APPENDIX A3.2.1-16

1. **THS 2 COMPARABILITY PROTOCOL**
2. **THS 2 REGULAR COMPARABILITY REPORT**
3. **THS 2 REGULAR COMPARABILITY REPORT SUPPLEMENT**
4. **THS 2 MENTHOL COMPARABILITY REPORT**

THS 2.2 PRODUCT PERFORMANCE COMPARABILITY PROTOCOL DORADO 2 – FR-1

PROGRAM NAME	ZURICH
PROJECT NAME	COMPARABILITY DORADO2 –FR-1
WBS NUMBER	N.A.
WORK PACKAGE NAME	N.A.
EXPERIMENTAL WORK TYPE	Exploratory ☐ Developmental ☐ Regulatory submission ☒
APPROVER	MARCO ESPOSITO
AUTHOR	MAXIM BELUSHKIN
CO-AUTHOR	JENNIFER HIRTER

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1 Purpose

(b) (4)

.

2 Introduction

(b) (4)

3 Research Question

(b) (4)

4 Methods

4.1 Product performance attributes

(b) (4)

.

4.2 Statistical approach

(b) (4)

(b) (4)

4.3 Definition of tolerance limits

(b) (4)

- (b) (4);
- (b) (4);
- (b) (4);
- (b) (4);

4.4 Historical data set

(b) (4)

4.5 Tolerance Limits

(b) (4) are listed in Table 1, (b) (4) for (b) (4) are listed in Table 2.

(b) (4):

(b) (4)

5 Reporting of results and acceptance criteria

(b) (4)

(b) (4)

(b) (4)

Table 1: (b) (4) .

(b) (4)

(b) (4)

Table 2: (b) (4)

(b) (4)

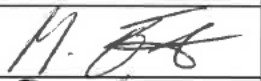
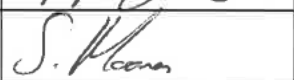
(b) (4)



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Owner	Marco Esposito	Director Product Stewardship.		10-08-16
QA Review	Shelley Moores	Manager QA Assessment & Quality Systems		10-8-16

THS 2.2 PRODUCT PERFORMANCE COMPARABILITY REPORT DORADO-II-RON – FR-1-RON

PROGRAM NAME	ZRH PLATFORM 1
PROJECT NAME	COMPARABILITY DORADO-II –FR-1
WBS NUMBER	N.A.
WORK PACKAGE NAME	N.A.
EXPERIMENTAL WORK TYPE	Exploratory ☐ Developmental ☐ Regulatory submission ☒
APPROVER	MARCO ESPOSITO
AUTHOR	MAXIM BELUSHKIN
CO-AUTHOR	JENNIFER HIRTER

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1 Executive Summary

(b) (4)

2 Purpose

(b) (4)

3 Introduction

(b) (4)

4 Research Question

(b) (4)

5 Methods

5.1 Product performance attributes

(b) (4)

(b) (4)

.

5.2 Statistical approach

(b) (4)

5.3 Definition of tolerance limits

(b) (4)

:

(b) (4)

(b) (4)

:

(b) (4)

(b) (4)

5.4 Reference data set

(b) (4)

(b) (4)

5.5 Tolerance Limits

(b) (4) are listed in Table 1, (b) (4)

(b) (4) are listed in Table 2.

(b) (4)

(b) (4)

5.6 Summary of Comparability Protocol Amendments

(b) (4)

1. Table 1, (b) (4) .
2. Table 1 (b) (4) .
3. Table 2, (b) (4) ".
4. Table 2, (b) (4) .

6 Reporting of results and acceptance criteria

(b) (4) are reported for the (b) (4) .

(b) (4)

(b) (4)

(b) (4)

Table 1: (b) (4) .

(b) (4)

(b) (4)

Table 2: (b) (4) .

(b) (4)

(b) (4)



7 Results

7.1 Data availability

Data considered in the present report were obtained and reported by Labstat.

Table 3 (b) (4) .

(b) (4)

7.2 Dorado-II–Ron

(b) (4) .

