product Evaluation	Final
1.2	22/8/2017	Standards Setting Directorate	This guideline replaces "Guidelines for production and quality control of blood product (Version 1.1)"
1.3	29/11/2023	Executive Directorate of Pharmaceutical Products Evaluation	Updated

What is New in version no. 1.3 ?

The following table shows the update to the previous version:

Section	Description of change
1. General Information (Summary)	**Update:** 1.1 Plasma-derived products' list 1.3 General logistics
2. Technical Information on Starting Materials	**Update:** 2.2.1 Compliance with European Pharmacopoeia Monographs 2.2.2 Testing of blood/plasma donations and pools for infectious agents, including information on test methods and, in the case of plasma pools, validation data on the tests used 2.2.3 Technical characteristics of bags for blood and plasma collection, including information on anticoagulant solutions used

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This document provides guidance on the structure and requirements for presentation of data on starting material in a Plasma Master File (PMF). This guidance shall also apply when the PMF certification scheme is not followed.

Introduction and Principle of a PMF

The PMF contains common information on plasma, from collection to plasma pool, relevant to the manufacture of all human plasma-derived medicinal products and medical devices for which this PMF is applicable.

Cryoprecipitates and any other intermediates are not part of the PMF dossier; these should be described in the relevant sections of the dossier for each individual medicinal product, medical device or investigational medicinal product. This Guideline describes the structure and scientific data required to be submitted in a PMF.

Applicants using the PMF certification system need to clearly identify' and make reference to the PMF in the dossier of each medicinal product. Reference to more than one PMF is possible but this must be clearly indicated. Where information is specific to a particular product (e.g. immunization scheme used for specific immunoglobulin) this should be included in the dossier for the relevant product and not in the PMF, unless otherwise stated in this guideline.

Annual updates:

The PMF shall be updated and re-submitted for approval on an annual basis. The scientific documentation for the annual update should include the following:

- Update as described in annex 1 "check list on annual update".
- A list of all changes applied for with the annual update
- List of commitments or follow up measures and accompanying requested data.
- A compiled updated integrated PMF including:
    - ❖ All changes submitted during the year and with the annual update, including updated lists with highlighted changes, and specifying historic information where this is still relevant for batches that may be on the market e.g. information on the period when an organization was actively supplying plasma.
    - ❖ Update in sections 1.2, 2.1.3 and 2.3. In addition, when relevant, update on deletions of country(ies) and/or organization(s)/establishment(s) used for blood/plasma collection, or in which testing of donation and plasma pools is carried

out, and deletion of blood bag(s) may be submitted at the annual update. The reason for the deletion should be specified.

- The newly available epidemiological data of the blood/plasma collection establishments together with its scientific evaluation.
- Update of inspection/audit status of blood establishments (see annexes).
- Cases for which it was retrospectively found that a donation should have been excluded from processing or has been excluded and a viral marker found retrospectively to be positive.
- The results of NAT (Nucleic Acid Amplification Technique) testing of plasma pools indicating how many positive pools/mini-pools were detected and how many positive donations were identified.
- Participation in proficiency studies (viral marker testing and NAT testing).

1. General Information (Summary)

1.1. Plasma-derived products' list

The Plasma Master File shall provide a list of the medicinal products for which the Plasma Master File is valid, whether the medicinal products have been granted a marketing authorization or are in the process of being granted such an authorization, with the relevant Competent Authority(ies) for each plasma-derived product. This list should also include medical devices incorporating stable derivatives of human blood or human plasma and investigational medicinal products.

In addition, a list of medicinal products incorporating stable derivatives of human blood or human plasma (e.g. active substances, excipients, stabilisers) should be also submitted whenever contracts and/or agreements exist between the PMF holder and third companies. When the final product is not known to the PMF holder, because intermediates are sold to other companies, a list of these cryoprecipitates and intermediates should be submitted.

