APPENDIX A3.2.1-3

PRODUCT SPECIFICATIONS

Product specification for Regular Tobacco Stick:

- Batch Release Specifications (5 pages)
- Performance Specifications (7 pages)

Product specification for Menthol 1 Tobacco Stick:

- Batch Release Specifications (9 pages)
- Performance Specifications (9 pages)

Product specification for Menthol 2 Tobacco Stick:

- Batch Release Specifications (7 pages)
- Performance Specifications (9 pages)

Confidentiality Statement

Confidentiality Statement: Data and information contained in this document are considered to constitute trade secrets and confidential commercial information, and the legal protections provided to such trade secrets and confidential information are hereby claimed under the applicable provisions of United States law. No part of this document may be publicly disclosed without the written consent of Philip Morris International.

PRODUCT PLATFORM: P1

PRODUCT GENERATION: THS 2.2

PRODUCT TYPE: RRP SMOKING SYSTEM AND RRP CONSUMABLE

REGULAR TOBACCO STICK BATCH RELEASE SPECIFICATIONS REPORT

Revision History

Version N°	Author	Description of change	Type of change
3.0 SV	Cédric Meyer	Submission Version (hyperlinks and internal references removed)	2
3.0	Cédric Meyer	Review of parameters according to PMI_RD_SOP_00355 and update of parameter according list of CQA and CQMA	1
2.0	Cédric Meyer	Addition of products and update of specifications	1
1.0	Cédric Meyer	Original version	1

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



Table of Contents

Revision History 1
1 Purpose 3
2 Introduction 3
3 Approach to Selection of Batch Release Specifications 3
4 Analytical Methods Used for Batch Release Specifications 4
5 Approach to Calculation of Batch Release Specifications and Acceptance Criteria 4
6 Batch Release Specifications 4
7 Change Management Log 5
8 Related Documents 5
9 Review and approval 5

1 Purpose

The purpose of this document is to establish the batch release specifications for the platform 1 THS 2.2 smoking system including the Tobacco Stick C3.2 with the Dorado 2 blend and the Aftercut Ron (Regular). The batch release specifications were approved by the Change Management Board (CMB).

2 Introduction

The smoking system Dorado 2 Ron (Regular – THS 2.2) concerned in this document is constituted of the Tobacco Stick Holder THD 2.2 or any later version considered as comparable and the Tobacco Stick C3.2 with the Cast Leaf Blend Dorado 2 and the flavor system Ron (Regular).

- The CQAs and CQMAs listed in Appendix A3.2.1-7.
- The Tobacco Stick C3.2 design change verification report is provided in Appendix A3.2.1-17.

3 Approach to Selection of Batch Release Specifications

The selection of batch release parameters is linked to the CQA and CQMA list provided in Appendix A3.2.1-7.

Parameter Name	Justification for Selection
(b) (4)	

4 Analytical Methods Used for Batch Release Specifications

Parameter Name	Method Description
(b) (4)	

5 Approach to Calculation of Batch Release Specifications and Acceptance Criteria

- All numerical values were calculated according to the applicable internal documentation.
- An expansion factor of 33% was applied to the tolerances of all the specifications as only one tobacco lot set was available.

6 Batch Release Specifications

Parameter Name	Target	Lower Limit	Upper Limit	Unit Of Measurement	Acceptance Criteria
(b) (4)					

7 Change Management Log

Version N°	Description of change (including reason for change)
3.0 SV	Submission Version (hyperlinks and internal references removed)
3.0	Review of parameters according to PMI_RD_SOP_00355 and update of parameter according list of CQA and CQMA [1]. Update of the document with the new Batch Release Specification template PMI_RD_FOR_000959.
2.0	Addition of products (Dorado I High Menthol, Dorado I low menthol and Dorado II regular) from the training center as well as Dorado I High Menthol, Dorado I low menthol and Dorado II regular from the IDC. The Tobacco Stick weight was also updated according to Comparability studies (for IDC products) and theoretical calculation (for Training Center products).
1.0	Original version

8 Related Documents

Appendix A3.2.1-7: Tobacco Stick CQAs and CQMAs

Appendix A3.2.1-17: AC Analysis Report THS2 MTB

9 Review and approval

This document has been reviewed and approved by:

