DETERMINATION OF ISO PARAMETERS UNDER ISO SMOKING REGIME FOR THS 2.2 DORADO I MINT VINNY LOW

Program Name	Platform 1
Project Name	THS 2.2 Commercial Product Characterization
Type of document	Regulatory Submission
Author	Rita Hajdu Schenk
Owner	Cyril Jeannet
Reviewed by	Shelley Moores
Reviewed & Approved by	Cyril Jeannet
Distribution	Beate Miller, Shelley Moores

THIS REPORT IS CONFIDENTIAL TO THE BUSINESS OF THE COMPANY. IT HAS BEEN ASSIGNED TO YOU. IT IS NOT TRANSFERABLE AND MUST NOT BE PHOTOCOPIED. IF THE REPORT HAS SERVED ITS PURPOSE AND IS NO LONGER NEEDED, PLEASE RETURN IT TO THE DOCUMENT OWNER FOR RECORD KEEPING AND ARCHIVING.

TABLE OF CONTENT

SUMMARY 3
1 INTRODUCTION 3
2 OBJECTIVE 3
3 MATERIAL AND METHOD 3
3.1 Samples 4
3.2 Instruments and Materials 4
3.3 Analytical methods 4
3.3.1 Sample conditioning and preparation 5
3.3.2 Aerosol generation and analyses 5
3.4 Data reprocessing 6
4 RESULTS AND DISCUSSION 6
5 CONCLUSION 7
6 RELATED DOCUMENTS / LITERATURE 7
7 REFERENCES 7
8 REVISION HISTORY 8
9 ABBREVIATIONS AND GLOSSARY 8
10 APPENDIX 9
11 REVIEW AND APPROVAL 12

SUMMARY

The report describes the results of ISO parameters determined for 3 Dorado I Mint Vinny Low tobacco stick batches produced in Training Center, Bologna.

1 INTRODUCTION

The present report supports the product characterization of THS 2.2 using commercial tobacco stick batches produced in Training Center, Bologna.
The report describes the results of ISO parameters (NFDPM, Nicotine and Carbon monoxide) determination in mainstream aerosol under ISO methodology for the 3 batches of Dorado I Mint Vinny Low tobacco sticks using Tobacco Heating Device (THD) 2.4.

2 OBJECTIVE

The purpose of this document is to describe the results obtained for the 3 mentholated batches the ISO parameters: NFDPM, nicotine, carbon monoxide (CO) in the mainstream aerosol using ISO test method.

3 MATERIAL AND METHOD

Mainstream aerosol of the tested samples was generated under ISO smoking regime with linear smoking machine on the basis of 20 replicates with 5 accumulations each. The samples were generated on two different days using the same smoking machine and analyzed in two different analytical batches. Therefore, on both days 10 replicates of each sample was generated.

The aerosol was collected on a Cambridge filter pad and the TPM was determined by gravimetric method. Water and nicotine were determined by applying in-situ extraction on the Cambridge filter pad and subsequent GC-FID analyses for nicotine and GC-TCD analyses for water. NFDPM is obtained by subtracting the nicotine and water yield from the TPM. CO is determined by an internal CO-meter on the smoking machine by non-dispersive infrared photometry.

NFDPM, nicotine and CO yields are reported in mg/stick basis.

3.1 Samples

Analyses were requested through PDIMS Testing Order: TO-10845. Samples are described in Table 1.

Table 1 Description of samples

Sample number	Tobacco Stick code	Pack code	Batch number of Tobacco Stick / Pack	THD code	Batch number of THD
SMP060517	CONS.02807.RD(3)	ME000041.01	41-2379112	THD 2.4 DV.000174(7)	B-23172
SMP060518	CONS.02807.RD(3)	ME000041.01	41-2374718	THD 2.4 DV.000174(7)	B-23172
SMP060519	CONS.02807.RD(3)	ME000041.01	41-2381531	THD 2.4 DV.000174(7)	B-23172

3.2 Instruments and Materials

As detailed in the appropriate work instructions (WKIs).

3.3 Analytical methods

The analyses were performed according to procedures and work instructions listed below.

- PMI_RD_SOP_000168 Perform Analysis V8.0
- PMI_RD_SOP_000038 Manage Sample V5.0

The 3R4F Reference Cigarette (purchased from the University of Kentucky) 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.

