BLOOD COMPONENT MONOGRAPH

WHOLE BLOOD PLASMA REDUCED LEUCOCTYE DEPLETED

REASON FOR ISSUE: DCR12119 to include the requirement to be DAT negative and to update format from specification to monograph.

Council of Europe Guide Monograph	Whole Blood, Leucocyte Depleted, Plasma Reduced for Exchange Transfusion
eProgesa Component Names	Whole Blood Plasma Reduced Leucocyte Depleted
eProgesa Component Codes	02080

1. DEFINITION and PROPERTIES:

Whole Blood, Plasma Reduced Leucocyte Depleted (WBPR) is a component derived from *Whole Blood, Leucocyte Depleted (LD)* with a proportion of the plasma removed. The approved anticoagulant is CPD. *WBPR* is primarily intended for neonatal exchange transfusion.

2. PREPARATION:

WBPR is selected within five days from a donation and a proportion of the plasma is removed to achieve a clinically prescribed haematocrit.

If the component is to be used for neonatal exchange transfusion the donation must come from a donor who has donated at least once in the last six months; if the maternal antibody is anti-RhD, the component must be prepared from a type O RhD negative donation. If the maternal antibody is other than anti-RhD, red cells are selected that are antigen negative for the relevant maternal allo-antibodies.

WBPR for neonatal use must be irradiated:

- If there is a prior history of intrauterine transfusion;
- For all other patients, unless compelling clinical circumstances indicate that delay would compromise the clinical outcome.

WBPR may be used in patients other than those requiring neonatal transfusion.

3. RELEASE REQUIREMENTS and QUALITY CONTROL:

Release requirements are as indicated for *Whole Blood, LD* with the following additional standards:

3.1 Release Requirements[1]

Parameter	Requirements	Frequency of control
CMV	Negative	All units
High Titre anti A or B	Negative	All units
Direct Antiglobulin Test	Negative	All units

1. These additional release requirements apply when *WBPR* is intended for neonatal transfusion

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3.2 Quality Monitoring Requirements

Parameter	Requirements	Frequency of control
Volume [2]	250 - 450mL	As determined by SPC
Haemoglobin [2]	≥ 43 g per unit	
Haematocrit [2]	0.45 – 0.55	
Residual leucocyte content [3]	< 5 x10^6 / unit	
Haemolysis at the end of storage[2]	<0.8% of red cell mass	All units

2. A minimum of 90% of units tested should meet the required value
3. This requirement is met when there is 95% confidence that 99% of the units tested comply.

4. STORAGE and TRANSPORT

The storage and transport of *WBPR* is as in the monograph described for *Whole Blood, LD*.

The storage time must not be longer than 24 hours after irradiation and five days from collection for neonatal use.

For adult use *WBPR* may be irradiated up to 14 days after collection and thereafter may be stored for a further 14 days before transfusion.

5. LABELLING:

Additional and / or amended labelling requirements to those of *Whole Blood, LD* are:

- the modified date and time of expiry;
- additional component information: irradiated etc. (as appropriate).

6. WARNINGS:

Blood group compatibility with any maternal allo-antibodies is essential. The rate of transfusion must be controlled to avoid excessive fluctuations in blood volume.

Adverse reactions:

In addition to the adverse reactions identified for *Whole Blood, LD*, particular concerns in the context of new-borns undergoing exchange transfusion are:

- Metabolic imbalance including: citrate toxicity, hypocalcaemia, hyperkalaemia, hypoglycaemia, hypokalaemia;
- Thrombocytopaenia;
- Cytomegalovirus infection;
- Graft versus host disease, unless irradiated;
- Transfusion associated circulatory overload;
- Haemolytic transfusion reaction;
- Hypothermia