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3.2.2 Tobacco Stick Manufacturing

The manufacturing process of the Tobacco Stick is comprised of a primary and a secondary phase as detailed in Section 3.2.2.1. The manufacturing is performed on two sites as shown in Table **1**.

The blending and grinding of tobacco leaves take place in the Neuchatel site (Switzerland). The Tobacco Stick manufacturing and the packaging operations are carried out at the Bologna site (Italy).

Specific control points are used for each step of the manufacturing process in order to ensure that the final product meets the required specifications.

General Overview

Table 1 Manufacturers of THS Tobacco Stick

Company	Location	Responsibility
Philip Morris Products S.A. (PMP S.A), part of the Philip Morris International group of companies.	Quai Jeanrenaud Neuchatel 2000 Switzerland	Blending and Grinding of tobacco leaf
Philip Morris Manufacturing and Technology Bologna S.p.A. (PMMTB), part of the Philip Morris International group of companies.	Via Fratelli Rosselli 4 40069 Zola Predosa Bologna – Italy	Tobacco Stick manufacturing and packaging operations Release testing (physical parameters)

Table 2 Control of THS Tobacco Stick

Company	Location	Responsibility
Philip Morris Products S.A. (PMP S.A), part of the Philip Morris International group of companies.	Quai Jeanrenaud Neuchatel 2000 Switzerland	Release testing (chemical parameters) Stability testing
(b) (4)		
Labstat	Labstat International ULC 262 Manitou Drive Kitchener, Ontario, Canada N2C 1L3	HPHC FDA 18+6 and PMI-58

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3.2.2.1 Manufacturing Process – Tobacco Stick

(b) (4)

A summary of the manufacturing process for Regular and Menthol Tobacco Sticks is provided herein, and a detailed description, including preparation of the fine tobacco powder is provided in Appendix A 3.2.2-1.

3.2.2.1.1 Manufacturing Process – Regular Tobacco Stick

The preparation of (b) (4) is undertaken at the PMP S.A facility in Switzerland. This (b) (4), is shipped to the PMMTB facility in Italy where all the remaining stages in the manufacture of Tobacco Sticks take place.

The tobacco selection and Tobacco Stick manufacturing processes are covered by the respective quality systems of the entities performing those activities. The equipment used for manufacturing processes is qualified.

An overview of the process flow for the manufacture of Regular Tobacco Sticks, and the stages at which raw materials are used, is shown in Figure 1 and a key for the symbols used in all the flow-charts in this chapter is provided in Figure 2.

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Major Manufacturing Stages	Material used in the process

(b) (4)



Figure 1 Summary of the Process Flow for Proposed Commercial Manufacturing of THS Regular Tobacco Sticks

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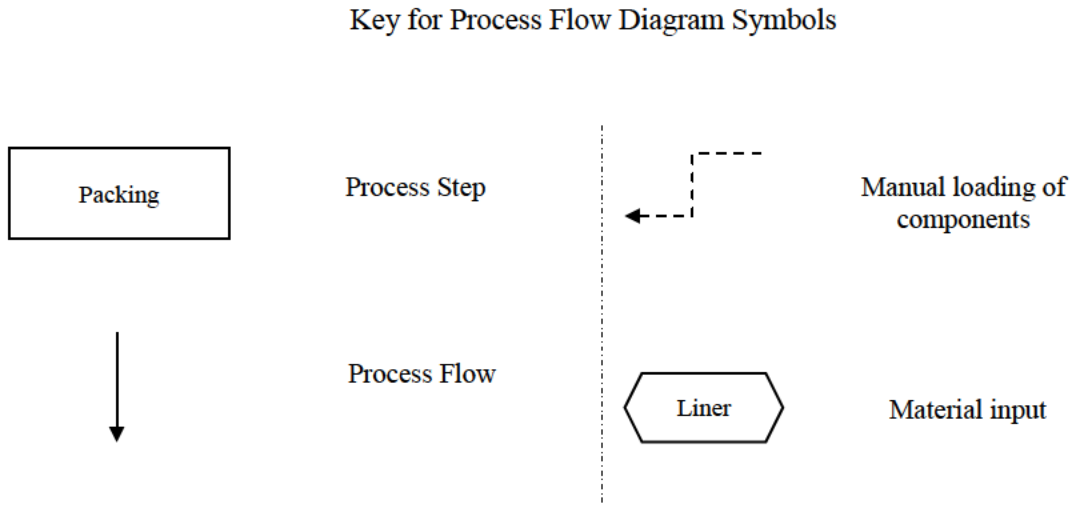


Figure 2 Symbols Used in the Process Flowcharts

The manufacturing process for Tobacco Sticks is performed in two phases. The first phase, referred to as 'Primary', includes the preparation of (b) (4) (b) (4). The second phase, referred to as 'Secondary', includes the preparation of the (b) (4), the assembly of these components into a completed Tobacco Stick, and the packaging of Tobacco Sticks into packs, bundles (cartons) and then into shipping cases.