Name	Function	Justification	Date (dd-mm-yyyy)	Signature
Meyer, Cédric	Manager Product Design / Author	Signed as Author	22-Jul-2016	
Schneider, Jean-Claude	Director Product & Process Development	Signed as Owner	22-Jul-2016	
Kapp, Florence	QA Officer	Signed as QA Reviewer	22JUL2016	

PRODUCT PLATFORM: P1
PRODUCT GENERATION: THS 2.2
PRODUCT TYPE: RRP SMOKING SYSTEM AND RRP CONSUMABLE

REGULAR TOBACCO STICK PERFORMANCE SPECIFICATIONS REPORT

Revision History

Version N°	Author	Description of change (including reason for change)	Type of change
2.0 SV	Cédric Meyer	Submission Version (hyperlinks and internal references removed)	2
2.0	Cédric Meyer	Review of parameters according to PMI_RD_SOP_00355 and update of parameter according to [1]	1
1.0	Cédric Meyer	Original version	1

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

Table of Contents

Revision History 1
1 Purpose 3
2 Introduction 3
3 Approach to Selection of Performance Specifications 3
4 Analytical Methods used for Performance Specifications 4
5 Approach to Calculation of Performance Specifications and Acceptance Criteria 5
6 Performance Specifications 5
7 Change Management Log 6
8 Related Documents 7
9 Review and approval 7

1 Purpose

The purpose of this document is to establish the performance specifications for the Platform 1 THS 2.2 smoking system including the Tobacco Stick C3.2 with the Dorado 2 blend and the Aftercut Ron (Regular). The performance specifications were approved by the Change Management Board (CMB).

2 Introduction

The smoking system Dorado 2 Ron THS 2.2 concerned in this document is constituted of the Tobacco Stick Holder THD 2.2 or any later version considered as comparable according to PMI_RD_SOP_00344 and the Tobacco Stick C3.2 with the Cat Leaf Blend Dorado 2 and the flavor system Ron (Regular).

The following inputs were used for the update of Performance Specifications

- The CQAs and CQMAs listed in Appendix A3.2.1-7.
- The Tobacco Stick C3.2 design change verification report is provided in Appendix A3.2.1-17.

3 Approach to Selection of Performance Specifications

- The performance specification parameters were selected from the list of CQA and CQMA, which was provided in Appendix A3.2.1-7.

Parameter Name	Justification for Selection
(b) (4)	

4 Analytical Methods used for Performance Specifications

Parameter Name	Method Description
(b) (4)	

Parameter Name	Method Description
(b) (4)	

5 Approach to Calculation of Performance Specifications and Acceptance Criteria

- All numerical values were calculated according to the applicable internal documentation.
- (b) (4) .
- (b) (4) .

6 Performance Specifications

Parameter Name	Target	Lower Limit	Upper Limit	Unit Of Measurement	Acceptance Criteria
(b) (4)					

Parameter Name	Target	Lower Limit	Upper Limit	Unit Of Measurement	Acceptance Criteria
(b) (4)					

7 Change Management Log

Version N°	Description of change (including reason for change)
(b) (4)	

8 Related Documents

Appendix A3.2.1-7: Tobacco Stick CQAs and CQMAs

Appendix A3.2.1-17: AC Analysis Report THS2 MTB

9 Review and approval

This document has been reviewed and approved by:

Name	Function	Justification	Date (dd-mm-yyyy)	Signature
Meyer, Cédric	Manager Product Design / Author	Signed as Author	22-JUL-2016	
Schneider, Jean-Claude	Director Product & Process Development	Signed as Owner	22-Jul-2016	
Kapp, Florence	QA Officer	Signed as QA Reviewer	22Jul2016	

PRODUCT PLATFORM: P1

PRODUCT GENERATION: THS 2.2

PRODUCT TYPE: NGP SMOKING SYSTEM AND NGP CONSUMABLE

DI VINNY LOW C3.2 BATCH RELEASE SPECIFICATIONS REPORT

Revision History

Version N°	Author	Description of change	Type of change
5.0	Mirko Minzoni	Final batch release specification	1
4.0	Cédric Meyer	Review of parameters with complete data set	1
3.0	Cédric Meyer	Review of parameters with limited data set and update of parameter according to [1]	1
2.0	Cédric Meyer	Addition of products and update of specifications	1
1.0	Cédric Meyer	Original version	1

Form is related to: PMI_RD_SOP_000299 Setting RRP Product Specifications for Performance Lock

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

Table of Contents

Revision History 1
1 Purpose 4
2 Introduction 4
3 Approach to Selection of Batch Release Specs 4
4 Analytical Methods used for Batch Release Specs 5
5 Approach to Calculation of Batch Release Specs and Acceptance Criteria 6
6 Batch Release Specs 6
7 Change Management Log 6
8 Related Documents 7
9 Review and approval 8
10 Abbreviations 8

1 Purpose

The purpose of this document is to establish the batch release specifications for the platform 1 THS 2.2 smoking system including the Heat Stick C3.2 with the Dorado 1 blend and the Aftercut Vinny low menthol configuration.

