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**Implementation:** To be determined by each Service

## **Change Notification UK National Blood Services No. 16 - 2006**

**To be applied to Guidelines for the Blood Transfusion Services in the United Kingdom – 7<sup>th</sup> Edition 2005**

### **New Specification**

#### **8.31. Platelets in Additive Solution and Plasma**

A platelet concentrate, derived from buffy coats or apheresis, which contain less than  $5 \times 10^6$  leucocytes and where the suspending medium comprises approximately 30% plasma and 70% additive solution.

##### **Technical Information**

The component is manufactured as a primary component and not as a re-manufactured secondary component.

Donations of whole blood where the bleed time exceeded 15 minutes are not suitable for platelet production.

The platelet component must be prepared at ambient temperature before the red cell component is cooled to below 20°C.

Where prepared from buffy coats, initial separation of buffy coat normally occurs within 12 hours of venepuncture, with secondary pooling and processing of buffy coats to produce the final component generally completed before the end of Day 1.

The volume of suspension medium must be sufficient to maintain the pH within the range 6.4 - 7.4 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 the correct identification number is put on the final component pack.

Platelets, Suspended in Plasma/ Additive Solution, should be transfused through a 170 - 200 µm filter.

##### **Labelling (for general guidelines see Section 6.6)**

The following shall be included on the label:

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



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Platelets, Suspended in Additive Solution / Plasma \* 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 name and volume of the platelet suspension medium  
 the expiry date\*  
 the temperature of storage and a comment that continuous gentle agitation throughout storage is recommended  
 the blood pack lot number\*

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

#### 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 and on whether an open or closed system is used.

Packs currently in use for this purpose allow for storage at a core temperature of 22°C ± 2°C with continuous gentle agitation for up to 5 days in a closed system. Appropriate pack and platelet concentration combinations may allow storage up to 7 days, but due to concerns over bacterial contamination would require either an assay to exclude bacterial contamination prior to transfusion or application of a licensed pathogen reduction procedure.

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°C ± 2°C with continuous agitation and used within 6 hours.

#### Testing

In addition to the mandatory and other tests required for blood donations described in Annex 4, and leucocyte counting (see Section 6.3 and 7.1), a minimum of 75% of those components tested for the parameters shown at Table 7.8 below shall meet the specified values.

Table 7.8. **Platelets in Additive Solution and Plasma - Additional Tests**

| PARAMETER               | FREQUENCY OF TEST                                    | SPECIFICATION                               |
|-------------------------|--|---|
| Volume                  | 1% or 10 per month whichever is greater              | Within locally defined nominal volume range |
| Platelet Count          |  | ≥240 x 10 <sup>9</sup> /pool                |
| pH at end of shelf life | If less than 10 per month, every available component | 6.4 - 7.4                                   |
| Leucocyte Count*        | As per Section 6.3 and 7.1                           | <5 x 10 <sup>6</sup> /pool*                 |

\*methods validated for counting low levels 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.



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### Transportation (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  $22^{\circ}\text{C} \pm 2^{\circ}\text{C}$  with continuous gentle agitation. Plastic overwraps should be removed prior to storage.

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