འབྲུག་བསང་རྫས་ཀྱི་གནས་ཚད།

BHUTAN STANDARD

FINAL DRAFT BHUTAN STANDARD FOR INCENSE POWDER

ICS 71.080.15

BHUTAN STANDARDS BUREAU
The National Standards Body of Bhutan
THIMPHU 11001

འདྲུག་བསང་རྫས་ཀྱི་གནས་ཚད།

BHUTAN STANDARD

FINAL DRAFT BHUTAN STANDARD FOR INCENSE POWDER

PDF disclaimer

This PDF may contain embedded typefaces. In accordance with Adobe's Licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. The Bhutan Standards Bureau accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

COPYRIGHT PROTECTED DOCUMENT

Director General
Bhutan Standards Bureau
Rijug Lam
Thimphu-11001
Tel: 00975-2-325104/325401
Fax: 00975-2-323712/328298
Web: www.bsb.gov.bt
Published in Thimphu, Bhutan

Contents

FOREWORD

This Bhutan Standard for INCENSE POWDER was adopted by Bhutan Standards Bureau after the draft finalized by the Sub-committee on Incense (TC 05/ SC 02) and Pharmaceuticals and Traditional Medicines Technical Committee (TC 05) and approved by the Bhutan Standards Bureau Board (BSB Board) on xxxx 2020.

This standard is subject to systematic review after five years to keep pace with the market trends,industrial and technological developments. Any suggestions and further information maybe directed to the concerned Technical Committee.

INTRODUCTION

Incense making and offering has been an integral part of the Buddhist practice and Bhutanese culture throughout its history. Incense is used in Bhutan for many purposes – purification, healing, devotion and meditation. It is unquestionably a deeply rooted component of everyday life in Bhutan. The incense symbolizes the purity and perfection of all objects of olfactory sense. It is personified in the form of the female goddess 'Dugpoema'.

The ingredients used differ with different formulations or recipes. There are many natural ingredients such as leaves, roots, stems, bark and other plant parts that are used for healing and promotion of general health. It is believed that these plant parts not only heal the physical conditions, but the fragrance from the incense have the same healing effects. The fragrance and essence from incense stick and powder when inhaled not only relaxes one's mind but also purifies and cleanses spiritually. Although, most of the ingredients used in incense production are handpicked for their quality and freshness, some essential materials are imported and are prone to adulteration. The addition of chemical flavours and colouring agent and continued exposure to smoke also poses health risks. Therefore, it is important to assess and control the quality of ingredients and incense production for the safety of consumers.

This standard on Incense powder contains basic requirements to assess and evaluate the quality and safety in incense production. While this standard is intended to outline only the minimum requirements, the technical committee could not verify specific heavy metal limits and some parameters prescribed herein under. However, this standard has been prepared in consultation with stakeholders to suit the intended purposes. This standard is current and dynamic that will be reviewed as per the changing needs and technological developments.

It is the responsibility and at the discretion of each individual or a company to adopt or comply with this standard. The standard organization or the technical committee will not be liable for any untoward events either health or material losses.

འབྲུག་བསང་རྫས་ཀྱི་གནས་ཚད།

BHUTAN STANDARD FOR INCENSE POWDER

1 Scope

This standard shall apply to Incense powder manufactured in Bhutan which is to be used for religious ceremonies or for fragrance purposes.

2 Normative References

There are no normative references in these documents.

3 Terms and Definition

For the purpose of this standard the following definitions shall apply:

3.1 Desiccator - a glass container or other apparatus holding a drying agent for removing moisture from specimens and protecting them from water vapour in the air.

3.2 Incense Stick - is a product in stick form made from raw materials when ignited has a natural fragrance and which stimulates the senses to bring physical pleasure and mental tranquility.

3.3 'Jaju' - The product that do not incorporate any animal products but only ingredients of plant origin.

3.4 'Lhatshog' – A group or host or assembly of deities.

