Change Description:
Revise IBTS/PMF/SPEC/0214. Set new volume specification for TACSI pooled platelets. Add new parameter of platelet concentration with quality requirement of \( \geq 35 \text{ ml per } 60 \times 10^9 \) of platelets and frequency of control of 1%. Change platelet content and leucocyte content frequency of control to 1%. Volume frequency of control to remain at 100%.

Reason for Change:
New pooling system validated as per IBTS/QA/VP/0570. Addition of platelet concentration parameter required as per validation. Amended frequency of control requirements as per CC 147/18/IBTS.

Change order No.:
IBTS/CO/0174/18
IBTS/CO/0357/18

Referenced Procedures
None

SmartTrain Roles
N/A

SmartSolve Document Category

<table>
<thead>
<tr>
<th>Category</th>
<th>Mobile</th>
<th>Cryobiology</th>
<th>Website</th>
<th>GDP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes / No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>
IRISH BLOOD TRANSFUSION SERVICE
PRODUCT MASTER FILE

Title: Platelets, Adult Dose with Plasma / PAS, Irradiated

Name of Products:

- PLATELETS, Adult Dose with Plasma / PAS, Irradiated

  This product can be extended into;

- PLATELETS, Adult Dose with Plasma / PAS, Irradiated

E Progesa Codabar Component Codes: 69740 / 66450

E Progesa ISBT – 128 Component Codes: E6953V00 / E6645V00

General Description: Platelets prepared from a pool of four buffy coats suspended in approximately 70% additive solution and 30% plasma. The removal of the majority of leucocytes is achieved by filtration.

General Specification:

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Quality Requirements</th>
<th>Frequency of Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volume</td>
<td>251 to 343 ml</td>
<td>100%</td>
</tr>
<tr>
<td>Platelet Content</td>
<td>&gt; 200 x 10^9/unit</td>
<td>1%</td>
</tr>
<tr>
<td>Platelet Concentration</td>
<td>≥ 35 ml per 60 x 10^9 of platelets</td>
<td>1%</td>
</tr>
<tr>
<td>Leucocyte Content</td>
<td>&lt; 1 x 10^6/unit</td>
<td>1%</td>
</tr>
<tr>
<td>pH measured (+22 C) at the end of the recommended shelf life</td>
<td>&gt; 6.4</td>
<td>4 per month</td>
</tr>
</tbody>
</table>

Labelling: See Appendix 1
Storage: Platelets Adult Dose with Plasma / PAS Irradiated (69740) should be stored at 22°C ± 2°C. The total storage time is 5 days when stored with continuous gentle agitation. The storage time may be extended to 7 days if a bacterial screen test is performed on day 4. If extended the component code then changes to 66450/E6645V00.

Irradiation: Platelets are irradiated routinely during preparation.

Transportation: Transport containers should be kept open at room temperature for 30 minutes before use. During transportation from the Irish Blood Transfusion Service to the place where they are intended for use the temperature of platelets must be kept as close as possible to the recommended storage temperature. On receipt, unless intended for immediate therapeutic use, they should be transferred to storage with continuous gentle agitation on a device approved for the purpose, at 22°C ± 2°C.

Indications for Use: To provide platelet replacement where deficiency or functional abnormality is causing significant haemostatic problems.

Precautions in Use:
- Swirling phenomenon must be demonstrated before infusion.
- Platelets must be infused intravenously through a fresh infusion set containing an in line 170 – 200 µm filter.
- Rh D negative female recipients of child bearing potential should preferably not be transfused with platelets from Rh D positive donors.
- Because of the temperature of storage and preparation the risk of bacterial contamination is increased.
- No solution should be added to the bag or giving set.
- Components should be inspected visually for defects, leakage, abnormal colour or visible clots.
- Not recommended in cases of plasma intolerance.
Adverse Effects Include:

- Circulatory overload

- Haemolytic transfusion reaction due to transfusion of ABO-incompatible plasma in the component.

- Non-haemolytic transfusion reaction (mainly chills, fever and urticaria). The risk is reduced by leucodepletion.

- Anaphylaxis

- Pathogen transmission
  - Despite careful donor selection and laboratory screening procedures, infections including Syphilis, Viral Hepatitis, HIV, HTLV 1 & 11 and other viruses and protozoa (e.g. malaria) may, in rare instances, occur.
  - vCJD transmission
  - Transmission of other pathogens that are not tested for or recognised.
  - The risk of CMV transmission is reduced by leucocyte depletion.
  - Acute Sepsis due to bacterial contamination is reduced by bacterial screening.

- Metabolic upset
  - Citrate toxicity, especially in neonates and in patients with impaired hepatic function.

Immunological effects

- Alloimmunisation to HLA and HPA antigens
- Post Transfusion purpura (PTP), especially in parous female recipients
- The risk of Graft vs Host Disease (GvHD) in immuno compromised recipients is eliminated by irradiation
- Transfusion related Acute Lung injury (TRALI) by donor HLA/granulocyte antibodies
Serious Adverse Reaction

Serious adverse reactions should be reported to:

National Haemovigilance Office  
Irish Blood Transfusion Service  
National Blood Centre  
James’s Street  
Dublin 8

AND

Quality Assurance Manager  
Irish Blood Transfusion Service

AT EITHER

National Blood Centre  
James’s Street  
Dublin 8

OR

St Finbarr’s Hospital  
Douglas Road  
Cork.
APPENDIX I

E Progesa Codabar Component Code: 69740

E Progesa ISBT-128 Component Code: E6953V00

Product Name:
PLATELETS, Adult Dose
with Plasma / PAS, Irradiated

Shelf Life:
5 days

Product Label and Barcode:
(for illustration purposes only – barcodes not suitable for scanning – label not to scale)

N.B. Stated volume for illustration purposes only.
APPENDIX I

E Progesa Codabar Component Code: 66450

E Progesa ISBT-128 Component Code: E6645V00

Product Name: Platelets, Adult Dose with Plasma / PAS, Irradiated

Shelf Life: 7 days

Product Label and Barcode:
(for illustration purposes only – barcodes not suitable for scanning – label not to scale)

Store at 22°C ± 2°C

Platelets, Adult Dose with Plasma/PAS, Irradiated

Rh D Negative
CMV Antibody Negative

Units in pool: 4

N.B. Stated volume for illustration purposes only.