APPENDIX A3.3-8

STABILITY INTERMEDIATE RESULTS (6 MONTHS) – MENTHOL 1

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Stability Study Report: STAB-2016_P1_M_1

INTERMEDIATE REPORT OF THE STABILITY STUDY FOR THS 2.2 LOW MENTHOL PRODUCT

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1 Purpose

The objective of this stability study is to demonstrate that the commercial product THS 2.2 Low Menthol (Dorado I Mint Vinny) 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) storage

This report summarizes the intermediate results after 6 months storage of the stability study STAB-2016_P1_M_1 performed according a protocol. The study was performed in (b) (4) Dorado I Vinny Low 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 I Vinny Low

Product/ Test item	Consumable Batch Number	Finished Product Code	Manufacturing Date
Dorado I Vinny Low	B-25900 / 41.2381531	ME000041.01	21.12.2015
	B-25901 / 41.2374718	ME000041.01	22.12.2015
	B-25902 / 41.2379112	ME000041.01	16.12.2015

The samples were stored in the climatic chambers in packs. The packs are polypropylene wrapped packs consisted of two collation, each collation containing 10 Tobacco Sticks.

(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)

Visual evaluation was performed on sticks received in close packs without any preliminary preparation.

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)		

(table continues)

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Parameter	Method Name	Specifications
(b) (4)		

(table continues)

Parameter	Method Name	Specifications
(b) (4)		

(b) (4) . The method version changed from (b) (4) which consisted in modification in standard preparation, modification in dilution factor for the monitor 3R4F, addition of another instrument with all related criteria and some documental changes. The change in the method was considered minor having no impact on the quantification of the constituents.

(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.

(b) (4) .

The visual inspections were performed in PMP QA laboratories.

Table 3 Testing Matrix Low Menthol product

Batch	Storage Conditions	Beginning of the Study	(b) (4)
(b) (4)			

M: Batch release parameters, Acrylonitrile, Isoprene; **P**: Physical measurements: Tobacco Stick Diameter and visual inspection; **S**: Sensorial analysis; **PF:** All performance specification parameters

The number of replicates performed per analyses were as follows:

(b) (4)

Analyses at (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 (b) (4) storage. (b) (4) (see Appendix A3.2.1-4).

(b) (4)

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 8.

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

Table 4 B-25900 (b) (4) (Std = Standard deviation)

(b) (4)

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Table 5 B-25901 (b) (4)

(b) (4)

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Table 6 B-25902 (b) (4)

(b) (4)

6.1.1 Aerosol Evaluation



Figure 1 (b) (4)

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



Figure 2 (b) (4)



Figure 3 (b) (4)



Figure 4 (b) (4)



Figure 5 (b) (4)



Figure 6 (b) (4)



Figure 7 (b) (4)

6.1.2 Physical Attributes Evaluation



Figure 8 (b) (4)

6.1.3 Sensorial Evaluation

(b) (4)

(b) (4) for B-25900 and (b) (4) for B-25902. The few other changes observed can be attributed to panel and batch to batch variation.

(b) (4)

6.1.4 Visual Evaluation

(b) (4)

6.2 Storage condition (b) (4)

All tested chemical or physical parameters remained within specification limit and stable after (b) (4) storage. (b) (4) was observed for (b) (4) but remained well within specification limits.

(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 9 to Figure 16.

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

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Table 7 B-25900 a(b) (4)

(b) (4)

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Table 8 B-25901 at (b) (4)

(b) (4)

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Table 9 B-25902 a(b) (4)

(b) (4)

6.2.1 Aerosol Evaluation

(b) (4)

Figure 9 (b) (4)

(b) (4)

Figure 10 (b) (4)



Figure 11 (b) (4)



Figure 12 (b) (4)



Figure 13 (b) (4)



Figure 14 (b) (4)

(b) (4)



Figure 15 (b) (4)

6.2.2 Physical Attributes Evaluation

(b) (4)



Figure 16 (b) (4)

6.2.3 Sensorial Evaluation

(b) (4)

6.2.4 Visual Evaluation

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

6.3 Storage condition (b) (4)

All tested chemical or physical parameters remained within specification limit and stable after (b) (4) storage for most of the parameters. (b) (4) but remained well within specifications limits.

(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 17 to Figure 24.

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

Table 10 B-25900 (b) (4)

(b) (4)

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Table 11 B-25901 (b) (4)

(b) (4)

Table 12 B-25902 at (b) (4)

(b) (4)

6.3.1 Aerosol Evaluation

(b) (4)

Figure 17 (b) (4)



Figure 18 (b) (4)



Figure 19 (b) (4)

(b) (4)

Figure 20 (b) (4)

(b) (4)

Figure 21 (b) (4)

(b) (4)

Figure 22 (b) (4)

(b) (4)

Figure 23 (b) (4)

6.3.2 Physical Attributes Evaluation

(b) (4)



Figure 24 (b) (4)

6.3.3 Sensorial Evaluation

(b) (4)

6.3.4 Visual Evaluation

(b) (4) .

7 Stability Assessment

Overall, it can be concluded that the THS 2.2 (b) (4) product has demonstrated an acceptable stability for all chemical, physical and sensorial parameters (b) (4) (b) (4) .

(b) (4)

8 Related Documents

Appendix A3.2.1-4 Stability Specifications

Appendix A3.3-7 P1 THS 2 2 Stability Study Protocol (b) (4)