

SCHEDULE

PART 5

QUALITY AND SAFETY REQUIREMENTS FOR BLOOD AND BLOOD COMPONENTS

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
4.	Granulocytes, apheresis

Status: This is the original version (as it was originally made).

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

Component	Quality measures required	Acceptable results for quality measures
<i>The required frequency of sampling for all measurements shall be determined using statistical process control</i>		
Red cells	Volume	Valid for storage characteristics to maintain product within specifications for haemoglobin and haemolysis
	Haemoglobin (*)	Not less than 45g per unit
	Haemolysis	Less than 0.8% of red cell mass at 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
	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 40g 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

Component	Quality measures required	Acceptable results for quality measures
	<i>The required frequency of sampling for all measurements shall be determined using statistical process control</i>	
Red cells, buffy coat removed, in additive solution	Haemoglobin (*)	Not less than 45g per unit
	Haemolysis	Less than 0.8% of red cell mass at end of the shelf life
	Volume	Valid for storage characteristics to maintain product within specifications for haemoglobin and haemolysis
	Haemoglobin (*)	Not less than 43g per unit
Red cells, leucocyte-depleted, in additive solution	Haemolysis	Less than 0.8% of red cell mass at the end of the shelf life
	Volume	Valid for storage characteristics to maintain product within specifications for haemoglobin and haemolysis
	Haemoglobin (*)	Not less than 40g per unit
	Leucocyte content	Less than 1×10^6 per unit
Red cells, apheresis	Haemolysis	Less than 0.8% of red cell mass at the end of the shelf life
	Volume	Valid for storage characteristics to maintain product within specifications for haemoglobin and haemolysis
	Haemoglobin (*)	Not less than 40g 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 450ml +/- 50ml
		For paediatric autologous whole blood collections – not to exceed 10.5ml per kg body weight

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Component	Quality measures required	Acceptable results for quality measures
	<i>The required frequency of sampling for all measurements shall be determined using statistical process control</i>	
Platelets, apheresis	Haemoglobin (*)	Not less than 45g per unit
	Haemolysis	Less than 0.8% of red cell mass at the end of the shelf life
	Volume	Valid for storage characteristics to maintain product within specifications for pH
	Platelet content	Variations in platelet content per single donation are permitted within the limits that comply with validated preparation and preservation conditions
Platelets, apheresis, leucocyte-depleted	pH	6.4 -7.4 corrected for 22°C, at the end of the shelf life
	Volume	Valid for storage characteristics to maintain product within specifications for pH
	Platelet content	Variations in platelet content per single donation are permitted within the limits that comply with validated preparation and preservation conditions
	Leucocyte content	Less than 1×10^6 per unit
Platelets, recovered, pooled	pH	6.4-7.4 corrected for 22°C, at the end of the shelf life
	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

Component	Quality measures required	Acceptable results for quality measures
	<i>The required frequency of sampling for all measurements shall be determined using statistical process control</i>	
Platelets, recovered, pooled, leucocyte-depleted	Leucocyte content	Less than 0.2×10^9 per single unit (platelet-rich plasma method)
		Less than 0.05×10^9 per single unit (buffy coat method)
	pH	6.4-7.4 corrected for 22°C, at the end of the shelf life
	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
Platelets, recovered, single unit	Leucocyte content	Less than 1×10^6 per pool
	pH	6.4-7.4 corrected for 22°C, at the end of the shelf life
	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
	Leucocyte content	Less than 0.2×10^9 per single unit (platelet-rich plasma method)
Platelets, recovered, single unit, leucocyte-depleted		Less than 0.05×10^9 per single unit (buffy coat method)
	pH	6.4-7.4 corrected for 22°C, at the end of the shelf life
	Volume	Valid for storage characteristics to maintain

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Component	Quality measures required	Acceptable results for quality measures
	<i>The required frequency of sampling for all measurements shall be determined using statistical process control</i>	
Plasma, fresh-frozen		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
	Leucocyte content	Less than 1×10^6 per unit
	pH	6.4-7.4 corrected for 22°C, at the end of the shelf life
	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 50g/l
Plasma, fresh-frozen, cryoprecipitate-depleted	Residual cellular content(*)	Red cells: less than 6.0×10^9 /l Leucocytes: less than 0.1×10^9 /l Platelets: less than 50×10^9 /l
	Volume	Stated volume +/-10%
	Residual cellular content(*)	Red cells: less than 6.0×10^9 /l Leucocytes: less than 0.1×10^9 /l Platelets: less than 50×10^9 /l
	Fibrinogen content(*)	Greater than or equal to 140mg per unit
	Factor VIIIc content (*)	Greater than or equal to 70 international units per unit
Granulocytes, apheresis	Volume	Less than 500ml
	Granulocyte content	Greater than 1×10^{10} granulocytes per unit