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African Traditional Medicine —Packaging, labelling, storage and transportation of raw medicinal plant materials

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This African Standard was prepared by ARSO *Technical Committee on African Traditional Medicine* (ARSO/TC 82)

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Introduction

Raw materials, processed herbal materials, herbal preparations and herbal dosage forms should be packaged as quickly as possible to preserve their quality.

The packaging material for the raw medicinal plant should be properly labelled, stored and transported in ideal conditions to preserve the integrity of the raw medicinal plant material.

Packaging should prevent deterioration of the herbal medicines and they should be protected against exposure to pest infestations and other sources of contamination. When applicable, the maximal holding time of the unpacked herbal medicines should be established. Continuous in-process QC measures should be implemented to eliminate substandard materials, contaminants and foreign matter prior to and during the final stages of packaging.

Processed herbal materials, herbal preparations and herbal dosage forms should be packaged in clean, dry boxes, sacks, breathable bags or other containers in accordance with the Standard Operating Procedure (SOP) and should comply with national and/or regional regulations of the producer and the end-user countries.

Materials used for packaging should be non-polluting, clean, dry and undamaged, and should conform to the quality requirements for the processed herbal materials, herbal preparations or herbal dosage forms concerned.

Fragile herbal materials should be packaged in rigid containers. Wherever possible, the packaging used should be agreed upon between the supplier and the buyer.

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African Traditional Medicine — Packaging, labelling and storage of raw medicinal plant materials

1 Scope

This African Standard provides the description and specification for the packaging, labelling and storage of raw materials for use in African Traditional Medicine and drug industries.. It is aimed at ensuring that these raw materials arrive safely in African Traditional Medicine and to the drug industries and usage.

2 Normative references

The following referenced documents are indispensable for the application 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

ISO 15378:2017,*Primary packaging materials for medicinal products — Particular requirements for the application of ISO 9001:2015, with reference to good manufacturing practice (GMP)*

ISO 9001:2015, *Quality management systems — Requirements*

3 Terms and definitions

For the purpose of this standard the following definitions apply.

3.1
Bulk product
Any raw material that has completed all post-harvest steps,up to, but not including, final packaging

3.2
Containers
A container for raw materials of medicinal plants use is an article which holds or is intended to contain and protect plant material and is or may be in direct contact with it. The closure is a part of the container. The container and its closure must not interact physically or chemically with the substance within in any way that would alter its quality. The following terms include general requirements for the permeability of containers.

3.3
Packaging material
Any material, including printed material, employed in the packaging of a raw material or its product, excluding any outer packaging used for transportation or shipment. Primary packaging materials are those that are in direct contact with the raw material or its product.

3.4
Packaging process
All operations, including filling and labelling, that a bulk product has to undergo in order to become a finished product

3.5
Bag

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A container consisting of surfaces, whether or not with a flat bottom, made of flexible material, closed at the bottom and at the sides by sealing; the top may be closed by fusion of the material, depending on the intended use.

3.6
Bottle
A container with a more or less pronounced neck and usually a flat bottom.

3.7
Quarantine
The status of starting or packaging materials, intermediates, or bulk or finished products isolated physically or by other effective means while a decision is awaited on their release, rejection or reprocessing.

3.8
Manufacturing
All operations including purchasing and receipt of materials to production packaging, labelling, quality control, release, storage, distribution of products and the related controls

3.9
Production
Processes resulting in primary packaging material

Note 1 to entry: The processes form the full production cycle, from receipt of starting materials through processing and packaging, to completion as a finished product

3.10
Contamination
Introduction of any unwanted material into the primary packaging material

Note 1 to entry: A finished product can be contaminated by physical (particulate), chemical or biological (bioburden and endotoxin) action.

Note 2 to entry: Contamination can occur for e.g. during production, packaging, storage and/or distribution from contaminated air systems, personnel, sampling equipment, materials, premises or containers.