The major steps in the 'Primary' manufacturing process are as follows:

- (b) (4)
  a. (b) (4).
  b. (b) (4).

(b) (4) is then transported from PMP S.A. to PMMTB.

- (b) (4)

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The major steps in the 'Secondary' manufacturing process (performed at PMMTB) are as follows:

- Manufacture the (b) (4)
  a. (b) (4)
  a. (b) (4) (see Appendix A3.1-1)
  b. (b) (4) .
  c. (b) (4) .
- (b) (4)
  a. (b) (4)
  b. (b) (4) .
  c. (b) (4)
- (b) (4)
  a. (b) (4)
  b. (b) (4)
  c. (b) (4)
- (b) (4)
  a. (b) (4) .
  b. (b) (4)
  c. (b) (4) .
  d. (b) (4) .
- Assemble components and cut to form final stick.
  a. (b) (4) .
  b. (b) (4)
- Pack
  a. (b) (4) .
  b. (b) (4) .
  c. (b) (4) .
  d. (b) (4)

3.2.2.1.2 Manufacturing Process – Menthol Tobacco Sticks

An overview of the process flow for the manufacture of the variant Menthol 1 Tobacco Sticks, and the stages at which raw materials are used, is shown in Figure 3 and a key for the symbols used in all the flow-charts in this chapter is provided in Figure 2.

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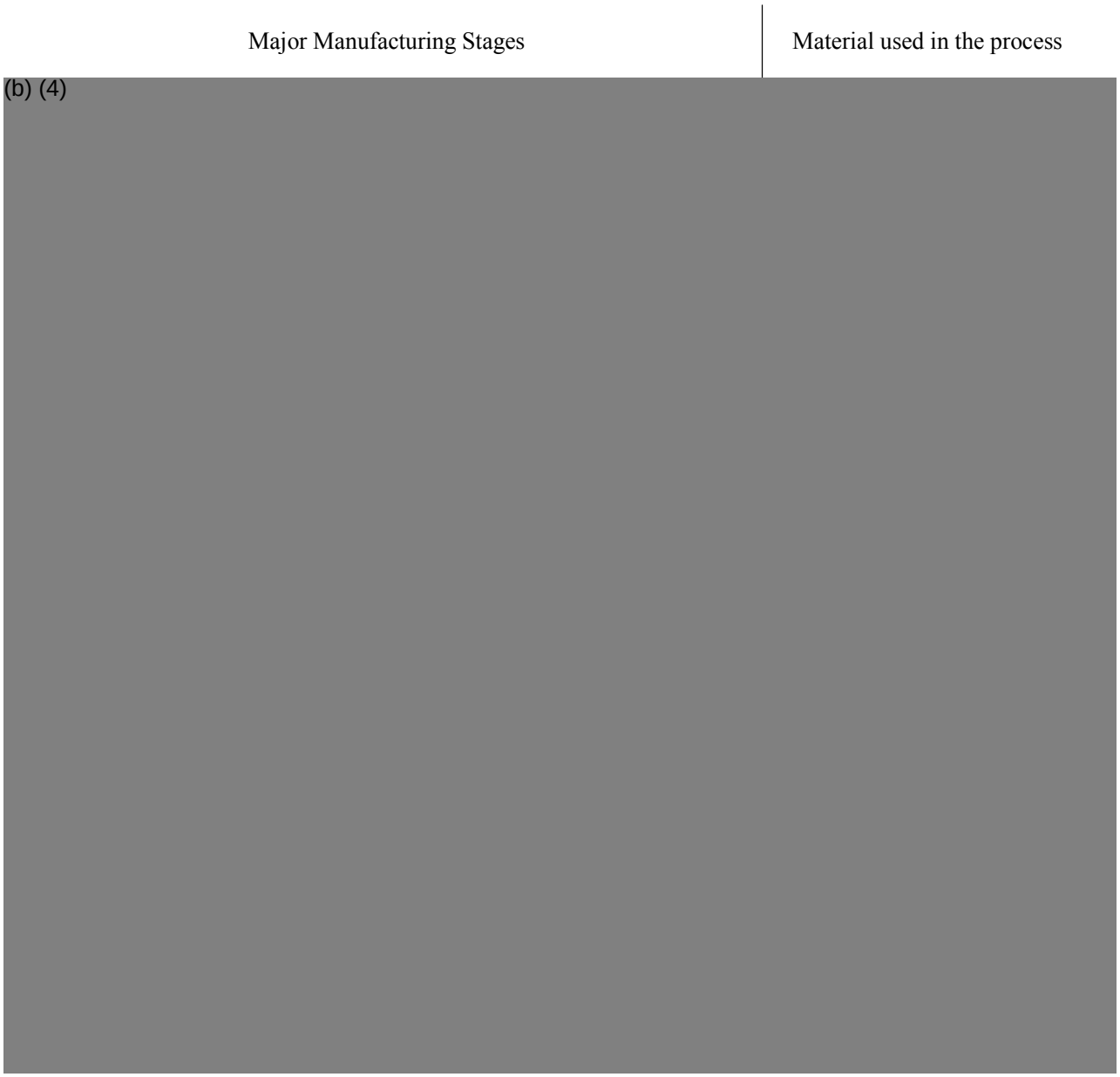