1.2 Overall safety strategy

Critical evaluation of the contribution of each of the significant steps in the processing of plasma from collection to preparation of the plasma pool to the overall safety strategy should be provided. It should demonstrate how different aspects of the PMF interrelate to contribute to the overall safety of the plasma. This critical evaluation should incorporate all aspects of the PMF and draw together the following information; the epidemiological data on blood transmissible infections known for the donor population, criteria for the use of donations from first time donors (when applicable), the system of donor selection criteria including measures that reduce the risk of (v)CJD, screening of donations, minipool strategy if relevant, the testing of the plasma pools, viral load limits for plasma pools and normal size of manufacturing pool, inventory hold and "look-back" procedures, The critical evaluation should be supported by diagrams, e.g. to describe the plasma donation test system and strategy of (mini/plasma) pool testing. The aim should be to demonstrate how the company's strategy integrates to robustly ensure that all measures taken throughout the collection, processing, testing, storage and transport of the plasma work together to provide a safe plasma pool.

The estimated residual risk of missing viraemic donations that may enter the production pool

should be described.

1.3 General logistics

A flow-chart, describing the complete supply-chain for plasma from collection to the manufacture of the plasma pool, should be provided. This should/include all relevant organizations involved in the collection, testing, storage and transport of blood or plasma. The arrangements in place between collection establishments and testing laboratories should be clearly indicated in the flow chart. The flow chart should describe the complete transport chain including details of international transport and customs.

2. Technical Information on Starting Materials

The quality and safety of products derived from human plasma rely both on the source plasma material and the further manufacturing processes. Therefore, the collection, testing, storage and transportation of human plasma are major factors in the quality assurance of the manufacture of plasma-derived products. These operations should be subject to periodic inspections in order to ensure the expected product quality.

If a blood establishment uses mobile or temporary equipped centres to collect blood or plasma, these centres should operate under the same quality system as the establishment they are connected to.

An exhaustive list of names and addresses of blood establishments and dedicated collection centers excluding mobile or temporary equipped sites, in which collection and/or testing, storage and transport of donations and testing of plasma pools is carried out, including any sub contractors should be provided using the tabular format given in the annexes II, III, IV and V together with the relevant supporting documents.

2.1 Plasma Origin:

2.1.1 Information on centers or establishments in which blood/plasma collection is carried out, including inspection and approval, and epidemiological data on blood transmissible infections.

A. Information on centers or establishments in which blood/plasma collection is carried out See Annex II.

An exhaustive list of names and addresses of blood establishments and dedicated collection centers, excluding mobile or temporary equipped sites, from which plasma is still available, should be provided as an appendix to this section. Suppliers of plasma should also indicate the address, duties and approval status by Saudi FDA of their look back department. The suppliers of plasma, for which special criteria have been defined (such as anti-D), should be identified.

Blood establishments and dedicated collection centers excluding mobile or temporary equipped sites, should be inspected and approved by Saudi competent authority in accordance with the (SFDA guidelines for collection and testing blood and blood products) . If blood/plasma centers

are closed and plasma is still available, they should be kept in the list clearly indicating the date of closure and the reason. For those centers that are temporarily closed and or have stopped delivering plasma, explanation of their status should be provided. Traceability should be guaranteed in all cases when the center is closed.

If mobile or temporary equipped sites are used, the PMF holder should indicate the total number of them and how they relate to the organization.

B. Characteristics of donations

For any organization responsible for collection it should be specified whether the donors are non-remunerated or remunerated. The nature of any compensation for donation should be described if applicable. "A donation is considered voluntary and non-remunerated if the person gives blood, plasma or cellular components of his/her own free will and receives no payment of it, either in the form of cash or in kind which could be considered a substitute for money. This would include time off work other than that reasonably needed for the donation and travel. Small tokens, refreshments and reimbursements of direct travel costs are compatible with voluntary, non-remunerated donations.

C. Epidemiological data on blood transmissible infections should be submitted in accordance with Guideline on Epidemiological Data on Blood Transmissible Infections.

2.1.2 Information on centers or establishments in which testing of donations and plasma pools is carried out, including inspection and approval status.

See Annex III.

The test laboratory used for each center should be specified.