3.11
cross-contamination
Contaminationof a material or of a product with another material or product

Note 1 to entry: Cross-contamination can also be referred to as mix-up or admixture.
Storage condition
describes a condition under which a substance or product is stored. Storage criteria may include temperature, humidity and brightness, and so on

3.12
batch document
batch record
documents and records that provide a history of the batch (3.5.1), including information relating to its production (3.5.7) and control, and which facilitate its traceability

3.13
return
process for sending back primary packaging material (s) (3.6.4) to the organization (3.1.1)

3.14
reconditioning
Processing or reprocessing primary packaging material (3.6.4) to meet specification requirements

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3.15
retained samples
Materials or finished products (3.6.1) stored for future reference

Note 1 to entry: These samples are generally taken in a sufficient amount and stored under recommended conditions for reference during a defined period of time.

3.16
finished product
Primary packaging material (3.6.4) which has completed all stages of production (3.5.7)

3.17
intermediate product
Primary packaging material (3.6.4) which has completed some but not all production stages

Note 1 to entry: An intermediate product needs further processing before it becomes a finished product (3.6.1).

3.18
assembly
fitting together of primary packaging materials (3.6.4) and/or components

3.19
quality assurance
Quality assurance is defined as “the totality of the arrangements made with the object of ensuring that the raw materials are of the quality required for their intended use”

4 Requirements for packaging

4.1 General considerations

4.1.1 The design of packaging shall take into account both the needs of the product and of the manufacturing and distribution system.

4.1.2 The packaging materials shall:
— not to leak, nor allow diffusion and permeation of the product;
— be strong enough to hold the contents when subjected to normal handling;
— not be altered by the ingredients of the formulation in its final dosage form.

4.1.3 The aspects of packaging shall consider the following:
a) The functions of packaging;
b) The selection of a packaging material;
c) The testing of the material selected;
d) filling and assembling;
e) Sterilization;
f) Storage and stability.
g) Quality of packaging materials
h) Specifications for packaging (number of layers, etc)

4.2 Raw materials used in packaging

4.2.1 Packaging materialsshall include printed material employed in the packaging of a raw materials or its product, but not anyouter packaging used for transportation or shipment. Examples of thetypes of materials used are shown in Table 1.

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Table 1 –Typesof raw materials used in packaging

S/N	Types of materials	Uses
i.	Cardboard	Boxes Display units
ii.	Paper	Labels Leaflets
iii.	Glass	Bottles and jars Vials
iv.	Plastic	Closures Bottles Bags Tubes Laminates with paper or foil
v.	Metal, e.g. aluminium	Collapsible tubes Rigid cans Foils Gas cylinders Pressurized containers
vi.	Rubber	Closures, including plungers
vii.	Wood and plant fibres	Barrels Corks Jute bags

4.2.2 A distinction shall be made between primary and secondary packaging components. The primary packaging components (e.g. bottles,).

4.2.3 Every effort shall be made to use the type of packaging that provides the best protection against physical damage to the processed materials; and at the same time to keep them away, as far as possible, from exposure to moisture, light, heat, insect and animal attack.

4.2.4 The choice / type of the packaging material shall be compatible with the active pharmaceutical ingredients that is very important in maintaining the integrity of the product.

4.2.5 Materials used for packaging shall be non-polluting, clean, dry and undamaged, and should conform to the quality requirements for the raw herbal material concerned.

4.3 External influences on packaging materials

The packaging shall protect the product against all adverse external influences that may affect its quality or potency, such as:
— light
— moisture
— oxygen
— biological contamination
— mechanical damage.

4.4 Specific considerations on packaging materials

4.4.1 The maximal holding time of the unpacked herbal medicines shall be established.

4.4.2 Continuous in-process quality control (QC) measures shall be implemented to eliminate substandard materials, contaminants and foreign matter prior to and during the final stages of packaging.

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4.4.3 Processed herbal materials, herbal preparations and herbal dosage forms shall be packaged in clean, dry boxes, sacks, breathable bags or other containers in accordance with the SOP and shall comply with national and/or regional regulations of the producer and the end-user countries.