2 Introduction

The smoking system Dorado 1 Vinny Low Menthol THS 2.2 concerned in this document is constituted of the Tobacco Stick Holder THD 2.2 or any later version considered as comparable according to PMI_RD_SOP_00344 V1 [7] and the Heat Stick C3.2 with the Cat Leaf Blend Dorado 1 and the flavor system Vinny with the low menthol level configuration. The low menthol level configuration is characterized by having the mentholation only on the crimped filter.

The CQA and CQMA list are listed in document [1]

- The Heat Stick C3.2 has no design change compared to the C3.1, and therefore no additional verification was needed. The increment in denomination is only to express the change to the new nomenclature definition which will be defined at later stage in the R&D QMS.

Previous batch release specifications for this system are recorded in document [3]. The parameters have been reviewed according to PMI_RD_SOP_00355 [8]. The specification have been approved by the CMB #49 [6]

3 Approach to Selection of Batch Release Specs

- The selection of batch release parameters is linked to the CQA and CQMA list provided in document [1].

Parameter Name	Justification for Selection
(b) (4)	

4 Analytical Methods used for Batch Release Specs

Parameter Name	Method Description	WKI Reference	Validated (OK/NOK)
(b) (4)			

As the tobacco plug length measurement method is under validation, a derogation [5] is attached to this document. No measurement will be performed for batch release purposes until the method is validated.

5 Approach to Calculation of Batch Release Specs and Acceptance Criteria

- All numerical values were calculated according to PMI_RD_SOP_000299 V2 [9]
- The estimated variation from the process and product was corrected to keep under control the normal range of the specification.

6 Batch Release Specs

Parameter Name	Target	Lower Limit	Upper Limit	UOM	Acceptance Criteria
(b) (4)					

7 Change Management Log

Version N°	Description of change (including reason for change)
5.0	Definition of final batch release specification
4.0	Review of parameters with complete data set according to PMI_RD_SOP_00355 and adding of equilibration time for Menthol in Aerosol. Update of Review and Approval according to PMI_RD_SOP_00320
3.0	Review of parameters with limited data set and according to PMI_RD_SOP_00355 and update of parameter according list of CQA and CQMA [1]. Update of the document with the new Batch Release Specification template PMI_RD_FOR_000959.
2.0	Addition of products (Dorado I High Menthol, Dorado I low menthol and Dorado II regular) from the training center as well as Dorado I High Menthol, Dorado I low menthol and Dorado II regular from the IDC. The Heat Stick weight was also updated according to Comparability studies (for IDC products) and theoretical calculation (for

	Training Center products).
Version N°	Description of change (including reason for change)
1.0	Original version

(b) (4)

8 Related Documents

[1] P1_THS 2.2_ List of CQAs and CQMAs.doc
https://disco.app.pmi/disco/drl/objectId/0901d4ec8050fa7b

[2] DI Low Performance and Batch release Specifications.xlsx
https://disco.app.pmi/disco/drl/objectId/0901d4ec805cd507

[3] ZRH_PDE_REP_P1 Model 2.2 Batch Release Specifications
https://disco.app.pmi/disco/drl/objectId/0901d4ec804b7ac7

[4] FOLDER0202590

http://rrpplm.app.pmi/Agile/PLMServlet?fromPCClient=true&module=AttachmentHandler&requestUrl=module%3DAttachmentHandler%26opcode%3DdisplayObject%26classid%3D6159%26objid%3D23342349%26tabid%3D0%26

[5] TPD_NC_0097.doc
https://disco.app.pmi/disco/drl/objectId/0901d4ec80524baf

[6] MNO010367

https://disco.app.pmi/disco/drl/objectId/0901d4ec805d1575

[7] PMI_RD_SOP_000344 Product Comparability Assessment

[8] PMI_RD_SOP_000355 RRPs specification management as of performance lock

[9] D1 Vinny low batch release specification.xlsx

[10] ISO 3951-1:2013

Sampling procedures for inspection by variables -- Part 1: Specification for single sampling plans indexed by acceptance quality limit (AQL) for lot-by-lot inspection for a single quality characteristic and a single AQL

