APPENDIX A3.2.2-12

ANALYSIS OF AMMONIA IN AEROSOL

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1. ANALYSIS OF AMMONIA IN AEROSOL

1.1. Applicability

The method described is used to determine ammonia in mainstream aerosol from conventional cigarettes (3R4F) and the reduced risk product (THS) under Health Canada Intense (HCI) and International Organization for Standardization (ISO) smoking conditions.

Results are expressed as µg/item for THS and µg/cigarette for 3R4F.

1.2. Analytical Procedure

Aerosol from a smoking machine is collected in 2 impingers connected in series behind a Cambridge filter pad (CFP) that contains10 mL of 0.1N H_2SO_4, using a linear smoking machine under HCI and ISO smoking regimens. The CFP and contents of both the impingers are combined in 50 mL polypropylene (PP) tube. Each impinger is rinsed with 10 mL of deionized water and the rinse solutions are added to the combined aerosol solution. The samples received from the aerosol collection laboratory, are shaken for 30 minutes on the shaker device at 250 rpm. Approximately 5 mL from the combined aerosol collection are filtered using a 20 mL syringe with a 0.45 µm polyvinylidene difluoride (PVDF) filter fixed to the syringe. The treated aerosol solution is transferred into a 15 mL PP tube. Approximately 1.5 mL of the treated aerosol solution is transferred into an autosampler vial and then analyzed by Ion Chromatography (IC) using cation conductivity detector according to USP <621> by suppressed ion conductivity. The equipment and conditions are described in sections 1.2.2.1 and 1.2.2.2 respectively.

The 3R4F and THS are conditioned at least 48h at target conditions of 22 ± 1 °C and a relative humidity of 60 ± 3%, before being used for aerosol generation.

Preceding each batch, calibration is performed according to the details given in section 1.2.3. Typically, five sequences of measurement are performed per batch. Each sequence consists of conditioning runs, calibration standard (STD) runs, blank-STD (0.05N H_2SO_4) run, smoking blank run, monitor run, followed by a number of sample runs, and is terminated by a STD solution run (STD 4) to validate the results and verify the calibration (requirement: deviation of not more than ± 15% from the theoretical value).

1.2.1. Preparation of Solutions

1.2.1.1. Calibration Solutions

Seven STD solutions containing different concentrations (highest: lowest =20:1) of ammonia (NH_4^+ and NH_3) and a fixed concentration of primary ammonium stock solution are prepared

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in 0.1N H_2SO_4. The ranges of concentrations cover the ranges relevant for analysis and are provided in Table 1.

Table 1: Calibration Standard Ranges

Compound	Range (µg/mL)
Theoretical NH_4^+ concentration	0.200 – 4.000
Theoretical NH_3 concentration ($NH4^+$ concentration x factor)*	0.189 – 3.778

*Conversion factor to ion NH_4^+ to NH_3: (factor = molar mass (NH_3) / molar mass (NH_4^+) = 17/18 = 0.9445)

1.2.1.2. Extraction Solution

The extraction solution is 20 mL of 0.1N H_2SO_4 and 20 mL of Milli-Q water.

1.2.2. Experimental Conditions

1.2.2.1. Equipment

Ion Chromatograph	A suitable ion chromatograph equipped with data acquisition software
Column	Ion Pack CS16, 3 x 250 mm
Guard column	CG16, 3 x 50 mm

1.2.2.2. Ion Chromatography Conditions

Column temperature	40°C
Column compartment temperature	20°C
Autosampler tray temperature	10°C
Detector cell temperature	35°C
Injection volume	25 µL
Suppressor current	55 mA
Injection mode	Push full
Flow	0.36 mL/min

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Eluent	Methanesulfonic acid (MSA)
Injection speed	Fast

1.2.3. Calibration

Calibration is performed with 7 STD solutions containing different concentrations of ammonia (highest:lowest = 20:1).

