Kenya Standard **KS 2976: 2023**

Smokeless Tobacco product -Specification

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TECHNICAL COMMITEE REPRESENTATION

The following organizations were represented on the Technical committee:

Government chemist Department
Pharmacy and poisons Board
Kenya Medical Research Institute
NACADA
Ministry of Health
National Public Health Laboratories
National Quality Control Laboratory

Kenya Bureau of standards-Secretariat

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Smokeless Tobacco Product-Specification

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Foreword

This Draft Kenya Standard has been developed by the Tobacco and tobacco products technical committee under the guidance of the standards projects committee in accordance with the procedures of the Kenya Bureau of standards.

Smokeless tobacco products(SLTPs) are non-combustible products that are consumed orally through the buccal mucosa route, chewing, or sniffing, or any other route of administration.

.
The products may be pouched in a cellulose matrix inside

During the preparation of this standard, reference was made to the following documents
PAS 8877:2022
Tobacco-free oral nicotine pouches
– Composition, manufacture and
testing – Specification (published by the British standards Institution)

SIS/TS 72:2020 Nicotine containing tobacco free oral pouches –Safety and quality related requirements (published by the Swedish Standards Institute)

PS 5468:2020**-** Pakistan standard specification for Nicotine containing tobacco free oral product.
Globally Harmonized System of Classification and
Labelling of Chemicals (GHS), United Nations, New York
and Geneva.
COUNCIL OF EUROPE. European Pharmacopoeia.
Strasbourg, France: European Directorate for the
Quality of Medicines and Healthcare. Nicotine
Monograph

UNITED STATES PHARMACOPEIA AND THE
NATIONAL FORMULARY. USP 32-NF 27. Rockville,
Maryland: The United States Pharmacopeial Convention
Inc., pp. 3079–3081, Nicotine Monograph.

The assistance derived from the above sources is hereby acknowledged with thanks.

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1.0 Scope

This Kenya Standard specifies requirements for smokeless tobacco products intended for human consumption by chewing, sniffing. sucking or any other route of administration. ,

2.0 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes. provisions 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.

Tobacco control Act,2007
Tobacco control regulations, 2014
Food, drugs and chemical substances Act, CAP 254
WHO _-Framework Convention on Tobacco Control(FCTC),2003
Protocol to eliminate illicit trade of tobacco products

COOPERATION CENTRE FOR SCIENTIFIC RESEARCH RELATIVE TO TOBACCO (CORESTA). Recommended Method No. 62: Determination of Nicotine in Tobacco

and Tobacco Products by Gas Chromatographic Analysis.

COOPERATION CENTRE FOR SCIENTIFIC RESEARCH RELATIVE TO TOBACCO (CORESTA). Recommended Method No. 87: Determination of Nicotine in Tobacco Products by GC/MS. 4)

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3.0. Definitions

For the purposes of this document, the following definitions and abbreviations Shall apply

3.1. batch
quantity of finished goods or intermediates of
consistent quality produced at one time as defined by the manufacturer.

3.2. component
functional element or part of an oral nicotine pouch.

3.3. constituent

An individual chemical substance within an ingredient, material or product

3.4. consumable
Single potion of smokeless tobacco product intended for human use through the mucosa including chewing,sucking and sneefing

3.5. Flavouring
An Ingredient that imparts taste, flavour or aroma to Smokeless tobacco product.

3.6 globally Harmonized System (GHS)
Globally Harmonized System of Classification and Labelling of Chemicals that defines and classifies the hazards of chemical products and communicates health and safety information on labels and safety data sheets and ingredient of a product.

3.7. importer
Authorised person, or any legal entity that imports smokeless tobacco product

3.8. ingredient
include tobacco, components (e.g. paper, filter), including materials used to manufacture those components, additives, processing aids, residual substances found in tobacco (following storage and processing), and substances that migrate from the packaging material into the product (contaminants are not part of the ingredients).

3.8. Manufacture
All operations of receiving of materials, production, processing, using of materials, packaging, repackaging, labelling, relabelling, quality control, storage, release, and distribution of smokeless tobacco products.

3.9. manufacturer
Authorised person, or legal entity that manufactures or designs a smokeless tobacco product.

3.10. nicotine
alkaloid chemical substance C10H14N2
, CAS 54-11-5

3.11. nicotine compound
substance in which nicotine is chemically or physically associated with other chemical species. This includes (but is not limited to nicotine salts, where the nicotine compound is produced by reaction of nicotine with a protonating species such as an acid functionality, and materials where nicotine is chemisorbed or physisorbed onto a substrate

3.12. outside packaging
packaging containing a unit packet or an aggregation of unit packets, in which oral nicotine pouches are placed on the market.

3.13. packaging material
material comprising the container holding, and in contact with, the oral nicotine pouches

3.14. Pharmaceutical grade
Substance that is approved for use in humans or for which a chemical purity standard has been established as the highest standard and exceeds 99% purity.