9 Review and approval

This document has been reviewed and approved by:

Name	Function	Justification	Date (dd-mm-yyyy)	Signature
Mirko, Minzoni	Manager Product Design	Signed as Author	05-10-2016	
Ceol, Mauro	Sr. Officer QA Product Mgmt	Signed as QA reviewer	06.Oct.2016	
Krasiev, Sergey	Program Manager Platform 1	SME Reviewer	21-10-2016	
Buclin, Hyun	Manager PT Systems & Quality	QC QA Reviewer	24Oct2016	
P.O. Berberat, Pascale				
Bonnely, Samuel	Director Product & process Development HTP	Signed as Approver	24.Oct.2016	
Cyril JEANNET	Manager Product Characterization	Head of QC unit	24-Oct-2016	

10 Abbreviations

Abbreviations		
CQA	:	Critical Quality Attribute
CQMA	:	Critical Quality Material Attribute
DoE	:	Design of Experiments
EDMS	:	Electronic Document Management System
FDS	:	Functional Design Specification
FTS	:	Functional Test Specification
LIMS	:	Laboratory Information Management System
PDIMS	:	Product Development Information Management System
PTS	:	Product Test Specification
RRP	:	Reduced Risk Product
SE	:	Sensory Evaluation
SME	:	Subject Matter Expert

TPP	:	Target Product Profile
UOM	:	Unit of Measure
WKI	:	Work Instruction

For complete definition, refer to PMI OPS Glossary and/or PMI RD Glossary

PRODUCT PLATFORM: P1
PRODUCT GENERATION: THS 2.2
PRODUCT TYPE: NGP SMOKING SYSTEM AND NGP CONSUMABLE

DI LOW C3.2 PERFORMANCE SPECIFICATIONS REPORT

Revision History

Version N°	Author	Description of change (including reason for change)	Type of change
3.0	Mirko Minzoni	Performance specification definition according to SOP_00355 (3)	1
2.0	Cédric Meyer	Review of parameters according to PMI_RD_SOP_00355 and update of parameter according to P1_THS 2.2_ List of CQAs and CQMAs.doc [1]	1
1.0	Cédric Meyer	Original version	1

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

Table of Contents

Revision History 1
1 Purpose 3
2 Introduction 3
3 Approach to Selection of Performance Specs 3
4 Analytical Methods used for Performance Specs 4
5 Approach to Calculation of Performance Specs and Acceptance Criteria 5
6 Performance Specs 6
7 Change Management Log 6
8 Related Documents 7
9 Review and approval 8
10 Abbreviations 8

1 Purpose

The purpose of this document is to establish the performance specifications for the Platform 1 THS 2.2 smoking system including the Heat Stick C3.2 with the Dorado 1 blend and the Aftercut Vinny and the low menthol level. The performance specifications version 2 were approved by the Change Management Board CMB #50 [4].

2 Introduction

The smoking system Dorado 1 Vinny THS 2.2 concerned in this document is constituted of the Tobacco Stick Holder THD 2.2 and THD 2.4 as well as any later version considered as comparable according to PMI_RD_SOP_00344 [6] and the Heat Stick C3.2 with the Cat Leaf Blend Dorado 1, the flavor system Vinny and the low menthol level in the crimped filter.

The following inputs were used for the update of Performance Specifications

- The CQA and CQMA lists are listed in document [1]
- Previous performance specifications for THS 2.2 system are recorded in document [3].

The parameters have been reviewed according to PMI_RD_SOP_000355 Rev 3.0 [7].

3 Approach to Selection of Performance Specs

- The performance specification parameters were selected from the list of CQA and CQMA, which was provided in document [1].

Parameter Name	Justification for Selection
(b) (4)	

4 Analytical Methods used for Performance Specs

Parameter Name	Method Description	WKI Reference	Validated (OK/NOK)
(b) (4)			

Parameter Name	Method Description	WKI Reference	Validated (OK/NOK)
(b) (4)			

5 Approach to Calculation of Performance Specs and Acceptance Criteria

- All numerical values were calculated according to PMI_RD_SOP_000299 [8].

