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Implementation: To be determined by each Service

Change Notification UK National Blood Services No. 19 - 2015

Platelets in Additive Solution and Plasma, Leucocyte Depleted

Applies to the Guidelines for the Blood Transfusion Services in the United Kingdom – 8th Edition 2013

Until recently this component has not been manufactured by any of the UK Blood Services. Following validations of this component and implementation into routine production a number of changes to the specification of this component are being made as follows:

- 1) The title of the component reflects that these components are only produced from whole blood donations
- 2) It is clarified that the required ratio of PAS:plasma should be determined by validation since this will differ between types of PAS and in combination with the source of platelets and type of storage bag and that this should be revalidated annually in a minimum of 25 units.
- 3) The requirement to label the component with the composition of the PAS is removed and this information will be included in the Component Portfolio of the relevant blood service.
- 4) That guidance be added in relation to interruption of agitation.

7.11 Platelets, Pooled, Buffy Coat Derived, in Additive Solution and Plasma, Leucocyte Depleted

Add “Pooled, Buffy Coat Derived” as above to the specification.

In the first sentence delete ‘or apheresis’.

A platelet concentrate, derived from buffy coats ~~or apheresis~~, which contains less than 1×10^6 leucocytes and where the suspending medium comprises approximately 30% plasma and 70% additive solution.

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7.11.1 Technical Information

Amend the text as follows:

- The component is manufactured as a primary component and not as a remanufactured secondary component.
- 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 proportion of plasma carried over into the final component should be determined by validation and will depend upon the type of additive solution and platelet storage pack. Re-validation of the proportion of plasma carried over must be performed at least annually on a minimum of 25 units and after any changes to production method.
- ~~Screening of female apheresis donors for HLA/HNA antibodies should be considered as a TRALI risk reduction strategy.~~
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- 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 audit trail and the correct identification number is put on the final component pack.
- Platelets, Pooled, Buffy Coat Derived, in Additive Solution and Plasma, Leucocyte Depleted, should be transfused through a 170–200 µm filter.

7.11.2 Labelling

Delete the fifth bullet point

- ~~'the name, composition and volume of the anticoagulant and platelet additive solution'.~~

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7.11.3 Storage

Amend 3rd bullet point as follows:

- 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. If platelet agitation is interrupted due to equipment breakdown or prolonged transportation, platelets are suitable for use provided that no single interruption lasts for more than eight hours, and the total length of all interruptions is no longer than 24 hours.

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