SLOVENSKI STANDARD
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Elektronske cigarete in e-tekočine - Ugotavljanje doslednosti pri dovajanju nikotina v določenem zaporedju vdihavanja pri več e-cigaretah enakega tipa

Electronic cigarettes and e□liquids - Determination of nicotine delivery consistency over defined puff sequences of a number of e-cigarettes of identical type

Elektronische Zigaretten und Liquids für elektronische Zigaretten - Bestimmung der Konsistenz der Nikotinabgabe über definierte Puffsequenzen einer Anzahl von E-Zigarette identischen Typs

Ta slovenski standard je istoveten z: **prEN 17634**

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65.160	Tobak, tobačni izdelki in oprema	Tobacco, tobacco products and related equipment

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Electronic cigarettes and e-liquids - Determination of nicotine delivery consistency over defined puff sequences of a number of e-cigarettes of identical type

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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European foreword

This document (prEN 17634:2021) has been prepared by Technical Committee CEN/TC 437 “Electronic cigarettes and e-liquids”, the secretariat of which is held by AFNOR.

This document is currently submitted to the CEN Enquiry.

1 Scope

This document specifies the method for the determination of nicotine delivery consistency from several e- cigarettes of identical type.

This document:

— defines the equipment to be used;

— specifies the preparation of the e-cigarettes for testing;

— specifies the aerosol collection process;

— specifies the analytical method.

Suitable sampling procedures are described for obtaining results from within a single production batch, as well as for sampling across batches.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 17375, *Electronic cigarettes and e-liquids - Reference e-liquids*

ISO 20768, *Vapour products — Routine analytical vaping machine — Definitions and standard conditions*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
aerosol
system of colloidal particles suspended in gas by the use of an e-cigarette

Note 1 to entry: Vapour is a generally accepted (but scientifically incorrect) term for aerosol.

3.2
clearomizer
e-liquid reservoir with in-built atomizer

3.3
coil
resistive component of the atomiser

Note 1 to entry: Made of metal, ceramic, or other resistive materials.

3.4
electronic cigarette
e-cigarette
product, that vaporises e-liquid to generate an inhalable aerosol carried by air drawn through the device by the user

Note 1 to entry: Electronic cigarette is also referred to as e-cig, vapour product, personal vaporizer or ENDS/ENNDS.

Note 2 to entry: Electronic cigarette differs from tobacco products in that they do not contain tobacco.

3.5
e-liquid
base liquid, which may or may not contain nicotine and/or additives, intended for transformation into an aerosol by an electronic cigarette

3.6
e-liquid cartridge
e-liquid container that can be loaded directly into an e-cigarette, which can be disposable

3.7
e-liquid vaporized mass
EVM
mass of e-liquid transferred from the vapour product to the aerosol

3.8
identical e-cigarettes
e-cigarettes made according to the same technical specifications and with the same brand and model name

3.9
nicotine
(S)-3-(1-methyl-2-pyrrolidinyl) pyridine, conforming to the Chemical Abstracts Service nomenclature under No CAS: 54-11-5

3.10
open system
electronic cigarette where the user fills a reservoir with e-liquid

3.11
sequence
defined number of puffs for aerosol generation

3.12
vaping
action of generating an aerosol with an airflow from an electronic cigarette

4 Principle

The test e-cigarettes are vaped on a routine analytical vaping machine that meets the requirements of ISO 20768, with collection of sequences of aerosol matter. If used, the consistency of the laboratory vaping process and subsequent analytical procedures are controlled by using a standardized clearomizer or a reference clearomizer together with a standardized e-liquid as specified in EN 17375. The collected aerosol matter is used for the subsequent determination of nicotine. The determined amount of nicotine

per sequence is used for the statistical determination of nicotine delivery consistency. Relevant ISO methods are currently under development. Once available, these shall be used.

5 Apparatus

Use the apparatus as defined by the ISO method for nicotine determination in aerosol. As long as this standard is not published use the Normal laboratory apparatus and, in particular, the following items listed in Annex A.

6 Sampling of test e-cigarettes

Measurements shall be performed across at least 2 e-cigarettes per batch and at least 10 e-cigarettes in total. If the purpose of the testing is to obtain data on the consistency of nicotine delivery within a production batch, or across several production batches, the e-cigarettes shall be randomly taken from the production batch(es).

7 Generation and collection of total aerosol matter

7.1 E-cigarette preparation for analytical vaping

7.1.1 General

For the overall protocol for the determination of the consistent nicotine delivery, at least 12 test e-cigarettes are needed: 2 for the determination of the required number of puffs and 10 for the determination of the consistent nicotine delivery. It is recommended to prepare at least 2 more e-cigarettes in the same way for redundancy in case of any problems occur during testing. For the determination of the required numbers of puff per sequence 2 additional e-cigarettes are needed.

7.1.2 Disposable e-cigarettes

For testing disposable e-cigarettes, a fresh e-cigarette shall be taken from an un-opened pack.

7.1.3 Rechargeable e-cigarettes

For any e-cigarettes equipped with rechargeable batteries ensure that the battery is fully charged following the instructions for use.

7.1.4 Refillable e-cigarettes

For any e-cigarettes vaporizing liquids supplied in pre- filled e-liquid cartridges a new e-liquid cartridge shall be taken from an un-opened pack and inserted into the e-cigarette following the instructions for use.