4.4.4 Fragile herbal materials shall be packaged in rigid containers.

4.4.5 Wherever possible, the packaging used shall be agreed upon between the supplier and the buyer.

4.5 Packaging materials and stability of the product

4.5.1 The active ingredients in the herbal products shall remain within their specification limits over the shelf-life of the herbal product.

4.5.2 The question of whether a packaging material shall provide the required protection for the herbal **product and the required stability** over a certain time period can only be answered by means of real-time stability studies. Such studies should evaluate the changes in the quality of the product, in contact with its packaging, during a period equivalent to its intended shelf-life.

4.5.3 In addition, the packaging shall meet the following requirements:

a) to preserve the physical properties of all herbal forms and protect them against damage or breakage;
b) to not alter the identity of the product;
c) to preserve the characteristic properties of the product, so that the latter complies with its specifications;
d) to protect the product against undesirable or adulterating chemical, biological or physical entities.

5 Requirements for Labelling

5.1 All packaged herbal materials shall be identified by labelling, as required by the national legislation, bearing at least the following information:

a) accepted scientific name of the herb(s);

b) Official common name of the herb(s), herbal material(s), herbal preparation(s) or herbal dosage form(s);

c) Brand name of the herbal medicines (herb(s), herbal material(s), herbal preparation(s) or herbal dosage form(s));

d) Date of the processing of the processed herb(s), herbal material(s), herbal preparation(s), or herbal dosage form(s) obtained;

e) Processing techniques used;

f) Names and addresses of the herbal materials or herbal preparations processor, herbal dosage forms (finished herbal products) manufacturer, importer and/or distributor (i.e. the entity responsible for receiving consumer complaints and conducting a recall should the need arise);

g) potency or strength of the active ingredient, if applicable (for example, for an extract the drug extract ratio of herbal material to extract, or the concentration of active or marker substance(s) used for standardization);

h) net amount in the immediate container in terms of weight, measure or unit number;

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i) In the case of a finished herbal dosage form, the quantity of each active ingredient or marker per dosage unit;

j) list of excipients;

k) recommended storage conditions; 128WHO Technical Report Series, No. 1010, 2018 WHO Expert Committee on Specifications for Pharmaceutical Preparations Fifty-second report

l) batch number;

m) manufacture/collection date;

n) expiry date; and

o) country of origin.

5.2 The label shall also contain information indicating quality approval and compliance with national and/or regional labelling requirements and certification marks.

5.3 Finished herbal product labelling should comply with the national/ regional regulation/requirements.

5.4 Records should be kept of batch packaging, and should include the product name, place of origin, batch number, weight, assignment number and date.

5.5 The records should be retained for a period of three years or as required by national and/or regional authorities.

6 Requirements for Storage Pest Control and transportation

6.1 Storage area

6.1.1 All raw materials and processed herbal medicines shall be properly stored and preserved before distribution or use. They shall be protected from microbial and insect contamination, as well as rodents and other pests.

6.1.2 Storage areas shall be designed or adapted to ensure good storage conditions. In particular, they should be clean and dry and maintained within acceptable temperature limits. Where special storage conditions are required (e.g. temperature, humidity) these should be provided, checked and monitored.

6.1.3 Good store house for storage of herbs shall be adequate space in the store house for ‘Under test;’ Approved and ‘Rejected’ herbs with arrangements and equipment to allow washing cleaning, drying and orderly placement of stored herbs with controlled temperature and humidity. The store house for storage of herbs, handling of herbs and drying space etc. shall be as per the provision of GMP.

6.1.4 Storage area shall be of sufficient capacity to allow orderly storage of the various types of processed herbal materials, herbal preparations or herbal dosage forms with proper separation and segregation. In particular, they should be clean, dry, sufficiently lit and maintained within acceptable temperature and humidity limits.

