RESPONSES TO OPEN CONSULTATION
on Draft Technical Requirements for blood and blood components

ANNEX IV
Quality requirements for blood components

	Subject	Original text	Proposed modification	Justification for modification
Spain	**General**		The quality exigencies must be expressed on statistics terms. Once the method is validated the number of units to control will depend of the statistic method, parametric or not parametric, used for the analysis of the results and for the detection of any deviation of the process.	Higher accuracy
Sweden	**General**		***Replace*** this annex with the tables proposed by EBA	The EBA proposal gives an up-dated, simplified and comprehensive version.
United Kingdom *UK Forum*	**General**		Add General statement: "The list of available components is not exhaustive. National Authorities may introduce other components, validated according to standard protocols".	
SFVTT **(Société Française de vigilance et de thérapeutique transfusionnelle)**	**General**			Dans le titre on ne parle que des "**dons de sang total et de plasma**" et dans la première ligne des dons par aphérèse. Cela concerne -t- il également les dons cellulaires par aphérèse (ce qui semblerait logique)? Lors d'un don de plasma destiné au fractionnement, il est dommage, même si pour l'utilisation du plasma cela ne représente aucun intérêt, de ne pas faire le groupe ABO RH1, car c'est un moyen de vérification d'identité du donneur (en cas d'homonymie, il y a déjà eu attribution d'un don à un autre donneur, découvert lors de la réalisation du groupe). Pour un don de sang total, la détermination de l'hémoglobine ou de l'hématocrite (non mentionné ici) est un moyen de garantir la qualité du CGR.

	Subject	Original text	Proposed modification	Justification for modification
Portugal	**Quality requirements for components**	all	For all red cells components appreciate the volume, haemoglobin, leucocytes before and after leucodepletion (when applicable) and haemolysis For platelet concentrates the parameters are: Volume, platelet count, leucocytes (before and after leucodepletion) and pH at the end of stoage time For granulocytes the volume and granulocytes count and the indication that all must be irradiated with at least 25Gy Plasma Components: Volume, FVIIIC (when applicable) Residual cellular content (whe applicable) Fibrinogen content(when applicable)	Rewrite in a more accurate and flexible way
United Kingdom *UK Forum*	**Quality requirements**		Add: "The % of units required to conform with the standard shall be established for each product".	
Hungary	**Quality requirements**		This annex should be supplemented by the description of techniques to be used for determining the relevant parameters. The reagents and reference standards should also be specified where appropriate	Quality requirements may be ambiguous unless the means of determining the corresponding parameter has not been specified
EMEA	**Title**	Quality Requirements For Blood Components	*Quality Requirements For Blood Components****** *****Excluding plasma for fractionation	To make it absolutely clear that plasma for fractionation is not covered by this Annex.
PPTA	**Title**	Quality Requirements for Blood Components	Quality Requirements for Blood Components * * = does not include plasma for fractionation	The exclusion of plasma for fractionation should be clearly mentioned to avoid wrong interpretations.
United Kingdom *UK Forum*	**Cryoprecipitate**		Volume spec is too limited – suggest upper limit only of 30 – 40 ml. No specification of pass rate for Factor VIII quality monitoring (same applies to FFP).	

	Subject	Original text	Proposed modification	Justification for modification
Poland	**Cryoprecipitate**		**Parameter to be checked** Add von Willebrand Factor (the same as for Factor VIII) **Quality requirements** Change: 30 – 40 ml	
Czech Republic	**Cryoprecipitate**		Factor VIIIc should be measured in system compatible with European Pharmacopoeia (mixture of six samples does not give a representative sample, what does it mean "mixed blood groups" etc).	
United Kingdom *UK Forum*	**Granulocytes**		spec as stated is not achievable without G-CSF/steroids.	
Czech Republic	**Granulocytes, apheresis**		number of granulocytes. There is sometimes difficult to obtain more than $10x10^9$ granulocytes per unit without stimulation of the donor. On the other hand 'granulocytes' are often indicated in small children and a full dose in not necessary in such a case. Is it in accordance to this document to prepare a "*split / reduced dose*" unit ?	
United Kingdom *UK Forum*	**Plasma, cryodepleted**		.	Why is volume required for all units? Don't understand "Stated volume ± 10%" under Quality Requirements for plasma, cryodepleted and FFP
PPTA	**Plasma**, **cryoprecipitate-depleted** **Plasma, fresh frozen**			Inconsistency: Only two types of plasma are listed in Annex IV whereas in Annex III three types (cryo, fresh frozen and thawed) are listed.
Italy	**Plasma**	**Quality Requirements Volume.** Stated volume plus or minus 10%	Calculated volume should be within the range of stated volume plus or minus 10%	To clarify that each unit should be weighed

