

The Determination of Selected Metals in RYO Hemp Cigarettes

Prepared for:

**HBI International, Inc
BBKTobacco Tobacco & Foods, LLP
3401 W. Papago St.
Phoenix, AZ 85009**

**Initial Report Issued: 29 August 2024
Revised Report Issued: 30 August 2024**



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I. REPORT REVISION HISTORY

Revision Type (Initial/Revision)	Version Number	Report Date	Reason for Revision
Initial	0.0	29 August 2024	Final Release
Revision	1.0	30 August 2024	Corrected method AM-021 LOQ for all requested analytes

II. OVERVIEW

The objective of this study was to determine the concentration of selected metals in RYO hemp cigarettes.

The client provided two samples, which are listed in Table I. Three replicates per sample were used for testing.

The analyses requested for this study are listed in Table II. Analytical method summaries and results are included in the attached appendices. The laboratory control type used for acceptance is included on each final table for a given test method, if applicable.

Any method deviation(s) that occurred during the course of this study are included in Section IV, C: Quality Control and Reporting Notes.

III. TESTING FACILITY

Activities were conducted at:

McKinney Specialty Labs, LLC
1470 East Parham Road
Richmond, VA 23228-2300
Phone: (804) 887 – 2100
Fax: (804) 271 – 5594

The results in this test report relate only to the samples identified in this report. This information is confidential and is only to be used by the client identified in this report. McKinney Specialty Labs accepts no liability in the use of this report or the results contained, herein. The original controlled report shall not be reproduced without written approval of McKinney Specialty Labs.

IV. TEST SAMPLES

A. Receipt, Storage, and Conditioning of Test Samples

- McKinney Specialty Labs facility received the samples on 18 July 2024 after being relinquished by HBI International, Inc. The samples were received at ambient temperature and in good condition and assigned project code: 0724-022. Prior to, during, and after analysis, the samples were kept under lock with access only to authorized personnel of McKinney Specialty Labs.
- The sample designations are given in Table I.
- Storage was maintained at ambient conditions (unless otherwise specified by the client) until testing was performed.

Table I. Sample Coding

Client Sample ID	Lab ID	Sample Type	Quantity Received
Regular Flint Lighter	A	Lighter	5
Piezo Lighter	B	Lighter	5

B. Sample Analysis and Constituents List

All applicable analytical methods have been fully validated (unless otherwise specified). For lists of specific compounds of interest identified in each analyte group to be reported, refer to Table II.

All sample analyses performed were conducted on site from the time the samples were received (18 July 2024) to the date the revised final report was issued (30 August 2024).

For combustible smoke analyses, smoking of the products was carried out using SM450 20-port linear analytical smoking machines. Each product was placed into a holder and smoked according to the applicable analytical method(s) and collected on Cambridge filter pads or impingers. Each product was smoked in replicates of three via the Canadian Intense (CINT) smoking regime. Ten cigarettes per replicate were used for testing.

- Canadian Intense (CINT) Smoking Regime: products were smoked using a 55mL, two-second puff every 30 seconds using a bell curve. All ventilation holes were blocked using a piece of scotch tape.

Refer to method summaries for more information.

Table II. Constituents List

Analyses	Analyte(s)	Analytical Method Reference and Version #	Validation Report #
Selected Metals in Mainstream Smoke by ICP-MS*	Cerium*, Lanthanum*	AM-021 v9.1	VR-021

*Please note, the hemp matrix and analytes tested are not validated or included on McKinney Specialty Labs' scope of accreditation

C. Quality Control and Reporting Notes

All quality control samples were within limits unless otherwise noted. The results presented in this report are representative of the samples as provided to the laboratory.

There was no statistical outlier testing performed on the results. All data were reviewed by the analyst and a second qualified party and if any inconsistent results were discovered, and an assignable cause was determined, they were noted and repeated.

Revised report 0724-022 v1.0 replaces the initial report 0724-022 v0.0.

D. Sample Generation and Records

All analytical results generated in this report were conducted per tobacco parameters and conditions.

Records will be stored by McKinney Specialty Labs for a period of ten years. Following this period, all records will be destroyed.

Sample and calibration curve chromatograms are available upon request.

E. Sample and LOD/LOQ Concentration Calculations

Depending on the analysis conducted, analyte concentrations are determined by either an internal or external standard calibration method using the regression equation derived from the calibration curve. Results are then converted and typically reported on a per weight, per device/cigar(ette), or per puff basis. Example calculations are provided below for varying analysis types. Please note in the example calculations, nanograms (ng) are shown, however the results may be expressed in other units (mg, µg, pg). Dilution factors may also be used in some methods depending on the sample preparation procedure.