A linear regression against concentration is performed for ammonia with statistical weights of 1/concentration according to:

$$C_{NH3}\left[{}^{\mu g}/_{cig}\right] = C_{NH3}\left[{}^{\mu g}/_{mL}\right] \times \frac{Vol_{ext}}{N_{cig}}$$

where

C_{NH3} [µg/cig]	NH_3 concentration in the sample
C_{NH3} [µg/mL]	NH_3 concentration in the sample determined from the calibration curve
Vol_{ext} [mL]	Extraction volume used during the smoking run
N_{cig}	Number of cigarettes smoked per replicate

Calibration is considered valid if the coefficient of determination $r^2 > 0.995$ is obtained and the deviation of back-calculated concentration to expected concentration (residuals) should be within ± 15% for the lowest calibration level and within ± 10% for all other calibration levels. Out of 7, at least 6 STD levels have to fulfill these criteria, including the lowest and highest STDs. If one standard is out of criteria, it must be excluded from calibration curve for calculations.

1.2.4. Example Chromatogram

An example chromatogram is provided in Figure 1.

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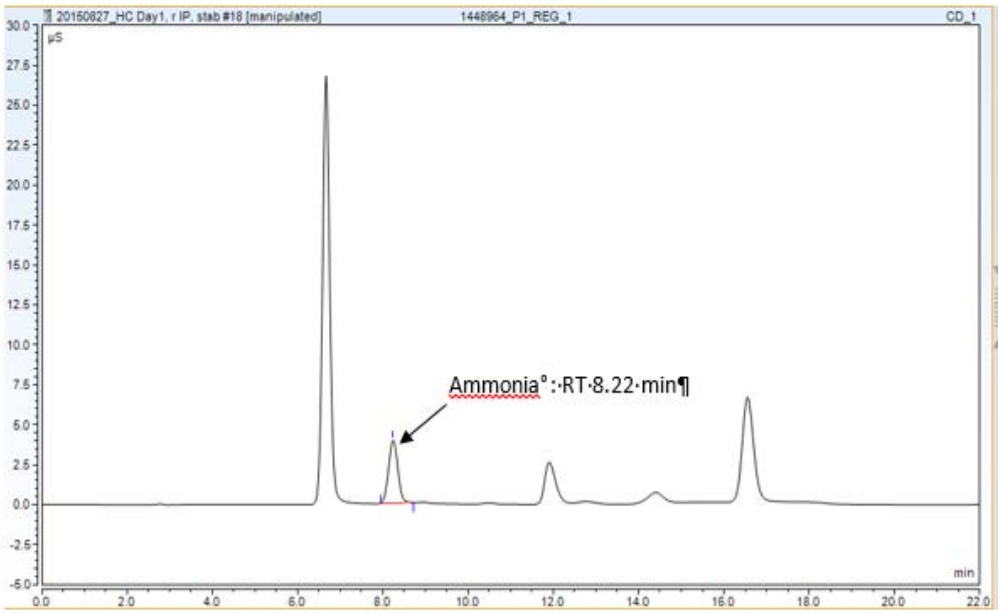


Figure 1: Example Chromatogram

1.2.5. Retention Time

The typical retention time obtained during validation for ammonia is 8.22 minutes.

1.2.6. System Suitability

A control solution (STD 1) is used to assess instrument performance. Peak width at 50% is selected to control peak resolution and to monitor the injection and the column performance and peak area is selected to monitor instrumental sensitivity. The acceptance criteria are provided in Table 2.

Table 2: System Suitability Acceptance Criteria

	Peak Width (50%)	**Area**
Lower limit	Average - 3S	N/A
Upper limit	Average + 3S	N/A
Acceptance criteria	0.126 min ≤ x ≤ 0.374 min	≥ 0.116 µS/min

N/A = Not applicable

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1.3. Validation

1.3.1. Specificity (Selectivity)

Selectivity was demonstrated for aerosol collected under the HCI and ISO smoking regimes and analytical blank by adding 3 different amounts of a spiking solution and evaluating the resulting signal.

The selectivity of target compound in the matrices was evaluated by adding at least 3 different amounts of spiking solutions to the matrix and comparing the response of the homogenized aerosol extract to the analyte-spiked homogenized aerosol extract. The addition of different volumes of a spiking solution to the matrix resulted in an increase of the peak area response for ammonia.

