QUANTITATIVE ANALYSIS OF N-NITROSODIMETHYLAMINE IN TOBACCO, TOBACCO PRODUCTS, FIBRE-BASED MATRICES AND TOBACCO DERIVED PRODUCTS WITH (b) (4)

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Purpose

To determine the concentration of N-nitrosodimethylamine (NDMA) in tobacco, tobacco products, fibre-based matrices and tobacco derived products (also called Purified Products) with (b) (4) .

Applies to

APS

General information

Principle of the method

Following the addition of (b) (4) to dry sample, NDMA is extracted from the sample matrix with (b) (4) . The (b) (4) phase of the extract is then centrifuged and transferred to a vial. Separation and detection are performed with (b) (4) through a (b) (4) . The calculations of concentrations are performed using the (b) (4) system software and (b) (4) The minimal capacity per instrument and person is (b) (4) single samples/week.

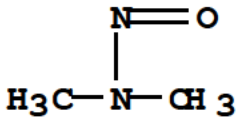

Figure 1. Chemical structural formula for NDMA.

Note: All reference documents and additional information stated "available upon request" are in Swedish. They are available upon request but need to be translated into English first.

(b) (4)

(b) (4)

Literature references

(b) (4)

Internal reference documents (available upon request)

(b) (4)

Risk assessment and safety instructions

Summarised risk assessment of the method

(b) (4)

(b) (4)

Substances hazardous to the environment

NDMA and (b) (4)

Flammable substances

(b) (4)

Mixtures containing flammable solvents are usually also classified as flammable. Internal procedures for handling flammable substances and mixtures must be followed.

Waste disposal

(b) (4)

Equipment

Apparatus

(b) (4)

(b) (4)

Laboratory utensils

(b) (4)

Chemicals, reagents and solvents

(b) (4)

Check samples

(b) (4)

Preparation of standards

(b) (4)

(b) (4)

(b) (4)

(b) (4)

Sample handling

Sample storage and preparation

Samples are to be stored and prepared in accordance with (b) (4) ” (available upon request).

Sample amount

The minimum amount of sample needed for duplicate analyses and re-analysis is (b) (4) g. The minimum amount of sample for performing a simple analysis is (b) (4) g depending on the type of the sample.

Analysis

Calibration and verification of apparatus

(b) (4)

(b) (4)

Sample stability

Prepared sample extracts in vials are stored in a refrigerator until they are analysed on (b) (4) (b) (4). Extracts have a shelf life of (b) (4) in the refrigerator.

Analytical procedure

(b) (4)

Special instructions

(b) (4)

Documentation

(b) (4)

Data

Collection and storage of data

(b) (4)

Calculations

(b) (4)

Confirmation

(b) (4)

Quality assurance

Standard curve criteria

(b) (4)

Control Chart

(b) (4)

(b) (4)

Actions when exceeding the alarm limit or action limit

(b) (4)

Duplicate and triplicate samples

(b) (4)

A response greater than the highest calibration standard

(b) (4)

Reporting of analysis results

(b) (4)

Revision history

27/02/2018

(b) (4)

06/07/2017

(b) (4)

03/05/2017

(b) (4)

02/07/2014

(b) (4)

Person responsible

Director APS

Validation

Validation report

(b) (4)

Selectivity

(b) (4)

(b) (4)

(b) (4)

Cross talk

(b) (4)

Carry-over

(b) (4)

Repeatability

(b) (4)

Precision within the laboratory

(b) (4)

Reproducibility

(b) (4)

Accuracy

(b) (4)

Bias from accuracy

(b) (4)

Limit of detection (LOD)

(b) (4)

Limit of quantification (LOQ)

(b) (4)

LOD and LOQ for (b) (4)

(b) (4)

Linearity

(b) (4)

Linearity for (b) (4)

(b) (4)

Measurement range

(b) (4)

Robustness

(b) (4)

Stability

(b) (4)

Measurement uncertainty

(b) (4)

Assessment of matrix effects and extraction yield

(b) (4)

(b) (4)

Conclusion

02/02/2018: (b) (4)

Appendices

(b) (4)

Appendix 1. Analysis on (b) (4)

(b) (4)

(b) (4)

(b) (4)

Appendix 2. Analysis on (b) (4)

(b) (4)

(b) (4)

(b) (4)

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