



Document Detail

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Title: **PLATELETS, ADULT DOSE, SUITABLE FOR NEONATAL USE, WASHED**
Owner: 1895 REBECCA WALDEN
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Review

Review: IBTS PMF REVIEW

<u>Level</u>	<u>Owner Role</u>	<u>Actor</u>	<u>Sign-off By</u>
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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/0103/18

**IRISH BLOOD TRANSFUSION SERVICE
PRODUCT MASTER FILE**

Title: Platelets, Adult Dose, Suitable for Neonatal Use, Washed

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 SSP 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	180 - 220 ml / unit	100%
Platelet Content	$\geq 160 \times 10^9$ / unit	100%
Protein Content	< 0.5g / unit	4 per year

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 6 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 reduced by leucocyte depletion.
 - Acute Sepsis due to bacterial contamination is reduced by bacterial screening.

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

AND

National 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:

66674

E Progesa ISBT-128 Component Code:

C6667V00

Product Name:

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

Shelf Life: 6 hours**Product Label and Barcode:**

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

IBTS ver 1.0

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

Store at 22°C ± 2°C

B

Rh D Positive

CMV Antibody Negative

Drawn 03 Apr 2018

300 ml

Expiry 05 Apr 2018 20:10

C6667V00

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 200 ml of SSP solution containing, in mmol/l: Na176.3, Cl 116.3, Citrate 10, Acetate 30

66674

Expiry 05/04/2018

B Pos

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: 6 hours

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

IBTS ver. 1.0

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

Store at 22°C ± 2°C

018087

Drawn 28 Mar 2018

300 ml

C6667VA0

Rh D Negative
CMV Antibody Negative

0180881736

Expiry 29 Mar 2018 17:36

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 200 ml of SSP solution containing, in mmol/l: Na176.3, Cl 116.3, Citrate 10, Acetate 30.

66675

Expiry 29/03/2018

A Neg

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: 6 hours

Product Label and Barcode:

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

IBTS ver 1.0

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

Store at 22°C ± 2°C

018093

Drawn 03 Apr 2018

300 ml

C6667VB0

0180952008

Expiry 05 Apr 2018 20:08

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 200 ml of SSP solution containing, in mmol/l: Na 176.3, Cl 116.3, Citrate 10, Acetate 30

66676

Expiry 05/04/2018

O Neg

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: 6 hours

Product Label and Barcode:

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

IBTS ver 1.0

5100

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

Store at 22°C ± 2°C

018093

Drawn 03 Apr 2018

C6667VC0

300 ml

0180952009

Expiry 05 Apr 2018 20:09

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 200 ml of SSP solution containing, in mmol/l: Na176.3, Cl 116.3, Citrate 10, Acetate 30

66677

Expiry 05/04/2018

O Pos

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