



Irish Blood Transfusion Service

Seirbhís Fuilastriúcháin na hÉireann

Document Detail

Type: PMF IBTS SPEC
Document No.: IBTS/PMF/SPEC/0214[7]
Title: **PLATELETS, ADULT DOSE WITH PLASMA / PAS,
IRRADIATED**
Owner: QA DOC CON QA DOC CONTROL
Status CURRENT
Effective Date: 25-Aug-2021
Expiration Date: 09-Oct-2027

Document Detail

Review

Review: IBTS PMF REVIEW

<u>Level</u>	<u>Owner Role</u>	<u>Actor</u>	<u>Sign-off By</u>
1	DOCUMENT CONTROLLER	DEBBIE MAC RORY	DEBBIE MAC RORY
2	QUALITY CONTROL REVIEWER NBC	ELIN JOHANSSON	SMARTCOMM
2	QUALITY CONTROL REVIEWER NBC	ENDA CADDEN	ENDA CADDEN
2	QUALITY CONTROL WRITER NBC	ZUZANNA MICHALSKA	ZUZANNA MICHALSKA
3	LABS PHS DIR IBTS	BARRY DOYLE	BARRY DOYLE
3	MEDICAL & SCIENTIFIC DIRECTOR	STEPHEN FIELD	STEPHEN FIELD
3	QUALITY CONTROL HEAD OF DEPT NBC	ENDA CADDEN	ENDA CADDEN
4	QUALITY ASSURANCE REVIEWER IBTS	COLIN JOHNS	COLIN JOHNS

Review: IBTS DOC PERIODIC REVIEW

<u>Level</u>	<u>Owner Role</u>	<u>Actor</u>	<u>Sign-off By</u>
1	DOCUMENT CONTROLLER	REBECCA WALDEN	REBECCA WALDEN
2	QUALITY ASSURANCE WRITER IBTS	REBECCA WALDEN	REBECCA WALDEN
3	SSCD HEAD OF DEPT IBTS	AILEEN FARRELLY	AILEEN FARRELLY
3	MEDICAL & SCIENTIFIC DIRECTOR	TOR HERVIG	TOR HERVIG
3	COMPONENTS HEAD OF DEPT MRTC	AINE FITZPATRICK	AINE FITZPATRICK
3	SSCD HEAD OF DEPT IBTS	AILEEN FARRELLY	AILEEN FARRELLY
3	LABS PHS DIR IBTS	BARRY DOYLE	BARRY DOYLE
4	DIRECTOR OF QUALITY	KAREN BYRNE	KAREN BYRNE
4	QUALITY ASSURANCE REVIEWER IBTS	COLIN JOHNS	COLIN JOHNS

Review: IBTS DOC PERIODIC REVIEW

<u>Level</u>	<u>Owner Role</u>	<u>Actor</u>	<u>Sign-off By</u>
1	DOCUMENT CONTROLLER	BECKY WHITE	BECKY WHITE
2	COMPONENTS WRITER IBTS	BARRY DOYLE	BARRY DOYLE
3	LABS PHS DIR IBTS	BARRY DOYLE	BARRY DOYLE
3	SSCD HEAD OF DEPT IBTS	AILEEN FARRELLY	AILEEN FARRELLY
3	COMPONENTS HEAD OF DEPT MRTC	AINE FITZPATRICK	AINE FITZPATRICK
3	MEDICAL & SCIENTIFIC DIRECTOR	ANDREW GODFREY	ANDREW GODFREY
3	SSCD HEAD OF DEPT IBTS	AILEEN FARRELLY	AILEEN FARRELLY
4	QUALITY ASSURANCE REVIEWER IBTS	KAREN BYRNE	KAREN BYRNE
4	DIRECTOR OF QUALITY	KAREN BYRNE	KAREN BYRNE

Change Orders

Changes as described on Change Order: Change Order No.

Document Detail

Change Orders - Incorporated

Changes as described on Change Order:

Change Order No.
IBTS/CO/0248/21

IBTS/PMF/SPEC/0214	Ver 7	Page 2 of 6
--------------------	-------	-------------

IRISH BLOOD TRANSFUSION SERVICE
PRODUCT MASTER FILE

TITLE: **PLATELETS, ADULT DOSE WITH PLASMA / PAS, IRRADIATED**

Change Description:

Change lower volume specification from 251ml to 271ml

Reason for Change:

As per CC107/21/IBTS

Change order No.:

IBTS/CO/0248/21

Referenced Documents

N/A

SmartSolve Roles

N/A

Training Type

N/A

SmartSolve Document Category

Category	Mobile	Cryobiology	Website	GDP
Yes / No	No	No	Yes	No

**IRISH BLOOD TRANSFUSION SERVICE
PRODUCT MASTER FILE**

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

Name of Product:

- PLATELETS, Adult Dose with Plasma / PAS, Irradiated

E Progesa Codabar Component Code: 69740

E Progesa ISBT – 128 Component Code: E6953V00

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:

Parameter	Quality Requirements	Frequency of Control
Volume	271 to 378 ml	100%
Platelet Content	$> 200 \times 10^9/\text{unit}$	1%
Platelet Concentration	$\geq 35 \text{ ml per } 60 \times 10^9 \text{ of platelets}$	1%
Leucocyte Content	$< 1 \times 10^6/\text{unit}$	1%
pH measured (+22 C) at the end of the recommended shelf life	> 6.4	4 per month

Labelling: See Appendix I

IBTS/PMF/SPEC/0214	Ver 7	Page 4 of 6
--------------------	-------	-------------

- Storage:** Platelets Adult Dose with Plasma / PAS Irradiated (69740) should be stored at 22°C ± 2°C. The total storage time is 7 days when stored with continuous gentle agitation.
- 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 minimal as the components are leucodepleted
 - Sepsis due to bacterial contamination (reduced but not eliminated 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 immunocompromised recipients is eliminated by irradiation
 - Transfusion related Acute Lung injury (TRALI) by donor HLA/granulocyte antibodies

Serious Adverse Reaction

Please inform the IBTS immediately about any event relating to suspected bacterial sepsis/ transfusion associated bacterial sepsis

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

Munster Regional Transfusion Centre
St Finbarr's Hospital
Douglas Road, Cork

IBTS/PMF/SPEC/0214	Ver 7	Page 6 of 6
--------------------	-------	-------------

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 :
7 days

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

IBTS ver 2.0



5100

**PLATELETS, Adult Dose
with Plasma/PAS, Irradiated**

Store at 22°C ± 2°C


021088
Drawn 29 Mar 2021


E6953V00


0210952359
Expiry 05 Apr 2021 23:59

300 ml

Rh D Positive

Units in pool: 1


69740


Expiry 05/04/2021


O Pos

This component must not be used if there are visible signs of deterioration. This component may transmit infection.
AGITATE GENTLY THROUGHOUT STORAGE
Must be administered using a suitable transfusion set incorporating a 170 – 200 µm filter. Resuspended in 250 ml platelet additive solution containing in mmol/l: Sodium 183.9, Citrate 10.8, Acetate 32.5, Chloride 77.3, Potassium 5.0, Magnesium 1.5, Phosphate 28.2

N.B. Stated volume for illustration purposes only.