	Subject	Original text	Proposed modification	Justification for modification
Italy	**Plasma fresh frozen.**	**Parameter to be checked on all units** Red cells < 6 X 10 to the ninth/l Factor VIIIc - Minimum 70% of original value	Cancel Factor VIIIc - Minimum 70 I.U.	6 X 10 to the ninth/l red cells is lower than the detection limit of cell counters, which is currently 500 X 10 to the ninth/l It is not feasible to compare the actual value, after 24 months, with the original value, because original value is not measured, but only assumed to be 100%
PPTA	**Plasma, fresh frozen**	…..inhibitors. European community legislation applies if source material for fractionated products	….inhibitors. Plasma which was intended for transfusion can be used as plasma for fractionation according the European Pharmacopoeia	This drafted sentence is misleading.
EMEA	**Plasma, fresh frozen**	**Plasma, fresh frozen** Contains normal plasma levels of stable coagulation factors, albumin & immunoglobulins; at least 70% of original Factor VIIIc, other labile coagulation factors, & naturally occurring inhibitors.	**Plasma, fresh frozen, for transfusion** Contains normal plasma levels of stable coagulation factors, albumin & immunoglobulins; at least 70% of original Factor VIIIc, other labile coagulation factors, & naturally occurring inhibitors. ~~European Community legislation applies if source material for fractionated products.~~	Unnecessary text. There is no need for any specific reference here as it is clear that, as regards plasma for fractionation, the Blood Directive is applicable for collection and testing of the donation only.
Czech Republic	**Plasma, fresh frozen**		Factor VIIIc should be measured according to European Pharmacopoeia “plasma humanun ad separationem”	

	Subject	Original text	Proposed modification	Justification for modification
United Kingdom *UK Forum*	**Plasma, fresh frozen**		would prefer VIII to be given in iu/ml rather than as % of fresh as for cryoprecipitate.	Why does there need to be a red cell contamination specification for FFP?
Czech Republic	**Platelets (all kinds):**		pH level: why such a strict criterion is used ? There is little evidence that pH as low as 6,5 alter platelet function irreversibly.	
Baxter	**Platelets:**		Definition of standard apheresis unit is not clear: what is 5-6 PRP in terms of platelet yield?	What is the justification for the maximal concentration of >40 mL/60 X 10E9?
United Kingdom *UK Forum*	**Platelets Apheresis**		The **volume** requirements appear to be higher than normal (where is the evidence to support this?) The **count** is extremely low @ 200 - UK spec at least 75% > 240 x 10^9/donation. The latter value of 240 x 10^9 is supported by the specification for pooled platelets of > 60 for each individual PRP or buffy coat derived (i.e. 240 for a pool of 4).	
United Kingdom *UK Forum*	**Platelet apheresis**	**Leucodepletion definition**	see General comment - requirement for 90% of units in LD spec is different from recovered platelets (75%). Only testing 1% or 10 is very low testing regime.	
United Kingdom *UK Forum*	**Platelet apheresis**	**Swirling**	?? when and explain +1 scoring system. This test is too subjective to pin down to this detail.	Why is this only required for apheresis platelets?
United Kingdom *UK Forum*	**Platelet apheresis**	**Platelet pH**	**–** pH at outdate given as 6.8 – 7.4. There is no evidence to support such a tight specification and the UK would find it difficult to comply.	

