

Bangladesh Standard Specification For Tobacco-Free Oral Nicotine Pouches (Draft Standard)

1. Scope

This specification standard specifies requirements for the composition, manufacture, and testing of tobacco-free oral nicotine pouches through:

1. requirements for ingredients and materials;
2. limits for nicotine contents, pH characteristics, and water activity of the pouches; and
3. product information and labelling.

This document also guides suitable test methods for the measurement of nicotine content, pH, and water activity. This specification standard applies to pre-portioned, tobacco-free oral nicotine pouches exclusively intended for oral use by placing them between the gum and buccal mucosa for a period of time, to facilitate uptake of nicotine via the oral mucosa, followed by disposal of the pouch after use.

This specification standard is intended for manufacturers, importers, distributors, and retailers involved in the production and sale of tobacco-free oral nicotine pouches, and for use in laboratories and testing houses engaged in measurements of these pouches.

This specification standard is not intended to cover:

- a) smokeless tobacco products, such as moist snuff, tobacco oral pouches, snus, nasal snuff, chewing tobacco or any other tobacco-containing smokeless tobacco products;
- b) nicotine-containing, tobacco-free oral products that are licensed medicinal nicotine products, such as Nicotine Replacement Therapies (NRT);
- c) inhaled-nicotine products, such as cigarettes, other combusted tobacco products, tobacco-heating products or e-cigarettes;
- d) products that are subject to an authorization requirement under Directive 2001/83/EC (Community code relating to medicinal products for human use) or to the requirements set out in Directive 93/42/EEC (Medical Device Directive).

2. Normative References

2.1 The Bangladesh Standards and international standards listed in Annex – A are necessary adjuncts to this standard. For references, the latest edition of the referenced document (including any amendments) applies.

3. Terminology

For the purposes of this specification standard the following terms and definitions 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 a tobacco-free oral nicotine pouch.

3.3 Constituent

Individual chemical substance within an ingredient, material, or product.

3.4 Consumable

A single portion of the tobacco-free oral nicotine pouch.

3.5 Flavouring

An ingredient that imparts a taste, flavour or aroma to tobacco-free oral nicotine pouches.

3.6 Importer

Person, organization, or legal entity that imports tobacco-free oral nicotine pouches.

3.7 Ingredient

A substance (individual chemical compound or mixture thereof, or natural or synthetic material) intentionally included in a tobacco-free oral nicotine pouch in accordance with product specifications.

3.8 Manufacturer

Person, organization, or legal entity that manufactures or designs tobacco-free oral nicotine pouches.

3.9 Nicotine

The chemical substance (S)-3-(1-Methyl-2-pyrrolidinyl) pyridine, CAS 54-11-5.

3.10 Nicotine Compound

Substance in which nicotine is chemically or physically associated with other chemical species.

3.11 Outside Packaging

Packaging (excluding transparent wrappers) containing a unit packet or an aggregation of unit packets, in which tobacco-free oral nicotine pouches are placed on the market.

3.12 Packaging Material

Material comprising the container holding, and in contact with, the tobacco-free oral nicotine pouches.

3.13 Pouch Material

Material that forms the outer surface of a consumable enclosing the integrated composition of the product ingredients.

3.14 Supplier

Person, company, or legal entity that provides a manufacturer any material, component, or packaging material that a manufacturer requires to design, manufacture, test, control, and market a tobacco-free oral nicotine pouch.

3.15 Tobacco-free

Absence in the consumable of tobacco leaves and natural processed or unprocessed parts of tobacco plants.

3.16 Tobacco-free Oral Nicotine Pouch

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

3.17 Toxicological Risk Assessment

Process by which the toxicological risks to consumers associated with the use of tobacco-free oral nicotine pouches are evaluated and subsequently reviewed by a trained toxicologist.

3.18 Unit Packet

Smallest individual package of tobacco-free oral nicotine pouches placed on the market for sale.

3.19 Abbreviations

CAS: Chemical Abstracts Service

FEMA : Flavor and Extract Manufacturers Association of the United States (FEMA)

JECFA : Joint FAO/WHO Expert Committee on Food Additives

CoE: Council of Europe

FL-numbers: EU FLAVIS Numbers

4. Ingredients

4.1 All ingredients shall conform to the relevant Bangladesh Standard specifications, where available. All materials shall be food grade and free from foreign matter, harmful microorganisms, insect infestation, objectionable flavours and odours, food additives and processing aids. Although tobacco-free oral nicotine pouches are not ingested and not intended to be a food or medicinal product, to ensure safety via the oral exposure route, all consumable ingredients shall be restricted to either those allowed for use in foods and/or assessed by expert bodies as generally recognised 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. This can include substances identified in the following:

