

Certificate of Analysis

Certified Reference Loose Leaf Smokeless Tobacco

Certificate Number: 2023-01-3S1-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Validity: This document is valid until 3/31/2028 unless superseded by a new CoA at an earlier date.

Superseded CoA: **2019-01_CTRP**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	Loose leaf tobacco
Lot/Batch Number	STRP 3S1
Matrix	Tobacco blend
Major starting materials	Air-cured tobacco (cigar binder, filler, wrapper), air-cured stems (cigar binder, filler), Glycerin, propylene glycol, sucrose, dextrose, maltose, fructose, other corn syrup solids, salt, potassium sorbate, sodium benzoate, water

Reference Loose Leaf Tobacco Certified Values and Uncertainties

Parameter	Certified Value	Certified Uncertainty * (U_{CRM})	Coverage Factor of U_{CRM}	Unit	Number of accepted data points
Total Nicotine	6.501	0.791	2.24	mg/g	420
Free Nicotine	0.109	0.030	2.50	mg/g	420
NNK	0.172	0.031	2.00	µg/g	420
NNN	0.796	0.069	2.02	µg/g	420
NAT	0.351	0.050	2.25	µg/g	420
NAB	0.034	0.007	2.05	µg/g	420
Acetaldehyde	1.59	1.15	2.45	µg/g	420
Crotonaldehyde	<LOQ	NA	NA	µg/g	NA
Formaldehyde	0.38	0.24	2.51	µg/g	420
Benzo[a]pyrene	3.62	1.42	2.25	ng/g	420
Cadmium	424	78	2.25	ng/g	420
Arsenic	75.8	19.1 *	2.27	ng/g	420
Moisture	25.1	1.1	2.02	%	420
pH	6.25	0.09	2.20	pH units	420

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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.

Values with an asterisk have large expanded uncertainties due to wide inter-laboratory variation as determined by failed Mandel's h consistency testing of one or more datasets. Similar values were reported in the CORESTA study "[Characterization of University of Kentucky Reference Smokeless Tobacco Products 2021 Analysis](#)", and showed no significant differences to the values reported in the CoA 2019-01_CTRP.

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:



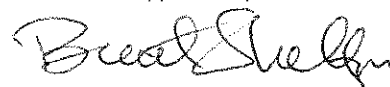
Ling Yuan, Ph.D.
Director, CTRP

Certificate Approved by:



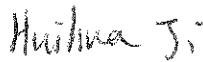
Orlando D. Chambers, Ph.D.
Principal Investigator

Certificate Approved by:



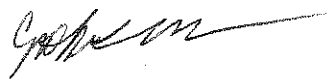
Brent J. Shelton, Ph.D.
Statistical design and
data processing

Certificate Approved by:



Huihua Ji, MS
Analytical Lab Director/
Deputy Quality Control

Certificate Approved by:



C. Ruth McNees, Ph.D.
Quality Control/Quality Assurance

Certificate Approved by:



Stacey Slone, MS
Statistical design and
data processing