	Subject	Original text	Proposed modification	Justification for modification
Italy	**Platelets, apheresis**	pH measured at the end of the recommended shelf life Sampling - 1% of all units, minimum of 4 units per month	pH measured at the end of the recommended shelf life on units reaching expiration time	It is a waste to leave every month 4 units of platelets collected by apheresis unused until expiration time
Norway	**Platelets, apheresis**	Platelet content per procedure variable depending on method of preparation and machine used. Same applies to leukocyte and red cell contamination of product. Standard unit = 5-6 single units by PRP	Platelet content per procedure variable depending on method of preparation and machine used. Same applies to leukocyte and red cell contamination of product. Standard unit = 4-6 single units by PRP	4 single units is in most cases sufficient
Poland	**Platelet apheresis**		**Properties:** Platelet content per procedure variable – Add: (200 –800 x10^9) Change: 4-6 single units **Parameter to be checked:** cancel: swirling, sampling, +1 (score)	
Eucomed	**Platelets, apheresis**	**Volume** > 40ml/60 x 10^9	Concentration <2.1 x 10^9 /ml	The term "volume" is somewhat misleading here as it is actually referring to minimum volume per number of platelets. Concentration is commonly used to express this i.e. number of platelets per ml. In practice some platelet solutions are more concentrated than this (> 40ml/60 x 10^9). The scientific advancements in the materials used in the production of platelet storage bags has led to more "breathable material" thus allowing for more platelets to be stored in less volume (relevant scientific data is available to support this).

	Subject	Original text	Proposed modification	Justification for modification
Eucomed	**Platelets, apheresis**	**Swirling** +1 (score)	≥+1 (score)	The rationale for including this subjective specification should be explained. A score of >+1 is more meaningful.
Eucomed	**Platelets, apheresis**	**pH** 6.8-7.4	**pH** >6.8	In practice some platelet solutions have a pH measurement of >7.4. The reason for this is as above i.e. platelet bags consist of more "breathable material" than in the past. The Council of Europe has a proviso that other pH limits may be applied if they can be shown to give acceptable in vivo recovery for the method used for the preparation and storage of platelets. This is a step in the right direction compared to the proposal for the Directive however a more appropriate specification would be pH > 6.8 with no upper limit (relevant scientific data is available to support this).
United Kingdom *UK Forum*	**Platelets Cryopreserved**		Residual Leukocyte count is probably below limits of most popular technologies for measuring LD components.	
Greece	**Platelets, recovered from single unit by PRP**		Platelets, recovered from single unit byPRP *or buffy coat*	
United Kingdom *UK Forum*	**Platelets recovered from single unit and Platelet pools from buffy coat**		Both require LD count before LD. This seems unnecessary. Would it not be easier to require a <1 x 10^6 90% (or 75%? – see general comments) of time for infused dose? Also for platelet count – better to specify total count for pool rather than count per single unit equivalent.	

	Subject	Original text	Proposed modification	Justification for modification
Czech Republic	**Platelets recovered from single unit by PRP** **Platelet pool from buffy coat**		- platelets from buffy-coat are not pooled in some situations - why 'more then 60 x 10^9/ single unit equivalent' has been chosen as a quality requirement?.	In many instances it is not achievable in buffy-coat platelets without preselection of donors. Such a strict quality requirement has limited medical basis (therapeutical dose could be achieved by giving more units) but this can cause a critical shortage of platelets at least in the Czech Republic
Eucomed	**Platelets, recovered from single unit by PRP**	pH 6.8-7.4	>6.8	In practice some platelet solutions have a pH measurement of >7.4. The reason for this is as above i.e. platelet bags consist of more 'breathable material' than in the past. The Council of Europe has a proviso that other pH limits may be applied if they can be shown to give acceptable in vivo recovery for the method used for the preparation and storage of platelets. This is a step in the right direction compared to the proposal for the Directive however a more appropriate specification would be pH > 6.8 with no upper limit (relevant scientific data is available to support this).
Eucomed	**Platelet pool from buffy coat**	pH 6.8 –7.4	>6.8	In practice some platelet solutions have a pH measurement of >7.4. The reason for this is as above i.e. platelet bags consist of more 'breathable material' than in the past. The Council of Europe has a proviso that other pH limits may be applied if they can be shown to give acceptable in vivo recovery for the method used for the preparation and storage of platelets. This is a step in the right direction compared to the proposal for the Directive however a more appropriate specification would be pH > 6.8 with no upper limit (relevant scientific data is available to support this).
Eucomed				There are no provisions for platelets in additive solution
United Kingdom *UK Forum*	**Red Cells**		Upper limit of Hct seems rather high (75%). No mention of required percentage pass for red cell QM.	