3.15. pouch material
porous material that forms the outer surface of a consumable enclosing the integrated composition of the product ingredients

3.16. supplier
person, or legal entity that provides to a manufacturer any material, component or packaging material that a manufacturer requires

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to design, manufacture, test, control and market a oral nicotine pouch

3.18. oral nicotine pouch
pre-portioned consumer product that does not contain tobacco but contains nicotine or nicotine compounds, and other materials; intended for oral use to facilitate uptake of nicotine via the oral mucosa

3.19 toxicological risk assessment (TRA)
process by which the toxicological risks to consumers associated with the use of oral nicotine pouches are evaluated and subsequently reviewed by a trained toxicologist

3.20. unit packet
smallest individual package of oral nicotine pouches placed on the market for sale

3.21. water activity
dimensionless ratio between the vapour pressure of water in the consumable to the vapour pressure of distilled water under identical conditions

4.0. Requirements

4.1 General requirements

4.1.1. Smokeless tobacco products shall not contain ingredients, materials or constituents from animal origin

4.1.2. Alcohol shall not be present as an ingredient. If any alcohol/ethanol is used in the manufacturing of smokeless tobacco products this should be removed from the final product and potential residual levels shall be less than 0.5

4.1.3. Ingredients shall not be used in the manufacture of Smokeless tobacco products if they are classified as either carcinogenic (category 1 or 2), germ cell mutagen (category 1, 1A, 1B or 2), or toxic to reproduction (category 1, 1A or 1B, or effects on or via lactation), by the oral route of exposure.

4.1.4. Nicotine used in oral nicotine pouches shall conform to pharmaceutical grade purity

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specifications. Nicotine shall be of natural origin, (purified from tobacco).

4.1.5. all consumable ingredients in smokeless tobacco products shall be restricted to either those allowed for use in foods and/or assessed by expert bodies as generally recognized as safe (GRAS) in foods, or those allowed by regulatory authorities for use in oral medicinal products. All consumable ingredients shall meet or exceed food-grade quality or pharma-grade purity, respectively.

4.1.6. The producer shall ensure that the use of ingredients in a final consumable is or has been subjected to a toxicological risk assessment demonstrating safety under reasonable and foreseeable use. The toxicological risk assessment or a summary thereof shall be documented by the producer for each commercial product.

4.2. Specific requirements

Nicotine containing oral pouches shall conform to the requirements set in table 1 below

Table 1. Requirements for nicotine containing oral pouches

s/no	Parameter	/Requirement/Limit	Test method
i			
i)	[a] Nicotine content per pouch , mg, max.	20	CORESTA Recommended Method No. 62 [N4]; or b) CORESTA Recommended Method No. 87 [N5].
ii)	pH, max,	9.1	CORESTA Recommended Method No. 69 [N6].
iii)	Water activity, max,	0.7	CORESTA Recommended Method No. 88 [N7].

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[a] If nicotine compounds are used in the product, the total nicotine content of the consumable from all sources shall not exceed 20 mg of nicotine per consumable, as sold.

5.0. Packaging, Product Information and labelling

The Tobacco control act defines a tobacco product as ' a product composed in whole or in part, of tobacco, including tobacco leaves and any extract of tobacco leaves intended for use by smoking, inhalation, chewing, sniffing or sucking and includes papers, tubes and filters".
Nicotine containing pouches therefore fall under this category and thus subject to packaging and labelling requirements specified by the tobacco control regulations

5.1. Packaging

5.1.1 Any wrapping material (including unit packet materials) coming into contact with the consumable shall meet requirements for materials and products intended to come into contact with foodstuffs**.**

5.1.2. The seal of the unit packet shall be tamper-evident such that a user can visually determine whether the product has been opened since manufacture.

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5.2. Product information and labelling

5.2.1. Unit packets and outside packaging that are visible to consumers shall meet the criteria specified in the tobacco control Act and regulations.
5.2.2. Product information stipulated in this standard shall be permanently and irremovably placed on the pack, such that it remains intact when opened, and be durable over the anticipated in-use lifetime of the product.

5.3. Warning information

5.3.1 Nicotine warning

Unit packets and outside packaging shall display the following warning in a clear and visible manner:
"This product contains nicotine which is a highly addictive substance."

5.3.2 Child safety

Outside consumer packaging and unit packets shall carry information that the product is for adult consumption only, e.g. by using a symbol(s) or the following statements:
a) keep out of reach of children; and/or
b) sale to persons under age 18 is prohibited

5.3.3 Warning information labelling requirements

The information specified in 5.3.1 and 5.3.2 shall:
a) be indelibly labelled on both unit packets and outside packaging;
b) be positioned in a prominent and clearly visible location on one panel of the packaging;
c) appear in conspicuous and legible type that contrasts with all other printed material on the package through effective use of typography, layout or colour; and
d) not be obscured by any external wrapping.

5.4 Product content information

5.4.1. Consumable composition

The product labelling shall include a list comprising nicotine and ingredients contained in the Smokeless tobacco products.