- As only limited amount of data was available, an expansion factor of 33% was applied to the tolerances to cope with future unknown variation.
- (b) (4)
- All numerical values and batch details used to calculate the specifications is detailed in [2]

6 Performance Specs

Parameter Name	Target	Lower Limit	Upper Limit	UOM	Acceptance Criteria
(b) (4)					

7 Change Management Log

Version N°	Description of change (including reason for change)
(b) (4)	

(b) (4)



8 Related Documents

[1] P1_THS 2.2_ List of CQAs and CQMAs.doc
https://disco.app.pmi/disco/drl/objectId/0901d4ec8050fa7b

[2] DI Low Performance and Batch release Specifications.xlsx
https://disco.app.pmi/disco/drl/objectId/0901d4ec80525958

[3] ZRH_PDE_REP_P1 Model 2.2 Performance specifications report
https://disco.app.pmi/disco/drl/objectId/0901d4ec804bbafc

[4] CMB meeting minutes

https://disco.app.pmi/disco/drl/objectId/0901d4ec805df67d

[5] Rational for the selection of reduced list of smoke constituents as CQA
http://disco.app.pmi/disco/drl/objectId/0901d4ec803529d9

[6] PMI_RD_SOP_000344 Product Comparability Assessment

[7] PMI_RD_SOP_000355 RRPs specification management as of performance lock

[8] PMI_RD_SOP_000299 Setting RRP specifications for performance lock

9 Review and approval

This document has been reviewed and approved by:

Name	Function	Justification	Date (dd-mm-yyyy)	Signature
Minzoni, Mirko	Manager Product Design / Author	Signed as Author	28-10-2016	
Ceol, Mauro	Sr. Officer QA Product Mgmt	Signed as QA reviewer	28.04.2016	
Krasiev, Sergey	Project Manager Platform 1	Signed as SME Reviewer	28-10-2016	
Jeannet, Cyril	Manager product characterization	Head of QC unit	28-oct-2016	
Bonnely, Samuel	Director Product&Process Development HTP	Signed as Approver	28-10-2016	

10 Abbreviations

Abbreviations

CQA	:	Critical Quality Attribute
CQMA	:	Critical Quality Material Attribute
DoE	:	Design of Experiments
EDMS	:	Electronic Document Management System
FDS	:	Functional Design Specification
FTS	:	Functional Test Specification
LIMS	:	Laboratory Information Management System
PDIMS	:	Product Development Information Management System
PTS	:	Product Test Specification
RRP	:	Reduced Risk Product
SE	:	Sensory Evaluation
SME	:	Subject Matter Expert

TPM	:	Total Particulate Matter
TPP	:	Target Product Profile
UOM	:	Unit of Measure
WKI	:	Work Instruction

For complete definition, refer to PMI OPS Glossary and/or PMI RD Glossary

PRODUCT PLATFORM: P1

PRODUCT GENERATION: THS 2.2

PRODUCT TYPE: NGP SMOKING SYSTEM AND NGP CONSUMABLE

DI HIGH C3.2 BATCH RELEASE SPECIFICATIONS REPORT

Revision History

Version N°	Author	Description of change	Type of change
1.0	Cédric Meyer	Original version	1
2.0	Mirko Minzoni	Update to final BR specification	1

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

Table of Contents

Revision History 1
1 Purpose 3
2 Introduction 3
3 Approach to Selection of Batch Release Specs 3
4 Analytical Methods used for Batch Release Specs 4
5 Approach to Calculation of Batch Release Specs and Acceptance Criteria 5
6 Batch Release Specs 5
7 Change Management Log 5
8 Related Documents 6
9 Review and approval 6
10 Abbreviations 6

1 Purpose

The purpose of this document is to establish the batch release specifications for the platform 1 THS 2.2 smoking system including the Heat Stick C3.2 with the Dorado 1 blend and the high menthol configuration. The batch release specifications version were approved by the Change Management Board CMB#49 [1].

2 Introduction

The smoking system Dorado 1 high Menthol THS 2.2 concerned in this document is constituted of the Tobacco Stick Holder THD 2.2 or any later version considered as comparable according to PMI_RD_SOP_00344 V1 [2] and the Heat Stick C3.2 with the Cast Leaf Blend Dorado 1 with the high menthol level configuration. The high menthol level configuration is characterized by having the mentholisation on both, the crimped filter and the inner liner.