If confirmatory tests are performed at separate laboratories full details should be supplied.

If test laboratories are no longer used they should be listed in a stand-alone table indicating the date when use of the laboratory ceased and the reason.

2.1.3. Selection / exclusion criteria for blood /plasma donors.

Confirm for each organization the compliance with the Selection / exclusion criteria for blood /plasma donors according to the requirements of the European pharmacopeia's Monographs. Where appropriate, indicate compliance with SFDA regulations and international recommendations. In addition, specify any requirements versus emerging infectious agents in a specific country and confirm that Selection / exclusion criteria for blood /plasma donors are in compliance with such requirements.

2.1.4. System in place which enables the path taken by each donation to be traced from the blood / plasma collection establishment through to finished products and vise versa.

Describe the system in place, which enables the path taken by each donation to be traced from the blood / plasma collection establishment through to finished products, including testing facility and vise versa. Confirm compliance with SFDA guidelines especially concerning traceability including labeling and record keeping. If several organizations / countries are involved, the information is given for each system. Include information on how traceability is maintained for closed collection centers.

Given information on steps that would be taken if it was found retrospectively that donation (S) should have been excluded from processing (look-back procedure , any system in place to retain samples) and justify the system . Specify the length of look-back period in accordance with SFDA guidelines.

The information on system for traceability and post-donation information measures should also be provided in the case of intermediates and plasma- derived products supplied to third parties (e.g. albumin supplied for use as excipient).

2.2 Plasma quality and safety

2.2.1 Compliance with European Pharmacopoeia Monographs.

Confirm compliance with the Ph. Eur, Monograph for Human Plasma for Fractionation. Confirm compliance with any requirements for particular products for which Ph. Eur. Monographs exist.

Describe the conditions for processing including freezing, and for storage of plasma for every establishment or centre responsible for collecting blood/plasma. Compliance with the Ph. Eur. requirements for freezing and storage should be included in Annex II, with an indication of whether requirements for recovery of proteins that are labile or not labile in plasma are met. Confirm validation of the freezing conditions.

2.2.2 Testing of blood/plasma donations and pools for infectious agents, including information on test methods and, in the case of plasma pools, validation data on the tests used.

Information should be provided:

- On screening tests for markers of infection required according to SFDA guidelines for collection and testing blood and blood products and the European Pharmacopoeia.
- On any other screening tests carried out

Test	Tests Performed on:		
	Individual Donation	Minipool (size) (if few, nil)	Plasma Pool
HBsAg			
HIV 1 and 2 Antibody			
HCV Antibody			
HCV RNA			
B19 DNA			
Other tests			

When minipools of donations are tested, the rationale and full details of this testing should be provided, including the size of the minipools. It should be clarified whether all donations are tested in the same way. Criteria for acceptance or rejection of donation/pool and re-testing policy should be described.

It should be clarified whether all minipools/pools are tested in the same way (e.g. size of minipool,

types of viruses). If this is not the case, the different strategies should be described.

Criteria for acceptance or rejection of donation/pool and re-testing policy should be described

List of kits used for each test, including NAT testing.

Parameter	**Test method**	**Brand name of the kit**	**CE mark (yes/No)**	**Used for**		**Testing site**
				Individual donations	**Minipool/Plasma pool**	
HBsAg						
HIV 1 and 2 Antibody						
HCV Antibody						
HCV RNA						
B19 DNA						
Other tests						

Validation of testing methods:

a. Testing of donations

Confirm that tests are carried out in accordance with the manufacturers' directions for use.

Copies of instructions for use of commercial kits are not needed.

For CE-marked test kits submission of complete validation data are not required. In the absence of a CE mark, the applicant should demonstrate that the test kit can be considered "state of the art" according to Common Technical Specifications (CTS), with particular attention to evidence for seroconvert ion sensitivity and sub-type sensitivity in comparison with a CE marked test kit .

