

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

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## Purpose

To determine the concentration of the mycotoxins: (b) (4)

(b) (4) cut tobacco, fiber-based matrices and tobacco derived products (also called purified products) with (b) (4)

## Applies to

APS

## General information

### Principle of the method

Mycotoxins are extracted from the sample matrix to a mixture of (b) (4) after the addition of internal standard solution. The extract is diluted with a buffer (b) (4) and then cleaned-up and enriched through a solid phase extraction (SPE) with an (b) (4) (b) (4). This SPE procedure is automated through the use of an (b) (4) and the sample is ultimately transferred automatically to a vial, whereupon sample preparation is complete. Separation and quantification are performed with (b) (4) through a microbore (b) (4) (b) (4). See **Figure 1** for the structural formula of mycotoxins.

The calculations are performed using the (b) (4) software and (b) (4). The capacity per instrument and person is (b) (4) single samples/week.

(b) (4)




**Figure 1.** Chemical structure formula for the five mycotoxins that are quantified in this method.

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.

#### **Method scope, measurement range and measurement uncertainty**


##### Scope

(b) (4)

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##### Measurement uncertainty

(b) (4)

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**Literature references**

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Internal reference documents (available upon request)

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### Risk assessment and safety instructions

#### Summarized risk assessment

The safety data sheet for mycotoxins is kept in the method description binder.

Particular care should be taken when working with mycotoxins. All work with mycotoxins, regardless of concentration, (b) (4)

### Hazard and precautionary statements

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## Equipment

### Apparatus and laboratory equipment

(b) (4)



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#### Chemicals, reagents, and solvents

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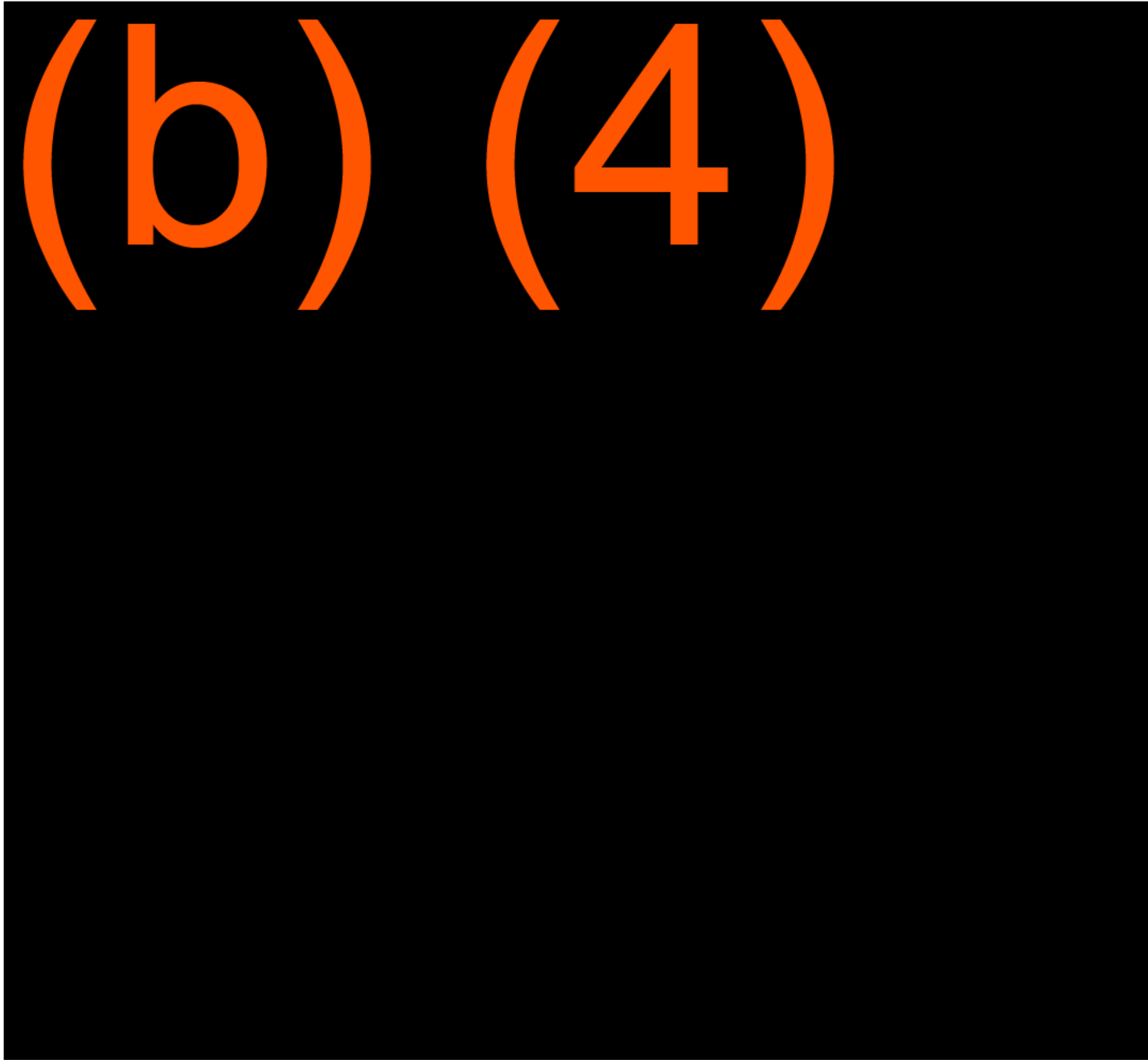
**Tobacco for matrix-matched calibration standards**

