



Irish Blood Transfusion Service

Seirbhís Fuilaeistriúcháin na hÉireann

Document Detail

Type: PMF IBTS SPEC
Document No.: IBTS/PMF/SPEC/0200[7]
Title: **PRODUCT MASTER FILE - LIST OF PRODUCT NAMES**
Owner: QA DOC CON QA DOC CONTROL
Status: CURRENT
Effective Date: 09-Nov-2020
Expiration Date: 09-Nov-2022

Review

Review: IBTS PMF REVIEW

<u>Level</u>	<u>Owner Role</u>	<u>Actor</u>	<u>Sign-off By</u>
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4	QUALITY ASSURANCE REVIEWER IBTS	COLIN JOHNS	COLIN JOHNS

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/0376/20

IRISH BLOOD TRANSFUSION SERVICE**PRODUCT MASTER FILE – LIST OF PRODUCT NAMES****Change Description:**

Revise IBTS/PMF/SPEC/0201,/0213,/0214,/0216 and IBTS/PMF/SPEC/0200.

- Update general requirements (IBTS/PMF/SPEC/0201) to describe revised platelet testing regime and adverse reactions
- Update listed product master file specifications documents to reflect changes in Platelet product expiry dates, to remove obsolete product codes and to describe revised platelet testing regime including removal of references to extension of platelet expiry date
- Update listed product master file specification documents to improve the information for customers for reporting of adverse reactions.
- Update index of product codes (IBTS/PMF/SPEC/0200) to reflect removal of obsolete codes
- Change upper volume limit for platelets in PAS (IBTS/PMF/SPEC/0214) to 378ml

Reason for Change:

Validation refs: CCP 0248/20/IBTS, IBTS/QA/VP/0641

The updating of relevant documents is a listed task as part of Project Plan ref PMO/0032/20 and described in CC 243/20/IBTS (Index) and CC 248/20/IBTS (eProgesa update to expiry date of product codes)

- BacT testing of platelets will change from day 1 and day 4 testing to day 2 testing only. All platelets will have a standard 7 day shelf life
- There will be no requirement for extended shelf life product codes and these can be removed from PMFs
- Review of PMF documents has provided the opportunity to revise the information for customers regarding reporting of adverse reactions. This is not a process change.
- Ensure index is consistent with correct codes
- Change in upper volume detailed in CC 211/20/IBTS. Change is derived from analysis of quality monitoring data.

Change order No.:

CO/0376/20/IBTS

CC 243/20/IBTS

CC 248/20/IBTS

Referenced Procedures

None

SmartSolve Roles

None	
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Training Type

N/A

SmartSolve Document Category

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

PMF Ref	E Progesa Product Name	E Progesa Codabar Component Code	E Progesa ISBT -128 Component Code
0203	WHOLE BLOOD , Suitable for Neonatal Use for 5 days after Date Drawn	03151	C6468V00
0203	WHOLE BLOOD , Suitable for Neonatal Use, Irradiated	39355	C5584V00
0204	WHOLE BLOOD for Autologous Transfusion (CPDA1)	30002	E4396100
0205	RED CELLS	04333	E7429V00
0205	RED CELLS , Irradiated	74420	E7442V00
0206	RED CELLS , Washed	04403	E4999V00
0206	RED CELLS , Washed, Irradiated	50000	E5000V00
0207	WHOLE BLOOD , Reconstituted, Suitable for Neonatal Use HCT.....	54270	E8211V00
0207	WHOLE BLOOD , Reconstituted, Suitable for Neonatal Use, Irradiated. HCT...	54271	E8213V00

PMF Ref	E Progesa Product Name	E Progesa Codabar Component Code	E Progesa ISBT -128 Component Code
0208	WHOLE BLOOD , Suitable for Neonatal Use for 5 days after Date Drawn. HCT Range: 0.50-0.60	54350	E8215V00
0208	WHOLE BLOOD , Suitable for Neonatal Use, Irradiated. HCT Range: 0.50-0.60	39360	E8212V00
0208	WHOLE BLOOD , Suitable for Neonatal Use for 5 days after Date Drawn. HCT Range: 0.50-0.55	39361	E8217V00
0208	WHOLE BLOOD , Suitable for Neonatal Use, Irradiated. HCT Range: 0.50-0.55	39362	E8216V00
0209	RED CELLS , Suitable for Neonatal Use, Split 1	56830	C7429VA0
0209	RED CELLS , Suitable for Neonatal Use, Split 2	56831	C7429VB0
0209	RED CELLS , Suitable for Neonatal Use, Split 3	56832	C7429VC0
0209	RED CELLS , Suitable for Neonatal Use, Split 4	56833	C7429VD0
0209	RED CELLS , Suitable for Neonatal Use, Split 5	56834	C7429VE0

PMF Ref	E Progesa Product Name	E Progesa Codabar Component Code	E Progesa ISBT -128 Component Code
0209	RED CELLS , Suitable for Neonatal Use, Irradiated, Split 1	74422	C7442VA0
0209	RED CELLS , Suitable for Neonatal Use, Irradiated, Split 2	74423	C7442VB0
0209	RED CELLS , Suitable for Neonatal Use, Irradiated, Split 3	74424	C7442VC0
0209	RED CELLS , Suitable for Neonatal Use, Irradiated, Split 4	74425	C7442VD0
0209	RED CELLS , Suitable for Neonatal Use, Irradiated, Split 5	74426	C7442VE0
0210	RED CELLS , Suitable for Intrauterine Transfusion, Irradiated. HCT Range: 0.70→0.85	30017	E8210V00
0211 (PMF not issued)	RED CELLS , Thawed and Washed	06460	E5713V00
0211 (PMF not issued)	RED CELLS , Thawed and Washed, Irradiated	57140	E5714V00