Table 3: Expected concentrations per dilution and spiking levels for ammonium

Concentration level	3R4F [µg/mL]	THS [µg/mL]
Nominal concentration	3.0	1.9
2-fold dilution	1.5	1.2
1.1-fold dilution	2.7	1.8
Spiking 1	3.3	2.4
Spiking 2	3.5	2.9
Spiking 3	3.8	3.3
Spiking 4	—	3.8

Selectivity of ammonia was evaluated by comparing the response of blank (0.05N H_2SO_4) and smoked blank to the lowest calibration level of ammonia. Response of ammonia in blanks (0.05N H_2SO_4) and smoked blanks was lower than 20% compared to the response of ammonia in the lowest calibration standard.

1.3.2. Linearity

The response function was demonstrated for a range of concentrations intended to be used routinely under repeatability conditions for ammonia.

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1.3.2.1. Regression Parameters

The linearity of the response function was demonstrated for the range of concentrations by injecting calibration standards covering the target concentration range.

The linearity of response functions was assessed using the range of concentrations shown in Table 4. The deviation of the determined concentration from the back calculated concentrations (residuals) were within ± 15% for the lowest calibration level and within ± 10% for the other calibration levels. Out of seven STD levels, six STDs were within the acceptance criteria including lowest and highest standard using the selected regression model (quadratic regression with 1/x weighing).

Table 4: Regression Parameters

Compound	**Range Tested**	**Factor x**	**Factor x^2**	**Intercept**	**r^2**
Ammonia	0.189 – 3.778 µg/mL				
Repeatability		6.96 E-0	-5.75 E-02	2.42 E-02	0.9992
Intermediate Precision		6.95 E-01	-5.58 E-02	2.80 E-02	0.9994

r^2 = coefficient of determination

1.3.2.1.1. Calibration Curve Parameters Under Repeatability Conditions

Calibration curve parameters under repeatability conditions using the selected regression model (quadratic regression with 1/x weighing) were evaluated. The deviation of the lowest determined concentration from the back calculated concentrations met the same criteria as above. The average factor x, factor x^2, intercept, and coefficient of determination (r^2) for ammonia and instrument are provided in Table **4**. The acceptance criteria were met in all cases

1.3.2.1.2. Calibration Curve Parameters Variability Under Intermediate Precision Conditions

The variability of the calibration curve parameters under intermediate precision conditions was evaluated. The calibration curves were obtained by varying the 1) preparation of primary standard (STD) and working STD dates 2) analytical laboratory technician and 3) injection date. The goal of this evaluation was to provide the laboratory with information regarding the variability of the calibration curves under intermediate precision conditions. Results are provided in Table **4**.

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1.3.2.2. Sample Calibration Plots

