Herbal products - Vocabulary (First Revision)

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DEPARTMENT OF STANDARDS MALAYSIA
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Committee representation

The Industry Standards Committee on Food, Food Products and Food Safety (ISC U) under whose authority this Malaysian Standard was developed, comprises representatives from the following organisations:

- Bahagian Keselamatan dan Kualiti Makanan
- Department of Agriculture
- Department of Chemistry, Malaysia
- Department of Standards Malaysia
- Federal Agricultural Marketing Authority
- Federation of Malaysian Manufacturers
- Jabatan Kemajuan Islam Malaysia
- Malaysian Agricultural Research and Development Institute
- Malaysian Association of Standards Users
- Malaysian Institute of Food Technology
- Malaysian Palm Oil Association
- Malaysian Palm Oil Board
- Ministry of Agriculture and Agro-Based Industry Malaysia
- Ministry of Health Malaysia
- Ministry of International Trade and Industry
- Ministry of Science, Technology and Innovation (National Biotechnology Division)
- Pati Bumi Sdn Bhd
- SIRIM Berhad (Secretariat)
- SME Corporation Malaysia
- Universiti Kebangsaan Malaysia
- Universiti Putra Malaysia

The Technical Committee on Herbs and Spices which developed this Malaysian Standard consists of representatives from the following organisations:

- Biotropics Malaysia Berhad
- Department of Agriculture
- Forest Research Institute Malaysia
- Institute for Medical Research
- Malaysian Agricultural Research and Development Institute
- National Pharmaceutical Control Bureau
- Nestle Manufacturing (Malaysia) Sdn Bhd
- SIRIM Berhad (Secretariat)
- TPM Biotech Sdn Bhd
- Universiti Putra Malaysia
- Universiti Sains Malaysia

Co-opted member:

Universiti Kebangsaan Malaysia
Foreword

This Malaysian Standard was developed by the Technical Committee on Herbs and Spices under the authority of the Industry Standards Committee on Food, Food Products and Food Safety.

Major modifications in this revision are as follows:

a) incorporation of a new paragraph on “Scope” in clause 1;

b) incorporation of new title “Normative references” in clause 2;

c) the terminologies division have been updated; and

d) the terminologies have been updated.

This Malaysian Standard cancels and replaces MS 1860:2005, Herbs and herbal products - Vocabulary.

Compliance with a Malaysian Standard does not of itself confer immunity from legal obligations.
Herbal products - Vocabulary  
(First Revision)

1 Scope

The Malaysian Standard provides a list of terms and definitions for herbs and other natural products, including those from plants, animals, minerals and marine-based origin.

It encompasses the fields of agronomy, animal husbandry, aquaculture, pharmacognosy, phytochemistry, pharmacology and toxicology, biotechnology, food and pharmaceutical technology, clinical studies and regulatory.

These terms apply to all industries related to the supply chain activities, evaluation, manufacturing, sales and marketing and use of herbal and other natural products.

2 Normative references

The following normative references are indispensable for the application of this standard. For dated references, only the edition cited applies. For undated references, the latest edition of the normative references (including any amendments) applies.

Control of Drugs and Cosmetics Regulations 1984.
Food Act 1983.
Malaysian herbal monograph, vol. 1, 2 and 3.
Sales of Drugs Act 1952.
Poison Act 1952.

3 General terminology on herbs and herbal products

3.1 complementary/alternative medicine (CAM)

The term refers to a broad set of health care practices that are not part of that country's own tradition and are not integrated into the dominant health care system.

NOTE. The term complementary medicine or alternative medicine is used interchangeably with traditional medicine in some countries.

3.2 extracts

A concentrated form of the herbal preparation obtained by processing the crude herb with an appropriate solvent, by maceration, fractionation, infusion, supercritical fluid extraction, or any other means of extraction.
3.3 **herbs**

Include raw or crude plant material such as leaves, flowers, fruits, seeds, stems, wood, barks, roots, rhizomes or other plant parts, which may be entire, whole, fragmented or powdered.

3.4 **herbal materials**

Include, in addition to herbs, fresh juices, gums, fixed oils, essential oils, resins and dry powders of herbs. In some countries, these materials may be processed by various local procedures, such as steaming, roasting or stirbaking with honey, alcoholic beverages or other materials.

3.5 **herbal substances**

All mainly whole, fragmented or cut plants, plant parts, algae, fungi, lichen in an unprocessed, usually dried form but sometimes fresh. Certain exudates that have not been subjected to a specific treatment are also considered to be herbal substances. Herbal substances are precisely defined by the plant part used and the botanical name according to the binomial system (genus, species, variety and author).

3.6 **herbal preparations**

The basis for finished herbal products and may include comminuted or powdered herbal materials, or extracts, tinctures and fatty oils, expressed juices and processed exudates of herbal materials. They are produced with the aid of extraction, distillation, expression, fractionation, purification, concentration, fermentation or other physical or biological processes. They also include preparations made by steeping or heating herbal materials in alcoholic beverages and/or honey, or in other materials.