Please note that approximate Limit of Detection (LOD) and Limit of Quantitation (LOQ) values are calculated using averages for each assay and are not specific to individual samples.

E-Liquid and Tobacco:

E-liquid and tobacco analysis results may be reported on a mass/mass basis, catch weight basis (ng) or mass/volume (ng/mL) basis. The calculation is as follows:

$$\text{Analyte Concentration (ng/g)} = \frac{\text{Concentration (ng/mL)} \times \text{Dilution Factor} \times \text{Extraction Volume (mL)}}{\text{E-Liquid or Tobacco Weight (g)}}$$

In instances where results are required to be reported on a dry weight basis (DWB), the moisture content of a sample (expressed as moisture or oven volatiles) can be determined by any one of several different analytical methods. The following calculation is used to convert an “as is” result to a “dry weight basis” result:

$$\text{Analyte Concentration (ng/g DWB)} = \frac{\text{Analyte Concentration (ng/g)} \times 100}{(100 - \% \text{ Moisture})}$$

Aerosol and Smoke:

The final results for aerosol or smoke analysis may be reported as catch weight basis (ng), ng/puff, ng/cig, ng/device, or ng/g Aerosol Collected Mass (ACM). The final sample concentrations are calculated using the following equations:

$$\text{Analyte Amount (ng/puff)} = \frac{\text{Concentration (ng/mL)} \times \text{Dilution Factor} \times \text{Extraction Volume (mL)}}{\text{Total \# of Puffs}}$$

$$\begin{aligned} \text{Analyte Amount (ng/cig or ng/device)} \\ = \frac{\text{Concentration (ng/mL)} \times \text{Dilution Factor} \times \text{Extraction Volume (mL)}}{\text{Total \# of Cigar(ette)s or Devices}} \end{aligned}$$

$$\text{Analyte Amount (ng/g ACM)} = \frac{\text{Concentration (ng/mL)} \times \text{Dilution Factor} \times \text{Extraction Volume (mL)}}{\text{ACM (g)}}$$

Limits of Detection and Quantitation:

The LOD and LOQ values are calculated using the same formulas above. The LOD/LOQ value in mass/mL is converted to the final unit by multiplying by the extraction volume and dividing by the preferred unit (grams, puffs, device, etc.). An example calculation is shown below:

$$\text{Limit of Detection (ng/g)} = \frac{\text{LOD (ng/mL)} \times \text{Dilution Factor} \times \text{Extraction Volume (mL)}}{\text{E-Liquid or Tobacco Weight (g)}}$$

V. QUALITY STATEMENT/SIGNATURES

I certify to the best of my knowledge, all analytical data presented in this report summary:

- Have been reviewed for consistency and completeness.
- Are accurate, error-free, and legible.
- Have been conducted in accordance with the ISO/IEC 17025 standard; in instances where no regulatory guidance exists or is not applicable, the study was conducted in accordance with McKinney Specialty Labs' quality and technical procedures, and/or approved protocol.

This report is considered to describe accurately the procedures used in this study and the results obtained.

Alexei
Korolev

Digitally signed by Alexei Korolev
DN: cn=Alexei Korolev,
o=McKinney Specialty Labs,
ou=Quality Assurance Director,
email=alexei.korolev@mckinneysl
.com, c=US
Date: 2024.08.30 18:49:59 -04'00'

QA Reviewed By: _____

APPENDIX A

METALS METHOD SUMMARY AND RESULTS

SELECTED METALS IN MAINSTREAM SMOKE BY ICP-MS

MCKINNEY SPECIALTY LABS ANALYTICAL METHOD AM-021, VERSION 9.1

This method is applicable to metals present in mainstream smoke samples within the range 0.1 – 50 ng/mL.

The smoke collection portion of this method can be combined with AM-036, The Determination of Mercury in Mainstream Smoke.

Data is generated by McKinney Specialty Labs (Richmond, VA), LLC in accordance with Method AM-021. Metals are quantitated from mainstream smoke collected from a number of cigarettes dependent on the testing regime (ISO, CINT, etc.) Smoking is performed on a Borgwaldt RM20 CSR analytical smoking machine equipped with an electrostatic precipitation (EP) unit. A quartz EP tube is used in the EP unit for smoke collection. This method describes the multi-element determination of selected trace metals by ICP-MS equipped with an octopole reaction system that allows for the determination of elements which normally suffer from severe polyatomic interferences. Analyte ions are separated on the basis of their mass to charge ratio by a quadrupole mass spectrometer. Instrumental drift is corrected for by the use of internal standards, which are tailored to the metal being quantitated.