- a) Council of Europe's reports on chemically defined flavouring substances and natural sources of flavourings;^{1, 2, 3, 4}
- b) European Food Regulation EU 1334/2008, Annex 1 (regarding flavourings);⁵
- c) European Food Additives Regulation EC 1333/2008 (regarding additives);⁶
- d) FDA's Substances Added to Food Inventory of the United States;⁷
- e) FEMA Flavour Ingredient Library;⁸
- f) IOFI Global Reference List of Natural Complex Substances/Natural Flavouring Complexes (regarding flavourings);⁹ or
- g) European Union list of flavouring substances, in the form of the Food Flavourings Database.¹⁰

4.2 Nicotine and Nicotine Compounds

Nicotine used in tobacco-free oral nicotine pouches shall conform to pharmaceutical-grade purity specifications. Nicotine shall meet appropriate pharmaceutical (EP or USP) grade purity requirements, such as the requirements specified in the European Pharmacopoeia - Nicotine Monograph (1452), or the United States Pharmacopoeia - Nicotine Monograph. If nicotine salts are used as either an ingoing ingredient, or formed in situ, the nicotine used to form the nicotine salts shall be of the afore-mentioned pharmaceutical grade quality and the acid added shall be equivalent to, or of better quality than, European or US food grade quality, with supporting documentation, including certificate(s) of analysis and/or conformity. The supplier shall provide the manufacturer with supporting purity documentation, including certificate(s) of analysis and/or certificate(s) of conformity.

¹ Chemically defined flavouring substances (2001). Available at: <https://book.coe.int/en/health-protection-of-the-consumer/2208-chemically-defined-flavouring-substances.html>

² Natural sources of flavourings - Report No. 1 (2000). Available at: <https://book.coe.int/en/health-protection-of-the-consumer/1948-natural-sources-of-flavourings-report-no-1.html>

³ Natural sources of flavourings - Report No. 2 (2007). Available at: <https://book.coe.int/en/health-protection-of-the-consumer/3746-natural-sources-of-flavourings-report-no-2.html>

⁴ Natural sources of flavourings - Report No. 3 (2008). Available at: <https://book.coe.int/en/health-protection-of-the-consumer/4005-natural-sources-of-flavourings-report-no-3.html>

⁵ Regulation (EC) No 1334/2008 of the European Parliament and of the Council on flavourings and certain food ingredients with flavouring properties for use in and on foods. Available at: <https://www.legislation.gov.uk/eur/2008/1334>

⁶ Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives. Available at: <https://www.legislation.gov.uk/eur/2008/1333>

⁷ The Substances Added to Food inventory of United States including FEMA and GRAS listings. Available at: <https://hfppappexternal.fda.gov/scripts/fdcc/index.cfm?set=FoodSubstances>

⁸ FEMA Flavor Ingredient Library. Available at: <https://www.femaflavor.org/flavor-library>

⁹ IOFI Regulatory Database. Available at: <https://www.flavordata.com/>

¹⁰ European Union Lists of Flavourings. Available at: https://food.ec.europa.eu/food-safety/food-improvement-agents/flavourings/eu-lists-flavourings_en

4.3 Pouch Materials

Pouch materials shall meet the requirements for material and products intended to come into contact with foodstuffs.

5. Requirements

5.1 Hygienic Requirement – During processing, handling, storage and transportation, effective measures must be taken to prevent cross-contamination with chemicals, microbial or physical contaminants.

5.1.1 The product shall be processed and packed under strict hygienic conditions in premises maintained in accordance with BDS 822.

5.2 Requirements for raw materials - All raw materials used in the manufacture of tobacco-free oral nicotine pouches shall be clean and fit for human consumption and shall comply with the requirements of the rules issued under the National regulations.

5.3 Disclosure of Ingredient Composition

To facilitate a toxicological risk assessment of the final tobacco-free oral nicotine pouch, the manufacturer shall require that its suppliers disclose the following information about each ingredient, including any flavouring pre-mixes used in its production:

- a. a full list of ingredients;
- b. the quality of each ingredient; and
- c. ingredient identification numbers, including CAS, FEMA, JECFA, CoE and/or FL-numbers, if available.

Where ingredients consist of natural raw materials or their extracts, the manufacturer shall obtain information on the natural source of the ingredient and the potential presence and maximum quantities of any toxicologically undesirable constituents. Such information shall be obtained either by supplier disclosure or by extrapolation from available scientific data.

5.4 Supply Chain

The manufacturer shall agree with each supplier on the minimum specification of the component to be supplied. All materials comprising the consumable shall be supplied to the manufacturer with a unique batch code. Material information shall be verified in accompanying documentation for each material batch based on a certificate of analysis or certificate of conformity from the material supplier, in combination with risk-based audits of the supplier by the manufacturer. Pouch materials shall be supplied to the manufacturer with a certificate of compliance with requirements for materials and products intended to come into contact with foodstuffs.