	Subject	Original text	Proposed modification	Justification for modification
Poland	**Red cells buffy coat removed**		**Parameter…** Add: haemolysis at the end of storage. **Quality requirements:** < 0.8% of red cell mass. Residual protein of final supernatant – change: < 30 mg per unit.	
Greece	**Red cells in additive solution**	All red cells from donated *unit* remain after centrifugation	All red cells from *the original unit* unit remain after centrifugation.	
Greece	**Red cells in additive solution, buffy coat removed**		Add: Contains all but 10-30 ml of red cells of the original unit	
United Kingdom *UK Forum*	**Red cells, cryopreserved**			Why is it necessary to measure residual leucocytes?
Poland	**Red cells, Red cells, buffy coat removed, Red cells in additive solution, buffy coat removed, Red cell leukocyte depleted**		**– Properties** Change: Contains all but 10 – 30 ml red cells of the original unit	
United Kingdom *UK Forum*	**Red cells leukocyte reduced**		Should state 90% compliance for residual WBC (or better still confidence limits).	
Poland	**Red cells leukocyte reduced**		change**: depleted** **Validation of filters** – cancel	
Italy	**Red cells, washed. Residual protein of final supernatant**	< 5 mg / unit	< 30 mg / unit	Not feasible. New limit provided by the 9th edition of the Guide

	Subject	Original text	Proposed modification	Justification for modification
United Kingdom *UK Forum*	**Red cells, washed**		Protein level <0.5g/unit (This may however not reduce IgA content to < 0.2mg as stated).	
Greece	**Whole blood**		Add; Freshly drawn whole blood to be used as source material for blood components	
Poland	**Whole blood**		**Properties** Add: Freshly drawn to be used as source material for blood components **Quality requirements** Change: ≤ 500 ml	
Czech Republic		**Red cells (all kinds), whole blood**	Haemolysis at the end of storage: why a quality requirement is expressed as percentage of original red cell mass ? (0.8 %) Exact starting red cell mass in a given / controlled unit is usually not known moreover free haemoglobin is usually measured instead of measurement of red cells loss. It seems to be much more practical to set quality requirement as ***total amount of free haemoglobin per unit*** (500mg of free haemoglobin is adequate to 0,08% red cell haemolysis in standard unit containing 62,5g of total haemoglobin)	
Eucomed	**Red cells buffy coat removed**		Haemolysis at end of storage < 0.8% of red cell mass 4 units per month	Specification given in Council of Europe
Eucomed	**Red cells, washed** **Residual protein of final supernatant**	<5mg/unit		Request that the level of <5mg/unit is double checked in the Proposal for the Directive as this value was significantly increased by the Council of Europe to <0.5g/unit
PPTA	**Definitions**			Definitions used in Annex IV are not consistent with the ones used in Annex III (blood products = blood components?).

RESPONSES TO OPEN CONSULTATION
ANNEX IV
Quality requirements for blood components

REVISED ANNEX IV

Proposed by Ireland, Luxembourg, Netherlands, Finland, United Kingdom, EBA

Replace the tables with the following.