PMF Ref	E Progesa Product Name	E Progesa Codabar Component Code	E Progesa ISBT -128 Component Code
0212	RED CELLS , Resuspended	04454	E8214V00
0232	RED CELLS , Suitable for Neonatal Use for 5 Days after Date Drawn	54481	C7429V00
0232	RED CELLS , Suitable for Neonatal Use for 5 days after Date Drawn, Irradiated	74421	C7442V00

PMF Ref	E Progesa Product Name	E Progesa Codabar Component Code	E Progesa ISBT -128 Component Code
0213	PLATELETS , Adult Dose, Irradiated	39290	E3929V00
0213	PLATELETS , Adult Dose, Split 1, Irradiated	39291	E3929VA0
0213	PLATELETS , Adult Dose, Split 2, Irradiated	39294	E3929VB0
0213	PLATELETS , Adult Dose, Split 3, Irradiated	39297	E3929VC0
0213	PLATELETS , Paediatric Dose, Split 1, Irradiated	39293	E3929VAa
0213	PLATELETS , Paediatric Dose, Split 2, Irradiated	39296	E3929VBa
0213	PLATELETS , Paediatric Dose, Split 3, Irradiated	39299	E3929VCa

PMF Ref	E Progesa Product Name	E Progesa Codabar Component Code	E Progesa ISBT -128 Component Code
0214	PLATELETS , Adult Dose with Plasma/PAS, Irradiated	69740	E6953V00
0215	PLATELETS , Adult Dose, Washed, Irradiated	66670	E6667V00
0215	PLATELETS , Adult Dose, Split 1, Washed, Irradiated	66671	E6667VA0
0215	PLATELETS , Adult Dose, Split 2, Washed, Irradiated	66672	E6667VB0
0215	PLATELETS , Adult Dose, Split 3, Washed, Irradiated	66673	E6667VC0
0216	PLATELETS , Adult Dose, Suitable for Neonatal Use, Irradiated	39300	C3929V00
0216	PLATELETS , Adult Dose, Suitable for Neonatal Use, Split 1, Irradiated	39301	C3929VA0
0216	PLATELETS , Adult Dose, Suitable for Neonatal Use, Split 2 Irradiated	39304	C3929VB0
0216	PLATELETS , Adult Dose, Suitable for Neonatal Use, Split 3, Irradiated	39307	C3929VC0

PMF Ref	E Progesa Product Name	E Progesa Codabar Component Code	E Progesa ISBT -128 Component Code
0216	PLATELETS , Paediatric Dose, Suitable for Neonatal Use, Split 1, Irradiated	39303	C3929VAa
0216	PLATELETS , Paediatric Dose, Suitable for Neonatal Use, Split 2, Irradiated	39306	C3929VBa
0216	PLATELETS , Paediatric Dose, Suitable for Neonatal Use, Split 3, Irradiated	39309	C3929VCa

PMF Ref	E Progesa Product Name	E Progesa Codabar Component Code	E Progesa ISBT -128 Component Code
0217	PLATELETS , Adult Dose, Suitable for Neonatal Use, Washed, Irradiated	66674	C6667V00
0217	PLATELETS , Adult Dose, Suitable for Neonatal Use, Split 1, Washed, Irradiated	66675	C6667VA0
0217	PLATELETS , Adult Dose, Suitable for Neonatal Use, Split 2, Washed, Irradiated	66676	C6667VB0
0217	PLATELETS , Adult Dose, Suitable for Neonatal Use, Split 3, Washed, Irradiated	66677	C6667VC0
0218	PLATELETS , Hyperconcentrated, Suitable for Neonatal Use, Irradiated	39310	C9310V00
0218	PLATELETS , Hyperconcentrated, Suitable for Neonatal Use, Split 1, Irradiated	39311	C9310VA0
0218	PLATELETS , Hyperconcentrated, Suitable for Neonatal Use, Split 2, Irradiated	39312	C9310VB0
0218	PLATELETS , Hyperconcentrated, Suitable for Neonatal Use, Split 3, Irradiated	39313	C9310VC0

PMF Ref	E Progesa Product Name	E Progesa Codabar Component Code	E Progesa ISBT -128 Component Code
0220	Fresh Frozen PLASMA	18270	E4048V00
0221	Fresh Frozen PLASMA Suitable for Neonatal Use	18266	C4048V00
0224	CRYOPRECIPITATE Suitable for Neonatal Use	80160	C6296V00
0226	LEUCOCYTES pooled, Irradiated (Source of Granulocytes)	36880	E8209V00
0227	LEUCOCYTES pooled, Red Cell Reduced, Irradiated (Source of Granulocytes)	54264	E8208V00
0236	Apheresis CONVALESCENT PLASMA COVID-19	97480	E9748V00
0236	Apheresis CONVALESCENT PLASMA COVID-19, SPLIT 1	97481	E9748VA0
0236	Apheresis CONVALESCENT PLASMA COVID-19, SPLIT 2	97482	E9748VB0