- The CQA and CQMA list are listed in document [3]
- The Heat Stick C3.2 has no design change compared to the C3.1, and therefore no additional verification was needed. The increment in denomination is only to express the change to the new nomenclature definition which will be defined at later stage in the R&D QMS.

Previous batch release specifications for this system are recorded in document [4]. The parameters have been reviewed according to PMI_RD_SOP_00355 [5].

3 Approach to Selection of Batch Release Specs

- The selection of batch release parameters is linked to the CQA and CQMA list provided in document [3].

Parameter Name	Justification for Selection
(b) (4)	

4 Analytical Methods used for Batch Release Specs

Parameter Name	Method Description	WKI Reference	Validated (OK/NOK)
(b) (4)			

As the tobacco plug length measurement method is under validation, a derogation [6] is attached to this document. No measurement will be performed for batch release purposes until the method is validated.

5 Approach to Calculation of Batch Release Specs and Acceptance Criteria

- All numerical values were calculated according to PMI_RD_SOP_000299 V2 [7].
- The estimated variation from the process and product was corrected to keep under control the normal range of the specification.

6 Batch Release Specs

Parameter Name	Target	Lower Limit	Upper Limit	UOM	Acceptance Criteria
(b) (4)					

7 Change Management Log

Version N°	Description of change (including reason for change)
1.0	Original version
(b) (4)	

8 Related Documents

[1] CMB notes

[2] PMI_RD_SOP_000344 Product Comparability Assessment

[3] P1_THS 2.2_ List of CQAs and CQMAs.doc
https://disco.app.pmi/disco/drl/objectId/0901d4ec8050fa7b

[4] ZRH_PDE_REP_P1 Model 2.2 Batch Release Specifications
https://disco.app.pmi/disco/drl/objectId/0901d4ec804b7ac7

[5] PMI_RD_SOP_000355 RRPs specification management as of performance lock

[6] PMI_RD_SOP_000299 Setting RRP specifications for performance lock

[7] DI 1.2M Batch release Specifications.xlsx
https://disco.app.pmi/disco/drl/objectId/0901d4ec805cd50b

[8] ISO 3951-1:2013
Sampling procedures for inspection by variables -- Part 1: Specification for single sampling plans indexed by acceptance quality limit (AQL) for lot-by-lot inspection for a single quality characteristic and a single AQL

9 Review and approval

This document has been reviewed and approved by:

Name	Function	Justification	Date (dd-mm-yyyy)	Signature
Mirko, Minzoni	Manager Product Design / Author	Signed as Author	05-10-2016	
Ceol, Mauro	Sr. Officer QA Product Mgmt	Signed as QA reviewer	06.Oct.2016	
Krasiev, Sergey	Program Manager Platform 1	SME Reviewer	21-10-2016	
~~Buclin, Hyun~~ P.O. Berbeyer, Pascale	Manager PT Systems & Quality	QC QA Reviewer	24. Oct. 2016	
Bonnely, Samuel	Director Product&Process Development HTP	Signed as Approver	24. Oct. 2016	
Cyril JEANNET	Manager Product characterization Head of QC unit		24-oct-2016	

10 Abbreviations

Abbreviations		
CQA	:	Critical Quality Attribute
CQMA	:	Critical Quality Material Attribute

DoE	:	Design of Experiments
EDMS	:	Electronic Document Management System
FDS	:	Functional Design Specification
FTS	:	Functional Test Specification
LIMS	:	Laboratory Information Management System
PDIMS	:	Product Development Information Management System
PTS	:	Product Test Specification
RRP	:	Reduced Risk Product
SE	:	Sensory Evaluation
SME	:	Subject Matter Expert
TPP	:	Target Product Profile
UOM	:	Unit of Measure
WKI	:	Work Instruction

For complete definition, refer to PMI OPS Glossary and/or PMI RD Glossary

PRODUCT PLATFORM: P1
PRODUCT GENERATION: THS 2.2
PRODUCT TYPE: NGP SMOKING SYSTEM AND NGP CONSUMABLE

DI HIGH C3.2 PERFORMANCE SPECIFICATIONS REPORT

Revision History

Version N°	Author	Description of change (including reason for change)	Type of change
3.0	Mirko Minzoni	Performance specification definition according to SOP_00355 (3)	1
2.0	Cédric Meyer	Review of parameters according to PMI_RD_SOP_00355 and update of parameter according to P1_THS 2.2_ List of CQAs and CQMAs.doc [3]	1
1.0	Cédric Meyer	Original version	1