Rationale:

The tables in the Commission's proposal do not cover many blood components in common use; for example there are no paediatric or neonatal components. These are serious omissions. The layout of the components included has no apparent logical sequence. The sampling requirements specified are outdated and lack a scientific basis. The inclusion of a column on Properties of the components listed becomes unnecessary when a glossary is included in the Proposal.

The below tables 1 & 2 are more accurate, up to date, comprehensive and flexible. They cover all components in use and provide a rational basis for extension to future developments in component specifications.

Table 1. The Blood Components

1.0	**RED CELL PREPARATIONS** In addition to the preparations listed below, other preparations may be developed
1.1	Red cells
1.2	Red cells, in additive solution
1.3	Red cells, apheresis
1.4	Red cells, buffy coat removed, in additive solution
1.5	Red cells, leucodepleted, in additive solution
1.6	Whole blood
The red cell preparations may be further processed, for example washed, irradiated, cryopreserved, modified for intrauterine, neonatal, or paediaric use.	
2.0	**PLATELET PREPARATIONS** In addition to the preparations listed below, other preparations may be developed
2.1	Platelets, apheresis
2.2	Platelets, apheresis, leucodepleted
2.3	Platelets, pooled

2.4	Platelets, pooled, leucodepleted
2.5	Platelets, recovered, single unit
2.6	Platelets, recovered, single unit, leucodepleted
The platelet preparations may be further processed, for example washed, irradiated, cryopreserved, modified for intrauterine, neonatal, or paediatric use.	
3.0	**PLASMA PREPARATIONS** In addition to the preparations listed below, other preparations may be developed
3.1	Fresh Frozen Plasma, for clinical use
3.2	Fresh Frozen Plasma, leucodepleted, for clinical use
3.3	Fresh Frozen Plasma, cryodepleted, for clinical use,
3.4	Cryoprecipitate
The plasma preparations may be further processed, for example processed for virus/bacteria inactivation, modified for intrauterine, neonatal, or paediatric use.	
4.0	Granulocytes, apheresis

Table 2. Required Quality Control Characteristics for Blood Components

COMPONENT	QUALITY MEASUREMENTS REQUIRED. The required frequency of sampling for all measurements shall be determined using a valid statistical process control process.	ACCEPTABLE RESULTS FOR QUALITY MEASUREMENTS
Red Cells, leucocyte depleted, in additive solution	Volume Haemoglobin Leucocyte content Haemolysis	Valid for storage characteristics to maintain product within specifications for haemoglobin and haemolysis. - Not less than 40 gm per unit. - 90% of all units tested are less than 1 x10^6/ unit; 100% are less than 5x 10^6/ unit. - Less than 0.8% of red cell mass.
Red cells, buffy coat removed, in additive solution	Volume Haemoglobin Haemolysis	Valid for storage characteristics to maintain product within specifications for haemoglobin and haemolysis. Not less than 40 gm per unit. Less than 0.8% of red cell mass.
Red cells, in additive solution	Volume Haemoglobin Haemolysis	Valid for storage characteristics to maintain product within specifications for haemoglobin and haemolysis. - Not less than 40 gm per unit. - Less than 0.8% of red cell mass.
Red cells, concentrated	Volume Haemoglobin Haemolysis	Valid for storage characteristics to maintain product within specifications for haemoglobin and haemolysis. - Not less than 40 gm per unit. - Less than 0.8% of red cell mass.
Red cells, apheresis[a]	Volume Haemoglobin haemolysis	Valid for storage characteristics to maintain product within specifications for haemoglobin and haemolysis. Not less than 40 gm per unit. Less than 0.8% of red cell mass.
Whole blood	Volume	Valid for storage characteristics to maintain product within specifications for

[a] * pH evidence from Dumont Transfusion (2003) 43 pp 143-150 on storage of platelets demonstrates that a pH range of 6.4-7.4 is a satisfactory range to maintain platelet functional viability and in vivo recovery.It is also the range that is most often achieved in practice. A lower limit of 6.8 is unrealistic and not often achieved.

