

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

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## Purpose

To determine the level of humectants (b) (4) in tobacco products, fibre-based matrices (also called purified products) and tobacco derived products.

The method is also used to determine the level of (b) (4) in tobacco, tobacco products and fibre-based matrices (excluding ZYN products/samples due to chromatographic interference).

The method is using (b) (4).

## Applies to

APS

## General information

### Principle of the method



The capacity is about (b) (4) single samples per week.

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

The method is used for quantitative analysis of humectants (b) (4) in tobacco products, fibre-based matrices and tobacco derived products.

The method is also used for the quantitation of (b) (4) in tobacco, tobacco products and fibre-based matrices.

**Please note!** The method is not used for the analysis of (b) (4) in ZYN as a product ingredient interferes chromatographically.

(b) (4)

#### Literature references

(b) (4)

#### Internal reference documents (available upon request)

(b) (4)

#### Risk assessment and safety instructions

##### Summarised risk assessment

When working with the method, use the customary personal protective equipment.

##### Risk assessment

The risk assessment is performed 12/07/2017.

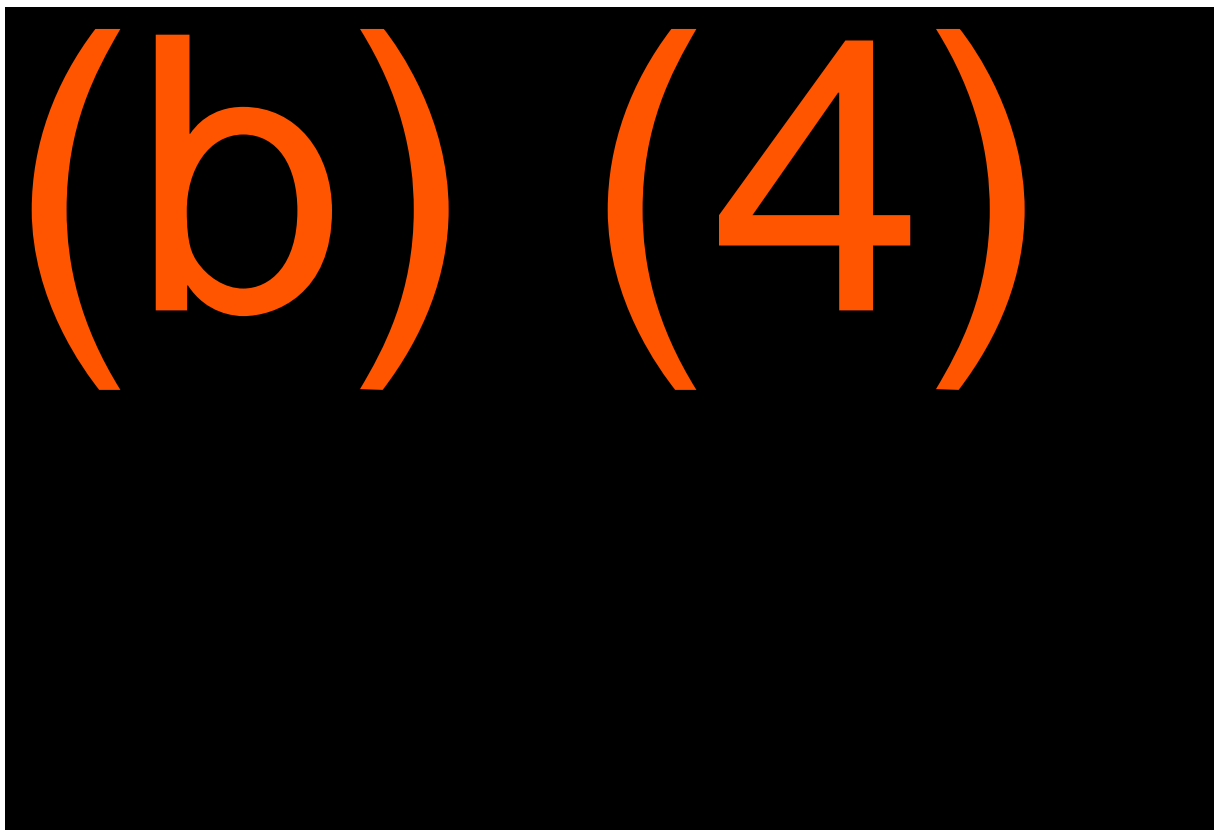
#### Hazard and precautionary statements

(b) (4)



## **Equipment**

### **Apparatus and laboratory utensils**



(b) (4)

**Chemicals, reagents and solvents**

Certificate of standards is saved in the instrument binder.

