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Change Notification UK National Blood Services No. 9 - 2022

Chapter 7: **Human** Plasma for Fractionation, leucocyte depleted

This change applies to the Guidelines for the Blood Transfusion Services in the United Kingdom 8th Edition 2013

New Specification

7.37 **Human** Plasma for **f**Fractionation, **l**Leucocyte **d**Depleted

Plasma that has been obtained from whole blood or by apheresis (as defined in section 7.3), containing less than 1×10^6 leucocytes per unit.

UK derived plasma may be used for the manufacture of immunoglobulins for domestic use provided all relevant vCJD risk mitigation measures currently in place for blood components for transfusion are applied and manufacturers submit an application to the MHRA to register the use of UK-sourced plasma including a product specific risk assessment. Manufacture of other blood products such as clotting factors or albumin is not currently permitted.

7.37.1: Technical information


- All aspects of collection and manufacture, testing and storage should satisfy the requirements defined in the current *British Pharmacopoeia* monograph on Human Plasma for Fractionation.
- See chapters 3, 4, 5, 9 and 12 for specific details on donor selection, care and testing for **Human** Plasma for Fractionation, Leucocyte **d**Depleted.
- Donations of whole blood where the bleed time exceeded 15 minutes are not suitable for the production of plasma components for clinical use.
- Plasma with a volume below 200 mL is not suitable for use.
- Plasma may be selected from both male and female donors. Female donors do not need additional screening for anti-HLA and anti-HNA antibodies.
- When obtained by plasmapheresis, plasma intended solely for the recovery of proteins that are not labile in plasma is frozen using validated conditions by cooling rapidly in a chamber at -20°C or below as soon as possible and at the latest within 24 h of collection.

- When obtained from whole blood, plasma intended solely for the recovery of proteins that are not labile in plasma is separated from cellular elements and frozen using validated conditions in a chamber at -20°C or below as soon as possible and at the latest within 72 h of collection.
- **Human** Plasma for Fractionation, Leucocyte Depleted must not be transfused directly to patients.

7.37.2: Labelling

For general guidelines, see section 6.6. The following shall be included on the label **in eye readable format**:

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

- Human **p**Plasma for Fractionation, Leucocyte Depleted* ~~and volume~~
- Recovered or **s**Source plasma
- **the component** ~~v~~volume
- the blood component producer's name 
- the donation number and, if divided, sub-batch number*
- the date of collection
- the expiry date of the frozen component*
- the temperature of storage
- the blood pack lot number*
- the name, composition and volume of the anticoagulant.
- Not for transfusion

7.37.3: Storage

For general guidelines, see section 6.7.

- The component should be stored at a core temperature of -20°C or below for a maximum of 36 months.

- Although frozen storage temperatures improve the preservation of labile and non-labile proteins, lower temperatures increase the fragility of plastic. Particular care must be taken when handling such packs.

7.37.4: Testing

- In addition to the mandatory and other tests required for blood donations for **Human Plasma for Fractionation, Leucocyte Depleted** described in Chapter 9, and leucocyte counting (see sections 6.3 and 7.1), components should be tested for the parameters shown in Table 7.37.
- Total protein testing will be undertaken according to the British Pharmacopeia 2021 – Plasma for Fractionation (*Human Plasma for Fractionation, Ph. Eur. 10.3 monograph 0853*) or using equivalent, validated assays.

Table 7.37 Human Plasma for Fractionation, Leucocyte Depleted – additional tests

Parameter	Frequency of test	Specification
Volume	1% or as determined by statistical process control (if ≤10 components produced per month then test every available component)	Stated volume ±10% **
Total protein		Mean ≥ 50 g/L
Platelet count		< 50 × 10 ⁹ /L **/***
Red cell count		< 6 × 10 ⁹ /L **/***
Leucocyte count *	As per sections 6.3 and 7.1	< 1 × 10 ⁶ /unit equivalent ***
* Methods validated for counting low numbers of leucocytes must be used		
** A minimum of 90 % of units tested should meet the required value		
*** Pre-freeze in starting component		

More than 90 % of leucocyte-depleted components from relevant processes must have less than 1 × 10⁶ leucocytes per unit and more than 99 % of components must contain less than 5 × 10⁶ leucocytes per unit, both with 95 % confidence.

Where plasma is collected into one container for final frozen storage the specification must be assessed based on volume ranges of 200 mL to ≤400 mL for a single unit equivalent, >400 mL to ≤680 mL for a double unit equivalent, and >680 mL for a triple unit equivalent collection.

7.37.5: Transportation

For general guidelines, see section 6.11.

The frozen plasma should be stored and transported under conditions validated to maintain a temperature of -20 °C or below. Temperature fluctuations in the plasma should be kept to a minimum during storage or transportation. A plasma temperature record during storage and transit of frozen plasma shall be available for inspection.

Short excursions of up to 30 minutes whilst preparing plasma for shipping are permissible.

Exceptional temperature deviations above -20 °C, e.g. in the case of equipment failure, on one or more occasions are acceptable so long as the following conditions are met:

- the total period of time above -20 °C does not exceed 72 hours
- the temperature does not exceed -15 °C on more than one occasion
- the temperature does not exceed -5 °C

Where plasma which has been subject to temperature deviations during storage or transportation this must be recorded and reported to any third party receiving the plasma.

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