Change Notification UK National Blood Services  No. 18 - 2015

Interruptions to agitation and testing of Platelets, Pooled, Buffy Coat Derived, Leucocyte Depleted and Platelets, Apheresis, Leucocyte Depleted


The current guidance in relation to interruption of agitation has been changed to indicate that no single interruption may last for more than eight hours. The minimum percentage of components that must meet the specified value of 6.4-7.4 for pH at end of shelf-life has been increased to 95% and a requirement to temporarily split double or triple apheresis donations at the point of collection has been added to the specification for Platelets, Apheresis, Leucocyte Depleted.

Therefore the fourth bullet point under “Storage” and the table under testing need to be amended, for the following:

7.9 Platelets, Pooled, Buffy Coat Derived, Leucocyte Depleted

7.9.3 Storage

- Platelets should be gently agitated during storage. If agitation is interrupted, for example due to equipment failure or prolonged transportation, the components are suitable for use, retaining the same shelf life, provided the interruption is for no longer than a total of 24 hours and no single interruption lasts for more than eight hours.

7.9.4 Testing

Table 7.6 Platelets, Pooled, Buffy Coat Derived, Leucocyte Depleted – additional tests

An additional footnote has been added to pH at end of shelf-life to note that a minimum of 95% of components tested shall meet the specified values. (See page 2)

The changes listed above are also required to be made to 7.11 Platelets in Additive Solution and Plasma, Leucocyte Depleted. These are contained in a separate change notification relating to this component (Change Notification No 19 2015).
7.10 Platelets, Apheresis, Leucocyte Depleted

A single-donor platelet component containing less than $1 \times 10^6$ leucocytes.

7.10.1 Technical information

An additional bullet point is required

- If a double or triple dose is collected the platelet concentrate must be temporarily split, as a continuous part of the collection process, into the storage packs integral to the collection set so that the capacity of an individual pack is not exceeded

7.10.3 Storage

- Platelets should be gently agitated during storage. If agitation is interrupted, for example due to equipment failure or prolonged transportation, the components are suitable for use, retaining the same shelf life, provided the interruption is for no longer than a total of 24 hours and no single interruption lasts for more than eight hours.

7.10.4 Testing

Table 7.7 Platelets, Pooled, Buffy Coat Derived, Leucocyte Depleted – additional tests

An additional footnote has been added to pH at end of shelf-life to note that a minimum of 95% of components tested shall meet the specified values. (See below)

Dr Sheila MacLennan
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Changes to Tables 7.6 and 7.7

<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</td>
<td>Within locally defined nominal volume range</td>
</tr>
<tr>
<td></td>
<td>(if ≤10 components produced per month then test every</td>
<td></td>
</tr>
<tr>
<td></td>
<td>available component)</td>
<td>≥240 x 10^9/pool**</td>
</tr>
<tr>
<td>pH at end of shelf life***</td>
<td>As per sections 6.3 and 7.1</td>
<td>6.4–7.4</td>
</tr>
<tr>
<td>Leucocyte count*</td>
<td>As per sections 6.3 and 7.1</td>
<td>&lt;1 x 10^6/pool</td>
</tr>
<tr>
<td>* Methods validated for counting low numbers of leucocytes must be used</td>
<td></td>
<td></td>
</tr>
<tr>
<td>** Units tested and found to have &lt;160 x 10^9/pool should not be issued for transfusion</td>
<td></td>
<td></td>
</tr>
<tr>
<td>*** A minimum of 95% of components tested shall meet the specified values.</td>
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</tbody>
</table>