APPENDIX A3.3-4

STABILITY INTERMEDIATE RESULTS (6 MONTHS) – REGULAR

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INTERMEDIATE REPORT OF THE STABILITY STUDY FOR THS 2.2 REGULAR PRODUCT

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1 Purpose

The objective of this stability study is to demonstrate that the commercial product THS 2.2 Regular (Dorado II Ron) version (Platform 1) produced at Philip Morris Manufacturing & Technology Bologna (PMMTB) remains within specifications over the determined shelf-life period, when stored under the defined (b) (4) (b) (4)) storage conditions.

This report summarizes the intermediate results after (b) (4) storage of the stability study STAB-2016_P1_R_1 performed according a protocol. The study was performed in (b) (4) Dorado II Ron batches.

The data are reported in tabular format for all tested parameters and presented in charts for the batch release constituents. Trend analyses and shelf life estimation will be performed only at the end of the study.

2 Batches

Table 1 - Identification of THS 2.2 Dorado II Ron

Product/ Test item	Consumable Batch Number	Finished Product Code	Manufacturing Date
THS 2.2 Dorado II Ron	B-25904 / 41-2397948	ME000004.02	18.01.2016
	B-25905 / 41-2397950	ME000004.02	18.01.2016
	B-25906 / 41-2382704	ME000004.02	14.01.2016

The samples were stored in the climatic chambers in packs. (b) (4) .

3 Tests Methods and Specifications

3.1 Preparation and Conditioning

The 3R4F Reference Cigarette (purchased from the University of Kentucky) or P1 monitor was used as an internal monitor for aerosol chemistry and values were compared to respective upper and lower limit defined in the control charts to verify the correct functioning of the experimental setup.

(b) (4) .

(b) (4) .

(b) (4) .

(b) (4) .

3.2 Aerosol Generation and Analyses

The atmosphere for aerosol generation was (b) (4) .

Aerosol generation was performed on Borgwaldt linear smoking machines.

The Health Canada Intense (HCI) smoking regimen using bell shaped puff profile was used with the below listed parameters to generate the aerosol for further chemical analyses:

- Puff volume: 55 mL
- Puff duration: 2.0 s
- Puff interval: 30 s
- Number of puffs: 12

All the instruments and materials are listed in the relevant work instructions listed in Table 2.

The tobacco heating device DV.000174 was used to generate aerosol for chemical analyses and DV.000101.RD was used for sensorial evaluation.

Table 2 Tests, Methods and Specifications

Parameter	Method Name	Specifications
(b) (4)		

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Parameter	Method Name	Specifications
(b) (4)		

(table continues)

*(b) (4)

(b) (4)
.

(b) (4)
.

(b) (4)
.

4 Stability Study Design

The samples were stored in climatic chambers in R&D Neuchâtel Product testing laboratories by the Test Item Management team.

The chemical and physical analyses were performed in R&D Neuchâtel Product testing laboratories.

The sensorial evaluations were performed in SEC Lausanne.

The visual inspections were performed in PMP QA laboratories.

Table 3 (b) (4)

(b) (4)

(b) (4)

The number of replicates performed per analyses were as follows:

(b) (4)

(b) (4) as explained in the Stability assessment Chapter 7.

5 Statement about Storage Conditions

The storage conditions predefined in the stability protocol and described in Table 3 were respected during the study.

6 Stability Data Evaluation

6.1 Storage condition (b) (4)

All tested chemical or physical parameters remained within specification limit and stable after 6 months storage. An increase in (b) (4) can be observed at (b) (4) but still within specification limit, this will be monitored in next time points.

Results are provided in terms of average value for all tested parameters per batch in Table 4 to Table 6. Average values for all batches are presented on graphs for the batch release parameters for each time point in Figure 1 to Figure 7.

Results obtained for sensorial evaluation and visual inspection are as well summarized in Chapter 6.1.3 and 6.1.4.

Table 4 B-25904 at (b) (4) (Std = Standard deviation)

(b) (4)

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Table 5 B-25905 at (b) (4)

(b) (4)

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Table 6 B-25906 at (b) (4)

(b) (4)

6.1.1 Aerosol Evaluation

(b) (4)

Figure 1 (b) (4)

LSL: Lower Stability Specification Limit, USL: Upper Stability Specification Limit

(b) (4)

Figure 2 (b) (4)



Figure 3 (b) (4)



Figure 4 (b) (4)



Figure 5 (b) (4)



Figure 6 (b) (4)

6.1.2 Physical Attributes Evaluation

(b) (4)

Figure 7 (b) (4)

6.1.3 Sensorial Evaluation

The changes observed up to (b) (4) were relatively low and sparse most likely due to batch to batch and/or panel variation and should not impact the consumer perception.

6.1.4 Visual Evaluation

The sticks are considered acceptable from visual point of view at (b) (4)

6.2 Storage condition (b) (4)

(b) (4)

Results in terms of average value for all tested parameters per batch are provided in Table 7 to Table 9. Average values for all batches are presented on graphs for the batch release parameters for each time point in Figure 8 to Figure 14.

Results obtained for sensorial evaluation and visual inspection are as well summarized in Chapter 6.2.3 and 6.2.4.

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Table 7 B-25904 at (b) (4)

(b) (4)

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Table 8 B-25905 a(b) (4)

(b) (4)

Table 9 B-25906 at (b) (4)

(b) (4)

6.2.1 Aerosol Evaluation

(b) (4)

Figure 8 (b) (4)



Figure 9 (b) (4)



Figure 10 (b) (4)

(b) (4)



Figure 11 (b) (4)

(b) (4)



Figure 12 (b) (4)

(b) (4)



Figure 13 (b) (4)

6.2.2 Physical Attributes Evaluation

(b) (4)



Figure 14 (b) (4)

6.2.3 Sensorial Evaluation

(b) (4)

.

6.2.4 Visual Evaluation

The sticks are considered acceptable from visual point of view at (b) (4)

6.3 Storage condition (b) (4)

All tested chemical or physical parameters remained within specification limit and stable after (b) (4) storage. (b) (4) .

Results in terms of average value for all tested parameters per batch are provided in Table 10 to Table 12. Average values for all batches are presented on graphs for the batch release parameters for each time point in Figure 15 to Figure 21.

Results obtained for sensorial evaluation and visual inspection are as well summarized in Chapter 6.3.3 and 6.3.4.

Table 10 B-25904 at (b) (4)

(b) (4)

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Table 11 B-25905 (b) (4)

(b) (4)

Table 12 B-25906 at (b) (4)

(b) (4)

6.3.1 Aerosol Evaluation

(b) (4)

Figure 15 (b) (4)

(b) (4)



Figure 16 (b) (4)

(b) (4)



Figure 17 (b) (4)



Figure 18 (b) (4)



Figure 19 (b) (4)



Figure 20 (b) (4)

6.3.2 Physical Attributes Evaluation



Figure 21 (b) (4)

6.3.3 Sensorial Evaluation

(b) (4)

(b) (4) .

6.3.4 Visual Evaluation

(b) (4) .

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7 Stability Assessment

Overall, it can be concluded that the THS 2.2 Dorado II Ron product has demonstrated an acceptable stability (b) (4) .

The product was found acceptable (b) (4) (b) (4) (b) (4) .

8 Related Documents

Appendix A3.2.1-4 Stability Specifications

Appendix A3.3-3 P1 THS 2 2 Stability Study Protocol Dorado II Ron