Guidelines for the Blood Transfusion Services

7.6: Granulocyte Components

http://www.transfusionguidelines.org/red-book/chapter-7/7-6

7.6: Granulocyte Components

Granulocyte components are manufactured from whole blood-derived buffy coats and are not leucodepleted.

Specifications

7.6.1: Granulocytes, Pooled, Buffy Coat Derived, in Platelet Additive Solution and Plasma

A pool of granulocytes, derived from buffy coats, with retention of neutrophils as the major cellular product, suspended in a portion of the plasma and platelet additive solution.

7.6.1.1: Technical information

- The component is not leucodepleted.
- The component contains red cells and requires compatibility testing.
- CMV seronegative granulocytes should be considered for CMV seronegative recipients.
- The component contains 2.0 adult transfusion doses (ATDs) of platelets[4] and additional platelet transfusion is therefore unlikely to be required.
- The component must not be agitated during storage.
- The component must be irradiated before use.
- Granulocytes should be administered through a CE/UKCA/UKNI marked transfusion set.
- The component must be stored in a pack that allows gas exchange (i.e. a platelet pack).
- The production process transfers the final component into a pack that was not part of the original pack assembly. Therefore 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.
- Recommended dose for adults is 1-2 packs daily and for a child 10-20 mL/kg.
- A clinical study has been undertaken in 30 human patients using this component. Leucocyte antibody formation occurred at a rate similar to historical multiply transfused controls (3 of 29 patients assessed).[5]

7.6.1.2: Labelling

For general guidelines, see section 6.6.

The following should be included on the label:

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

- Granulocytes, Pooled, Buffy Coat Derived, in Platelet Additive Solution and Plasma* and volume
- the blood component producer's name*
- a unique pool or batch number or the donation number of all contributing units*
- the ABO group*
- the RhD group stated as positive or negative*
- the date of collection
- the expiry date and time*
- the temperature of storage
- the statement 'Do not agitate'
- the blood pack lot number*
- the name, composition and volume of the anticoagulant solution
- the name, composition and volume of the platelet 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

7.6.1.3: Storage

For general guidelines, see section 6.7.

- Granulocytes should be used as soon as possible after their preparation. If storage is unavoidable, provided the component is produced using a closed system, the component should be stored, without agitation, at a core temperature of 22 ±2°C and transfusion should commence by midnight on Day 1 (the day following donation).

7.6.1.4: Testing

In addition to the mandatory and other tests required for blood donations described in Chapter 9, 95% or more of components tested for the parameters shown in Table 7.6.1 shall meet the specified values. Where a unit is tested and found to have a granulocyte yield $<3.8 \times 10^9$/unit the production process should be reviewed.

Table 7.6.1 Granulocytes, Pooled, Buffy Coat Derived, in Additive Solution and Plasma

Parameter	Frequency of test	Specification
Volume [1]	1% or as determined by statistical process control (if <=10 components produced per month then test every available component)	175 – 250 mL
Total granulocyte count [1]		>5 × 10^9/unit
[1] Based on production from ten whole blood donations		

7.6.1.5: Transportation

For general guidelines, see section 6.11.

- Containers for transporting granulocytes should be equilibrated at room temperature before use. During transportation the temperature of the component 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 ±2°C without agitation.

- Plastic overwraps should be removed prior to storage.