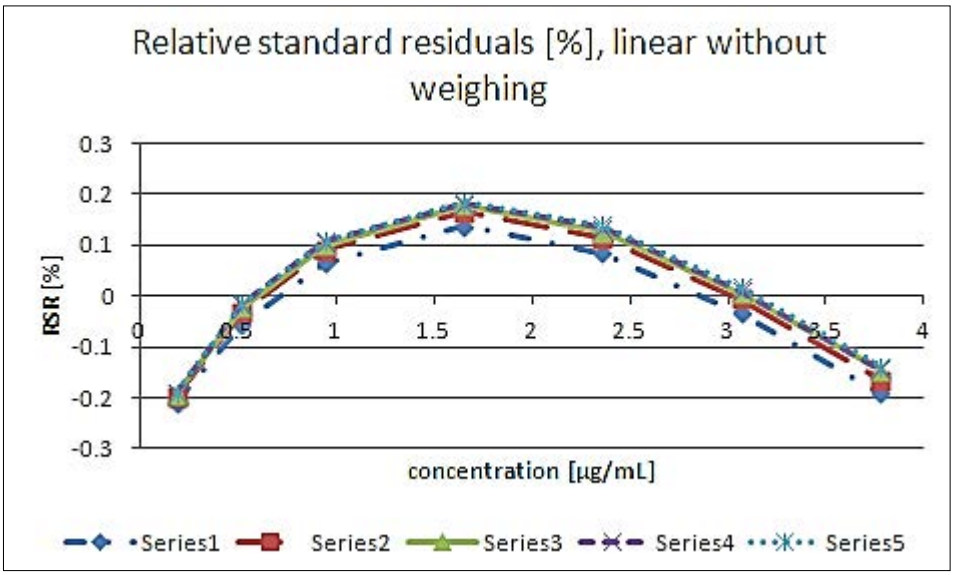


Figure 2: Relative Standard Residuals (%), Linear Without Weighing Calibration Plot

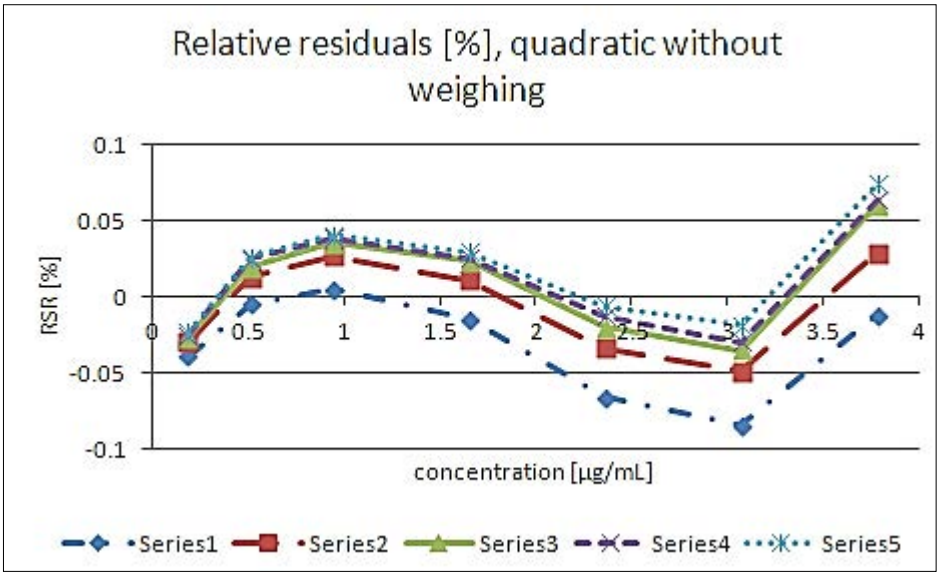


Figure 3: Relative Residuals (%), Quadratic Without Weighing Calibration Plot

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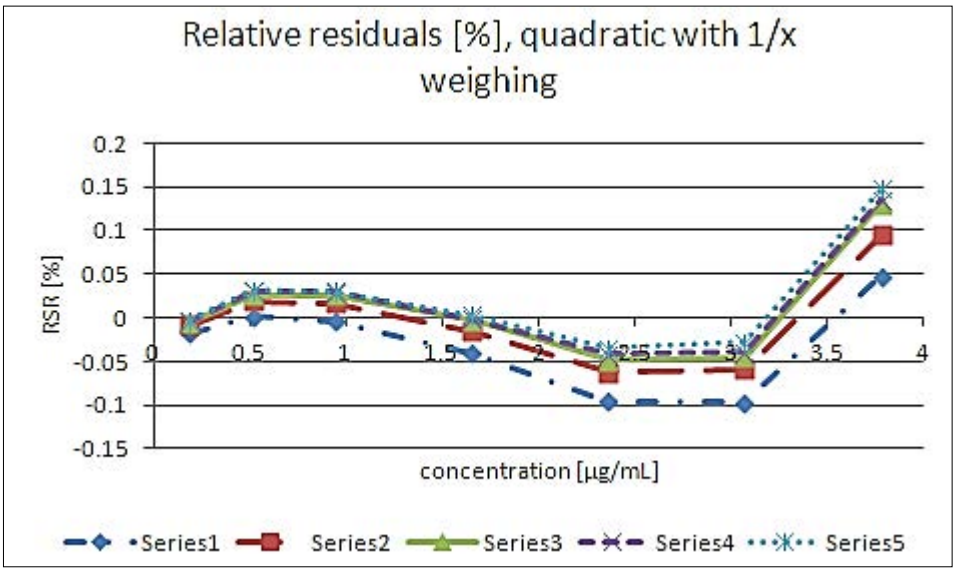