4 Acronyms

AAS – Atomic Absorption Spectrometry

ICP-OES – Inductively Coupled Plasma Optical Emission Spectroscopy

ICP-MS – Inductively Coupled Plasma Mass Spectrometry

ISO – International Organization for Standardization

NLT – Not Less Than

NMT – Not More Than

PPM – Parts per million. One ppm is equivalent to 1 milligram per liter (mg/l) or 1 milligram per kilogram (mg/kg).

USP – United States Pharmacopeia

5 Types

The Incense powders are broadly categorized into two types depending on the variety of ingredients used. The one incorporates animal products and other without the animal products.

6 Requirements

6.1 Physical characteristics

The uniformly mixed coarse incense powder is a blend of appropriate colour depending on the types and quantities of ingredients used. The powder is free flowing without crumbling or caking when visually inspected. It must ignite easily.

6.2 Colour

The coarse incense powder must have consistent blend of natural or nature's identical colour intended for its purpose. No colouring agent must be used and if used must be safe for the users.

6.3 Fragrance

The coarse incense powder shall give out pleasant aroma continuously while burning and when tested as per the procedure in **Annex A**. It must preserve its fragrance under any environmental conditions. The fragrance agent if used must be safe for the users.

6.4 Powder Size & Fineness

The incense powder should be coarse powder between 1400 to 355 µm (micrometers) sieves. A coarse incense powder must pass not less than 95 per cent by mass through a number 1400 sieve and not more than 40 per cent by mass through a number 355 sieve in accordance with British Pharmacopeia 2019 edition and when analysed using Dry Sieving method in **Annex B** or any other suitable methods.

6.5 Burn Quality

6.5.1 The incense shall burn continuously and shall not extinguish even once before burning completely.

6.5.2 The smoke or fumes produced as a result of burning the incense powder shall not be overly irritating to nostrils and/or eyes.

6.5.3 While burning the incense powder, no sparks shall be produced that may cause fire hazards.

6.6 Burn Time

One tablespoonful or 15g of coarse incense powder when burnt under ideal environment shall burn for a pre-defined time in accordance and appropriate to its amount of use. The burn time shall be determined as per procedure in **Annex C.**

6.7 Moisture and Volatile substances content

The moisture and volatile substances content in coarse incense powder shall not exceed 10% by weight when determined as per loss on drying method in **Annex D**.

6.8 Toxic substances

The incense powder should not contain any toxic substances that are harmful to the health. The heavy metal content if any must not exceed the limits specified in Table 1. The specific methods for determination of the listed heavy metals are not prescribed. Laboratories may use any validated method of analysis provided the selected method meets the specific performance criteria.

Table 1 –Heavy Metal Limits

(Clause 6.8)

Heavy Metal	Limits (Milligrams per Kilogram or ppm)
Lead	20
Cadmium	10
Chromium	20
Arsenic	2
Mercury	0.5

7 Packing and Marking

7.1 Packing

7.1.1 The coarse incense powder shall be packed in an appropriate material suitable for the nature of the product and trade.

7.1.2 The packages should be able to prevent or minimize the loss of aroma and moisture ingression during movement and transportation.

7.2 Marking and Labelling

Each package shall be marked and labelled with the following:

- **a)** Name of the product (Trade name, Trade mark or Identification mark)
- **b)** Composition
- **c)** Net Weight
- **d)** Burn time
- **e)** Batch number
- **f)** Price
- **g)** Manufacturing date

h) Used by date/expiry date
i) Full address of the Manufacturer
j) Use and Handling Instructions
k) Hazard Warnings
l) Disclaimer if any

8 Sampling

8.1 Scale of Sampling

8.1.1 In a single consignment, all cartons of Incense belonging to the same batch of manufacture shall be grouped together and each group shall constitute a lot.

8.1.2 For ascertaining the conformity of the material to the requirements of the specification, samples shall be tested from each lot separately.

