Licensing of Haemonetics Products
FDA Licensing Workshop
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Donor Division

Haemonetics' Platforms

- MCS®+8150
- Cymbal® Automated Blood Collection System
- MCS®+9000
- ACP® 215

MCS+ 8150: Overview

- Red Cell Apheresis Systems intended to collect 2RBC, 2RBCF, and RBCP.
- Targeted volume of Red Cells and Plasma based on FDA-cleared nomograms for autologous and allogeneic donors
- Two Unit Filtered protocol, target collection pre-filtration is 360mls red cells.
- Filtration of 2RBCF protocol completed via gravity using RC2H filter (PALL Corp.)
- Single red cell unit can be saved from an aborted

MCS+8150: QC Criteria

2RBC and RBCP Protocols (list number 832 and 822)

- 95% of Red Cells should be within +/15% of the target
- AABB Criteria may be used if the target red cell mass is at least 200mls

(mean red cell mass of 180mls and at least 95% of the units have a minimum red cell mass of 150mls)

2RBCF Protocol (list number 832F)

AABB Criteria may be used

(mean red cell mass of 153mls and at least 95% of the units have a minimum red cell mass of 128mls)

>85% recovery

<5 x10 exp6 residual leukocytes

MCS+8150: Filtration Guidelines

- Warm filtration (room temperature) must be completed within 8 hours of collection**(10-25 minutes)**
- Cold filtration (1-6^{0}C) must be completed within 72 hours of collection.(20-35 minutes)
- Checklist states that if the product fails to filter within these timeframes the unit should be evaluated for residual leukocytes. 510k was filed to modify this statement to the following:

  Note: Filtration times can be influenced by collection and processing conditions and biological variability of donors. Experimental data with some filter products indicate that a prolonged filtration time can be an indication of sub-optimal leukocyte reduction.

MCS+8150: Tips for Success

- **Stripping, mixing, proper sampling technique and timing**
- **Daily check of weigher**
- **Maintenance of equipment**
- **Calibration of devices, cell counters, scales**
- **Stability of machine at mobile sites**

Cymbal: Overview

- The Cymbal Automated Blood Collection System is designed to collect two units of filtered red cells
- Portable device with optional battery power
- Data Transfer System (DTS) used to collect and transfer procedure information
- Standard collection target of 360mls pre-filtration
- RC2H filter (PALL Corporation)
- Filtration is automatically completed at the end of each collection cycle (no reservoir bag)
- No option to save one unit of red cells in the case of an

Cymbal: QC Criteria

- **Mean red cell mass 153mls (51g Hgb). At least 95% of the units >128mls (42.5g Hgb)**
- **All units should have < 5 x 10^6 residual leukocytes**
- **No QC requirement for Red Cell Recovery**
- **For units where the device displays the message "QC products", volume of the unit should also be determined**

MCS+9000: Overview

- **Mobile Platelet Collection System used to Collect Platelets and Platelets/Plasma with or without Saline Compensation**
- **994CF-CPP, 994CF*, 994F*** (*obsolete)
- **Continuous Filtration: No QC requirement for recovery**
- **Storage up to 5 days**
- **Cleared for 7 day storage, currently not participating in PASSPORT Study**

MCS+9000

994CF-CPP (CPP bags)

- Cleared for storage of up to 5.0 x 10^{11} for up to 5 days
- Maximum concentration of 2600 x10^{6} platelets per ml.

994CF and 994F (CLX bags) *Note: no longer available

- Cleared for storage of up to 3.5 x 10^{11} for up to 5

MCS+ 9000

Volumes

- Typical range for a single platelet pheresis is 250mls-300mls (minimum 200mls)
- Typical range for a double platelet product is 350mls-450mls Volumes

Leukoreduction

- 95 % confidence that 95 % of products have <5.0 x 10 exp 6 residual WBCs

MCS+9000: Tips for Success

- **Consider safety margins in machine programming: Target 4.0 to get 3.0 and target 7.0 for 6.0**
- **Actual Pre-donation count for best results**
- **Average of historical pre-donation counts gives very reliable results**
- **Respect product storage and sampling procedures for higher accuracy of sampling**

ACP 215: Overview

- **Cell Processing System mainly used for Glycerolization/Deglycerolization and Cell Wash**
- **Closed System, Extended Storage of Deglycerolized Red Cells (14-day post deglycerolization)**
- **Red Cells can be frozen for up to 10 years prior to deglycerolization**

ACP 215: QC Criteria

- **95% confidence that 95% of the units have <1% hemolysis after 14 days of storage post-deglycerolization**

- **95% confidence that 90% of the units have a recovery of at least 80% post-deglycerolization compared preglycerolization**

Questions????

Comments??