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**Preparation of standards**

(b) (4)





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(b) (4)

**Internal standard stock and standard solutions**

(b) (4)



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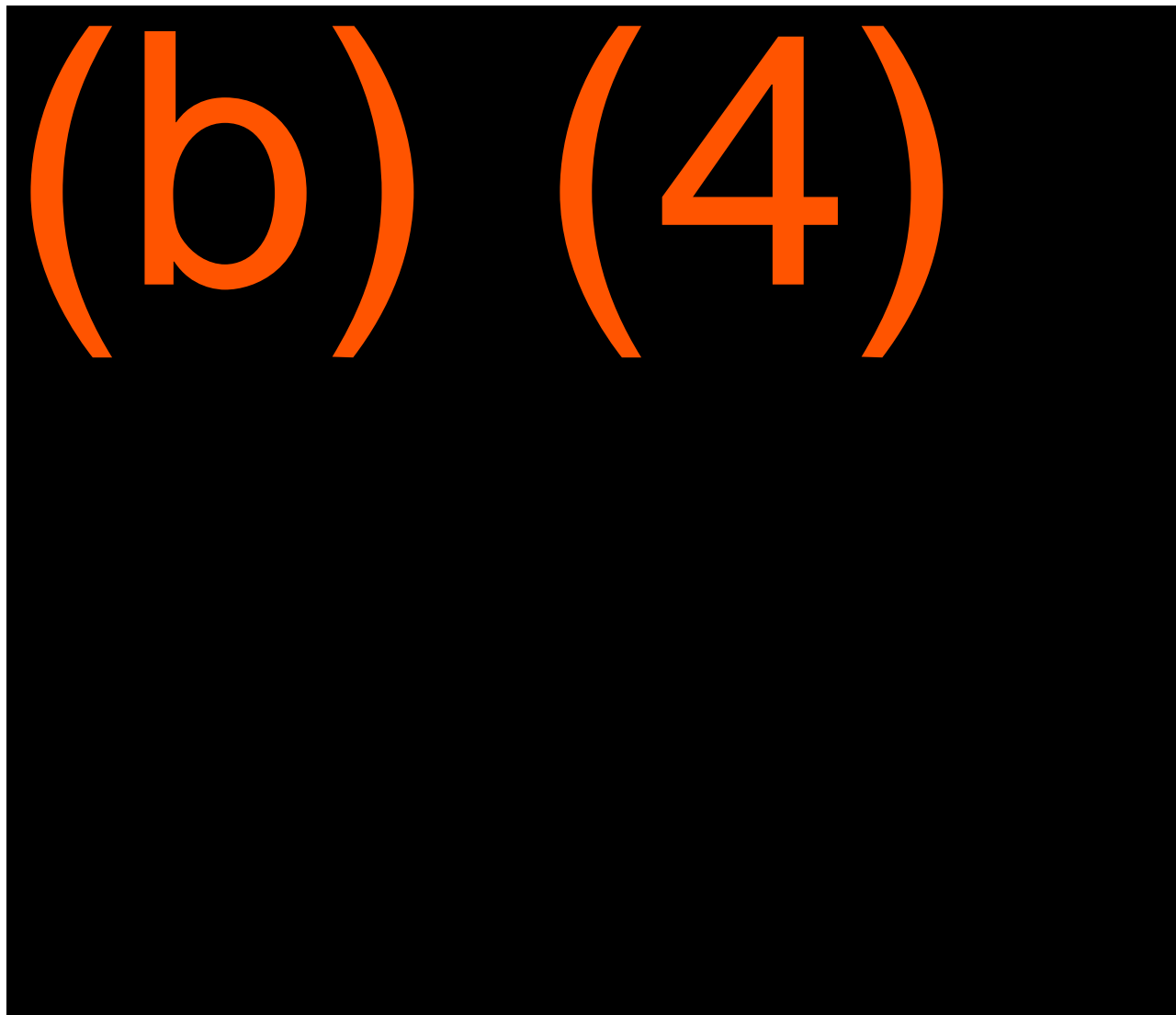
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**Calibration standard solutions**







