



Document Detail

Type: PMF IBTS SPEC
Document No.: IBTS/PMF/SPEC/0217[5]
Title: **PLATELETS, ADULT DOSE, SUITABLE FOR NEONATAL USE, WASHED, IRRADIATED**
Owner: QA DOC CON QA DOC CONTROL
Status: CURRENT
Effective Date: 18-Apr-2021
Expiration Date: 04-Aug-2025

Review

Review: IBTS PMF 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	LABS PHS DIR IBTS	BARRY DOYLE	BARRY DOYLE
3	NATIONAL MEDICAL DIRECTOR	STEPHEN FIELD	STEPHEN FIELD
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>
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2	QUALITY ASSURANCE WRITER IBTS	REBECCA WALDEN	REBECCA WALDEN
3	NATIONAL MEDICAL DIRECTOR	TOR HERVIG	TOR HERVIG
3	COMPONENTS HEAD OF DEPT MRTC	AINE FITZPATRICK	AINE FITZPATRICK
3	LABS PHS DIR IBTS	BARRY DOYLE	BARRY DOYLE
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4	QUALITY ASSURANCE REVIEWER IBTS	COLIN JOHNS	COLIN JOHNS
4	DIRECTOR OF QUALITY	KAREN BYRNE	KAREN BYRNE

Change Orders

Changes as described on Change Order: Change Order No.

Change Orders - Incorporated

Changes as described on Change Order: Change Order No.
 IBTS/CO/0167/21

**IRISH BLOOD TRANSFUSION SERVICE
PRODUCT MASTER FILE**

**TITLE: PLATELETS, ADULT DOSE, SUITABLE FOR
NEONATAL USE, WASHED, IRRADIATED**

Change Description:

Revise IBTS/PMF/SPEC/0203 – 0218, 0220, 0221, 0224, 0226, 0227, 0232, 0236 to update the product labels in the appendices for each product.

Reason for Change:

Fix to the labels as part of the semester patch reference CC 126/19/IBTS and reference IBTS/QA/IQ/0600 Deviation 008

Change order No.:

IBTS/CO/0167/21

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, Suitable for Neonatal Use, Washed, Irradiated

Name of Product:

PLATELETS, Adult Dose, Suitable for Neonatal Use, Washed, Irradiated.

PLATELETS, Adult Dose, Suitable for Neonatal Use, Split 1, Washed, Irradiated

PLATELETS, Adult Dose, Suitable for Neonatal Use, Split 2, Washed, Irradiated

PLATELETS, Adult Dose, Suitable for Neonatal Use, Split 3, Washed, Irradiated

E Progesa Codabar Component Codes: 66674 / 66675 / 66676 / 66677

E Progesa ISBT – 128 Component Codes: C6667V00 / C6667VA0 / C6667VB0 / C6667VC0.

General Description: A platelet preparation with the majority of leucocytes removed, suspended in plasma obtained from a single donor using automated cell separation equipment and washed in InterSol platelet additive solution to remove most of the plasma. The selected donors meet the additional criteria for neonatal use.

General Specification:

Parameter	Quality Requirement	Frequency of Control
Volume	195-225 ml / unit	100%
Platelet Content	A reduction in platelet count of approximately 15% is to be expected*	All units tested during routine hrs unless clinically urgent
Protein Content	< 0.5g / unit	4 per year

* From the starting component ($\geq 200 \times 10^9$ per unit)

Components with $< 160 \times 10^9$ / unit are referred for medical review prior to release

Labelling: See Appendix 1

Storage: Platelets, Adult Dose, Suitable for Neonatal Use, Washed, Irradiated should be used immediately. If delay is unavoidable, platelets should be stored with continuous gentle agitation at $22^\circ \text{C} \pm 2^\circ \text{C}$ and used within 24 hours of preparation.