In case of mini pool testing by NAT as part of the screening of individual donations, a brief description of the analytical procedures for all the NAT methods should be provided, whether non CE-marked in-house methods or commercial kits are used. A summary of the validation reports should also be provided and should include specificity, detection limit and robustness. The description of the analytical procedures and validation are not required for the testing of small pools by NAT if the test is CE marked for this purpose. In the latter case, though, information on

the detection limit as related to the single donation, should be provided.

b. Viral marker testing of the plasma pool(s)

For every testing laboratory, provide a description of the test method and a report on the validation of the test methods used on each plasma pool & according to the guidelines:

- Guideline on Validation of Immunoassay for the Detection of Antibody to human immunodeficiency Virus (Anti-HIV) in Plasma Pools, (EMEA/CHMP/BWP/298388/2005) .
- Guideline on Validation of Immunoassay for the Detection of Hepatitis B Virus Surface Antigen (HBsAg) in Plasma Pools, (EMEAJCHMP/BWP/298390/2005).

Information on the sensitivity of the test for each marker as a function of pool size should also be included.

c. NAT testing of the Plasma pool(s)

All NAT methods used for plasma pool testing should comply with the requirements in Ph Eur General Methods 2.6.21 Nucleic acid amplification techniques. For every testing laboratory, provide a description of the test method and a validation report for each of the NAT tests performed.

NAT for HCV RNA is required by the Ph. Eur. Monograph “Human Plasma for Fractionation”. Validation is carried out according to the Ph. Eur. Guidelines for validation of NAT for the detection of HCV RNA in plasma pools. As recommended in this guideline, the ability of the analytical procedure to detect all HCV genotypes is demonstrated.

If the list of plasma-derived products for which the PMF is valid includes anti-immunoglobulin for intravenous and/or intramuscularly administration and/or human plasma (pooled and treated for virus inactivation), NAT for B 19 DNA is also carried out as required by the respective Ph. Eur. Monographs. The maximum B19 virus burden should be in accordance to the current version of the Ph. Eur. monograph. Validation is performed according to the guideline for validation of NAT for quantifation of B 19 virus DNA in plasma pools . Included in this guideline is the recommendation that for the design of primers and probes the existence of the B19 variants A6

and V9 is taken into account, The International Committee on the Taxonomy of Viruses (ICTV) classifies these variants under B19 virus (Eighth report of the ICTV, Eds,; C.M. Fauquet, M.A. Mayo et al., Elsevier, page 361).

In case that the applicant performs NAT testing for viruses other than HCV and B 19 the validation studies are carried out according to the following guidelines:

- ICH Topic Q2A Note for guidance on validation of analytical methods: definitions and terminology (CPMP/ICH/38 1/95).
- ICH Topic Q2B Note for guidance on validation of analytical procedures: methodology (CPMP/ICH/28 1/95).
- Ph. Eur. General method 2.6.21 "Nucleic acid amplification techniques" (NAT).

For practical purposes, in the case of NAT qualitative methods, validation is carried out taking into consideration the above mentioned guideline Validation of NAT for the Detection of 1-WV RNA in Plasma Pools.

Provide information on specificity, including the ability of the assays to detect different genotypes, sensitivity and robustness.

Proficiency Studies: Results arising from participation in proficiency studies should be reported.

2.2.3 Technical characteristics of bags for blood and plasma collection, including information on anticoagulant solutions used.

Name of bag 1, 2, 3... etc	Manufacturer	Anticoagulant Solution	CE-Marked yes/no

Justification should be given when the bag is not CE marked under Council Directive 93/42/EEC concerning Medical Devices, as amended. In addition, for non-CE marked bags the following information should be provided in an Appendix to this section:

Describe the material of the bag, the composition of the bag and its specification; confirm that materials comply with Ph. Eur., any leachables like plasticisers and adhesives, demonstrating that they do not pose any undue risk, describe the sterilization procedure including its validation. Proof of absence of residual toxic substances. Where the bag contains an anticoagulant solution, give information on production and quality control as for a medicinal product, confirm compliance with Ph. Eur. requirements and results of a real time storage stability study of plasma in the container concerned.