Figure 3 Summary of the Process Flow for Proposed Commercial Manufacturing of THS Variant Menthol 1 Tobacco Sticks

An overview of the process flow for the manufacture of the variant Menthol 2 Tobacco Stick, and the stages at which raw materials are used, is shown in Figure 4 and a key for the symbols used in all the flow-charts in this chapter is provided in Figure 2.

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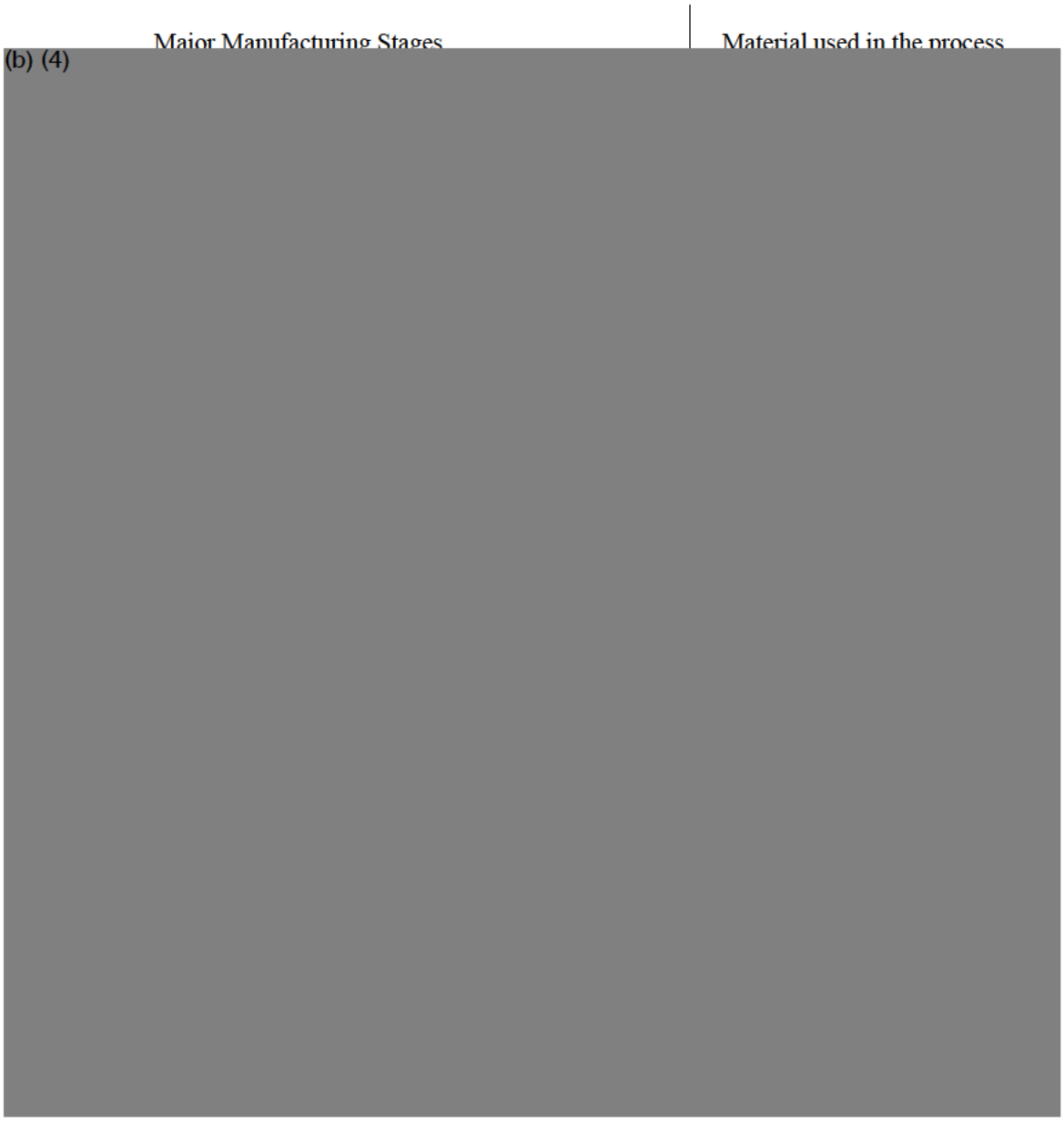


