7.16: Fresh Frozen Plasma, Methylene Blue Treated and Removed, Leucocyte Depleted

This component is intended for use in children and is made from plasma from a country with a low risk of variant Creutzfeldt-Jakob Disease (vCJD).

Fresh Frozen Plasma, Methylene Blue Treated (MBT) and Removed, Leucocyte Depleted, is plasma that has been obtained from whole blood or by apheresis from a previously tested donor (as defined in section 7.3), contains less than $1 \times 10^6$ leucocytes and has been treated with methylene blue and exposure to visible light to inactivate pathogens.

Following methylene blue treatment and removal, the plasma is rapidly frozen to a temperature that will maintain the activity of labile coagulation factors.

7.16.1: Technical information

- Where the starting component is sourced outside 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 consideration should be given to screening female donors for HLA/HNA antibodies, as a TRALI risk reduction measure.

- The plasma should be separated before the red cell component is cooled to its storage temperature. Greater FVIII:C yields will be obtained when the plasma is separated as soon as possible after venepuncture, methylene blue treated and rapidly frozen to $-25^\circ C$ or below.

- The method of preparation should ensure the component has the maximum level of labile coagulation factors with minimum cellular contamination. The production process should be validated to ensure that components meet the specified limits for FVIII:C concentration.

- 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.
• The MBT process reduces the FVIII:C content by approximately 30% when compared to standard fresh frozen plasma.

• Intact white blood cells in the plasma should be reduced to less than $1 \times 10^6$ per unit prior to exposure to methylene blue and visible light.

• The process for methylene blue removal should be validated to give components with a methylene blue concentration $<=0.30 \, \mu\text{mol/L}$ (less than approximately $30 \, \mu\text{g per unit}$).

• Fresh Frozen Plasma, Methylene Blue Treated and Removed, Leucocyte Depleted should be transfused through a 170–200 $\mu\text{m}$ filter.

7.16.2: Labelling

For general guidelines, see section 6.6.

The following shall be included on the label:

(* = in eye-readable and UKBTS approved barcode format)

- Fresh Frozen Plasma, Methylene Blue Treated and Removed, 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 should be used within 4 hours of thawing if maintained at $22 \pm 2^\circ\text{C}$ and 24 hours if maintained at $4 \pm 2^\circ\text{C}$
- the name, composition and volume of the 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

7.16.3: 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 36 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 waterbath or other equipment designed for the purpose, within a vacuum-sealed overwrap bag according to a validated procedure. The optimal temperature at which the component should be thawed is 37°C; temperatures between 33°C and 37°C are acceptable.

- Protocols must be in place to ensure that the equipment is cleaned daily and maintained to minimise 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 transfused as soon as possible. If delay is unavoidable, the component may be stored and should be used within 4 hours if maintained at 22 ±2°C or 24 hours if stored at 4 ±2°C, but it should be borne in mind that extended post-thaw storage will result in a decline in the content of labile coagulation factors.

7.16.4: 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 7.13 shall meet the specified values.

Table 7.13 Fresh Frozen Plasma, Methylene Blue Treated and Removed, Leucocyte Depleted – additional tests

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Frequency of test</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volume</td>
<td>1% or as determined by statistical process control (if &lt;=10 components produced per month then test every available component)</td>
<td>Within locally defined nominal volume range and within any limits specified for the MBT process used</td>
</tr>
<tr>
<td>Platelet count</td>
<td></td>
<td>&lt;30 × 10^9/L**</td>
</tr>
<tr>
<td>FVIII:C</td>
<td></td>
<td>&gt;=0.50 IU/mL</td>
</tr>
<tr>
<td>Leucocyte count*</td>
<td>As per sections 6.3 and 7.1</td>
<td>&lt;1 × 10^6/unit**</td>
</tr>
</tbody>
</table>

* Methods validated for counting low numbers of leucocytes must be used

** Pre-freeze in starting component
7.16.5: 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 straightaway it should be transferred immediately to storage at the recommended temperature.