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## Preparation of other solutions

(b) (4)

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## Sample handling

### Sample storage and preparation

Samples should be stored in accordance with INS “Sample Preparation” (available upon request).

### Sample amount

The minimum amount of sample needed for duplicate analyses is (b) (4) g and (b) (4) g for re-analysis.

## Analysis

### Calibration and verification of apparatus

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**Special instructions**

(b) (4)

**Documentation**

(b) (4)

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## Data

### Collection and storage of data

(b) (4)

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### Calculations

(b) (4)

[Redacted text block]

### Quality assurance

(b) (4)

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Confirmation

(b) (4)

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Duplicate and triplicate samples

(b) (4)

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**If the response in a sample is higher than the highest standard**

(b) (4)

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**Reporting of analysis results**

(b) (4)

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**Revision history**

2013 March:

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[Redacted]

2014-October:

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2016-February:

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2016-July

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2017-October

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2018-February

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**Person responsible**

Director APS.



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## Validation

(b) (4)



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### Repeatability

(b) (4)

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**Precision within the laboratory**

(b) (4)

**Reproducibility/proficiency testing (reports available upon request)**

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**Bias from accuracy data**

(b) (4)

**Limit of detection (LOD) and Limit of quantification (LOQ)**

(b) (4)

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**Linearity of the standard curve (curve fitting)**

(b) (4)





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#### **Robustness**

(b) (4)

#### **Measurement range and measurement uncertainty**

(b) (4)

#### **Assessment of matrix effects and extraction yield**

(b) (4)

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**Matrix effect**

(b) (4)

**Yield**

(b) (4)

**Process efficiency**

(b) (4)



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**Additional validation for the implementation of** (b) (4)

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**Additional validation for the implementation** (b) (4)

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#### Conclusion

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#### Appendices

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**Appendix 1 – Analysis on instrument** (b) (4)

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Quality assurance

(b) (4)

**Appendix 2 - Analysis on instrument (b) (4)**

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Data (b) (4)

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**Appendix 3 – Analysis instrument** (b) (4)

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Data (b) (4)

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(b) (4)