		haemoglobin and haemolysis. Generally 450mls +/- 10%
	Haemoglobin	- Not less than 40 gm per unit.
	Haemolysis	- Less than 0.8% of red cell mass.
Platelets, apheresis, leucocyte depleted	Volume	Valid for storage characteristics to maintain product within specifications for pH.
		- Variations in platelet count per single donation are allowable. However platelet
	Platelet count	count per volume and derived or measured platelet count must be stated.
	Leukocyte content	- 90% of all units tested are less than 1 x10^6/ unit; 100% are less than 5x 10^6/ unit.
	pH	- 6.4 – 7.4* corrected for 22^0C, at expiry.
Platelets, apheresis,	Volume	Valid for storage characteristics to maintain product within specifications for pH.
	Platelet count	- Variations in platelet count per single donation are allowable. However platelet
		count per volume and derived or measured platelet count must be stated.
	pH	- 6.4 – 7.4 *corrected for 22^0C, at expiry.
Platelets, pooled, leucodepleted	Volume	Valid for storage characteristics to maintain product within specifications for pH.
	Platelet count	- Variations in platelet count per pool are allowable. However platelet count per
		volume and derived or measured platelet count must be stated.
	Leucocyte content	- 90% of all units tested are less than 1 x10^6/ unit; 100% are less than 5x 10^6/ unit.
	pH	- 6.4 – 7.4* corrected for 22^0C, at expiry.
Platelets, pooled	Volume	Valid for storage characteristics to maintain product within specifications for pH.
	Platelet count	- Variations in platelet count per pool are allowable. However platelet count per
		volume and derived or measured platelet count must be stated.
	Leukocyte count	< 0.2 x 10^9 /single unit (prp method)
		< 0.05 x 10^9/single unit (buffy coat method)
	pH	-6.4– 7.4* corrected for 22^0C, at expiry.
Platelets, recovered, single unit, leucodepleted	Volume	Valid for storage characteristics to maintain product within specifications for pH.
	Platelet count	- Variations in platelet count per single unit are allowable. However platelet count
		per volume and derived or measured platelet count must be stated.
	Leukocyte content	- 90% of all units tested are less than 0.2 x10^6/ unit; 100% are less than 1x 10^6/ unit.
	pH	- 6.4– 7.4* corrected for 22^0C, at expiry.
Platelets, recovered, single unit	Volume	Valid for storage characteristics to maintain product within specifications for pH.
	Platelet count	- Variations in platelet count per single unit are allowable. However platelet count
		per volume and derived or measured platelet count must be stated.
	Leucocyte count	- < 0.2 x 10^9 /single unit (prp method)
		< 0.05 x 10^9 /single unit (buffy coat method)
	pH	- 6.4- 7.4 *corrected for 22^0C, at expiry.

Plasma, fresh frozen, for clincal use	Volume Factor VIIIc Residual cellular content	Stated volume +/- 10% >0.7 iu/ml (this is used as a marker for preservation of labile plasma factors: plasma is not used for VIIIc replacement, except where present as part of a complex acquired coagulopathy). - Red cells: < 6.0 x 10^9/l - Leucocytes:< 0.1 x 10^9/l - Platelets: < 5.0 x 10^9/l
Plasma, Fresh Frozen, cryoprecipitate-depleted, for clinical use,	Volume Residual cellular content	Stated volume +/- 10% - Red cells: < 6.0 x 10^9/l – Leucocytes:< 0.1 x 10^9/l – Platelets: < 5.0 x 10^9/l
Cryoprecipitate	Volume Fibrinogen content Factor VIIIc content	10 – 30 mls >140gms per unit
Granulocytes, apheresis	Volume Granulocyte count	<500ml >1 x 10^{10} granulocytes per unit