8.1.3 The number of container to be sampled or taken from the lot depends on the size of the lot and shall be in accordance with column *1* and *2* of Table 2. From each selected carton approximately equal amount of Incense powder shall be taken from each packet so as to constitute the required sample size.

8.1.4 The required number of packets from each selected carton and the required quantity of powder from each selected packet shall be chosen at random.

8.2 Sampling procedure

8.2.1 Draw sample incense powder from upper, middle and lower part of a randomly sampled container or packet using a sampling thief.

8.2.2 Combine individual samples to make pooled sample and mix them thoroughly.

8.2.3 Quarter the pooled sample to obtain the average sample. While quartering, place the material in an even square shape and divide it diagonally into four equal parts and take two equal diagonal parts.

8.2.4 Quarter the average sample again to get the final sample.

8.3 Tests and Criteria for Conformity

8.3.1 Physical and Visual Characteristics (6.1, 6.2, and 6.5)

Each sample selected according to 7.1 and 7.2 shall be examined for physical and visual characteristics requirements. A sample powder failing to satisfy any of these requirements shall be considered as defective. The lot, having been found satisfactory for these requirements, shall be further examined under 8.3.2.

8.3.2 Characteristics other than Physical and Visual

For testing other quality parameter requirements, the required sample size given in column *3* of Table 2 shall be sampled. For this purpose, the required sample shall be taken from those already examined according to 8.3.1 and found satisfactory. The lot shall be declared to have met these requirements if there is no failure under 8.3.2.

8.3.3 The lot shall be considered as conforming to the requirement of the specification in 8.3.1 and 8.3.2 are satisfied.

Table 2 - Scale of Sampling

(Clause 8.1.3)

Total No. of Cartons/containers in lot	Number of Cartons to be sampled	Quantity to be Sampled in grams
Up to 5	All of them	215
6 – 50	5	430
Over 50	10% of the packages rounding up the number of units to the next highest figure.	645

Annex A

(Clause 6.3)

Method to Assess Fragrance

1 General

The method is based on olfactory assessment of a given material by a panel of three persons.

2 Requirements

2.1 General Requirements

2.1.1 Selection

Better results are obtained if individuals with a keen sense of smell are selected for making the olfactory assessment.

2.1.2 Fatigue

The person engaged in testing should be relaxed and adequate interval should be maintained in between the tests. Continuous smelling cause olfactory fatigue and decreases critical odour perception. To avoid this, the number of samples assessed during a session should be limited.

2.1.3 Time of Assessment

Ideally the olfactory assessment should be carried out during the morning hours.

2.1.4 Freedom from Contaminating Odour

It is necessary to ensure that the individuals responsible for assessing odour are free from contaminating odour. It is recommended that they wash their hands several times during assessment session.

2.2 Material Requirements

2.2.1 Burner/Holder

An appropriate incense burner or any other suitable devices to burn incense powder.

2.2.2 Environment

A well-ventilated room, as free as possible from all outside disturbances and fragrances. Ideally, the temperature and humidity suited are about 20^{o}C and 80 percent relative humidity, respectively.

3 Methods

3.1 Procedure

3.1.1 Take three tablespoonful or 15 grams of incense powder from the sample and place in the appropriate burner.

3.1.2 Arrange the burner in such a way and at safe distance from the nose that there is incipient yet distinct perception of odour.

3.1.3 Light or ignite the coarse incense powder in the burner and smell the aroma.

3.1.4 While smelling, concentrate wholly on the sensations received and make mental observations. The powder should give out pleasant aroma while burning.

3.1.5 Test each sample powder separately and independently to assess the aroma.

3.1.6 It is important to note that, although the room shall be well ventilated, the powder kept under examination should not be exposed to a direct draft.

3.2 Acceptance Criteria

All the three persons of the panel should agree to uniformity and pleasing aroma of the incense sample.

