APPENDIX A 3.2.1-17

COMPARABILITY REPORT FOR MANUFACTURING CHANGE

PLATFORM 1 PRODUCT PERFORMANCE COMPARABILITY REPORT
DORADO-II RON

PROGRAM NAME	PLATFORM 1 (ZRH; THS 2)
PROJECT NAME	PRODUCT PERFORMANCE COMPARABILITY DORADO-II RON
WBS NUMBER	N/A
WORK PACKAGE NAME	N/A
EXPERIMENTAL WORK TYPE	Exploratory ☐ Developmental ☐ Regulatory submission ☒
OWNER & APPROVER	MARCO ESPOSITO
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DATE OF ISSUE	13th June 2016

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1 Executive Summary

(b) (4)

2 Purpose

(b) (4)

3 Introduction

(b) (4)

4 Research Question

(b) (4)

5 Methods

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

6 Results

6.1 Data availability

Data considered in the present report were obtained and reported by Labstat International ULC. Labstat International ULC warrants that all sample(s) were tested in accordance with its standard test procedures and in accordance with its ISO 17025 accreditation.

(b) (4)

(b) (4)

6.2 Results Dorado-II Ron

(b) (4)

Table 2: (b) (4)

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(b)(4)

Figure 2:

(b) (4)



Figure 2: (b) (4)

7 Conclusions Data Evaluation

(b) (4) .

8 References

1. Appendix A 3.2.1-13 Version 1.0

9 Version History

Version	Date	Changes
1.0	7th May 2015	Original Document
1.0 SV	13th June 2016	Submission version – references updated to interlink within the submission

10 Approvals

	Name	Role	Signature	Date
Author	Maxim Belushkin	Manager Scientific & QA Governance.		13-06-2016
Owner	Marco Esposito	Director Product Stewardship.		13-06-2016
QA Review	Shelley Moores	Manager QA Assessment & Quality Systems		13-06-2016