Figure 4 Summary of the Process Flow for Proposed Commercial Manufacturing of THS variant Menthol 2 Tobacco Sticks

The manufacturing process for the menthol Tobacco Sticks is (b) (4) to that described in Section 3.2.2.1.1 for (b) (4) :

(b) (4)

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(b) (4)

- Pack (b) (4)
  a.
  b.
  c.
  d.

3.2.2.2 Materials and Specifications

This section contains a description of the tests performed on the incoming materials used for manufacturing and packaging of the Tobacco Sticks, and shows the control parameters for the critical materials.

(b) (4)

Flavors are described in a Tobacco Product Master File. The authorization letter is provided in Module 1.

An overview of the materials and the tests performed upon receipt are given in Table 3.
(b) (4)

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Table 3 Materials, Source, Tested Parameters, Testing Frequency and Acceptance Criteria

Material / Sub-component	Source	Parameter	Testing Frequency	Acceptance Criteria
(b) (4)				

(table continues)

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Material / Sub-component	Source	Parameter	Testing Frequency	Acceptance Criteria
(b) (4)				

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Material / Sub-component	Source	Parameter	Testing Frequency	Acceptance Criteria
(b) (4)				

(table continues)

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Material / Sub-component	Source	Parameter	Testing Frequency	Acceptance Criteria
(b) (4)				

(table continues)

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Material / Sub-component	Source	Parameter	Testing Frequency	Acceptance Criteria
(b) (4)				

(table continues)

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Material / Sub-component	Source	Parameter	Testing Frequency	Acceptance Criteria
(b) (4)				

* Exclusive supplier
** Products released upon review of the Supplier's Certificate of Analysis
*** (b) (4), for further description see Appendix 3.2.2-1
NMT = not more than

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3.2.2.2.1 Regular Tobacco Stick

For a complete Bills of Materials (BOM), please refer to Appendix A3.2.2-2.

3.2.2.2.2 Menthol Tobacco Sticks

For a complete Bills of Materials for variants Menthol 1 and Menthol 2, please refer to the BOMs in the Appendix A3.2.2-3.

These appendices are intended to provide information regarding the ingredients used in the manufacture of the Tobacco Sticks and are not intended to be a manufacturing BOM. Information regarding all of the materials used in the manufacture is provided.

(b) (4)

3.2.2.3 Tobacco Sourcing, Selection and Blend

3.2.2.3.1 Tobacco Sourcing and Tobacco Blend Maintenance Introduction

(b) (4)

(b) (4) . Each type contributes characteristic sensory attributes, determined by the differing chemical composition of the leaves, including the levels of nitrogenous compounds (including nicotine), sugars and a number of other constituents. Important differences also result from the growing conditions and in particular the curing process. In addition, the climatic conditions of each crop year, the geographical location and leaf position on the plant stalk are important contributing factors on the variability of tobacco as a natural product.

In order to achieve a tobacco product with consistent quality characteristics (esp. with respect to sensory and chemical composition of the aerosol) over time and between batches a blending concept is applied. (b) (4) :

1. (b) (4)
2.

