

Document Detail

	PMF IBTS SPEC 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:	18-Apr-2023

<u>Review</u>

Review: IBTS PMF REVIEW

Level	Owner Role	<u>Actor</u>	Sign-off By
1	DOCUMENT CONTROLLER	REBECCA WALDEN	REBECCA WALDEN
2	QUALITY ASSURANCE WRITER IBTS	REBECCA WALDEN	REBECCA WALDEN
3	NATIONAL MEDICAL DIRECTOR	STEPHEN FIELD	STEPHEN FIELD
3	LABS HEAD OF MANUFACTURING & ISSUE IBTS	BARRY DOYLE	BARRY DOYLE
4	QUALITY ASSURANCE REVIEWER IBTS	COLIN JOHNS	COLIN JOHNS

Change Orders

Changes as described on Change Order: <u>Change Order No.</u>

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

Jse. Status CURRENT **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.

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

General Specification:

* 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.

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 < 0.5g/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 $170 200 \,\mu m$ 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:

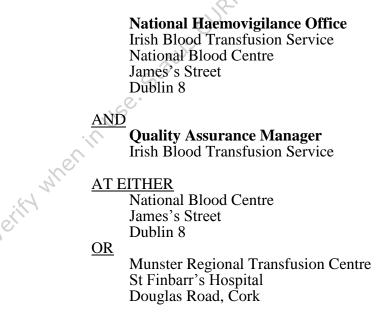
- <u>Circulatory overload</u>
- <u>Non-haemolytic transfusion reaction</u> (mainly chills, fever and urticaria). The risk is reduced by leucodepletion.
- <u>Anaphylaxis</u>
- <u>Pathogen transmission</u>
 - Despite careful donor selection and laboratory screening procedures, infections including Syphilis, 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)

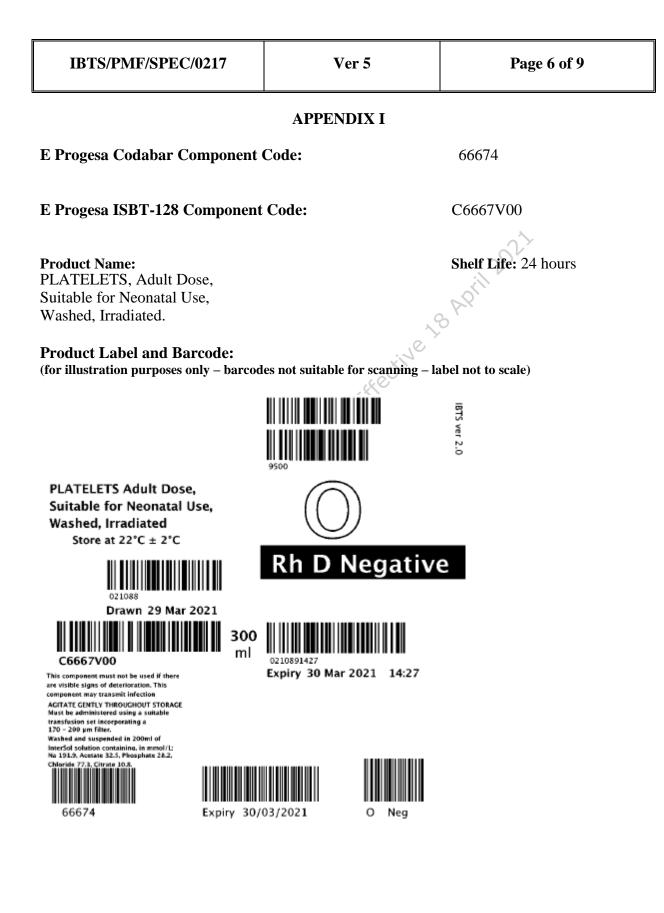
- <u>Metabolic upset</u>
 - Citrate toxicity, especially in neonates and in patients with impaired hepatic function.
- <u>Immunological effects</u>
 - Alloimunisation to HLA and HPA antigens
 - Post Transfusion purpura (PTP), especially in parous female recipients
 - The risk of Graft vs Host Disease (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:





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

IBTS/PMF/SPEC/0217	Ver 5	Page 7 of 9	
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, Product Label and Barcode:		helf Life: 24 hours	
Product Label and Barcode: (for illustration purposes only – barcodes not suitable for scanning – label not to scale)			
		IBTS ver 2.0	
PLATELETS, Adult Dose, Suitable for Neonatal Use, Split 1, Washed, Irradiated Store at 22°C ± 2°C			
Rh D Positive			
Drawn 29 Mar 2021 C6667VA0 This component must not be used if there are visible signs of deterioration. This component may transmit infection ACITATE GENTLY THROUGHOUT STORAGE Must be administered using a suitable transfusion set incorporating a 170 - 200 µm filter. Washed and suspended in 200ml of			
htter501 solution containing, in mmol/L: Na 191,9, Acetate 32-5, Phosphate 28-2, Chieride 77-3, Circate 10-5, 66675 Expiry 30/	03/2021 O Pos		

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

IBTS/PMF/SPEC/0217	Ver 5	Page 8 of 9		
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,	ctive	Shelf Life: 24 hours		
Product Label and Barcode: (for illustration purposes only – barcod				
		IBTS ver 2.0		
PLATELETS, Adult Dose, Suitable for Neonatal Use, Split 2, Washed, Irradiated Store at 22°C ± 2°C				
Rh D Positive				
C6667VB0 This component must not be used if there are visible signs of deterioration. This component may transmit infection AGITATE GENTLY THEOUCHOUT STORAGE				
Must be administered using a suitable transfusion set incorporating a 170 - 200 µm filter. Washed and suspended in 200mi of Inter50 solution containing, in amono/(L: Na 191.9, Acetate 32.5, Phosphate 28.2, Chloride 77.3, Citrate 10.3, 666676 Expiry 30/	03/2021 O Pos			

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