Figure 4: Relative Residuals (%) Quadratic with 1/x Weighing Calibration Plot

1.3.3. Range

The range is the interval between the upper and lower levels that have been demonstrated to be determined using the accuracy profiles methodology.

The intersection point of the beta-expectation tolerance intervals with the acceptance intervals corresponds to the smallest quantity measurable with the desired accuracy. The corresponding concentration of the intersection point represents the lower working range limit (LWRL) in the matrix (see Figure 5).

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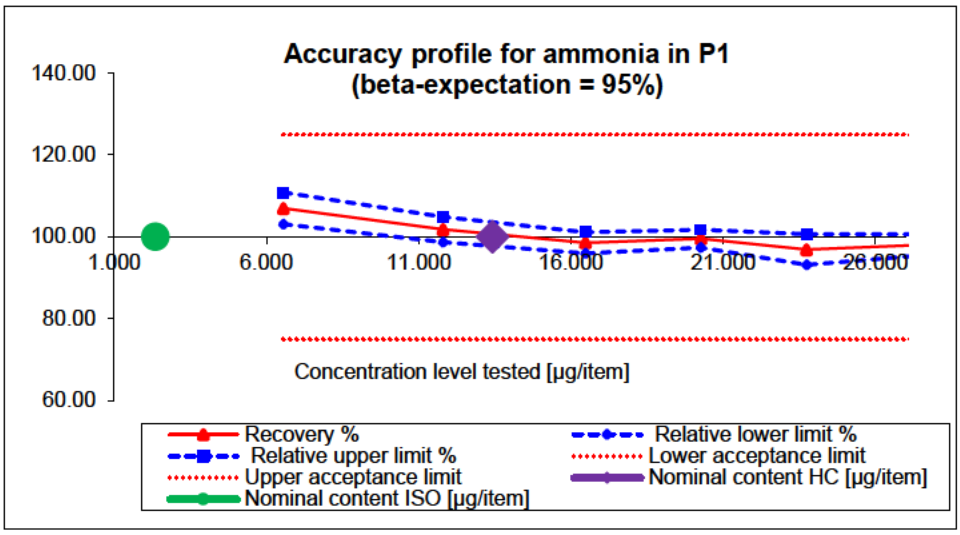


Figure 5: Accuracy Profile for Ammonia

The working range for ammonia is provided in Table 5.

Table 5: Working Range

Compound	Working Range (µg/item) HCI	Working Range (µg/item) ISO
Ammonia (3R4F)	16.3-43.1	9.79-25.8
Ammonia (THS)	6.56-27.1	6.56-27.1

1.3.4. Accuracy and Precision

1.3.4.1. Repeatability

Within-instrument repeatability was assessed by evaluation of the intra-assay precision of the method under the same operating conditions using a short period of time (same sequence injected on the same day). All values for the coefficient of variation were well within the acceptance range. Results for repeatability limits are given in Table 6.

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Table 6: Within-Instrument Repeatability (Same Day)

Compound	3R4F (µg/cig)				THS (µg/item)			
	Mean	r	std	CV	Mean	r	std	CV
Ammonia	32.94	1.53 E-02	2.69 E-01	0.82	14.190	1.53 E-02	0.269	0.77

r = correlation coefficient, std = standard deviation, CV = coefficient of variation

Table 7 provides the results of repeatability limits for the whole process in aerosol matrices at nominal content, which was determined by injecting each aerosol collection replicate once (one single analytical replicate), collected on 4 different days under HCI and ISO smoking regimens. Only intra-day variability was considered for estimation of repeatability limits for the whole process.