5.4.2 Allergens

If any ingredients or processing aids that contain or are derived from the allergenic products or substances listed in Table 2 (other than those listed as exceptions) are used in the manufacture or preparation of the smokeless tobacco products and are still present in the finished product, the presence of the allergenic product or substance shall be declared as part of the product labelling

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NOTE: Table 2 identifies substances or products that are capable of causing allergies or intolerances and can. constitute a danger to health to those concerned

Table 2 – Substances or products capable of causing food allergies or intolerance

SL/NO	Allergenic product substance or product	Exceptions
i)	Gluten, obtained from cereals, particularly wheat (such as spelt and khorasan wheat), rye, barley, oats or their hybridized strains and products thereof	Wheat-based glucose syrups, including dextrose, and products thereof Wheat-based maltodextrins and products thereof Glucose syrups based on barley Cereals used for making alcoholic distillates, including ethyl alcohol of agricultural origin
ii)	Crustaceans and products thereof	-
iii)	Eggs and products therefore	-
iv)	Fish and products thereof	Fish gelatin
v)	Peanuts and products thereof	-
vi)	Soybeans and products thereof	Fully refined soybean oil and fat and products thereof Natural mixed tocopherols, natural D-alpha tocopherol, natural D-alpha tocopherol acetate and natural D-alpha tocopherol succinate from soybean sources Vegetable oils, derived phytosterols and phytosterol esters from soybean sources Plant stanol ester produced from vegetable oil sterols from soybean sources
vii)	Milk and products thereof(including lactose)	Whey used for making alcoholic distillates, including ethyl alcohol of agricultural origin

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		Lactitol
viii)	Nuts, namely: almonds *(Amygdalus communis* L.), hazelnuts (*Corylus avellana),* walnuts (*Juglans regia*), cashews (*Anacardium occidentale*), pecan nuts (*Carya illinoinensis* (Wangenh.) K. Koch), Brazil nuts (Bertholletia pistachio nuts *(Pistacia* vera), macadamia or Queensland nuts (*Macadamia ternifoliia*), and products thereof	Nuts used for making alcoholic distillates including ethyl alcohol of agricultural origin -
ix)	Celery and products thereof	-
x)	Mustard and products thereof	-
xi)	Sesame seeds and products thereof	-
xii	Lupin and products thereof	-
xiii)	Molluscs and products thereof	-

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5.4.4 Contact sensitizers

5.4.4.1

Any ingredients or processing aids that meet the classification criteria for contact sensitization and are present in the finished consumable at the following levels shall be declared on the packaging as:

a) Category 1 contact sensitizer: above 0.1% (weight/weight); or

b) Category 1B contact sensitizer: above 0.1%

(weight/weight); or
c) Category 1A contact sensitizer: above 0.01% (weight/weight).

5.4.4.2

The identity of the contact sensitizer shall be indelibly printed adjacent to the ingredient list on the product labelling using the trivial name, if available, or otherwise the chemical name, as "Contains [name of the sensitizing substance]".

5.5 Product labelling

The labelling information specified in this standard shall:
a) be indelibly labelled on the unit packet; and
b) be printed on the outside packaging, where the product labelling location on the unit packet is obscured by outside packaging

5.6 Other information

5.6.1 Manufacturer information

The product labelling shall contain manufacturer, importer and/or distributor contact details not limited to physical address for consumer questions, feedback and adverse event reporting. The manufacturer information shall meet the labelling requirements set out in this standard

5.6.2 General product information

All unit packaging shall provide a
i) batch number,
ii)manufacturing date and/or a Best Before or
iii)Expiry date
iv)Country of origin and country of sale. .
v) storage conditions
vi)instructions for use
vii)Disposal instructions
a full list of ingredients;
b) the quantity of each ingredient; and
c) ingredient identification numbers.

This information shall be indelibly labelled on the unit packet

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ANNEX(NORMATIVE)

Non-exhaustive list of toxicologically undesirable constituents

SL/NO	SUBSTANCE NAME	CAS Number(s)i
i)	1,2-benzopyrone (coumarin)	91-64-5
ii)	1-allyl-3,4-methylenedioxybenzene (safrole)	94-59-7
iii)	1-allyl-4-methoxybenzene (estragole)	140-67-0
iv)	4-allyl-1,2-dimethoxy-benzene (methyl eugenol)	93-15-2
v)	4-(Methylnitrosamino)-1-(3-pyridyl)-1-butanone	64091-91-4
vi	agaric acid	666-99-9
vii	Aloin	1415-73-2
viii)	beta-asarone	5273-86-9
ix)	Capsaicin	404-86-4
x)	Hydrocyanic acid	3017-23-0
xii)	Hypericine	548-04-9
xiii)	Menthofuran	494-90-6
xiv)	N'-nitrosonornicotine (NNN)	16543-55-8
xv)	Pulegone	89-82-7, 15932-80-6
xvi)	Quassin	76-78-8
xvii	teucrin A	12798-51-5
xviii)	alpha-thujone	546-80-5
xix)	beta-thujone	471-15-8

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