Packing Configuration Apheresis or Pooled Platelets using E38 Shipping Container

VALIDATION SUMMARY REPORT

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REPORT APPROVAL

This document was prepared by:

Department	Name / Title	Signature	Date
Quality System Support	Paul Birch Associate, Validation	Paul Birch	2011-01-14

VALIDATION SUMMARY ACCEPTANCE

The Canadian Blood Services representatives, by signing and dating in the spaces below, have reviewed and approved this validation summary report.

Department	Name / Title	Signature	Date
Quality System Support	Danita Leung Manager, Validation		2011-01-14
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1.0 REVISION HISTORY

Document Version	Date Created	Author	Remarks
0.1	2010-12-14	P.Birch	• Draft release
0.2	2011-01-13	P.Birch	• Updated to current template • Incorporated review comments
1.0	2011-01-14	P.Birch	• Sent for signatures

2.0 EXECUTIVE SUMMARY

Canadian Blood Services transports apheresis and pooled platelet units in E38 shipping containers following established packing instructions. It was determined through investigations by the Shipping Process Renewal project team that a new packing configuration is required to improve survival time of apheresis or pooled platelet units in shipments containing 4 or less units. Existing packing instructions for shipments of 5 or more apheresis or pooled platelet units in E38 shipping containers are out of scope and will remain unaffected by this qualification effort.

The results of the qualification effort demonstrated that a 3-gel packing configuration provides improved performance for low to minimum load platelet shipments; the platelet survival time is equivalent to or better than that of shipments packed according to existing packing instructions for full payloads.

No deficiency was encountered during qualification. The effort demonstrated that E38 shipping containers with low to minimum load simulated platelet units, packed by trained staff following approved-for-validation procedures, will survive at least as long as containers with full loads.

In conclusion, all requirements and the objective of the qualification effort have been met. The test results and deficiencies observed during the execution of the protocol are summarized in this report.

3.0 BACKGROUND INFORMATION

3.1 PURPOSE

The Validation Summary Report is intended to provide a summary of the tasks completed at Canadian Blood Services, **Head Office** for shipping process renewal project, specifically the packing configuration for low to minimum load platelet shipments in E38 shipping containers. The report will also summarize the results, the deficiencies encountered and the current status of these deficiencies.

3.2 SCOPE

Platelet components (pooled & apheresis) are placed in an E38 shipping container comprised of an EPS container with 4" plug (T057081), outside corrugated sleeve (T057083) and strap (T056079). As part of the Shipping Process Renewal project, a change to include a new packing configuration is preferred for minimum load apheresis or pooled platelet shipments of ≤ 4 units.

This document outlines the qualification activities completed to verify the E38 shipping containers, using a 3-gel packing configuration for low to minimum load apheresis or pooled platelet shipments, will provide performance equivalent or better to that seen with 2 gels and 6 apheresis or pooled platelet units.

Performance of the shipping containers when exposed to ambient temperatures of -30 °C, +5 °C, +30 °C and +40 °C is in scope to parallel the range of temperature exposures from previous studies conducted by the Buffy Coat Project team in 2005. Performance data was also collected

when containers were exposed to an ambient temperature of +17 °C which was the mean ambient temperature observed during site-to-customer shipment study performed in 2010 by Medical, Scientific and Research Affairs, Quality Monitoring Program.

4.0 DOCUMENTATION

These documents were generated or referenced to support the qualification effort. They will be retained in the Logistics Department at Head Office as per the agreement of project team members.

- The *User Requirements Specification* shipping containers, Document Number SPR-014, v5.0, approved on 2010-03-08.
- Protocol PQ-SC-001-135-2010-6 , *Packing Configuration Apheresis or Pooled Platelets using the E38 Shipping Container* Approved 2010-08-26.
- SOP 05 071,*Packing Blood and Components*, version 2.0.
- Directive D30050 revision 1.0, *Packing Configurations and Shipping Guidelines for CPD Platelets,Pooled, LR and Platelets, Apheresis.*

5.0 RESULTS

Survival time is rounded down to the nearest 15 minutes. Only the most stringent results are reported from triplicate run data. Refer to executed protocols for the entire dataset, as required.

Ambient Temperature and Payload	Survival Time Tested (hours:mm)	Acceptance Criteria (hours:mm)
30C Single component, 3 gels	19:15	11:15
30C 4 components, 3 gels	21 hr	11:15
5C Single component, 3 gels	11:30	7:0
5C 4 components, 3 gels	12:15	7:0
40C Single component, 3 gels	7:15	6:30
40C 4 components, 3 gels	8:45	6:30
minus 30C Single component, 3 gels	4:15	3:45
minus 30C 4 components, 3 gels	4:15	3:45
17C Single component, 3 gels	>24 hr	N/Ap
17C 4 components, 3 gels	>24 hr	N/Ap

TABLE 6.1 – QUALIFICATION TEST RESULTS

Protocol #	Test Title	Test Results Met Stated Acceptance Criteria?	Deficiency Report
PQ-SC-001-135-2010-6	Packing Configuration Apheresis or Pooled Platelets using the E38 Shipping Container	Yes	None

6.0 CONCLUSION

The results of the qualification effort demonstrated that a 3-gel packing configuration provides improved performance for low to minimum load platelet shipments. Qualification was completed successfully without deficiencies. The results have been accepted by Logistics and Quality Assurance group.