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New Specification

8.30 Cryoprecipitate Pooled, Leucocyte Depleted

The pooled component represents a source of concentrated FVIII:C, von Willebrand factor, fibrinogen, Factor XIII and fibronectin from primary cryoprecipitate components derived from units of fresh frozen plasma. The plasma from which the cryoprecipitate was produced was derived from a previously tested donor (as defined in Section 7.3) and contains less than 5 x 10^6 leucocytes per primary component.

Technical Information

- Donations of whole blood where the bleed time exceeded 15 minutes are not suitable for the production of plasma components for direct clinical use.
- Cryoprecipitate Pooled, Leucocyte Depleted is the cryoglobulin fraction of plasma obtained by thawing and pooling five single Cryoprecipitate components or pooling five single Cryoprecipitate components immediately after production from thawed fresh frozen plasma.
- For storage, Cryoprecipitate Pooled, Leucocyte Depleted should be rapidly frozen to a core temperature of -30°C or below within 2 hours of preparation.
- Component samples collected for the Quality Monitoring assessment of FVIII:C should have approximately the same ABO group distribution as issued components.
- Initial process validation must ensure that for a minimum of 20 tested Cryoprecipitate Pooled, Leucocyte Depleted components a minimum of 75% of those components tested for the parameters shown at Table 8.30 below shall meet the specified values.
- Annual process validation is acceptable for Quality Monitoring purposes, provided that the primary components, Fresh Frozen Plasma, Leucocyte Depleted and/or Cryoprecipitate, Leucocyte Depleted are separately monitored as part of monthly testing. If this is not the case, a minimum of 1% or 10 components, whichever is greater, of Cryoprecipitate Pooled, Leucocyte Depleted components must be tested monthly and a minimum of 75% of those components tested for the parameters shown at Table 8.30 below shall meet the specified values.
- Cryoprecipitate Pooled, Leucocyte Depleted should be transfused through a 170 - 200 µm filter.

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Labelling (for general guidelines see Section 6.6)

The following shall be included on the component label:
(* = in eye readable and UKBTS approved barcode format.)

- Cryoprecipitate Pooled, Leucocyte Depleted* and volume
- the blood component producer's name*
- the donation number*
- the ABO group*
- the RhD group stated as positive or negative*
- the date of collection
- the expiry date of the frozen component*
- the temperature of storage
- the blood pack lot number*
- a warning that the component must be used within 4 hours of thawing
- the name and volume of anticoagulant

In addition, the following statements should be made:

INSTRUCTION
Always check patient/component compatibility/identity
Inspect pack and contents for signs of deterioration or damage
Risk of adverse reaction/infection

Storage (for general guidelines see Section 6.7)

- The component should be stored at a core temperature of -30°C or below for a maximum of 24 months.

- Although a storage temperature below -30°C improves the preservation of labile coagulation factors, lower temperatures increase the fragility of plastic. Particular care must be taken when handling such packs.

- The component should be thawed at 37^{o}C in a waterbath or other equipment designed for the purpose, within a vacuum sealed overwrap bag. Protocols must be in place to ensure that the equipment is cleaned daily and maintained to minimise the risk of bacterial contamination.

- Once thawed, the component must not be refrozen and should be transfused as soon as possible. If delay is unavoidable, the component should be stored at ambient temperature and used within 4 hours.

Testing

In addition to the mandatory and other tests required for blood donations described in Annex 4, and leucocyte counting (see Section 6.3 and 7.1), a minimum of 75% of those components tested for the parameters shown at Table 8.30 below shall meet the specified values.

Table 8.30 Cryoprecipitate Pooled, Leucocyte Depleted - Additional Tests

PARAMETER	FREQUENCY OF TEST	SPECIFICATION
Volume	1%	100 to 250mL
Fibrinogen	Refer to **Technical Information** above	>700 mg/unit
FVIII:C		>350 iu/unit
Leucocyte Count	As per Section 6.3 and 7.1	<5 x 10^6 per unit* in the starting component

*prefreeze methods validated for counting low numbers of leucocytes must be used

Transportation (for general guidelines see Section 6.11)

Every effort should be made to maintain the core storage temperature during transportation. Unless the component is to be thawed and used straight away it should be transferred immediately to storage at the recommended temperature.

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