Table 7: Repeatability Limits for Whole Process

Compound	3R4F (µg/cig)					THS (µg/item)				
	Mean	r	std	CV	CD95%	Mean	r	std	CV	CD95%
Ammonia (HCI)	30.8	2.83	1.00	3.26	3.73	13.4	0.966	0.341	2.54	1.36
Ammonia (ISO)	10.4	0.78	0.276	2.65	1.58	2.36	1.14	0.402	17.01	0.751

r = correlation coefficient, std = standard deviation, CV = coefficient of variation, CI 95% = 95% confidence interval, CD= critical difference

1.3.4.2. Intermediate Precision Limit

The intermediate precision limit was evaluated at nominal content (whole process) by injecting once each smoking replicate for each matrix (1 single analytical replicate) collected under the HCI and ISO smoking regimes on different days, considering both intra-day and inter-day variability. The varying parameters for the estimation of intermediate precision limit were the aerosol collection day, smoking machine, analytical lab operators and STD solutions preparation. Results are given in Table 8.

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Table 8: Intermediate Precision Limit at Nominal Content (Whole Process)

Compound	3R4F (µg/cig)					THS (µg/item)				
	Mean	IP	std	CV	CD95%	Mean	IP	std	CV	CD95%
Ammonia (HCI)	30.8	4.46	1.58	5.13	3.73	13.4	1.60	0.564	4.20	1.36
Ammonia (ISO)	10.4	1.72	0.607	5.83	1.58	2.36	1.24	0.438	18.53	0.751

IP = intermediate precision, std = standard deviation, CV = coefficient of variation, CD 95% = 95% critical difference

1.3.4.2.1. Intermediate Precision Limit at Different Concentrations

Coefficients of variation were determined for repeatability and intermediate precision of the analytical method over a wide range of concentrations. All coefficients of variation for repeatability and intermediate precision were lower than the acceptance criterion 8% and 16% coefficients of variation for repeatability and intermediate precision respectively (0.33% for 3R4F and 1.23% for THS).

All coefficients of variation values for intermediate precision for ammonia were within the acceptance range.

1.3.4.3. Reproducibility

No other laboratory is currently using this method.

1.3.4.4. Expanded Combined Uncertainty

The uncertainty of concentration determination of ammonia in the sample is in Table 9. The minimal and maximal concentrations in 3R4F and THS are reported in Table 10.

Table 9: Combined Uncertainty (Standard Deviation)

	3R4F	THS
Ammonia	1.6% – 8.9%	1.6% – 8.9%

1.3.5. Limit of Detection (LOD)/Limit of Quantitation (LOQ)

The LOD and Lower Limit of Quantitation (LLOQ) were both calculated in terms of the standard deviation of the lowest calibration level as determined during validation (5 injections over different days by at least 2 different operators using different calibration standard preparations derived from different primary stock solution preparations).

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$$LOD = 3 \times SD_{level1}$$

$$LLOQ = 10 \times SD_{level1}$$

The LLOQ was found to be lower than the concentration of the lowest calibration level for all compounds. Detailed results are provided in Table 10.

Table 10: Limits of Detection and Quantitation for Ammonia (HCI and ISO Regimes)

	3R4F (µg/cig)			THS (µg/item)		
	LOD	**LLOQ**	**ULOQ**	**LOD**	**LLOQ**	**ULOQ**
HCI	0.0172	0.0575	50.4	0.0103	0.0345	30.2
ISO	0.0103	0.0345	30.2	0.0103	0.0345	30.2

ULOQ = upper limit of quantitation (highest calibration level)

1.3.6. Robustness

The parameters were evaluated for robustnes are available in Table 11.

