Date of publication: 26 June 2013	**Implementation:** To be determined by each Service

Change Notification UK National Blood Services No. 11 - 2013

Cryoprecipitate, Pooled, Methylene Blue Treated and Removed, Leucocyte Depleted

Applies to the Guidelines for the Blood Transfusion Services in the United Kingdom 8th Edition 2013

New Specification

7.33 Cryoprecipitate, Pooled, Methylene Blue Treated and Removed, Leucocyte Depleted

This component is intended for use for patients born on or after 1st January 1996.

The component represents a source of concentrated FVIII:C, and von Willebrand factor, fibrinogen, Factor XIII and fibronectin produced from units of Fresh Frozen Plasma, Methylene Blue Treated and Removed. The plasma from which the cryoprecipitate, methylene treated and removed, Leucocyte Depleted was produced contains less than 1 x 10^6 leucocytes per component and is from a country with a low risk of vCJD.

7.33.1 Technical information

- Where the starting component is sourced outwith the UK, a detailed and agreed specification must be available.
- Donations of whole blood where the bleed time exceeded 15 minutes are not suitable for the production of plasma components for direct clinical use.
- Plasma should be selected from male donors or screening of female donors for HLA / HNA antibodies should be considered, as a TRALI risk reduction strategy.
- Cryoprecipitate, Pooled, Methylene Blue Treated and Removed, Leucocyte Depleted is the cryoglobulin fraction of plasma obtained by thawing and pooling six single Cryoprecipitate, Methylene Blue Treated and Removed plasma components.

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- A secure system must be in place to ensure a full audit trail and the correct identification number is put on the final component pack.

- The process for methylene blue removal should be validated to give components with a methylene blue concentration ≤0.30 µM (< approximately 30 µg per unit) in the starting components.

- Annual process validation is acceptable for leucodepletion quality monitoring purposes, provided that the primary components, Methylene Blue Treated and Removed Fresh Frozen Plasma, Leucocyte Depleted are separately monitored as part of monthly testing. If this is not the case, test monthly 1% or as determined by statistical process control (if ≤10 components produced per month then test every available component), of Cryoprecipitate Pooled, Methylene Blue Treated and Removed Leucocyte Depleted components. A minimum of 75% of those components tested for the parameters shown at **Table 7.26** below shall meet the specified values.

- For storage, Cryoprecipitate, Pooled, Methylene Blue Treated and Removed, Leucocyte Depleted should be rapidly frozen to a core temperature of –25 °C or below within two hours of preparation.

- Component samples collected for the Quality Monitoring assessment of FVIII:C should be from an equal mix of group O and non-O donations due to the difference in FVIII levels between ABO blood groups.

- Cryoprecipitate, Pooled, Methylene Blue Treated and Removed, Leucocyte Depleted, should be transfused through a 170–200 µm filter.

7.33.2 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, Methylene Blue Treated and Removed, Leucocyte Depleted * and volume
- the blood component producer's name*
- a unique pool or batch number or the donation number of all contributing units*
- 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 four hours of thawing
- the name, composition and volume of the anticoagulant or additive solution.

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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

7.33.3 Storage (for general guidelines see Section 6.7)

- The component should be stored at a core temperature of –25 °C or below for a maximum of 24 months.
- Although a storage temperature below –25°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 in a water bath or other equipment designed for the purpose, within a vacuum sealed over wrap bag according to a validated procedure. The optimal temperature at which the component should be thawed is 37 °C; temperatures between 33 - 37 °C are acceptable.
- Protocols must be in place to ensure that the equipment is cleaned daily and maintained to minimize the risk of bacterial contamination. After thawing, the content should be inspected to ensure that no insoluble cryoprecipitate is visible and that the container is intact.
- Once thawed, the component must not be refrozen and should be used immediately. If delay is unavoidable, the component should be stored at ambient temperature and used within four hours.

7.33.4 Testing

In addition to the mandatory and other tests required for blood donations described in **Chapter 9**, and leucocyte counting (**see Sections 6.3 and 7.1**), a minimum of 75% of those components tested for the parameters shown in Table 8.29 shall meet the specified values.

Table 7.26 Cryoprecipitate, pooled, methylene blue treated and removed, leucocyte depleted – additional tests

Parameter	Frequency of test	Specification
Volume	1% or as determined by statistical process control (if ≤10 components produced per month then test every available component)	100 – 300 mL
Fibrinogen		>700 mg/unit
FVIII:C	Refer to Technical Information above	≥250 IU/unit
Leucocyte Count*	**As per Sections 6.3 and 7.1**	<1 x 10^6/unit**

*Methods validated for counting low numbers of leucocytes must be used.
**Prefreeze in starting component.

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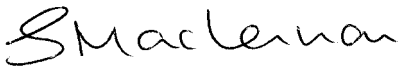
7.33.5 Transportation (for general guidelines see Section 6.11)

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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