Any e-cigarettes designed for individual filling (open systems) shall be filled with the type of e-liquid specified in the e-cigarette's instructions for use. If no specific e-liquids or e-liquid characteristics are specified, one of the standard e-liquids as specified in EN 17375 shall be used. The e-cigarette shall be filled to its maximum level following the instructions for use.

7.2 Preliminary tests before vaping

The following tests shall be performed prior to the vaping process:

a) check the e-cigarette for any leakages (see [2]);

b) make sure that the battery works;

c) for manually filled e-cigarettes note the amount of e-liquid filled (in ml);

d) the e-cigarette shall be primed in accordance with its instructions for use. If no specific instructions are provided, the first 5 puffs shall be puffed to waste prior to the first weighing of the e-cigarette;

e) weigh the filled e-cigarette prior to vaping to the nearest 1 mg.

7.3 Vaping and collection of aerosol matter

7.3.1 Vaping plan

E-cigarettes with a fixed power setting are to be tested as they are. E-cigarettes with adjustable power settings have to be tested using the settings recommended by the instructions for use. If multiple settings are recommended, the maximum and minimum recommended power settings shall be tested. If the e-cigarette is intended for use with various coils, as indicated in the instructions for use, each combination of e-cigarette and coil shall be tested separately. If the instructions for use do not provide recommended power settings, the maximum and minimum feasible power settings shall be used. Testing for consistency of nicotine delivery shall be performed for each applicable power setting and e-cigarette - coil combination using at least 10 test e-cigarettes.

7.3.2 Preparation of aerosol traps

For all operations, the operator shall prevent contamination by wearing gloves (see A.5).

Prepare and attach aerosol traps to the vaping machine following the procedure described in the used international standard for the determination of nicotine in the aerosol of e-cigarettes.

NOTE As long as no international standard (ISO or CEN) for the determination of nicotine in the aerosol of e-cigarettes is published follow Coresta recommended method No.84 for this purpose. [1]

7.3.3 Setting up the vaping machine

If necessary, replace any protective filters on the machine. Switch on the machine and allow it to warm up on automatic cycling for at least 20 min.

With the machine warmed up, check that the puff volume, the puff duration and the puff period on each channel are in accordance with the standard conditions given in ISO 20768. Adjust the machine if necessary.

7.3.4 Procedure for vaping run

7.3.4.1 General

Insert the e-cigarettes to be tested into the e-cigarette holders. Avoid any leaks or deformations. Any e-cigarettes found to have obvious defects shall be discarded and replaced by prepared spare e-cigarettes.

Ensure that the e-cigarettes are positioned correctly so that the axes of the mouthpiece coincide with the axes of the ports. If available or needed, adjust the position of each e-cigarette support and push button activator following the user instructions given by in the vaping machine manual.

7.3.4.2 Determination of sequence size

Perform this procedure for two e-cigarettes. Puff 20 puffs to waste. Weigh the e-cigarette to the nearest 1 mg and based on the differential with the pre-vaping weight, estimate the e-liquid vaporized mass (EVM). The number of puffs per sequence are chosen based on the average estimated EVM and taking into account the aerosol collection method and the analytical method for nicotine. A recommendation is given in Table 1.

Table 1 — Determination of number of puffs per sequence

Per puff estimated EVM	Recommended # of puffs/sequence
≤ 5mg/puff	50
> 5 mg/puff, ≤ 15 mg/puff	20
> 15 mg/puff, ≤ 30 mg/puff	10
> 30 mg/puff	5

Adapt the number of puffs to be captured in the aerosol trap.

7.3.4.3 Vaping run

Prepare a new e-cigarette in accordance to the described procedure. Weigh the filled e-cigarette. Weigh the unloaded aerosol trap. Re-start the vaping process with the identified number of puffs per sequence. Replace the aerosol trap after every sequence by a freshly prepared one. Take the first two sequences of every single e-cigarette for analysis.

Immediately after removing the aerosol trap from the machine, weigh it to the nearest 1 mg. Note the result and seal the trap with suitable caps. Calculate the differential weight between the loaded and unloaded trap. Also weigh the e-cigarette to the nearest 1 mg. Calculate the differential weight between the e-cigarette weight before and after the vaping into the second trap.

Repeat the procedure for the remaining test e-cigarettes.

Calculate the ratio of the EVM to the captured aerosol mass for each of the test e-cigarettes. Unusually high ratios are an indication of e-cigarette leakage or other issues that invalidate the result for that e-cigarette. Therefore, if this ratio represents a statistical outlier for up to 2 out of 10 of the e-cigarettes, results from these e-cigarettes may be replaced in the evaluation described in 7.4, with any additional e-cigarettes that were run as per 7.1.1.

7.3.5 Determination of nicotine

For the determination of nicotine follow the procedure given by the related international ISO- or CEN-Standard.

NOTE As long as no international standard (ISO or CEN) for the determination of nicotine in the aerosol of e-cigarettes is published follow Coresta recommended method No.84 for this purpose [1].

Analyse the captured aerosol of all e-cigarettes.

7.4 Determination of nicotine consistency

For the determination of nicotine consistency, the deviation of the nicotine content of any single analysed trap compared to the determined mean value of all analysed traps related to one e-cigarette shall be calculated.

NOTE To determine acceptability criteria for the measured nicotine consistency, the different sources of variability that affect the test result need to be taken into account. This will include not only the variability of the analytical test method, but also knowledge of what is a reasonable variation in e-cigarette performance given the current state of vaping product technology.