Table 11: Robustness of Method

Parameter	Recommendation/Comment
Trapping efficiency (on third impinger connected behind first 2 impingers)	No significant difference was observed for the trapping efficiency for ammonia for the first 2 impinger solutions obtained during aerosol collection. Recoveries for the trapping efficiency for first 2 impingers were within the acceptance limits for all matrices tested. The acceptance criteria for the trapping efficiency (recoveries should be ≥ 90%) for ammonia was fulfilled. In routine, the aerosol collection recommended to be performed with 2 impingers.
Extraction time (± 10 min)	No significant differences were found in between 20, 30, and 40 minutes of extraction times. Results of recoveries for 20 and 40 minutes extraction time were within the acceptance limits as recoveries for the 30 minute extraction time.

table continues

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Parameter	Recommendation/Comment
	The acceptance criteria of extraction time (recoveries should be ≥ 90%) for ammonia were fulfilled. In routine, it is recommended to extract the Cambridge pad for 30 ± 5 minutes in the impinger solution.
Variation of H_2SO_4 concentration in extraction solution (varying the rinsing volume by ± 1 mL)	No significant differences in results were found in the 9 mL, 10 mL, and 11 mL extraction solution volumes. Results of recoveries for 9 mL and 11 mL extraction solution volumes were within the acceptance limits as recoveries for the 10 mL extraction solution volume. The acceptance criterion of the extraction solution volume for ammonia was fulfilled. In routine, it is recommended to extract the Cambridge pad with 10 mL of extraction solution.
Testing of analytical columns Column -1 with pre-column column: 014-27-082/n° series: 004170 Pre-column:014-27-054/n° series: 004630 Column -2 with pre-column column: 014-27-082/n° series: 004065 Pre-column: 014-27-054/n° series: 004482 Column -3 with pre-column column: 014-27-082/n° series: 004312 Pre-column: 014-27-054/n° series: 004624	No significant differences in results were found among the different columns used for analysis. Results of recoveries for the different columns were within the acceptance limits when compared with one another. The acceptance criterion of comparison of different columns for the quantification of ammonia was fulfilled.

table continues

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Parameter	Recommendation/Comment
Simulation of a leak (Decreasing the flow of the eluent from 0.36 mL/min to 0.35 mL/min)	No significant differences in results were found between the 2 different flows of eluent used for the analysis. The retention time using a flow rate of 0.35 mL/min was shifted from 9.05 min to 9.21 min for ammonia. However, the shift of the retention time did not impact the quantitaion of ammonia in the different matrices tested, which leads to the conclusion that even with a small leak, ammonia can be quantitated. Results obtained with a flow rate of 0.35 mL/min were comparable with those obtained with the reference conditions of 0.36 mL/min. The acceptance criterion of simulation of leak for the quantification of ammonia was fulfilled.

1.3.7. Stability of Solutions

The stability of the primary STD solution, working STD solutions and homogenized aerosol extract solutions was evaluated in the refrigerator at ~4°C. The individually prepared STD solutions STD 1, STD 4, STD 7, the THS aerosol matrix and the ammonia primary stock solution are stable for up to 30 days refrigerated at ~4°C. Because of a strong increasing trend in the result of the THS matrix throughout the tested time period of 30 days, the THS aerosol matrix is considered unstable when kept refrigerated at ~4°C and should be injected on the day of aerosol collection.

1.3.7.1. Stability of Standard Solutions and Homogenized Aerosol Extract Solutions in the Autosampler at ~10°C

The stability of STD and aerosol extract solutions on the autosampler at ~10°C was evaluated using pierced vials by preparing STD 1, STD 4, STD 7 and 3R4F, and THS1 matrices obtained under the HCI regime. The STD and THS aerosol extract solutions are stable for up to 72 hours and the THF aerosol extract solution is stable for up to 48 hours when kept in the autosampler at ~10°C.

1.3.7.2. Stability of 0.05N H_2SO_4 and 0.1N H_2SO_4 at Room Temperature

The solution 0.1N H_2SO_4 is stable for up to 20 days and 0.05N H_2SO_4 is stable for up to 30 days when kept at room temperature.

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2. APPROVALS

	Name	Role	Signature	Date
Author (Validation Report)	Iris Hofer	Scientist		22.7.2016
Owner	Serge Maeder	Director PMI Testing Laboratories Governance		26.7.1.2016
QA Review	Florence Kapp	QA Officer Audit		28.7.2016

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