Change Notification UK National Blood Services  No. 30 - 2015

Red Cells, Washed, Leucocyte Depleted


Following a review of data from UKBTS and published studies, a number of changes are being made in relation to this component as follows:

1) haematocrit is added to the tested parameters to make the UK consistent with Council of Europe Guidelines on this component,

2) the frequency of testing has been increased to 100% unless the process capability demonstrates this is not necessary,

3) the section on irradiation has been amended so that the acceptable shelf-life following irradiation for Red Cells, Washed, Leucocyte Depleted is now shorter than that of Red Cells in Additive Solution, Leucocyte Depleted.

Therefore the specification 7.7: Red Cells, Washed, Leucocyte Depleted has been changed as follows:

Table 7.4  Red Cells, Washed, 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>100% unless the process capability by SPC demonstrates otherwise</td>
<td>Within locally specified volume range</td>
</tr>
<tr>
<td>Haemoglobin content</td>
<td></td>
<td>≥40 g/unit</td>
</tr>
<tr>
<td>Haematocrit</td>
<td></td>
<td>0.50-0.70</td>
</tr>
<tr>
<td>Residual protein**</td>
<td></td>
<td>&lt;0.5 g/unit</td>
</tr>
<tr>
<td>Leucocyte count* (pre-wash)</td>
<td>As per sections 6.3 and 7.1</td>
<td>&lt;1 × 10⁶/unit</td>
</tr>
</tbody>
</table>

* Methods validated for counting low numbers of leucocytes must be used
** units tested and found to have >0.5g/Unit should not be issued for transfusion

Continued
and **Section 7.31: Irradiated components** changed as follows:

### 7.31.4: Storage

For general guidelines, see section 6.7.

Red cell components, other than washed red cells and those for intrauterine transfusion, exchange transfusion, or large-volume transfusion of neonates and infants can be irradiated at any time up to 14 days after collection and stored for up to 14 days thereafter, provided the other requirements of this section are adhered to.

Following irradiation washed red cells that are suspended in a validated additive solution should be transfused as soon as possible and no later than a maximum of 5 days if irradiated at the point of manufacture or 48 hours if irradiated later in shelf-life. Red cells washed and stored in saline must be transfused within 24 hours of irradiation or production.