- 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, if not transfused immediately, they should be transferred to storage with continuous gentle agitation on a device approved for the purpose, at $22^{\circ}\text{C} \pm 2^{\circ}\text{C}$.
- Indications for Use:** To provide platelet replacement where deficiency or functional abnormality is causing significant haemostatic problems, in patients with significant reactions to plasma.
Washed platelets (protein content $< 0.5\text{g/unit}$) are not designated for the transfusion of patients with IgA deficiency.
- Precautions in Use:**
- Platelets, Adult Dose, Suitable for Neonatal Use, Washed, Irradiated 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.
 - Swirling phenomenon should be demonstrated before infusion.
- Adverse Effects Include:**
- Circulatory overload
 - 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 immuno compromised 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

APPENDIX I

E Progesa Codabar Component Code:

66674

E Progesa ISBT-128 Component Code:

C6667V00

Product Name:PLATELETS, Adult Dose,
Suitable for Neonatal Use,
Washed, Irradiated.**Shelf Life:** 24 hours**Product Label and Barcode:**

(for illustration purposes only – barcodes not suitable for scanning – label not to scale)

IBTS ver 2.0

9500

**PLATELETS Adult Dose,
Suitable for Neonatal Use,
Washed, Irradiated**
Store at 22°C ± 2°C

Rh D Negative

021088
Drawn 29 Mar 2021

300 ml
C6667V00

0210891427
Expiry 30 Mar 2021 14:27

66674 Expiry 30/03/2021 O Neg

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. Washed and suspended in 200ml of InterSol solution containing, in mmol/L: Na 191.9, Acetate 32.5, Phosphate 28.2, Chloride 77.3, Citrate 10.8.

N.B. Stated label volume is for illustration purposes only

APPENDIX I

E Progesa Codabar Component Code: 66675

E Progesa ISBT-128 Component Code : C6667VA0

Product Name: PLATELETS, Adult Dose,
Suitable for Neonatal Use,
Split 1, Washed, Irradiated,

Shelf Life: 24 hours

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,
Suitable for Neonatal Use,
Split 1, Washed, Irradiated**
Store at 22°C ± 2°C

O

Rh D Positive

021088
Drawn 29 Mar 2021

300 ml
0210891427
Expiry 30 Mar 2021 14:27

C6667VA0

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.
Washed and suspended in 200ml of InterSol solution containing, in mmol/L:
Na 191.9, Acetate 32.5, Phosphate 28.2, Chloride 77.3, Citrate 10.3.

66675 Expiry 30/03/2021 O Pos

N.B. Stated label volume is for illustration purposes only

APPENDIX I

E Progesa Codabar Component Code: 66676

E Progesa ISBT-128 Component Code: C6667VB0

Product Name: PLATELETS, Adult Dose,
Suitable for Neonatal Use,
Split 2, Washed, Irradiated,
Shelf Life: 24 hours

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,
Suitable for Neonatal Use,
Split 2, Washed, Irradiated**
Store at 22°C ± 2°C

021088
Drawn 29 Mar 2021

Rh D Positive

300 ml
0210891427
Expiry 30 Mar 2021 14:27

C6667VB0

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.
Washed and suspended in 200ml of InterSol solution containing, in mmol/L:
Na 191.9, Acetate 32.5, Phosphate 28.2, Chloride 77.3, Citrate 10.8.

66676 Expiry 30/03/2021 O Pos

N.B. Stated label volume is for illustration purposes only

APPENDIX I

E Progesa Codabar Component Code: 66677

E Progesa ISBT-128 Component Code: C6667VC0

Product Name: PLATELETS, Adult Dose,
Suitable for Neonatal Use,
Split 3, Washed, Irradiated.

Shelf Life: 24 hours

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

Effective 18 April 2021

8400

IBTS ver 2.0

PLATELETS, Adult Dose,
Suitable for Neonatal Use,
Split 3, Washed, Irradiated
Store at 22°C ± 2°C

021088
Drawn 29 Mar 2021

300 ml
C6667VC0

0210891427
Expiry 30 Mar 2021 14:27

66677

Expiry 30/03/2021

AB 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.

Washed and suspended in 200ml of InterSol solution containing, in mmol/L:
Na 191.9, Acetate 32.5, Phosphate 28.2, Chloride 77.3, Citrate 10.3.

N.B. Stated label volume is for illustration purposes only