

ood and Environment Center for Tobacco Reference Products

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Certificate of Analysis

Certified Reference Snus

Certificate Number: 2023-01-1S5-CTRP

Certification Date: 3/31/2023

Validity: This document is valid until 3/31/2028 unless superseded by a new CoA at an earlier date.

Superseded CoA: 2019-01_CTRP

Description of CRM

Snus

Lot/Batch Number

STRP 1S5

Matrix

Tobacco blend

Major starting materials

Dark air-cured lamina, dark air-cured stem, sodium carbonate, propylene glycol, sodium chloride, water,

pouch paper

Reference Snus Certified Values and Uncertainties

		Certified	Coverage Factor		Number of
Parameter	Certified Value	Uncertainty (U_{CRM})	of U _{CRM}	Unit	accepted data points
Free Nicotine	3.378	0.627	2.34	mg/g	216
NNK	0.225	0.033	2.92	μg/g	216
NNN	0.839	0.063	2.85	μg/g	216
NAT	0.376	0.066	3.03	μg/g	216
NAB	0.049	0.008	2.38	μg/g	216
Acetaldehyde	1.79	0.98	2.57	μg/g	215
Crotonaldehyde	<loq< td=""><td>NA</td><td>NA</td><td>μg/g</td><td>NA</td></loq<>	NA	NA	μg/g	NA
Formaldehyde	0.80	0.45	2.56	μg/g	216
Benzo[a]pyrene	0.58	0.26	2.76	ng/g	162
Cadmium	366	94	2.70	ng/g	216
Arsenic	53.2	26.3	2.16	ng/g	216
Moisture	32.6	0.5	2.43	%	216
рН	7.72	0.07	# 2.17	pH units	216

CX LY CHMI HJ BS 35

CERTIFIED VALUES AND UNCERTAINTIES:

The "Certified Values" listed above are unweighted means of results submitted by four ISO 17025-accredited laboratories using a combination of methods and instrumentation that emulate actual methods and instrumentation techniques currently utilized in the analysis of each parameter in the analytical community. No assumptions were made regarding the accuracy or precision of each laboratory therefore no weighting is done on the results of each lab.

The "Certified Uncertainty", U_{CRM} , listed above are expanded uncertainties intended to provide approximately 95% confidence interval around the respective reference values obtained by multiplying the combined standard uncertainty with a coverage factor k, equal to the t-value based on the approximated degrees of freedom using the Welch-Satterthwaite equation. Each "Certified Uncertainty" includes an uncertainty component that accounts for systematic error among the methods used by different laboratories.

Values reported as <LOQ have concentrations reported as below the level of quantification by the ISO 17025 contract labs that analyzed the samples.

The Certified Values and Uncertainties for the analytical parameters contained herein are on an "as received" basis.

STATEMENT OF TRACEABILITY:

The traceability of the reference values and uncertainties certified herein are maintained through an unbroken chain of comparisons to appropriate standards with suitable procedures and measurement uncertainties by virtue of the ISO 17025 – accreditations possessed by the Four participating laboratories. The accredited analytical methods used by participating laboratories are listed below.

LIST OF METHODS USED:

Analytes in smokeless tobacco

Carbonyls	LP-743/AM-240/TWT-00355		
Nicotine	LP-411/ENT182/AM-072/T-301		
Moisture	LP-801.1/ENT046/AM-071/TWT-00324		
pH	LP-031/ENT058/AM-071/T-310		
Metals	LP-416/AM-052/T-306		
Benzo[α]pyrene	LP-711/ENT212/AM-125/TWT-00357		
Tobacco Specific Nitrosamines (TSNAs)	LP-412.1/ENT210/AM031/TWT-00333		

INTENDED USE: This product may be used for analytical method development, assigning values to materials (when applicable), and, equipment calibration to any applicable extent.

INSTRUCTIONS FOR CORRECT USE: This reference material should be stored in sealed containers or bags at -20°C until testing. Prior to analysis, the reference materials should be unopened and transferred to a refrigerator for a minimum of 24 hours or until they are completely thawed, and then moved to room temperature for at least 2 hours until it reaches temperature equilibrium. Once the reference materials are equilibrated to room temperature, the reference materials may be stored at 4°C for up to one week, if they will not be analyzed immediately. Any reference materials found to have damaged package should be discarded.

HAZARD INFORMATION: N/A

HOMOGENEITY: Homogeneity of this material is reflected as an uncertainty component of "Certified Uncertainty" as indicated in this Certificate of Analysis.

NAMES AND SIGNATURES OF CERTIFYING OFFICERS:

Certificate Approved by

Ling Yuan, Ph.D. Director, CTRP Certificate Approved by:

Orlando D. Chambers, Ph.D.Principal Investigator

Certificate Approved by:

Huihua Ji, MS

Huihua Ti

Analytical Lab Director/ Deputy Quality Control Certificate Approved by:

C. Ruth McNees, Ph.D.

Quality Control/Quality Assurance

Certificate Approved by:

Brent J. Shelton, Ph.D. Statistical design and data processing

Certificate Approved by:

Statestical design and data processing