Annex B

(**Clause 6.4**)

Dry Sieving Method to determine Powder Particle size

1. General

The method is to determine the particle size of the sampled incense powder. Sieve analysis is a technique used to determine the particle size distribution of a powder. This method is performed by sifting a powder sample through a stack of sieves, separating it into discrete size ranges. Care should be taken to choose an appropriate agitation time, so that particle fracture does not occur.

2. Tools Requirement

2.1. Precision scales or balance
2.2. Weighing boat
2.3. Calculator
2.4. Designated standard Test Sieves conforming either to BP, USP or ISO 1310-1
2.5. Sieve shakers or other suitable methods

3. Dry Sieving Method

3.1. Arrange a nest of designated Test sieves with larger openings sieve on top and smaller opening sieve on the bottom with a powder collecting pan underneath.
3.2. Place 25 – 100 grams of accurately weighed test sample on the top of coarsest sieve, and replace the lid.
3.3. Agitate the nest of sieves for 5 -15 minutes and then carefully remove each sieve from the nest without loss of material.
3.4. Reweigh each sieve, and determine the mass of material on each one.
3.5. Similarly, determine the mass of material in the collecting pan.
3.6. Reconcile the masses of material. The total loss must not exceed 5 per cent of the mass of the original test sample.
3.7. Calculate the percent by mass of powder that has passed through the respective sieve number or size.

4. Acceptance Criteria

Not less than 95 per cent by mass passes through a number 1400 sieve and not more than 40 per cent by mass passes through a number 355 sieve.

Annex C

(**Clause 6.6**)

Method for determining Burn Time

1. General

The method is to determine burn time of the coarse incense powder sample using stop watch or timer.

2. Material Requirement

2.1. Stop watch or Timer
2.2. Match or lighter
2.3. Incense burner

3. Procedure

3.1. Set the stop watch or timer to zero before lighting or igniting the incense powder sample.
3.2. Ignite or burn one tablespoonful or 15 grams of the incense powder in the burner and simultaneously start the timer. The incense should burn continuously and not extinguish even once before burning completely.
3.3. Note the time taken to completely burn the sample incense powder.

Annex D

(**Clause 6.7**)

Loss on Drying Method for determining Moisture and Volatile substances

1. General

The method is to determine moisture content and volatile substances of the incense powder sample by Loss on Drying.

2. Tools Requirement

2.1. Electrical oven with temperature control at 100^{o}C ± 5^{o}C.
2.2. Precision scales or balance with 0.0001 grams least count.
2.3. Bottle Weighing
2.4. Desiccator

3. Test Methods

3.1. Bake a Bottle Weighing at 100^{o}C ± 5^{o}C until the mass is stable. Record the exact weight.
3.2. Put 2 to 5 gram sample of the coarse incense powder into a jar. Determine the exact mass.
3.3. Bake the jar with sample at 100^{o}C ± 5^{o}C for 20 minutes or until the mass is stable.
3.4. Leave it to cool in desiccators and then weigh again.

4. Calculation Method

Calculate the percentage of loss on drying of sample using the formula.

$$\text{Percentage of loss on drying by weight} = \frac{(m_0 - m_1)}{m_0} \text{ X } 100$$

Where

m_0 is the mass of the sample before baking in grams.
m_1 is the mass of the sample after baking in grams.

Annex E

Manufacturing Process Requirements

1. Control of Production

The organization shall implement production and service provision under controlled conditions. Controlled conditions shall include, as applicable:

1.1. The availability of documented information that defines the characteristics of the products to be produced or the activities to be performed and the results to be achieved;
1.2. The availability and use of suitable monitoring and measuring resources;
1.3. The implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services have been met;
1.4. The use of suitable infrastructure and environment for the operation of processes;
1.5. The appointment of competent persons, including any required qualification;
1.6. The ability to achieve planned results of the processes for production, where the resulting output cannot be verified by subsequent monitoring or measurement;
1.7. The implementation of actions to prevent human error;
1.8. The implementation of release, delivery and post-delivery activities.