CAS number

(b) (4)

**Check samples and reference materials**

(b) (4)

## Preparation of standards

(b) (4)



(b) (4)

**Preparation of other solutions**

(b) (4)

## Sample handling

### Sample storage and preparation

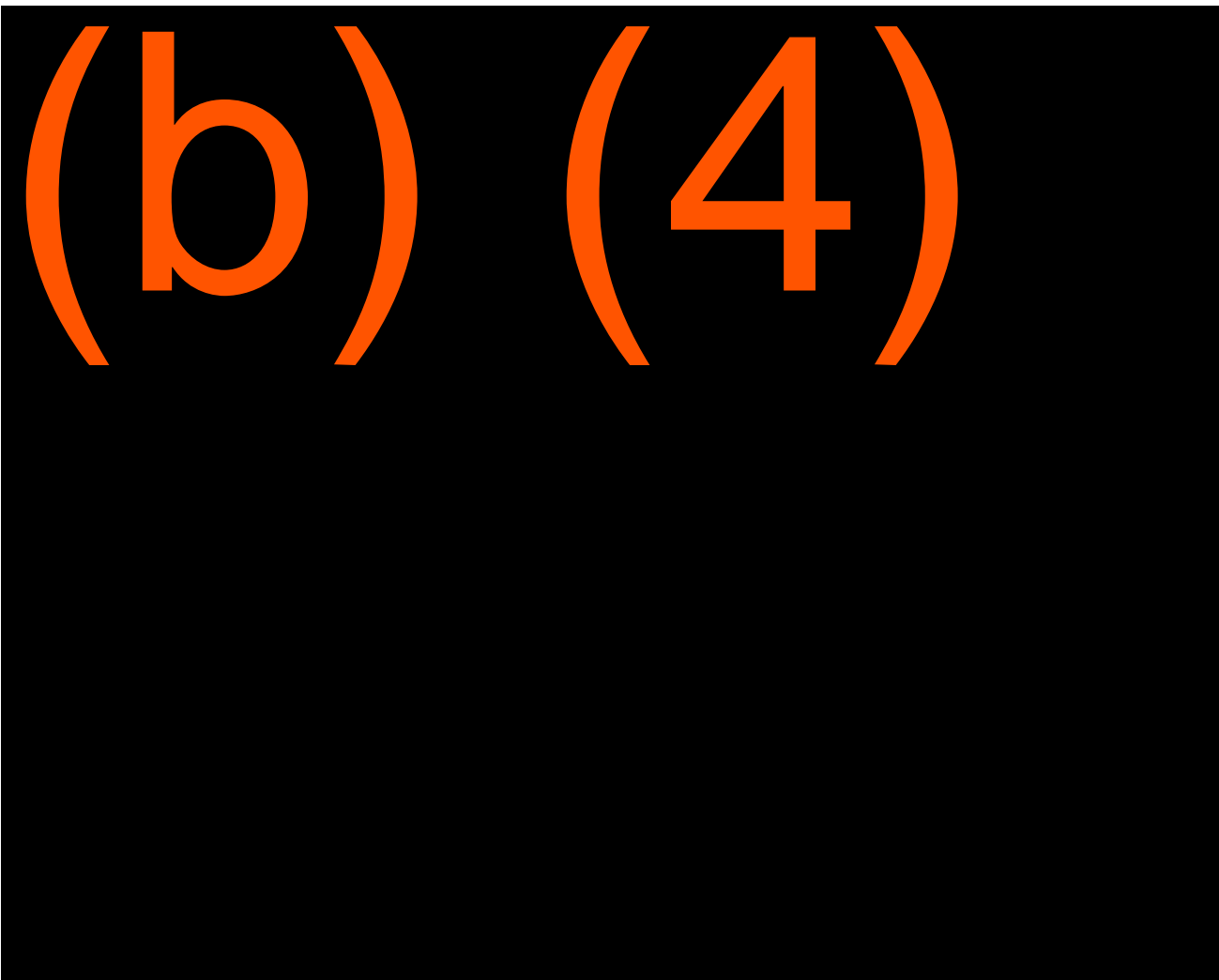
Samples should be stored and pretreated in accordance with INS “Sample Preparation”.