2.2.4 Conditions of storage and transport of plasma.

See Annex IV and V.

Describe the conditions for freezing and storage of plasma for every establishment responsible for collecting blood/plasma (i.e. time to freezing, time to reach the target core temperature, at which temperature, to which temperature,) including the following:

- Compliance with Ph. Eur. with respect to freezing and storage.
- Sites/organizations which are involved in the storage and indicate whether they have been inspected by a Competent Authority.
- Conditions of storage (temperature and maximum time).
- Data on the validation of the freezing conditions.

Describe the conditions of transport of plasma including the following:

- Confirm compliance with requirements in the Ph. Eur. Monograph for Human Plasma for Fractionation and if applicable, with any Ph. Eur. requirements for particular products.
- Transport flows from centers of collection to interim storage, if relevant, and further to fractionation sites.
- Organizations which are involved in the transport (own and contractors) and indicate whether they have been inspected by a Competent Authority.
- Provide a summary of the system in place to ensure the transport is performed under appropriate conditions. (Time, temperature and GMP compliance). Provide validation data to support the storage and transport conditions.

2.2.5 Procedures for any inventory hold period.

Provide details of any inventory hold procedure and provide the justification for the chosen period. Specify whether the procedure applies to all plasma or specify for which plasma it is applicable.

2.2.6 Characterization of the plasma pool.

Plasma pool preparation:

Provide details of all sites at which the pooling of plasma is performed.

(Give a short description of all the relevant procedures in preparation of the plasma pool: thawing process, inspection of individual bags or bottles before pooling, opening and pooling.

Indicate the size of the plasma pool, in number of donations and in liters.

Clarify whether or not the plasma pool is the same for all products.

Sampling of plasma pool:

Define and justify the plasma pool (e.g. cryosupernatant or complete plasma pool) from which the samples for the viral marker testing are obtained.

Describe the sampling procedure, any manipulation of samples and the storage conditions of the pool samples.

Testing of the plasma pools for all sites should be performed in accordance with the details provided in this plasma master file.

2.3 System in place between the plasma-derived medicinal product manufacturer and/or plasma fractionators/processor on the one hand, and blood establishments on the other hand, which defines the conditions of their interaction and their agreed specifications.

Confirm that a contract exists between the blood establishments on one hand and the manufacturer on the other hand to ensure the interaction between them. In addition, confirm that adequate criteria have been agreed between these organizations in order to allow action to be taken when appropriate.

Concerning systems for notification, confirm compliance with Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 200 l/83/EC, and Commission Directive 2005/61/EC of 30 September 2005 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards tractability requirements and notification of serious adverse reactions and events.

It should be declared that all blood establishments have signed the contracts mentioned above.

ANNEX I: CHECK LIST ON THE ANNUAL UPDATE

Checklist to be used with the Annual Update of the PMF

Change/Update	Submitted with annual update (AU) or Notified/Approved during the year (N or A)	Scope and reason for change	Type[11]	Variation Number[12]	PMF procedural number	Date of Notification /Approval	Comment/ Implementation date	Implemented current PMF[13]
Item: 1.1 Plasma-derived products' list								
Change								
Item: 2.1.1 Information on centres or establishments in which blood/plasma collection is carried out, including inspection and approval, and epidemiological data on blood transmissible infections								
Addition of country of blood/plasma collection centres or establishments								
Deletion of country of blood/plasma collection centres or establishments								
Change in the organisation								
Change in the name of organisation								

Change/Update	Submitted with annual update (AU) or Notified/Approved during the year (N or A)	Scope and reason for change	Type[11]	Variation Number[12]	PMF procedural number	Date of Notification /Approval	Comment/ Implementation date	Implemented current PMF[13]
Addition of organisation								
Deletion of organisation								
Addition of a new blood/plasma collection establishment for an organisation **already** included in the PMF.								
Addition of a blood/plasma collection establishment for an organisation **not yet** included in the PMF								
Deletion of a blood/plasma collection establishment								
Change of characteristics of donations								
Item: 2.1.2 Information on centres or establishments in which testing of donations and plasma pools is carried out, including inspection and approval status								
Addition or change of a site testing the donations within an organisation **already** included in the PMF								