The metals are reported in units of mass-to-volume (ng/mL). The measured concentration, the number of cigarettes smoked, and the sample solution volume are also used to calculate the total analyte mass on a per-cigarette basis.

CALIBRATION AND QC STANDARD ACCEPTANCE CRITERIA

The following method performance criteria must be achieved prior to analysis of product samples:

- Each calibration curve must have a correlation coefficient (R) of 0.9975 or better. Note: The ICP-MS reports R for each curve, not r^2 .
- No more than 15% deviation can occur between the as-prepared and as-measured standard concentration.
- All quality control and continuing calibration standards must be within $\pm 15\%$ RE of their calculated values.

The method was included on the laboratory's A2LA scope of accreditation at the time of testing and internal quality control procedures were followed. McKinney Specialty Labs, LLC – Richmond is accredited by the American Association for Laboratory Accreditation (Certificate number 1873.01).

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Job No.: 0724-022-1,-2 AM-021 Metals in Mainstream Smoke by ICP-MS*

HBI International, Inc Cerium and Lanthanum in RYO Hemp

Detection Limits (Approximate Averages)

Compound	LOD (ng/cig)	LOQ (ng/cig)
cerium*	0.0500	0.500
lanthanum*	0.0500	0.500

*The hemp matrix and analytes tested are not validated or included on McKinney Specialty Labs' scope of accreditation.

McKinney Specialty Labs

Job No.: 0724-022-1,-2 AM-021 Metals in Mainstream Smoke by ICP-MS*

HBI International, Inc Cerium and Lanthanum in RYO Hemp

Sample Results

Sample Name	Lab ID	Run	Port	Cig Count	Puffs/ Cig	ACM mg/cig	cerium* ng/cig	lanthanum* ng/cig
Regular Flint Lighter	AM021 R1C P3 0724-022 A	1	3	10	22.2	109	150	64.0
	AM021 R1C P4 0724-022 A	1	4	10	19.5	114	48.5	16.8
	AM021 R1C P5 0724-022 A	1	5	10	20.8	106	133	51.6
	Average				20.8	110	110	44.1
	Std Dev				1.3	4	54	24.4
	RSD				6.5%	3.9%	49.2%	55.4%
Piezo Lighter	AM021 R2C P3 0724-022 B	2	3	10	17.8	118	<LOQ (<0.500)	ND (<0.0500)
	AM021 R2C P4 0724-022 B	2	4	10	17.1	112	<LOQ (<0.500)	ND (<0.0500)
	AM021 R2C P5 0724-022 B	2	5	10	17.5	109	ND (<0.0500)	ND (<0.0500)
	Average				17.5	113	<LOQ (<0.500)	ND (<0.0500)
	Std Dev				0.4	5	NA	NA
	RSD				2.1%	4.0%	NA	NA
Collection Blank	AM021 R1C P1 0724-022 blank	1	1	1	200	NA	ND (<0.500)	ND (<0.500)
	AM021 R2C P1 0724-022 blank	2	1	1	200	NA	ND (<0.500)	ND (<0.500)

*The hemp matrix and analytes tested are not validated or included on McKinney Specialty Labs' scope of accreditation.

APPENDIX B

CHAIN OF CUSTODY



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Nicotine Containing/Related Products Chain of Custody Record

McKinney Specialty Labs, LLC

1470 East Parham Road., Richmond, Virginia 23228

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Date of Submission: 8 Jul 2024

Company Name: HBI International

Contact: Ulli Becker

Address: 3401 W. Papago St

City, State, Zip: Phoenix, AZ 85009

Project / Quote #: Q24212

Email Address: ulli@hbiin.com

Phone Number: 336-207-6150

Purchase Order #: pay by credit card

Standard Turn Around Time*

Rush Turn Around Time*

Date Needed:

Special Storage Requirements: n/a

Special Disposal Requirements: n/a

Unless otherwise specified, samples will be disposed of per laboratory's sample retention policy (90 days after final report is sent). Additional disposal fees may apply

*All TATs subject to approval by McKinney Specialty Labs, LLC

[illegible]

Additional Notes: also sending cones filled with hemp

Relinquished: Print Name / Signature

Kelsey Hargis

Received: Print Name / Signature

CGibson

Signature _____

Sample condition/temperature upon receipt:

Comments: n/a

Relinquished Date / Time

07	09	24	11:00am
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Received Date / Time

18 Ju / 24	1200
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Ambient



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