5.5 Excluded and Toxicologically Undesirable Ingredients

Ingredients shall not be used in the manufacture of tobacco-free oral nicotine pouch 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 have effects on or via lactation, by the oral route of exposure. The tobacco-free oral nicotine pouch shall not contain any ingredients or materials of animal origin. Alcohol (chemical name: ethanol) shall not be present as an ingredient. If alcohol is used as a processing aid during production, this should be removed from the final product such that the total residue levels in the final product are less than 0.5%.

Some ingredients can contain toxicologically undesirable substances as natural constituents or impurities; these substances shall not be used in tobacco-free oral nicotine pouches as ingredients in their own right, but could be present as constituents of materials used. Their presence in the final consumable shall be restricted to levels deemed supportable by a toxicological risk assessment. The Non-exhaustive list of toxicologically undesirable constituents is given in **Annex B**.

5.6 Toxicological Risk Assessment

The manufacturer shall conduct a toxicological risk assessment (TRA) on all consumable components, packaging materials in contact with the consumables, and their quantities present, to determine their suitability for use in the finished Tobacco-free Oral Nicotine Pouch product. To determine the toxicologically supportable level of material use, the TRA shall evaluate the potential hazards associated with the materials, including, where applicable, those of any undesirable constituents. The TRA shall evaluate likely exposure to the consumer, considering both duration and site of product use, based on reasonable and foreseeable use of the product. The TRA shall be conducted either by a trained toxicologist or under the supervision of a trained toxicologist, using established procedures. The completed TRA shall be reviewed by a trained toxicologist and documented by the manufacturer for each commercial product. An updated TRA is required in the event of any modification to the product or if new information becomes available regarding the hazards of the ingredients.

Note: If the materials of the pouches are certified as compliant with the requirements for materials in contact with foodstuffs, no additional TRA is required.

5.7 Final Product

5.7.1 Product Name

The product and flavour name shall be factual, non-promotional, and not appealing particularly to children.

5.7.2 Maximum Nicotine Content

The maximum amount of nicotine per consumable, as sold, shall be no more than 7mg. If nicotine compounds are used in the product, the total nicotine content of the consumable from all sources shall not exceed 7mg of nicotine per consumable, as sold. The nicotine content of the consumable shall be measured using one of the following approaches:

- a) CORESTA Recommended Method No. 62; or
- b) CORESTA Recommended Method No. 87.

5.7.3 Pouch pH

The maximum pH value of the final consumable shall not exceed 9.1, unless a document toxicological risk assessment of the final product, substantiated by data, supports use of the consumable at a pH value >9.1. The pH of the consumable shall be measured using:

- a) CORESTA Recommended Method No. 69.

5.8 Legal requirement – The product shall in all other aspects, comply with the requirements of the legislation enforced in the country.

6. Packing And Marking

6.1 Packing – Although the consumables are not ingested and are not a food, 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. 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.

6.2 Marking

6.2.1 The packets shall be marked with the following particulars:

- a) Name of the product, declared as Tobacco-Free Oral Nicotine Pouches;
- b) Manufacturers'/Importer name and full address with recognized trademark brand name, if any;
- c) Batch/code number;
- d) Date of manufacture;
- e) Date of Expiry, (In case of imported product, the remaining expiry date shall not be less than two-third of the original period;

- f) Net content;
- g) Maximum retail price (MRP);
- h) List of ingredients in descending order of proportion;
- i) Information for storage, where necessary.

6.2.2 Warning

Consumer packaging and labelling of the tobacco-free oral nicotine pouch shall be in accordance with applicable local regulatory requirements. Where no alternative nicotine addiction warning is prescribed by local legislation, products shall carry a clear and visible general health warning about the addictiveness of nicotine:

"This product contains nicotine and is addictive"

The required warning statement shall be indelibly imprinted directly on the package and shall be clearly visible underneath any cellophane or other clear wrapping. In addition, the required warning statement shall:

1. be located in a conspicuous and prominent place on one side panel of the external package, and
2. appear in conspicuous and legible type that contrasts by typography, layout, or colour with all other printed material on the package.

Additionally, product labelling shall include a contact telephone number for feedback on products, including complaints and adverse events.

6.2.3 Child Safety

Unless alternative child-safety text is mandated by local legislation, any potential outer packaging in which the product is sold to consumers, as well as the product label and product information, shall carry the statements:

"Keep out of reach of children"

and

"Not for sale to persons under XX years of age" (XX is dependent on national legislation).

6.2.4 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 tobacco-free oral nicotine pouches and are still present in the finished product, the presence of the allergenic product shall be declared as part of the product labelling. The substances or products capable of causing food allergies or intolerances is listed in **Annex C**.

6.2.5 Contact Sensitizers

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 1C contact sensitizer: above 0.01% (weight/weight).

