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

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** *The required frequency of sampling for all measurements shall be determined using statistical process control*	**Acceptable results for quality measures**
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** *The required frequency of sampling for all measurements shall be determined using statistical process control*	**Acceptable results for quality measures**
	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, in additive solution	Volume	Valid for storage characteristics to maintain product within specifications for haemoglobin and haemolysis
	Haemoglobin (*)	Not less than 43g 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 40g per unit
	Leucocyte content	Less than 1 x 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 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

Component	**Quality measures required** *The required frequency of sampling for all measurements shall be determined using statistical process control*	**Acceptable results for quality measures**
	Haemoglobin (*)	Not less than 45g 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 the limits that comply with validated preparation and preservation conditions
	pH	6.4 -7.4 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 the limits that comply with validated preparation and preservation conditions
	Leucocyte content	Less than 1 x 10^6 per unit
	pH	6.4-7.4 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

Component	**Quality measures required** *The required frequency of sampling for all measurements shall be determined using statistical process control*	**Acceptable results for quality measures**
	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
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	6.4-7.4 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
	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
Platelets, recovered, single unit, leucocyte-depleted	Volume	Valid for storage characteristics to maintain

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