(b) (4)

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(b) (4)

3.2.2.3.2 Tobacco Blends and Blends Structure

For the purpose of this submission, two blends are considered: Dorado I for the Menthol variants and Dorado II for Regular.

The blend components are listed based on country of origin, tobacco type and tobacco sub-type in Table 4 and Table 5.

Table 4 Dorado I Blend (Menthol 1 and 2) Components and Origin

Blend Component			Blend Percentage
Country of Origin	Tobacco Type	Sub-Type	
(b) (4)			
Tobacco Blend			100%

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Table 5 Dorado II Blend (Regular) Components and Origin

Blend Component			Blend Percentage
Country of Origin	Tobacco Type	Sub-Type	
(b) (4)			
Tobacco Blend			100%

3.2.2.3.3 TLA Ranges for Tobacco Stick

(b) (4) (see Appendix A 3.2.2-4). (b) (4)

(b) (4)

:

(b) (4)

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(b) (4) (See Table 6). The HPHC analyses were performed by Labstat International ULC.

(b) (4)

(b) (4)) listed in Table 6 (b) (4) .

Table 6 Blend Limits

(b) (4)

UTL = Upper Tolerance Limit, LTL = Lower Tolerance Limit, DWB = Dry Weight Basis

(b) (4) (Section 3.2.1.4.2).

3.2.2.4 Manufacturing Control Strategy

As highlighted in this section, the manufacturing process of the Tobacco Stick includes a primary and a secondary phase, as detailed in Section 3.2.2.1.

Control strategy is defined as a combination of the (b) (4) (b) (4) are put in place to monitor and regulate the (b) (4) . Therefore, (b) (4) to ensure the desired quality of the final product.

Control strategy applies to the following manufacturing processes:

(b) (4)

Control diagrams show (b) (4) (Appendix A3.2.2-1).

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3.2.2.4.1 Overview – Quality Attributes

The quality attributes associated to a given process step are classified as either:

- Critical Quality Material Attributes (CQMAs): apply to intermediate products (including Tobacco Stick physical parameters)
- Critical Quality Attributes (CQAs): critical attributes of the aerosol

The CQAs are identified as follows:

(b) (4)

(b) (4)
.

Justification for the criticality of these quality attributes can be found in Appendix A3.2.1-7 (b) (4) can be found in Table 9 and Table 11.

(b) (4)

Appendix 3.2.1-13, (b) (4)

3.2.2.4.2 Overview – Control Factors (Process Parameters)

Critical Process Parameter (CPP) is a process parameter whose variability has an impact on a critical quality attribute and these are identified, monitored and controlled to ensure the process produces desired quality.

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Table 7 Overview of Control Factors

Step	Product Component	Critical Quality Material Attribute	Measurement
(b) (4)			

(table continues)

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Step	Product Component	Critical Quality Material Attribute	Measurement
(b) (4)			

3.2.2.5 Analytical Methods

3.2.2.5.1 Aerosol Composition

The aerosol generated during the user experience contains both liquid droplets and gaseous components (gases and volatilized compounds).

3.2.2.5.2 Aerosol Generation

In order to obtain, as closely as possible, a consistent composition of the aerosol, two standardized smoking regimes are widely used for cigarettes using smoking machines (see Table 8); the Health Canada Intense (HCI) regime and the ISO regime.

Table 8 Smoking Regimes

	ISO	HCI
Puff volume	35 mL	55 mL
Puff duration	2 sec	2 sec
Puff interval	60 sec	30 sec
Ventilation holes	Open	Closed

3.2.2.5.3 Sampling

The classical set-up for the sampling of mainstream tobacco aerosol is shown in Figure 5. The aerosol is guided through a trapping system consisting of a Cambridge Filter Pad (fiberglass sheets which collect >99% of particles down to 0.1µm) and one or more impingers, which contain a liquid to absorb gaseous components. For the assessment of Nicotine-Free Dry Particulate Matter (NFDPM), the filter's weight gain (Total Particulate Matter [TPM]) in the aerosol collection process is determined and the amounts of nicotine and water subtracted. Condensed matter is extracted by immersing/washing the filter pad in an appropriate solvent. Depending on the amount/concentration required by the analytical procedure employed, the aerosol from multiple items may be accumulated.

