Irish Blood Transfusion Service
Seirbhís Fuilaistriúcháin na hÉireann

Document Detail

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Title: **PLATELETS, ADULT DOSE WITH PLASMA / PAS, IRRADIATED**
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Review

Review: IBTS PMF REVIEW

Level	Owner Role	Actor	Sign-off By
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
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3	NATIONAL MEDICAL 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

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Change Orders

Changes as described on Change Order: **Change Order No.**

Valid on Day of Printing, Verify Current Version
Printed By: **Date:**

Document Detail

Change Orders - Incorporated

Changes as described on Change Order:

Change Order No.
IBTS/CO/0248/21

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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 x 10^9/unit	1%
Platelet Concentration	≥ 35 ml per 60 x 10^9 of platelets	1%
Leucocyte Content	< 1 x 10^6/unit	1%
pH measured (+22 C) at the end of the recommended shelf life	> 6.4	4 per month

Labelling: See Appendix I

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
  - 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:

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

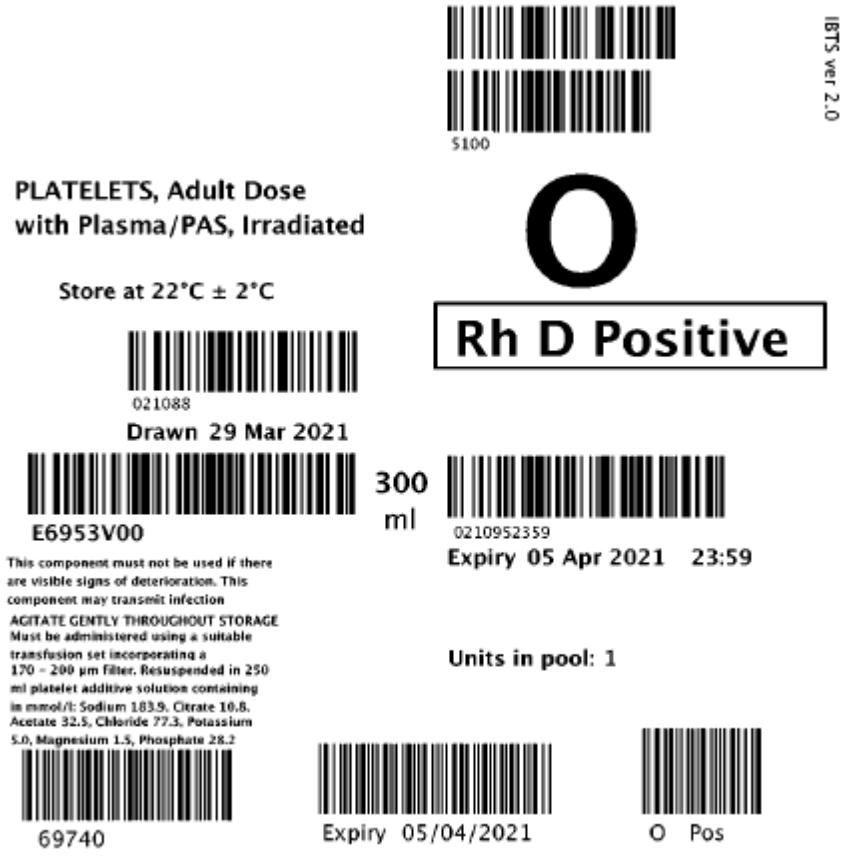
E Progesa Codabar Component Code: 69740

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)



N.B. Stated volume for illustration purposes only.