3.3.1 Sample conditioning and preparation

Sampling was performed on the packs level by Test Item Management team. The tobacco sticks were taken out of the packs and mixed together gently in order to obtain a volume of sticks of 4 times the needed amount for the analysis.
Tobacco sticks and 3R4F monitor cigarettes were conditioned following ISO standard 3402 (1999), at least 48h at 60±3% RH and 22±1°C prior to aerosol generation according to the following work instructions (WKIs):

- PMI_RD_WKI_000489 Preparation of items V7.0
- PMI_RD_WKI_000380 Reception and storage of items V9.0
- PMI_RD_WKI_000858 Nombre d'articles à fumer et réplicats selon le type de fumage et de machine à fumer V8.0

3.3.2 Aerosol generation and analyses

Aerosol generation was conducted at 22±2°C and 60±5% RH applying ISO smoking regime:

- Puff volume: 35 mL
- Puff duration: 2.0 s
- Puff interval: 60 s
- Puff profile: bell shaped
- Number of puffs: 6

The following work instructions were used during the analyses:

- PMI_RD_WKI_000529 Guide d’utilisation de la machine à fumer linéaire à 20 canaux KC V5.0
- PMI_RD_WKI_000084 Use of Tobacco heating system with a linear and rotary smoking machine (THS 2.2) V5.0
- PMI_RD_WKI_000530 Trappage en phase particulaire pour la détermination des constituants de l’aérosol V7.0
- PMI_RD_WKI_000527 Guide d’utilisation de l’extracteur in situ, nettoyage des seringues, des pistons, des aiguilles et des pièges V5.0
- PMI_RD_WKI_000966 Determination of water, nicotine and triacetin in aerosol condensates V6.0

3.4 Data reprocessing

Raw data are stored in LIMS and SDMS under project number in: RLS-ZRH-2016-91. Mean value, standard deviation and the uncertainty of the mean at 95% confidence level were calculated and used for reporting.

4 RESULTS AND DISCUSSION

Nicotine, NFDPM and carbon monoxide yields in mg per stick basis are reported in Table 2, Table 3 and Table 4. Individual values are available in the Appendix (Table 5, Table 6 and Table 7).

Table 2 Nicotine, NFDPM and carbon monoxide for THS 2.2 Dorado I Mint Vinny Low (SMP060517/41-2379112)

	Nicotine	NFDPM	Carbon monoxide
	mg/stick		
Mean	0.41	5.1	0.3
stdev	0.031	0.84	0.02
n	20	20	20
Uncertainty of mean	0.015	0.39	0.01

Table 3 Nicotine, NFDPM and carbon monoxide for THS 2.2 Dorado I Mint Vinny Low (SMP060518/41-2374718)

	Nicotine	NFDPM	Carbon monoxide
	mg/stick		
Mean	0.43	4.9	0.3
stdev	0.029	0.88	0.02
n	20	20	20
Uncertainty of mean	0.013	0.41	0.01

Table 4 Nicotine, NFDPM and carbon monoxide for THS 2.2 Dorado I Mint Vinny Low (SMP060519/ 41-2381531)

	Nicotine	NFDPM	Carbon monoxide
	mg/stick		
Mean	0.43	5.2	0.3
stdev	0.024	1.11	0.02
n	20	20	20
Uncertainty of mean	0.011	0.52	0.01

5 CONCLUSION

Nicotine, NFDPM and carbon monoxide in mainstream aerosol of 3 tobacco stick batches were determined using ISO test method. Average values for the 3 samples for nicotine lies between 0.41 and 0.43 mg/stick, NFDPM between 4.9 and 5.2 mg/stick and carbon monoxide at 0.3 mg/stick.

6 RELATED DOCUMENTS / LITERATURE

N/A

7 REFERENCES

- ISO Standard 3402:2000, Tobacco and tobacco products – Atmosphere for conditioning and testing
- ISO Standard 4387:2000, Cigarettes -- determination of total and nicotine free dry particulate matter using a routine analytical smoking machine
- ISO Standard 8454:2007, Cigarettes -- Determination of carbon monoxide in the vapour phase of cigarette smoke -- NDIR method
- ISO Standard 10315:2013 Cigarettes -- Determination of nicotine in smoke condensates -- Gas-chromatographic method

8 REVISION HISTORY

Version N°	Description of change	Type of change
1.0	Original issue	1

(1. Major change/new version; 2. Minor change; 3. Review without change)

9 ABBREVIATIONS AND GLOSSARY

Abbreviations		
CO	:	Carbon Monoxide
FID	:	Flame Ionization Detector
GC	:	Gas Chromatography
ISO	:	International Organization for Standardization
LIMS	:	Laboratory Information Management System
NFDPM	:	Nicotine Free Dry Particulate Matter
PDIMS	:	Product Development Information Management System
RH	:	Relative Humidity
SDMS	:	Scientific Data Management System
TCD	:	Thermal Conductivity Detector
THD	:	Tobacco Heating Device
THS	:	Tobacco Heating System
TNC	:	Tar Nicotine CO
TPM	:	Total Particulate Matter

