Cooperation Centre for Scientific Research Relative to Tobacco

CORESTA Guide N° 15

CORESTA Reference Products Production and Evaluation Requirements

July 2020

Tobacco and Tobacco Products Analytes Sub-Group

CORESTA TECHNICAL GUIDE N° 15

Title:

CORESTA Reference Products Production and Evaluation Requirements

Status: Valid

Note: This document will be periodically reviewed by CORESTA

Document history:

Date of Review	**Information**
July 2009	Version 1
July 2014	Version 2
July 2020	Version 3: Periodic review, editorial updates. Includes CRPs produced in 2016.

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1. Introduction

CORESTA Reference Products (CRPs) are useful for monitoring the stability of analytical methodologies when conducting routine smokeless tobacco analyses. In particular, they can be used to assess whether the analytical methods are in control. This document describes the CRPs produced in 2016 and can be used as a guideline for the future remanufacture of the CRPs. Four different CRPs were produced in 2009 in an effort to have products that cover a wide range of smokeless tobacco product categories. A new batch of CRPs was produced in 2016 due to low supply of the 2009 CRPs. The products produced in 2009 and 2016 were similar in style and composition; however, the chemistries differed due to the fact they were produced seven years apart using different tobaccos and three of the products were produced by different manufacturers. Additionally, the loose-leaf chewing tobacco was produced in a chopped format in 2016. A chopped format was chosen to decrease the particle size, thus improving homogeneity both within and between the pouches/cans. Product descriptions for the 2009 and 2016 CRPs are given in Tables 1 and 2, respectively.

Table 1: 2009 CRP Product Descriptions

Product	Description	Quantity per Can or Pouch
CRP1	Swedish style snus pouch	24 g – 1 g portions
CRP2	American-style loose moist snuff	34 g
CRP3	American-style loose dry snuff powder	34 g
CRP4	American-style loose-leaf chewing tobacco	85 g

Table 2: 2016 CRP Product Descriptions

Product	Description	Quantity per Can
CRP1.1	Swedish style snus pouch	24 g – 1 g portions
CRP2.1	American-style loose moist snuff	34 g
CRP3.1	American-style loose dry snuff powder	34 g
CRP4.1	American-style chopped loose-leaf chewing tobacco	28 g

In 2016, 7000 cans of CRP1.1, 3.1, and 4.1 were produced while 10000 cans of CRP2.1 were produced. A greater quantity of CRP2.1 was produced because this CRP had the highest usage for the 2009 CRPs. These quantities were chosen to provide sufficient quantities of the CRPs to last for at least ten years. The Tobacco and Tobacco Products Analytes Sub-Group (TTPA) initially conducted annual stability analyses on the CRPs, but more recently conducts the stability analyses biennially. The final stability analysis of the 2009 CRPs was completed in 2020 and the products have been shown to be stable for ten years when stored at the recommended temperature of −20 °C [1].

[1] CORESTA Tobacco and Tobacco Products Analytes Sub-Group Technical Report: CORESTA 2009 Reference Products, 2019 Analysis, July 2020.

2. CORESTA Reference Product Specifications and Materials

The CRPs were intended to be representative of market products except that the CRPs were produced without any flavorings added apart from those required to obtain the specific smokeless tobacco product attributes of the style. As a point of reference, the 2016 CRP product parameters, determined post-manufacturing, are listed in Table 3 while the tobacco and non-tobacco materials are listed in Table 4.

Table 3: 2016 CRP Product Parameters Determined After Manufacturing

Measure	CRP1.1	CRP2.1	CRP3.1	CRP4.1
Moisture Content (%)	53,95	51,41	7,33	24,19
pH	8,296	7,737	6,96	6,082
Nicotine Content (%wwb)[1]	0,762	1,069	1,722	0,886

1. %wwb - percent wet weight or as-is basis.

Table 4: 2016 CRP Materials - Target values

Materials (%wwb)[1]	CRP1.1	CRP2.1	CRP3.1	CRP4.1
Dark air-cured lamina	--		--	--
Dark-fired tobacco	--	26,6	54,8	--
Dark air-cured stem	--		--	--
Air-cured tobacco	8,4	8,1	--	32,4
Air-cured stem	0,2		--	5,8
Burley stem	--	3,8	33,6	--
Sun-cured tobacco	5,4	--	--	--
Sun-cured stem	9,7	--	--	--
Flue-cured stem	12,8	--	--	--
Water	51,4	53,0	8	23,0
Sodium chloride	4,0	8,0	1,1	1,8
Sodium carbonate	1,8	0,5	1,1	--
Ammonium carbonate			1,4	
Propylene glycol	2,2	--	--	--
Glycerin	--	--	--	6,8
Sucrose	--	--	--	10,9
Dextrose	--	--	--	3,5
Maltose	--	--	--	1,6
Corn syrup solids	--	--	--	13,9
Sodium propionate	--	--	--	0,3
Pouch paper	4,1	--	--	--
Total	100	100	100	100

1. %wwb - percent wet weight basis.
2. The (--) symbol indicates the material was not included

