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ANNEX V

QUALITY AND SAFETY REQUIREMENTS FOR BLOOD AND BLOOD COMPONENTS
(as referred to in Article 6)

1. THE BLOOD COMPONENTS

1.	*Red cell preparations*	The components listed in points 1.1 to 1.8 may be further processed within blood establishments and must be labelled accordingly
1.1		Red cells
1.2		Red cells, buffy coat removed
1.3		Red cells, leucocyte-depleted
1.4		Red cells, in additive solution
1.5		Red cells, buffy coat removed, in additive solution
1.6		Red cells, leucocyte-depleted, in additive solution
1.7		Red cells, apheresis
1.8		Whole blood
2.	*Platelet preparations*	The components listed in points 2.1 to 2.6 may be further processed within blood establishments and must be labelled accordingly
2.1		Platelets, apheresis
2.2		Platelets, apheresis, leucocyte-depleted
2.3		Platelets, recovered, pooled
2.4		Platelets, recovered, pooled, leucocyte-depleted
2.5		Platelets, recovered, single unit
2.6		Platelets, recovered, single unit, leucocyte-depleted
3.	*Plasma preparations*	The components listed in 3.1 to 3.3 may be further processed within blood establishments and must be labelled accordingly.
3.1		Fresh-frozen plasma
3.2		Fresh-frozen plasma, cryoprecipitate-depleted
3.3		Cryoprecipitate

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4.		Granulocytes, apheresis
5.	*New components*	Quality and safety requirements for new blood components must be regulated by the competent national authority. Such new components must be notified to the European Commission with a view to Community action

2. QUALITY CONTROL REQUIREMENTS FOR BLOOD AND BLOOD COMPONENTS

2.1. Blood and blood components must comply with the following technical quality measurements and meet the acceptable results.

2.2. Appropriate bacteriological control of the collection and manufacturing process must be performed.

2.3. Member States must take all necessary measures to ensure that all imports of blood and blood components from third countries, including those used as starting material/ raw material for the manufacture of medicinal products derived from human blood or human plasma, shall meet equivalent standards of quality and safety to the ones laid down in this Directive.

2.4. For autologous donations, the measures marked with an asterisk (*) are recommendations only.

Component	***Quality measurements required The required frequency of sampling for all measurements shall be determined using statistical process control***	***Acceptable results for quality measurements***
Red cells	Volume	Valid for storage characteristics to maintain product within specifications for haemoglobin and haemolysis
	Haemoglobin (*)	Not less than 45 g per unit
	Haemolysis	Less than 0,8 % of red cell mass at the end of the shelf life
Red cells, buffy coat removed	Volume	Valid for storage characteristics to maintain product within specifications for haemoglobin and haemolysis
	Haemoglobin (*)	Not less than 43 g per unit

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	Haemolysis	Less than 0,8 % of red cell mass at the end of the shelf life
Red cells, leucocyte-depleted	Volume	Valid for storage characteristics to maintain product within specifications for haemoglobin and haemolysis
	Haemoglobin (*)	Not less than 40 g per unit
	Leucocyte content	Less than 1×10^6 per unit
	Haemolysis	Less than 0,8 % of red cell mass at the end of the shelf life
Red cells, in additive solution	Volume	Valid for storage characteristics to maintain product within specifications for haemoglobin and haemolysis
	Haemoglobin (*)	Not less than 45 g per unit
	Haemolysis	Less than 0,8 % of red cell mass at the end of the shelf life
Red cells, buffy coat removed, in additive solution	Volume	Valid for storage characteristics to maintain product within specifications for haemoglobin and haemolysis
	Haemoglobin (*)	Not less than 43 g per unit
	Haemolysis	Less than 0,8 % of red cell mass at the end of the shelf life
Red cells, leucocyte-depleted, in additive solution	Volume	Valid for storage characteristics to maintain product within specifications for haemoglobin and haemolysis
	Haemoglobin (*)	Not less than 40 g per unit
	Leucocyte content	Less than 1×10^6 per unit
	Haemolysis	Less than 0,8 % of red cell mass at the end of the shelf life
Red cells, apheresis	Volume	Valid for storage characteristics to maintain product within specifications