For complete definition, refer to PMI OPS Glossary

10 APPENDIX

Table 5 Individual values for Nicotine, NFDPM and Carbon monoxide for THS 2.2 Dorado I Mint Vinny Low (SMP060517/41-2379112)

		Nicotine	NFDPM	Carbon monoxide
		mg/stick		
LIMS no.	Replicate			
1503606-1	rep 1	0.40	4.3	0.2
1503606-2	rep 2	0.41	4.9	0.2
1503606-3	rep 3	0.37	3.5	0.2
1503606-4	rep 4	0.38	3.4	0.2
1503606-5	rep 5	0.41	4.5	0.2
1503606-6	rep 6	0.41	4.1	0.2
1503606-7	rep 7	0.43	4.5	0.2
1503606-8	rep 8	0.45	4.8	0.2
1503606-9	rep 9	0.39	5.3	0.2
1503606-10	rep 10	0.35	5.9	0.2
1503643-1	rep 11	0.44	5.1	0.3
1503643-2	rep 12	0.46	5.2	0.3
1503643-3	rep 13	0.47	5.5	0.3
1503643-4	rep 14	0.43	6.0	0.3
1503643-5	rep 15	0.42	6.0	0.3
1503643-6	rep 16	0.41	5.7	0.3
1503643-7	rep 17	0.41	5.8	0.3
1503643-8	rep 18	0.44	5.8	0.3
1503643-9	rep 19	0.45	6.3	0.3
1503643-10	rep 20	0.37	4.4	0.2

Table 6 Individual values for Nicotine, NFDPM and Carbon monoxide for THS 2.2 Dorado I Mint Vinny Low (SMP060518/41-2374718)

		Nicotine	NFDPM	Carbon monoxide
		mg/stick		
LIMS no.	Replicate			
1503645-1	rep 1	0.45	4.7	0.2
1503645-2	rep 2	0.46	3.8	0.2
1503645-3	rep 3	0.40	3.8	0.2
1503645-4	rep 4	0.45	4.0	0.2
1503645-5	rep 5	0.42	3.5	0.2
1503645-6	rep 6	0.47	4.2	0.2
1503645-7	rep 7	0.35	5.8	0.2
1503645-8	rep 8	0.40	5.5	0.2
1503645-9	rep 9	0.43	4.2	0.2
1503645-10	rep 10	0.42	4.3	0.2
1503646-1	rep 11	0.40	5.8	0.3
1503646-2	rep 12	0.40	5.8	0.3
1503646-3	rep 13	0.42	5.6	0.3
1503646-4	rep 14	0.42	5.6	0.3
1503646-5	rep 15	0.45	6.3	0.3
1503646-6	rep 16	0.44	5.2	0.3
1503646-7	rep 17	0.42	4.4	0.2
1503646-8	rep 18	0.41	5.7	0.2
1503646-9	rep 19	0.45	6.1	0.3
1503646-10	rep 20	0.46	4.6	0.3

Table 7 Individual values for Nicotine, NFDPM and Carbon monoxide for THS 2.2 Dorado I Mint Vinny Low (SMP060519/ 41-2381531)

		Nicotine	NFDPM	Carbon monoxide
		mg/stick		
LIMS no.	Replicate			
1503648-1	rep 1	0.41	4.2	0.2
1503648-2	rep 2	0.42	4.1	0.2
1503648-3	rep 3	0.45	5.4	0.2
1503648-4	rep 4	0.42	4.4	0.2
1503648-5	rep 5	0.46	7.5	0.2
1503648-6	rep 6	0.43	4.2	0.2
1503648-7	rep 7	0.42	2.7	0.2
1503648-8	rep 8	0.41	5.3	0.2
1503648-9	rep 9	0.44	4.9	0.2
1503648-10	rep 10	0.41	5.5	0.2
1503649-1	rep 11	0.42	5.2	0.3
1503649-2	rep 12	0.42	4.2	0.3
1503649-3	rep 13	0.38	4.8	0.3
1503649-4	rep 14	0.49	6.9	0.3
1503649-5	rep 15	0.44	6.7	0.3
1503649-6	rep 16	0.41	5.9	0.3
1503649-7	rep 17	0.43	5.7	0.2
1503649-8	rep 18	0.44	5.5	0.2
1503649-9	rep 19	0.41	5.8	0.2
1503649-10	rep 20	0.43	6.0	0.3

11 REVIEW AND APPROVAL

This document has been reviewed and approved by:

Name	Justification / Function	Date and Signature
Rita Hajdu Schenk	signed as Author Scientist	26 April 2016
Cyril Jeannet	signed as Owner Manager Product Characterization	26-Apr-2016
Shelley Moores	signed as QA Reviewer Manager QA Assessment & Quality Systems	26-Apr-2016