6.1.5 Storage areas shall be of sufficient capacity to allow orderly storage of the various categories of materials and products: starting and packaging materials, intermediates, bulk and finished products, products in quarantine, and released, rejected, returned or recalled products.

6.1.6 The storage area shall be controlled, monitored and recorded where appropriate to ensure good storage conditions, and comply with the “first-in and first-out” principle.

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6.1.7 Toxic or controlled herbal materials or preparations shallbe checked, labelled and stored according to the government's regulations.

6.1.8 Separate store shall be for different categories of medicinal and aromatic plants e.g. fresh herbs, dry herbs, extracts/gums, volatile oils, poisonous drugs.· Allow free movement of men, machine and equipment.

6.1.9 Separate sections for 'Under test' 'Approved' and 'Rejected' lots.

6.1.10 Do not store physically similar looking herbs in the vicinity; it may lead to wrong identity.
6.1.11 Each lot of herbs stored should bear a label with following details.

- Name of drug
- Name of supplier
- Part (root, stem, bark, leaf, flower, rhizome etc)
- Inspection status (tested/rejected/approved)
- Date of arrival and consignment number
- Test report number and date Time of collection

6.1.12 Rejected samples shall be kept in a separate designated quarantined area, clearly labelled and with a specified handling period.

6.1.13 Receiving and dispatch bays should protect materials and products from the weather. Reception areas should be designed and equipped to allow containers of incoming materials to be cleaned if necessary before storage.

6.1.14 Where quarantine status is ensured by storage in separate areas, these areas must be clearly marked and their access restricted to authorized personnel. Any system replacing the physical quarantine should give equivalent security.

6.1.15 There should normally be a separate sampling area for starting materials. If sampling is performed in the storage area, it should be conducted in such a way as to prevent contamination or cross contamination.

6.1.16 Segregation should be provided for the storage of rejected, recalled or returned materials or products.

6.1.17 Printed packaging materials are considered critical to the conformity of the herbal product to its labelling, and special attention should be paid to the safe and secure storage of these materials.

6.2 Pest control in storage area

6.2.1 Pest infestation control in conveyances and in storage areas shall be carried out by licensed or trained personnel.

6.2.2 Only registered chemical agents authorized by the regulatory authorities of the source country and the countries of intended end-use should be used.

6.2.3 All fumigation, fumigation agents and dates of application should be documented.

6.2.4 When freezing or saturated steam is used for pest control, the humidity of the stored herbal medicines should be checked after treatment.

6.3 Transportation

Conveyances used for transporting raw medicinal plant material shall be clean and, where appropriate, well ventilated to maintain an appropriate airflow and to prevent condensation.

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In case of bulk transport, it is important to secure dry conditions and furthermore, in order to reduce the risk of mould formation or fermentation, it is extremely advisable to use of aerated containers.

As a substitute, the use of sufficiently aerated transport vehicle and other aerated facilities is recommended.

Essential oils transport must conform to appropriate National Regulations.

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Annex A
(normative) or (informative)

Recommended packaging for medicinal produce

Type of the Produce	Packaging Options
Woody in nature – roots, stem, wood, woody bark etc.	1. Gunny Bags 2. Jute Bags 3. Woven Sacks
Annual whole herbs, creepers, twiners, leaves, etc.	1. Woven sacks with low density liner 2. Jute bags
Fleshy materials-fleshy rhizomes (e.g.Shatavari), fruit rinds (Kokum butter) of flowers (Mahua)	1. Jute bags with high gauge polyethylene liners 2. Woven sacks with high gauge polyethylene liners
Delicate flowers and floral parts – Anthers, Stigma, Petals etc.	1. Corrugated box with polyethylene liners 2. Card-board box with woven sacks
Gums and resins	1. Air-tight Plastic drums 2. Corrugated box with polyethylene liners
Aromatic plant produces	1. Air tight High Density Polyethylene (HDPE) containers 2. Fiber board drums with polyethylene liners

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