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

Table of Contents

Revision History 1
1 Purpose 3
2 Introduction 3
3 Approach to Selection of Performance Specs 3
4 Analytical Methods used for Performance Specs 4
5 Approach to Calculation of Performance Specs and Acceptance Criteria 5
6 Performance Specs 6
7 Change Management Log 6
8 Related Documents 7
9 Review and approval 8
10 Abbreviations 8

1 Purpose

The purpose of this document is to establish the performance specifications for the Platform 1 THS 2.2 smoking system including the Heat Stick C3.2 with the Dorado 1 blend and the high menthol level. The performance specifications version 2 were approved by the Change Management Board CMB50 [1].

2 Introduction

The smoking system Dorado 1 Ron THS 2.2 concerned in this document is constituted of the Tobacco Stick Holder THD 2.2 and THD 2.4 as well as any later version considered as comparable according to PMI_RD_SOP_00344 [2] and the Heat Stick C3.2 with the Cast Leaf Blend Dorado 1 and with the high menthol level configuration. The high menthol level configuration is characterized by having the menthol on both, the crimped filter and the inner liner.

The following inputs were used for the update of Performance Specifications

- The CQA and CQMA lists are listed in document [3]
- Previous performance specifications for THS 2.2 system are recorded in document [4].

The parameters have been reviewed according to PMI_RD_SOP_000355 Rev 3.0 [5].

3 Approach to Selection of Performance Specs

- The performance specification parameters were selected from the list of CQA and CQMA, which was provided in document [3].

Parameter Name	Justification for Selection
(b) (4)	

4 Analytical Methods used for Performance Specs

Parameter Name	Method Description	WKI Reference	Validated (OK/NOK)
(b) (4)			

Parameter Name	Method Description	WKI Reference	Validated (OK/NOK)
(b) (4)			

5 Approach to Calculation of Performance Specs and Acceptance Criteria

- All numerical values were calculated according to PMI_RD_SOP_000299 [6].

- As only limited amount of data was available, an expansion factor of 33% was applied to the tolerances to cope with future unknown variation.
- (b) (4)
- All numerical values and batch details used to calculate the specifications is detailed in [7]

6 Performance Specs

Parameter Name	Target	Lower Limit	Upper Limit	UOM	Acceptance Criteria
(b) (4)					

7 Change Management Log

Version N°	Description of change (including reason for change)
(b) (4)	
2.0	1. Updated spec numerical values according to PMI_RD_SOP_00355[5]

(b) (4)

1.0	Original version which is stored in ZRH_PDE_REP_ZRH FPD 4.2 Specifications Report December 2013

8 Related Documents

[1] CMB minutes
https://disco.app.pmi/disco/drl/objectId/0901d4ec805df67d

[2] PMI_RD_SOP_000344 Product Comparability Assessment

[3] P1_THS 2.2_ List of CQAs and CQMAs.doc
https://disco.app.pmi/disco/drl/objectId/0901d4ec8050fa7b

[4] ZRH_PDE_REP_P1 Model 2.2 Performance specifications report
https://disco.app.pmi/disco/drl/objectId/0901d4ec804bbafc

[5] PMI_RD_SOP_000355 rev 3.0 RRPs specification management as of performance lock

[6] PMI_RD_SOP_000299 Setting RRP specifications for performance lock

[7] DI 1.2M Performance Specifications.xlsx
https://disco.app.pmi/disco/drl/objectId/0901d4ec805dfd11

[8] Rational for the selection of reduced list of smoke constituents as CQA
http://disco.app.pmi/disco/drl/objectId/0901d4ec803529d9

9 Review and approval

This document has been reviewed and approved by:

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10 Abbreviations

Abbreviations

CQA	:	Critical Quality Attribute
CQMA	:	Critical Quality Material Attribute
DoE	:	Design of Experiments
EDMS	:	Electronic Document Management System
FDS	:	Functional Design Specification
FTS	:	Functional Test Specification
LIMS	:	Laboratory Information Management System
PDIMS	:	Product Development Information Management System
PTS	:	Product Test Specification
RRP	:	Reduced Risk Product
SE	:	Sensory Evaluation
SME	:	Subject Matter Expert

TPM	:	Total Particulate Matter
TPP	:	Target Product Profile
UOM	:	Unit of Measure
WKI	:	Work Instruction

For complete definition, refer to PMI OPS Glossary and/or PMI RD Glossary