2. Quality Planning

2.1. Production planning and ensuring quality of ingredients for use in the incense manufacturing.
2.2. Organizing and cleaning processing facility and necessary equipment.
2.3. Engaging trained and qualified personnel.

3. Material and Equipment Planning

3.1. Defining the ratios of main ingredients and other materials to be used in the particular formulation.
3.2. Defining and maintaining standard formulary for each product category.
3.3. Washing, sorting and prepping ingredients to be used.
3.4. Maintaining clean and serviced equipment and tools.

4. Manufacturing Process

4.1. Issue the materials as per defined ratios and recipes.
4.2. Grind all ingredients into a coarse powder.
4.3. Mix them into a uniform blend of coarse powder.
4.4. Weigh and pack them into unit packages.
4.5. Label it as per the labelling requirements and bulk pack them for shipment.

BIBLIOGRAPHY

[1]. British Pharmacopoeia (2019) British Pharmacopoeia Commission Office, Department of Health, Social Services and Public Safety, London.
[2]. IS 13582 T: 1992 Tentative Indian Standard Agarbattis – Specification (1992), Bureau of Indian Standards, New Delhi.
[3]. ISO 9001:2015 Quality Management Systems – Requirements (2015), Geneva.
[4]. ISO 565:1990(E) Test sieves – Metal wire cloth, perforated metal plate and electroformed sheet – Nominal sizes of openings (1990), Geneva
[5]. Rules for Structure and Drafting of Bhutan Standards (2017), Bhutan Standards Bureau, Thimphu.
[6]. TIS. 2345 – 2007 Standard Incense, Notification of the Ministry of Industry, Issue No. 3767 (2007), Bangkok.

Organization	*Representative(s)*
National Biodiversity Centre, MoAF	Mr. Chencho Dorji (Chairperson)
Menjong Sorig Pharmaceuticals Corporation Ltd, Thimphu	Mr. Sherab Tenzin)
Desang Poezokhang, Jemina,Thimphu	Mr. Ugyen Wangchuk
Himalayan Sangzay Ja-Tsha-Gaey,Thimphu	Mr. Dolay Tshering
Medical Supplies and Procurement Division, DOMSHI, MoH	Mr. Jangchub Peljor
National Drug Testing Laboratory, Dept. of Public Health, MoH	Ms. Sonam Choden
Quality Assurance and Standardization Division, MoH	Mr. Kuenzang Dorji
Yoesel Samteling Goendey Poezokhang ,Wangdiphodrang	Mr. Rinzin Wangchuk

Member Secretary

Ms. Cheten Zangmo
StandardizationDivision
BhutanStandardsBureau

PHARMACEUTICAL AND TRADITIONAL MEDICINES TECHNICAL COMMITTEE (TC05)

Organization	*Representative(s)*
Essential Medicines and Technology Division, Ministry of Health	Mr. Dechen Chophel (Chairperson)
Drug Regulatory Authority	Ms. Jambay Wangmo)
National Biodiversity Centre, MoAF	Mr. Chencho Dorji
Medical Supplies and Procurement Division, DOMSHI, Ministry of Health	Mr. Jangchup Peljor
Menjong Sorig Pharmaceuticals Corporation Ltd., Thimphu	Mr. Sherab Tenzin
National Drug Testing Laboratory, Dept. of Public Health, Ministry of Health	Mr. Kelzang Wangdi
Office of Consumer Protection, Department of Trade, MoEA	Mr. Tshering Wangchuk
Quality Assurance and Standardization Division, Ministry of Health	Mr. Tshering Choeda
Bhutan Standards Bureau	Mr. Sonam Phuntsho, Director General (Ex-officio member)

Member Secretary

Cheten Zangmo
Standardization Division
Bhutan Standards Bureau