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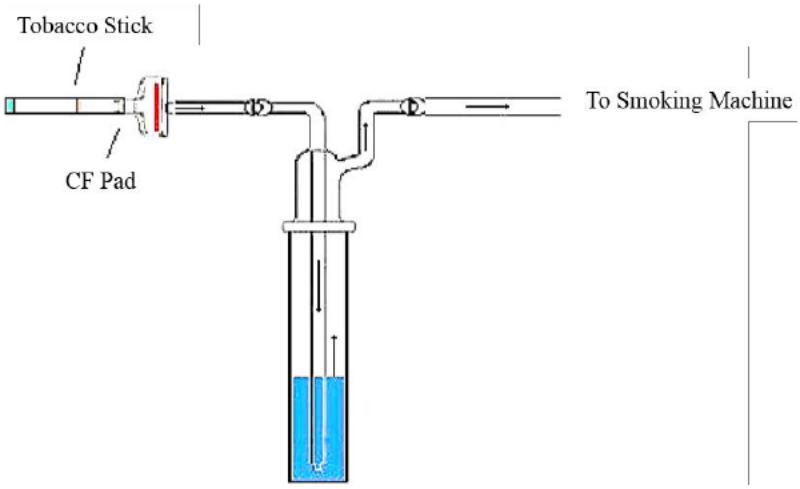


Figure 5 General Set-Up for Aerosol Sampling

3.2.2.5.4 Reference Product

The University of Kentucky has been providing reference cigarettes for tobacco research since the late 1960s. The reference product used is termed 3R4F.

3.2.2.5.5 Control Parameters Regular Tobacco Stick

(b) (4)

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Table 9 Chemical Parameters for Target Batch Release (TBR) and Performance Specification (PS) for Regular Tobacco Stick

Parameter	CAS #	Test Method	Type*(*)*	BR Acceptance Criteria	LOD µg/stick	LOQ µg/stick	Summary Link (Appendix)
(b) (4)							

(*) TBR = Target Batch Release;
Note: acceptance criteria for TBR are reviewed on a regular basis as more data are generated and analyzed.

Acceptance criteria for target batch release and performance specifications can be found in Appendix A3.2.1-3. Summary of the test methods can be found in Appendix A3.2.2-5 to Appendix A3.2.2-12.

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Table 10 Physical Parameters for Target Batch Release for Regular Tobacco Stick

Parameter	Method	Range	Summary Link (Appendix)
(b) (4)			Appendix A3.2.2-13

(b) (4)

3.2.2.5.6 Control Parameters Menthol Tobacco Sticks

(b) (4)

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Table 11 Chemical Parameters for Target Batch Release (TBR) and Performance Specification (PS) for Menthol Tobacco Sticks

Parameter	CAS #	Test Method	Type*(*)*	BR Acceptance Criteria (M1)	BR Acceptance Criteria (M2)	LOD µg/stick	LOQ µg/stick	Summary Link (Appendix)
(b) (4)								

(table continues)

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Parameter	CAS #	Test Method	Type*(*)*	BR Acceptance Criteria (M1)	BR Acceptance Criteria (M2)	LOD µg/stick	LOQ µg/stick	Summary Link (Appendix)
(b) (4)								Appendix A3.2.2-5

Acceptance criteria for performance specifications can be found in Appendix A3.2.1-3. Summary of the test methods can be found in Appendix A3.2.2-5 to Appendix A3.2.2-12.

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Table 12 Physical Parameters for Target Batch Release Menthol Tobacco Stick

Parameter	Method	Range	Summary Link (Appendix)
(b) (4)			Appendix A3.2.2-13

The rationale for selection of the Performance Specifications and Target Batch Release specifications are available in Appendix A3.2.2-14.

3.2.2.6 Packaging Materials

The purpose of the primary packaging for the Tobacco Sticks is protection from physical damage and to retain flavor and moisture of the product. Each pack contains 20 Tobacco Sticks.

Table 13 contains an overview of the major components of the primary packaging. (b) (4) . The packaging components are accepted based on the supplier's Certificate of Analysis.

Table 13 Tobacco Stick Primary Packaging Material

Component	Material	Supplier
Inner liner (b) (4)	(b) (4)	
Inner liner (b) (4))		
Inner frame		
Hinge lid blank		
Wrapping film		
Tear tape		

* (b) (4)

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3.2.2.6.1 Manufacture of Menthol Inner Liner

(b) (4) [redacted].

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