### Sample amount

The minimum amount for performing an analysis is (b) (4) g

## Analysis

### Calibration and verification of apparatus



### Sample stability

Ready prepared samples that are filtered into vials and stored in a refrigerator remain stable for up to (b) (4) days.

### Analytical procedure

(b) (4)

### Documentation

(b) (4)

### Chemstation

(b) (4)

(b) (4)

#### Raw data binder

A printout of import file is saved in raw data binder.

The names of incoming QC batches, dates and signatures must be recorded in the printed import file with raw data.

#### Log book

The list at the first page of the log book details the information to be entered.

(b) (4)

#### Instrument binder

A (b) (4) service is documented in the instrument binder.

#### Data

##### Collection and storage of data

For a detailed description of the preparation of sample lists and data files see (b) (4)  
 (available upon request).

#### Calculations

(b) (4)

(b) (4)

**Quality assurance**

(b) (4)

(b) (4)

If the response of a sample is higher than the highest standard

(b) (4)

Reporting of analysis results

(b) (4)

Revision history

22/11/2010: (b) (4)

06/12/2012

26/06/2015:

22/02/2018:

(b) (4)

**Responsible person**

Director APS

## Validation

### Validation report

(b) (4)



(b) (4)

**Specificity**

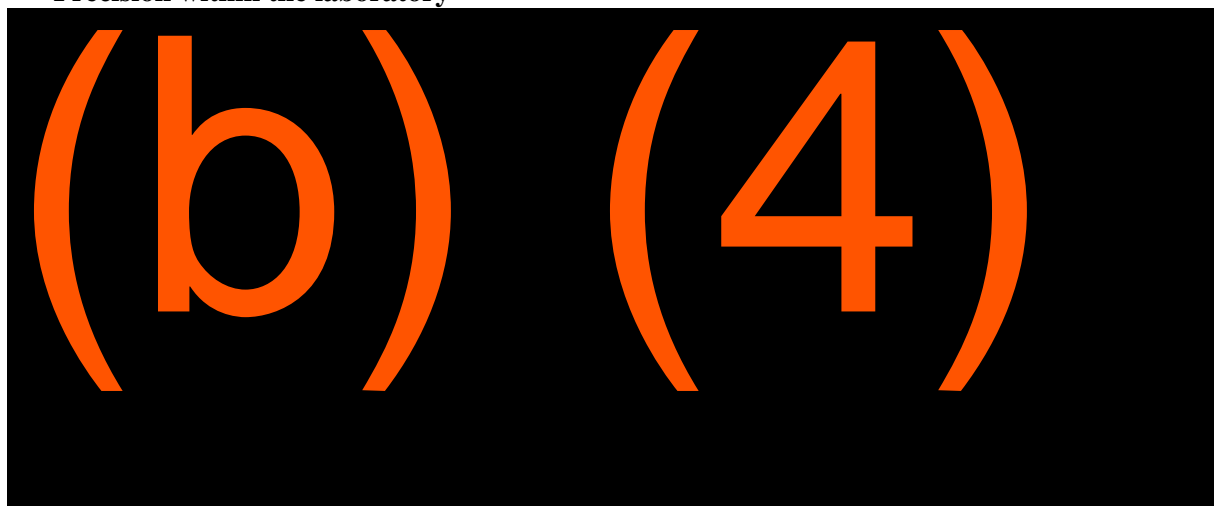
(b) (4)

(b) (4)

### Repeatability



### Precision within the laboratory



### Reproducibility/Sampling comparison



(b) (4)

**Accuracy**

(b) (4)

(b) (4)

**Extraction yield (Recovery)**

(b) (4)

**Limit of detection (LOD)**

(b) (4)

**Limit of quantitation (LOQ)**

(b) (4)

(b) (4)

#### Linearity

(b) (4)

#### Robustness

(b) (4)

(b) (4)

#### Measurement uncertainty

(b) (4)

#### Conclusion

The method has been used for analysis of sugar, humectants and (b) (4) at APS since the initial validation in 2005.

(b) (4)

### Appendix 1

(b) (4)