3. General Production Requirements

- It is critical that future producers of the CRPs have experience producing smokeless tobacco products of that product style (i.e. Swedish snus, moist snuff, dry snuff, and loose leaf chew). Differences in tobacco analyte levels between the different production lots of the CRPs should be expected due to year-to-year agricultural crop variability and manufacturing practices.
- The quantity of CRPs produced should be sufficient to cover the needs of a period of at least 5 to 10 years. It is recommended that future production quantities be set according to the most current CRP stability data, usage, and the storage capacity of the distributor.
- Each of the CRPs shall be produced from one production batch. Every effort should be made to maximize sample homogeneity.
- For reasons of homogeneity, the tobaccos used shall be taken from one well-mixed batch.
- The non-tobacco materials used, such as salts, humectants, and preservatives, shall be taken from one batch and be of a similar quality as would be used in commercial product.
- The CRPs should be produced without any flavorings added except for those required to obtain the specific smokeless tobacco product attributes.
- Final pouch weight for Swedish snus should be tightly controlled during manufacturing to reduce pouch-to-pouch weight variability.
- Specifications for moisture content, pH, as well as pouch weight of Swedish snus, should be set before production. The specifications should encompass not only the target values but also the maximum variability for the specific manufacturing process employed.
- Appropriate manufacturing specifications should be defined prior to production. These specifications should be similar to those used for commercial smokeless tobacco products of the given product style produced at that time. Due to this fact, the materials and percentages shown in Table 3 are shown for guidance and may be altered for future CRPs.

4. Packaging

It is also essential that the CRPs be packaged in containers with a defined quantity of product per container. The 2009 and 2016 CRPs were packaged in similar containers as would be used for commercial products. Specifically, CRP1, CRP2 and CRP3 were packaged in non-hermetically sealed polypropylene or high-density polyethylene cans, with lids and side labels to seal the lid to the can. CRP4 was packaged in a laminated foil pouch. Therefore, all stability data for the 2009 CRPs is based upon these types of packaging. Similarly, the 2016 CRPs were packaged in non-hermetically sealed polypropylene or high-density polyethylene cans, with lids and side labels to seal the lid to the can. Therefore, all stability data for the 2016 CRPs is based upon these types of packaging. It is recommended that future productions of the CRPs be packaged in similar containers as are used for commercial products to help ensure stability data are applicable.

Photographs of the four 2009 and 2016 CRPs are shown in Figures 1 and 2, respectively. It is essential that the CRPs be clearly distinguishable from commercial smokeless tobacco products by the can and case labels, as shown below:

Figure 1 – 2009 CORESTA Reference Products

Figure 2 – 2016 CORESTA Reference Products

Additionally, the can labels should clearly identify the style of product, the quantity of product, and the manufacturing date as shown below:

FOR NON-CONSUMER LABORATORY TESTING PURPOSES ONLY

NOT TO BE OFFERED FOR SALE, SOLD, OR OTHERWISE DISTRIBUTED TO CONSUMERS

CORESTA Reference Product
Snus Smokeless Tobacco, 24 g – 1 g Pouches
Manufactured in 2016
CRP1.1

CORESTA Reference Product
Moist Smokeless Tobacco, 34 g
Manufactured in 2016
CRP2.1

CORESTA Reference Product
Dry Smokeless Tobacco, 34g
Manufactured in 2016
CRP3.1

CORESTA Reference Product
Chopped Loose Leaf Smokeless Tobacco, 34 g
Manufactured in 2016
CRP4.1

4.1 Health warnings

These products are not intended for consumer use. However, depending on the country in which they are manufactured or distributed, local regulations or manufacturer policies may require affixing specific health warnings, as was the case with the 2009 and 2016 CRPs.

5. Evaluation of the CORESTA Reference Products

- The CRPs shall be stored at a temperature of −20 °C in order to stabilize the products before chemical characterization. The CRPs should remain at −20 °C until they are distributed for use.
- Each of the CRPs must show consistent values for moisture, pH, nicotine, and tobacco specific nitrosamines (TSNA). The consistency shall be assessed by means of a comparative study of sufficient size using samples representing the entire production run.
- This comparative study is coordinated by the CORESTA TTPA Sub-Group and the results are statistically evaluated to ensure acceptably low variation prior to the release of the CRPs for laboratory use.

6. Considerations for the Future Production of the CORESTA Reference Products

- CRP1 and CRP2 have had greater usage than the other CRPs; therefore, the current inventory should be evaluated in conjunction with the most recent stability data in order to determine production volume.
- CRP1 could be produced in a 0,5 g version as opposed to a 1,0 g version as this may allow laboratories to use the entire pouch, even if the analytical method was developed for sample quantities less than 1,0 g.
- CRP4 exhibited more within-pouch and pouch-to-pouch variability as compared to the other CRPs. This is likely due to the physical characteristics of an American-style loose-leaf chewing tobacco product which leads to the greater heterogeneity. This variability was decreased with the CRP4.1 because it was produced in a chopped format.
- Future CRP productions should be characteristic in chemistry and composition to commercial products at the time of manufacture. For this reason, the materials or percentages of those materials used for future productions may differ from those shown in Table 4.