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		for haemoglobin and haemolysis
	Haemoglobin (*)	Not less than 40 g per unit
	Haemolysis	Less than 0,8 % of red cell mass at the end of the shelf life
Whole blood	Volume	Valid for storage characteristics to maintain product within specifications for haemoglobin and haemolysis 450 ml +/- 50ml For paediatric autologous whole blood collections — not to exceed 10,5 ml per kg body weight
	Haemoglobin (*)	Not less than 45 g per unit
	Haemolysis	Less than 0,8 % of red cell mass at the end of the shelf life
Platelets, apheresis	Volume	Valid for storage characteristics to maintain product within specifications for pH
	Platelet content	Variations in platelet content per single donation are permitted within limits that comply with validated preparation and preservation conditions
	pH	**[**[F1]Minimum 6,4 corrected for 22 °C, at the end of the shelf life**]**
Platelets, apheresis, leucocyte-depleted	Volume	Valid for storage characteristics to maintain product within specifications for pH
	Platelet content	Variations in platelet content per single donation are permitted within limits that comply with validated preparation and preservation conditions
	Leucocyte content	Less than 1×10^6 per unit

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	pH	**[**[F1]Minimum 6,4 corrected for 22 °C, at the end of the shelf life**]**
Platelets, recovered, pooled	Volume	Valid for storage characteristics to maintain product within specifications for pH
	Platelet content	Variations in platelet content per pool are permitted within limits that comply with validated preparation and preservation conditions
	Leucocyte content	Less than $0,2 \times 10^9$ per single unit (platelet-rich plasma method) Less than $0,05 \times 10^9$ per single unit (buffy coat method)
	pH	**[**[F1]Minimum 6,4 corrected for 22 °C, at the end of the shelf life**]**
Platelets, recovered, pooled, leucocyte-depleted	Volume	Valid for storage characteristics to maintain product within specifications for pH
	Platelet content	Variations in platelet content per pool are permitted within limits that comply with validated preparation and preservation conditions
	Leucocyte content	Less than 1×10^6 per pool
	pH	**[**[F1]Minimum 6,4 corrected for 22 °C, at the end of the shelf life**]**
Platelets, recovered, single unit	Volume	Valid for storage characteristics to maintain product within specifications for pH
	Platelet content	Variations in platelet content per single unit are permitted within limits that comply with validated preparation and preservation conditions

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	Leucocyte content	Less than $0,2 \times 10^9$ per single unit (platelet-rich plasma method) Less than $0,05 \times 10^9$ per single unit (buffy coat method)
	pH	**[**[F1]Minimum 6,4 corrected for 22 °C, at the end of the shelf life**]**
Platelets, recovered, single unit, leucocyte-depleted	Volume	Valid for storage characteristics to maintain product within specifications for pH
	Platelet content	Variations in platelet content per single unit are permitted within limits that comply with validated preparation and preservation conditions
	Leukocyte content	Less than 1×10^6 per unit
	pH	**[**[F1]Minimum 6,4 corrected for 22 °C, at the end of the shelf life**]**
Plasma, fresh-frozen	Volume	Stated volume +/- 10 %
	Factor VIIIc (*)	Average (after freezing and thawing): 70 % or more of the value of the freshly collected plasma unit
	Total protein (*)	Not less than 50 g/l
	Residual cellular content (*)	Red cells: less than $6,0 \times 10^9$/l Leucocytes: less than 0, 1×10^9/l Platelets: less than 50×10^9/l
Plasma, fresh-frozen, cryoprecipitate-depleted	Volume	Stated volume: +/- 10 %
	Residual cellular content (*)	Red cells: less than $6,0 \times 10^9$/l Leucocytes: less than $0,1 \times 10^9$/l Platelets: less than 50 × 109/l
Cryoprecipitate	Fibrinogen content (*)	Greater than or equal to 140 mg per unit
	Factor VIIIc content (*)	Greater than or equal to 70 international units per unit

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Granulocytes, apheresis	Volume	Less than 500 ml
	Granulocyte content	Greater than 1×10^{10} granulocytes per unit

Textual Amendments

F1 Substituted by Commission Implementing Directive 2011/38/EU of 11 April 2011 amending Annex V to Directive 2004/33/EC with regards to maximum pH values for platelets concentrates at the end of the shelf life (Text with EEA relevance).