Change/Update	Submitted with annual update (AU) or Notified/Approved during the year (N or A)	Scope and reason for change	Type[11]	Variation Number[12]	PMF procedural number	Date of Notification /Approval	Comment/ Implementation date	Implemented current PMF[13]
Addition or change of a site testing the donations within an organisation **not yet** included in the PMF								
Deletion of a site testing the donations within an organisation included in the PMF								
Addition or change of a site testing mini-pools/plasma pools within an organisation **already** included in the PMF								
Addition or change of a site testing mini-pools/plasma pools within an organisation **not yet** included in the PMF								
Deletion of a site testing mini-pools/plasma pools within an organisation included in the PMF								
Item 2.1.4. System in place which enables the path taken by each donation to be traced from the blood/plasma collection establishment through to finished products and vice versa								
Change in the system in place, which enables the path taken by each donation to be traced from the blood/plasma collection establishment through to finished products and vice versa								

Change/Update	Submitted with annual update (AU) or Notified/Approved during the year (N or A)	Scope and reason for change	Type[11]	Variation Number[12]	PMF procedural number	Date of Notification /Approval	Comment/ Implementation date	Implemented current PMF[13]
Change in 'look-back' procedure								
Item: 2.2.2 Testing of blood/plasma donations and pools for infectious agents, including information on test methods and, in the case of plasma pools, validation data on the tests used								
Change of test performed on donations/mini-pools/plasma pools (specification)								
Change in kits/methods to test donations/mini-pools/plasma pools								
Item: 2.2.3 Technical characteristics of bags for blood and plasma collection, including information on anticoagulant solutions used								
Addition of or replacement with a CE marked blood bag								
Addition of or replacement with a **non-**CE marked blood bag								
Changes of the composition, production, shelf life and control of non-CE marked blood bags								
Deletion of CE marked blood bag								

Change/Update	Submitted with annual update (AU) or Notified/Approved during the year (N or A)	Scope and reason for change	Type[11]	Variation Number[12]	PMF procedural number	Date of Notification /Approval	Comment/ Implementation date	Implemented current PMF[13]
Item: 2.2.4 Conditions of storage and transport of plasma								
Change in the sites/organisations involved in the storage and/or transport								
Change in storage and/or transport conditions								
Item: 2.2.5 Procedures for any inventory hold period								
Introduction/extension/ a more stringent procedure e.g. release only after retesting of donors								
Removal or reduction in length of period								
Item: 2.2.6 Characterisation of the plasma pool								
Change in plasma pool preparation (e.g. manufacturing method, pool size, storage, control procedures, sampling)								

ANNEX II: INFORMATION ON CENTRES OR ESTABLISHMENTS IN WHICH BLOOD/PLASMA COLLECTION IS CARRIED OUT

Address	Sequential Number[14]	Activity		Inspection by an EEA competent authority			Inspection by a non-EEA competent authority			Audit/Certification			
		Plasma-pheresis	Whole Blood collection	Member State	Date of last inspection	Final outcome (observations[15])	Country	Date of last inspection	Final outcome (observations)	Description[17]	Name of organisation[18]	Outcome	Date
Organisation 1 responsible for collection													
Country 1													
Full address site 1 Organisation 1 Country1		☐	☐										
Full address site 2 Organisation 1 Country 1		☐	☐										
Full address site 3 Organisation 1 Country 1		☐	☐										
Organisation 2 responsible for collection													
Country 1													
Full address site 1 Organisation 2 Country 1		☐	☐										
Full address site 2 Organisation 2 Country 1		☐	☐										
Country 2													
Full address site 3 Organisation 2 Country 2		☐	☐										