The identity of the contact sensitizer shall be indelibly printed using the trivial name, if available, or otherwise the chemical name, as "Contains [name of the sensitizing substance]".

6.2.6 Nicotine Content

The product labelling shall include information about the content of nicotine per pouch, in units of mg/consumable.

6.2.7 Shelf Life

All unit packaging shall provide a batch number, a manufacturing date and 'Best Before' or 'Expiry' date. This information shall be permanently labelled on the unit packet.

6.2.8 Instruction for Use and Disposal

The product labelling shall include an 'Instruction for use' leaflet that informs consumers on product use and disposal.

6.2.9 Manufacturer Information

The product labelling shall contain manufacturer, importer, and/or distributor contact details for consumer questions, feedback, and adverse event reporting.

6.2.10 The packets may also be marked with the BSTI Certification Mark.

NOTE – The use of BSTI Certification Mark is governed by the provisions of Bangladesh Standards and Testing Institution Act, 2018 and the Rules and Regulations made thereunder. Details of conditions, under which a license for the use of BSTI Certification Mark may be granted to manufacturers or processors, may be obtained from the Bangladesh Standards and Testing Institution.

7. Sampling

Representative samples of the material shall be drawn as described in Appendix D.

8. Tests

8.1 Test shall be carried out according to the section 5 including all sub-sections.

Annex A (Clause 2)

List of Relevant Reference Documents

1. Globally Harmonized System of Classification and Labelling Chemicals (GHS), United Nations, New York and Geneva.¹¹
2. COUNCIL OF EUROPE. European Pharmacopoeia. Strasbourg, France: European Directorate for the Quality of Medicines and Healthcare. Nicotine Monograph (1452).
3. UNITED STATES PHARMACOPOEIA AND THE NATIONAL FORMULARY. *USP 32-NF 27*. Rockville, Maryland: The United States Pharmacopoeial Convention Inc. pp. 307903081, Nicotine Monograph
4. 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.¹²
5. CORESTA. Recommended Method No. 69: Determination of pH of Tobacco and Tobacco Products.¹³
6. CORESTA. Recommended Method No. 87: Determination of Nicotine in Tobacco Products by GC/MS.¹⁴

¹¹ Available at: <https://digitallibrary.un.org/>

¹² Available at: <https://www.coresta.org/determination-nicotine-tobacco-and-tobacco-products-gas-chromatographic-analysis-29185.html>

¹³ Available at: <https://www.coresta.org/determination-ph-tobacco-and-tobacco-products-29192.html>

¹⁴ Available at: <https://www.coresta.org/determination-nicotine-tobacco-products-gc-ms-33537.html>

Annex - B
(Clause-5.5)
Non-exhaustive List of Toxicologically Undesirable Constituents

Serial	Substance Name	CAS Number(s)
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-dimethoxybenzene (methyleuganol)	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
XI.	Hypericine	548-04-9
XII.	Menthofuran	494-90-6
XIII.	N'-nitrosornicotine (NNN)	16543-55-8
XIV.	Pulegone	89-82-7, 15932-80-6
XV.	Quassin	76-78-8
XVI.	teucrin A	12798-51-5
XVII.	alpha-Thujone	546-80-5
XVIII.	beta-Thujone	471-15-8

Annex - C
(Clause-6.2.4)
Substances or Products Capable of Causing Food Allergies or Intolerances

Allergenic substance or product	Exceptions
Gluten, obtained from cereals, particularly wheat (such as Spelt and Khorasan wheat), rye, barley, oats or their hybridised strains, and products thereof	<ul style="list-style-type: none"> • 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
Crustaceans and products thereof	
Eggs and products thereof	
Fish and products thereof	<ul style="list-style-type: none"> • Fish gelatin
Peanuts and products thereof	
Soybeans and products thereof	<ul style="list-style-type: none"> • 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
Milk and products thereof (including lactose)	<ul style="list-style-type: none"> • Whey used for making alcoholic distillates, including ethyl alcohol of agricultural origin • Lactitol
Nuts, namely: almonds (<i>Amygdalus communis</i> L.), hazelnuts (<i>Corylus avellana</i>), walnuts (<i>Juglans regia</i>), cashews (<i>Anacardium occidentale</i>), pecan nuts (<i>Carya illinoensis</i> (Wangenh.) K. Koch), Brazil nuts (<i>Bertholletia excelsa</i>), pistachio nuts (<i>Pistacia vera</i>), macadamia or Queensland nuts (<i>Macadamia ternifolia</i>), and products thereof	<ul style="list-style-type: none"> • Nuts used for making alcoholic distillates, including ethyl alcohol of agricultural origin
Celery and products thereof	
Mustard and products thereof	

Allergenic substance or product	Exceptions
Sesame seeds and products thereof	
Lupin and products thereof	
Molluscs and products thereof	

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