Modification s proposed by Afssaps

Original text	Proposed modification	Justification for modification
Quality requirements for blood components	Quality requirements for blood **<u>and blood</u>** components	
	Ajouter la phrase suivante: The required frequency of sampling for all measurements shall be determined using a valid statistical process control process in each blood establishment.	
	Ajouter la phrase suivante: La liste des composants érythrocytaires est longue et modifiable en fonction des méthodes de prélèvement, de transformation et de conservation. Aussi, les exigences relatives à la qualité des principaux composants érythrocytaires sont définies ci-après. Lorsque des transformations supplémentaires telle que l'irradiation, la déplasmatisation, la cryoconservation ou la préparation pédiatrique sont effectuées, les exigences relatives à la qualité des composants issus de ces transformations doivent être définies en référence aux composants érythrocytaires ci-après.	
Red cells, red cells in additive solution, red cells in additive solution buffy-coat removed, red cells leukocytes reduced, red cells washed, whole blood	Red cells, in additive solution ; Red cells, leucodepleted, in additive solution ; Red cells, buffy coat removed, in additive solution ; Red cells, apheresis ; Whole blood Quality measurements required and acceptable results for quality measurements Volume : Valid for storage characteristics to maintain product within specifications for haemoglobin and haemolysis. For whole blood, volume generally 450 ml ± 10% Haemolysis : Less than 0.8% of red cell mass. Haemoglobin : • not less 45 g per unit of whole blood, red cells, red cells in additive solution and red cells, apheresis • not less 43 g per unit of red cells buffy coat removed and red cells buffy coat removed in additive solution • not less 40 g per unit of whole blood leucodepleted, red cells leucodepleted and red cells leucodepleted in additive solution Leucocyte content : less than 1 $x10^6$/ unit of whole blood leucodepleted, red cells leucodepleted and red cells leucodepleted in additive solution	

	Ajouter la phrase suivante: La liste des composants plaquettaires est longue et modifiable en fonction des méthodes de prélèvement, de transformation et de conservation. Aussi, les exigences relatives à la qualité des principaux composants plaquettaires sont définies ci-après. Lorsque des transformations supplémentaires telle que l'irradiation, la déplasmatisation, la cryoconservation ou la préparation pédiatrique sont effectuées, les exigences relatives à la qualité des composants issus de ces transformations doivent être définies en référence aux composants plaquettaires ci-après**.**
Platelets (single unit, concentrate recovered, buffy-coat pool, apheresis)	Platelets apheresis leucodepleted ; platelet apheresis ; Quality measurements required and acceptable results for quality measurements Volume : Valid for storage characteristics to maintain product within specifications for pH Platelet count : Variations in platelet count per single donation are allowable. However platelet count per volume and derived or measured platelet count must be stated. pH : 6.5 – 7.4 corrected for 22^0C, at expiry Leucocyte content : • less than < 0,2 $x10^9$/ single unit (PRP method); < 0,05 $x10^9$/ single unit (buffy coat method) for Platelets pooled and Platelets, recovered single unit • less than 0,2 $x10^6$/ unit of Platelets recovered single unit leucodepleted • less than 1 $x10^6$/ unit of Platelets apheresis leucodepleted and Platelets pooled leucodepleted
Granulocytes apheresis	Granulocytes apheresis Quality measurements required and acceptable results for quality measurements Volume : < 500 ml Granulocyte count : > 1 $x10^{10}$ per unit
	Ajouter la phrase suivante: La liste des plasmas est modifiable en fonction des méthodes de prélèvement, de transformation et de conservation. Aussi, les exigences relatives à la qualité des principaux plasmas sont définies ci-après. Lorsque des transformations supplémentaires telle que l'inactivation virale ou la préparation pédiatrique sont effectuées, les exigences relatives à la qualité des plasmas issus de ces transformations doivent être définies en référence aux plasmas ci-après.
Plasma fresh frozen	Plasma fresh frozen leucodepleted for clinical use Quality measurements required and acceptable results for quality measurements Volume : stated volume ± 10% Factor VIIIc : > 0.7 iu/ml (this is used as a marker for preservation of labile plasma factors: plasma is not used for VIIIc replacement, except where present as part of a complex acquired coagulopathy). Leucocytes content :< 1 x 10^4/l