ANNEX III: INFORMATION ON CENTRES OR ESTABLISHMENTS IN WHICH TESTING OF DONATIONS AND PLASMA POOLS IS CARRIED OUT

Address	Specify the sequential number(s) of the collection centre(s) for which the testing is performed	Testing					Inspection by an EU competent authority			Inspection by a non-EU competent authority			Audit			
		Viral Marker		NAT testing			Member State	Date of last inspection	Final outcome (observations[19])	Country	Date of last inspection	Final outcome observations	Description[21]	Name of organisation[22]	Outcome	Date
		Donations	Plasma Pools	Donations	Mini Pools	Plasma Pools										
Organisation 1 responsible for collection																
Country 1																
Full address site 1 Organisation 1 Country 1		☐	☐	☐	☐	☐										
Full address site 2 Organisation 1 Country 1		☐	☐	☐	☐	☐										
Country 2																
Full address site 3 Organisation 1 Country 2		☐	☐	☐	☐	☐										
Organisation 2 responsible for collection																
Country 1																
Full address site 1 Organisation 2 Country 1		☐	☐	☐	☐	☐										
Full address site 2 Organisation 2 Country 1		☐	☐	☐	☐	☐										

Documented evidence of satisfactory outcome should be submitted (e.g. certificate, close-out letter, inspection report). If the final outcome is not satisfactory, a summary objections found during the last inspection, the follow-up and the appropriate corrective actions should be included.

Describe nature of and frequency of audit/certification
Specify name of organization carrying out the audit/certification.

ANNEX IV: INFORMATION ON CENTRES AND ESTABLISHMENTS IN WHICH STORAGE OF DONATIONS AND PLASMA POOLS IS CARRIED OUT

Address	Specify the sequential number(s) of the collection centre(s) for which the storage is performed	Storage		Inspection by an EU competent authority			Inspection by a non-EU competent authority			Audit (Frequency and date of last audit)				Conditions of storage (temperature and maximum time) Compliance with Ph Eur with respect to freezing and storage
		Freezer	Freezing Room	Member State	Date of last inspection	Final outcome (observations[23])	Country	Date of last inspection	Final outcome observations	Description[25]	Name of organisation[26]	Out come	Date	
Organisation 1 responsible for collection														
Country 1														
Full address site 1 Organisation 1 Country 1		☐	☐											
Full address site 2 Organisation 1 Country 1		☐	☐											
Country 2														
Full address site 3 Organisation 1 Country 2		☐	☐											
Organisation 2 responsible for collection														
Country 1														
Full address site 1 Organisation 2 Country 1		☐	☐											

Documented evidence of satisfactory outcome should be submitted (e.g. certificate, close-out letter, inspection report). If the final outcome is not satisfactory, a summary of the objections found during the last inspection, the follow-up and the appropriate corrective actions should be included.

Describe nature of and frequency of audit/certification
Specify name of organization carrying out the audit/certification.

ANNEX V: INFORMATION ON CENTRES AND ESTABLISHMENTS IN WHICH TRANSPORT OF DONATIONS AND PLASMA POOLS IS CARRIED OUT

Address	Specify the sequential number(s) of the collection centre(s) for which the storage is performed	Inspection by an EU competent authority			Inspection by a non-EU competent authority			Audit				Conditions of transport (temperature and maximum time) Compliance with Ph Eur with respect to freezing and storage
		Member State	Date of last inspection	Final outcome (observations[27])	Country	Date of last inspection	Final outcome observations	Description[29]	Name of organisation[30]	Out come	Date	
Organisation 1 responsible for collection												
Country 1												
Organisation site 1 Organisation 1 Country 1												
Organisation site 2 Organisation 1 Country 1												
Country 2												
Organisation site 3 Organisation 1 Country 2												
Organisation 2 responsible for collection												
Country 1												
Organisation site 1 Organisation 2 Country 1												
Organisation site 2 Organisation 2 Country 1												

Documented evidence of satisfactory outcome should be submitted (e.g. certificate, close-out letter, inspection report). If the final outcome is not satisfactory, a summary of the objections found during the last inspection, the follow-up and the appropriate corrective actions should be included.

Describe nature of and frequency of audit/certification
Specify name of organization carrying out the audit/certification.