

## Guidelines for the Blood Transfusion Services

### 7.4.4: Platelets in Additive Solution, Leucocyte Depleted

<http://transfusionguidelines.org/red-book/chapter-7/7-4/7-4-4>

### 7.4.4: Platelets in Additive Solution, Leucocyte Depleted

A platelet concentrate derived from buffy coats or apheresis, which contains less than  $1 \times 10^6$  leucocytes and where the suspending medium is additive solution. This component is indicated for patients with reactions to plasma-containing components.

#### 7.4.4.1: Technical information

- Donations of whole blood where the bleed time exceeded 15 minutes are not suitable for platelet production.
- Where prepared from buffy coats, the buffy coats must be prepared at ambient temperature from whole blood where the surface temperature of packs has not dropped below 18°C.
- Where prepared from buffy coats, initial separation of buffy coat must occur within 24 hours of venepuncture (unless supported by additional validation), with a minimum buffy coat rest period of 2 hours before secondary pooling and processing of buffy coats to produce the final component, which is generally completed before the end of Day 1.
- The volume of suspension medium must be sufficient to maintain the pH at  $\geq 6.4$  at the end of the shelf life of the component.
- Where the production process transfers the final component into a pack that was not part of the original pack assembly, a secure system must be in place to ensure a full audit trail and that the correct identification number is put on the final component pack.
- Platelets in Additive Solution, Leucocyte Depleted, should be administered through a CE/UKCA /UKNI marked transfusion set.

#### 7.4.4.2: Labelling

For general guidelines, see section 6.6.

The following shall be included on the label:

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

- Platelets in Additive Solution, Leucocyte Depleted\* and volume
- the blood component producer's name\*
- a unique pool or batch number or the donation number of all contributing platelet units\*
- the ABO group\*
- the RhD group stated as positive or negative\*

- the expiry date and time\*
- the temperature of storage and a comment that continuous gentle agitation throughout storage is recommended
- the blood pack lot number\*
- the name, composition and volume of the additive solution.

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, including vCJD*

#### **7.4.4.3: Storage**

For general guidelines, see section 6.7.

- The storage period depends on a number of factors including the nature of the container, the concentration of platelets, the additive solution used and whether an open or closed system is used.
- Platelets in Additive Solution, Leucocyte Depleted, should be used within 24 hours of production.
- If any production stage involves an open system, after preparation the component should be used as soon as possible. If storage is unavoidable, the component should be stored at a core temperature of  $22 \pm 2^\circ\text{C}$  with continuous agitation and used within 6 hours.

#### **7.4.4.4: 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 7.1.1), a minimum of 75% of those components tested for the parameters shown in Table 7.4.4 shall meet the specified values.

**Table 7.4.4 Platelets in Additive Solution, Leucocyte Depleted – additional tests**

| Parameter  | Frequency of test   | Specification                               |
|--|---|---|
| Volume   | 1% or as determined by statistical process control (if $\leq 10$ components produced per month then test every available component) | Within locally defined nominal volume range |
| Platelet count <sup>1</sup>  |   | $\geq 200 \times 10^9/\text{unit}$          |
| pH at end of shelf life <sup>2</sup>   |   | $\geq 6.4$                                  |
| Leucocyte count <sup>3</sup>   | As per sections 6.3 and 7.1.1   | $< 1 \times 10^6/\text{unit}$               |
| <sup>1</sup> Units measured and found to have $< 160 \times 10^9/\text{pool}$ , or more than the maximum recommended by the manufacturer of the storage pack where stated, should only be issued for transfusion under concessionary release |   |   |
| <sup>2</sup> A minimum of 95% of those components tested shall meet the specified values   |   |   |
| <sup>3</sup> Methods validated for counting low numbers of leucocytes must be used   |   |   |

*Note: Visual inspection of platelet components for the swirling phenomenon, clumping, excessive red cell contamination and abnormal volume is a useful pre-issue check.*

#### **7.4.4.5: Transportation**

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For general guidelines, see section 6.11.

- Containers for transporting platelets should be equilibrated at room temperature before use. During transportation the temperature of platelets must be kept as close as possible to the recommended storage temperature and, on receipt, unless intended for immediate therapeutic use, the component should be transferred to storage at a core temperature of  $22 \pm 2^{\circ}\text{C}$  with continuous gentle agitation.
- Plastic overwraps should be removed prior to storage.