

Appendix 2.1

Leaf Moisture (% Oven Volatiles (OV)) Measured During the (b) (4)

We provide complete datasets for leaf moisture (% OV) measured during the (b) (4) of the manufacturing process for the proposed MRTP. See *Tables 2A.2 – 2A.4*. This data was collected in (b) (4) on hogsheads of tobacco used to manufacture the proposed MRTP prior to submission of the MRTPA. See *Table 2A.1*.

We conducted % OV testing on the (b) (4)

(b) (4) This method was validated following our internal method validation guidelines that were based upon ICH Harmonized Tripartite Guideline, “Validation of Analytical Procedures: Methodology Q2B”, published in November 1996, and US FDA, Center for Drug Evaluation and Research, “Guidance for Industry – Analytical Procedures and Methods Validation, August 2000. See (b) (4) for the validation report for (b) (4).

The USSTC QA Laboratories are not accredited to a national or international standard but follow internal quality control procedures in accordance with the Altria Quality Requirements Manual (AQRM), *see MRTPA, Section 3.1.3.1*. By using the date of testing given in *Table 2A.1*, we also provide copies of the effective versions used at the time of testing, (b) (4) in *Appendices 2.2 – 2.5*.

¹ ALCS’s vendor conducts % OV on (b) (4) tobaccos.

² The validation reports associated with each analytical test method are cited in the method’s reference section. To review the validation reports and other supporting documentation associated with a test method, we refer CTP to TPMF (b) (4), Amendment titled (b) (4), (b) (4), dated March 30, 2021. The validation reports are organized in the TPMF by the associated method number.

Table 2A.1: Date of % OV Testing of Hogsheads Used to Manufacture the Proposed MRTP

Tobacco Type	Number of Production Days	Dates of Testing Hogsheads Used for the Proposed MRTPT
(b) (4)		

Table 2A.2 % OV Measured by Vendor during (b) (4)

Hogshead Count	Dates of Testing			
	02/05/2014	02/06/2014	01/05/2015	01/06/2015
(b) (4)				

Hogshead Count	Dates of Testing			
	02/05/2014	02/06/2014	01/05/2015	01/06/2015
(b) (4)				

Hogshead Count	Dates of Testing			
	02/05/2014	02/06/2014	01/05/2015	01/06/2015
(b) (4)				

Hogshead Count	Dates of Testing			
	02/05/2014	02/06/2014	01/05/2015	01/06/2015
(b) (4)				
Average	(b) (4)			
StdDev	(b) (4)			
Grand Average:	(b) (4)			
Grand StdDev:	(b) (4)			

Table 2A.3 % OV Measured during (b) (4)

Hogshead Count	Dates of Testing									
	11/06/12	11/07/12	11/28/12	11/29/12	11/30/12	12/07/12	12/17/12	12/18/12	12/19/12	01/08/13
(b) (4)										
Average	(b) (4)									
StdDev	(b) (4)									
Grand Average:	(b) (4)									
Grand StdDev:	(b) (4)									

³ (b) (4)
See Appendix 2.7.

Table 2A.4 % OV Measured during (b) (4)

Hogshead Count	Dates of Testing						
	12/06/12	12/11/12	01/30/13	01/31/13	02/01/13	02/22/13	03/04/13
(b) (4)							

⁴ (b) (4)
See Appendix 2.8. (b) (4)

⁵ (b) (4)
See Appendix 2.9.

Hogshead Count	Dates of Testing						
	12/06/12	12/11/12	01/30/13	01/31/13	02/01/13	02/22/13	03/04/13
(b) (4)							
Average	(b) (4)						
StdDev	(b) (4)						
Grand Average:	(b) (4)						
Grand StdDev:	(b) (4)						

(b) (4)

See Table 2A.5 and Table 2A.6.

Table 2A.5: Date of % OV Testing for

(b) (4)

Lot #	Date of Testing
(b) (4)	

Table 2A.6: Measured % OV for

(b) (4)

Proposed MRTP

Proposed MRTP Lot ^A	% OV
(b) (4)	

A

(b) (4)

(b) (4)

This method was validated following our internal method validation guidelines that were based upon ICH Harmonized Tripartite Guideline, “Validation of Analytical Procedures: Methodology Q2B”, published in November 1996, and US FDA, Center for Drug Evaluation and Research,

“Guidance for Industry – Analytical Procedures and Methods Validation, August 2000. See *TPMF* (b) (4) for the validation report for (b) (4).

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(b) (4) in *Appendix 2.6.*

⁶ The validation reports associated with each analytical test method are cited in the method’s reference section. To review the validation reports and other supporting documentation associated with a test method, we refer CTP to *TPMF* (b) (4), Amendment titled (b) (4) (b) (4),” dated March 30, 2021. The validation reports are organized in the *TPMF* by the associated method number.