Table 4: (b) (4)

(b) (4)

(b) (4)



Table 5: (b) (4)

(b) (4)

(b) (4)

(b) (4)

8 Conclusions

(b) (4)

9 Version History

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Owner	Marco Esposito	Director Product Stewardship.		10-08-16

QA Review	Shelley Moores	Manager QA Assessment & Quality Systems	S. Moores	10-8-16

SUPPLEMENT REPORT

SUPPLEMENT REPORT TO DORADO-II

COMPARABILITY REPORT

PROGRAM NAME	ZRH PLATFORM 1
PROJECT NAME	COMPARABILITY DORADO-II –FR-1
WBS NUMBER	N.A.
WORK PACKAGE NAME	N.A.
EXPERIMENTAL WORK TYPE	Exploratory ☐ Developmental ☐ Regulatory submission ☒
APPROVER	MARCO ESPOSITO
AUTHOR	JENNIER HIRTER

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1 Executive Summary

(b) (4)

2 Purpose

The (b) (4) reported in the supplement report from Labstat does not affect the conclusions of the comparability.

3 Methods

(b) (4)

.

(b) (4)

.

(b) (4)

).

Table 1: Summary of reference data and tolerance limits for primary endpoints.

(b) (4)

Table 2: Summary of reference data and tolerance limits for secondary endpoints.

(b) (4)

4 Data Availability

(b) (4) data reported in (b) (4) reported by Labstat International ULC for the following samples (Table 3):

Table 3: Data considered in the present report.

(b) (4)

5 Results

(b) (4) .

Table 4: (b) (4) .

(b) (4)

Table 5: (b) (4)

(b) (4)

(b) (4)

6 Conclusions

(b) (4)

7 Version History

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Owner	Marco Esposito	Director Product Stewardship.		10-08-16
QA Review	Shelley Moores	Manager QA Assessment & Quality Systems		10-8-16

PLATFORM 1 PRODUCT PERFORMANCE COMPARABILITY REPORT DORADO-I-MINT VINNY LOW

PROGRAM NAME	PLATFORM 1 (ZRH; THS 2)
PROJECT NAME	COMPARABILITY DORADO-I-MINT VINNY LOW
WBS NUMBER	N.A.
WORK PACKAGE NAME	N.A.
EXPERIMENTAL WORK TYPE	Exploratory ☐ Developmental ☐ Regulatory submission ☒
OWNER	MARCO ESPOSITO
APPROVER/AUTHOR	MAXIM BELUSHKIN
AUTHOR	OLIVER MOENNIKES

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1 Executive Summary

(b) (4)

(b) (4)

2 Purpose

(b) (4)

3 Introduction

(b) (4)

.

4 Research Question

(b) (4)

5 Methods

5.1 Product performance attributes

(b) (4)

5.2 Statistical approach

(b) (4)

(b) (4)

.

5.3 Definition of tolerance limits

(b) (4)

:

(b) (4)

(b) (4) :

(b) (4)

5.4 Reference data set

(b) (4)

(b) (4)

(b) (4)

5.5 Tolerance Limits

(b) (4) are listed in Table 1, (b) (4) (b) (4) are listed in Table 2.

(b) (4) :

- (b) (4) ,
- (b) (4)
- (b) (4) ,
- (b) (4) .

5.6 Summary of Comparability Protocol Amendments

(b) (4)

(b) (4) (b) (4)

(b) (4) (b) (4)

6 Reporting of results and acceptance criteria

(b) (4) are reported for the (b) (4) , respectively. (b) (4)

(b) (4) product performance is concluded if:

- (b) (4) ;
- (b) (4) ;
- (b) (4) ;
- (b) (4)

Table 1: Summary of reference data and tolerance limits for primary endpoints.

(b) (4)

(b) (4)

Table 2: Summary of reference data and tolerance limits for secondary endpoints.

(b) (4)

(b) (4)

7 Results

7.1 Data availability

Data considered in the present report were obtained and reported by Labstat International ULC. Labstat International ULC (b) (4)

Table 3: Data considered in the present report.

(b) (4)

7.2 Results

(b) (4)

Table 4: Summary of results and comparison to tolerance limits for primary endpoints, Dorado-I-Mint Vinny Low

(b) (4)

(b) (4)



Table 5: Summary of results and comparison to tolerance limits for secondary endpoints, Dorado-I-Mint Vinny Low

(b) (4)

[redacted]

(b) (4)

8 Conclusions Data Evaluation

(b) (4)

9 Version History

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Owner	Marco Esposito	Director Product Stewardship.		10-08-16
QA Review	Shelley Moores	Manager QA Assessment & Quality Systems		10-8-16