3.7 **herbal medicines**

Products containing as active substances exclusively herbal drugs or herbal drug preparations. They may consist of herbal preparations made from one or more herbs. If more than one herb is used, the term "mixed herbal product" may also be used. They may contain excipients in addition to the active ingredients.

3.8 **traditional medicine (TM)**

Any product used in the practice of indigenous medicines, in which the drug consist solely of one or more naturally occurring substances of a plant, animal or mineral, of parts thereof, in the unextracted or crude extract form, and a homeopathic medicine.

Any product employed in the practice of indigenous medicine to treat, mitigate, cure and prevent disease in human and to maintain human health, whereby the drug used only consists of one or more naturally occurring substances of plant, animal and mineral or part thereof, or in extracted form or non-extracted form, and any homeopathic medicine.
4 Classification of terminology on herbal cultivation and sourcing

4.1 cultivation practices

The steps to prepare the land/farm to grow and harvest which is guided by the standard agronomy practices (fertilizer, weeds management, pest and disease control, irrigation/watering) to achieve optimal yield and quality (phytochemical components).

4.2 collector

Entities involved in commercial collection of herbs from the wild including individuals and companies.

4.3 crop producer

Entities involved in commercial production of crops including individuals and companies.

4.4 essential element

Critical, main or key factor.

4.5 environmentally sound

Farm and collection practices that do not have adverse effects on the environment, e.g. chemical pollution of water ways, effluent discharge.

4.6 economically viable production

Production that gives positive returns on a sustainable basis.

4.7 good agricultural practices

A collection of principles to apply for on-farm production and post-production processes, those are necessary to produce safe and wholesome agricultural products.

4.8 herbal drug preparation

Herbal drug preparation is obtained by subjecting herbal drugs to treatment such as extraction, distillation, expression, fractionation, purification, concentration or fermentation. These include comminute or powdered herbal drugs, tinctures, extracts, essential oils, expressed juices and processed exudates.

4.9 herbal drugs

Herbal drugs are mainly whole, fragmented or cut, plants, parts of plants, algae, fungi, lichen in an unprocessed state, usually in dried form but sometimes fresh. Certain exudates that have not been subjected to a specific treatment are also considered to be herbal drugs. Herbal drugs are precisely defined by the botanical scientific name according to the binomial system (genus, species, variety and author).
4.10 Integrated Pest Management (IPM)
A management system that uses all suitable techniques and methods in a manner as compatible as possible to maintain pest population at levels below those causing economic injury.

4.11 legally compliant
Adherence to all existing national legislation.

4.12 pests
Organisms those are capable of causing injury and loss to crops. These organisms include insects, other invertebrates, fungi, bacteria, viruses, weeds and vertebrates.

4.13 post-harvest
An act of activities to ensure the crop either fresh or in processed form can be preserved well before reaching the consumer including harvesting, activities, transportation, cleaning, selection, drying and storage.

4.14 plant material
Whole plants/plant parts (including seed, root and fruit) that are used in food supplement, beverages, cosmetic and toiletry.

4.15 quality produce
Produce that is wholesome and safe for consumption and/or suitable for utilisation.

4.16 socially acceptable
Meeting concerns on the welfare and safety of persons working or living in the farm.

4.17 sustainable crop production
A holistic, systems-oriented approach to farming that is efficient in resource management and focuses on the interrelationship of social, economic and environmental processes. This approach is based upon environmentally sound, socially responsible and economically profitable practices.

4.18 wild sources
Collection of plants or plant parts which are not cultivated. It is also known as wild crafted.
5 Classification of terminology on pharmacognosy

5.1 Good Manufacturing Practices (GMP)

An aspect of quality assurance which ensures that herbal products are produced and controlled according to appropriate quality standards for the product use and as the regulatory requirements or product specifications. In Malaysia, manufacturing of herbal products should be done in a premise that complies with Good Manufacturing Practice (GMP), that is, the premise must be inspected and approved by the National Pharmaceutical Control Bureau, Ministry of Health, Malaysia. Good practices in the manufacture cover the aspects of premise, work area and storage, equipment, raw material, packaging material, manufacturing procedure, documentation, quality control testing, personnel and waste.

5.1.1 active ingredients

The herbal material(s) or the herbal preparation(s) will be considered to be active ingredient(s) of a herbal medicine(s). However, if constituents with known therapeutic activities are known, the active ingredients should be standardized to contain a defined amount of this/these constituent(s).

5.1.2 blending

Blending is the process of combining materials or different batches to produce a homogeneous intermediate or finished product.

5.1.3 documentation

All written procedures, instructions and records involved in the manufacture of a traditional medicine or health supplement.

5.1.4 expiry date

A date fixed for each individual batch before which the batch still meets the required standard specifications for quality based on its shelf life.

5.1.5 manufacture

The complete cycle of production and quality control of a traditional medicine or health supplement from the acquisition of all materials through all processing and subsequent packaging to the distribution or release of the finished product.

5.1.6 packaging materials

Any material including printed material, employed in the packaging of a traditional medicine or health supplement, such as capsules, containers, closures, bags, packing, label materials (labels, inserts, etc.), seals, binding materials, adhesives and tapes.

5.1.7 raw materials

All materials whether active or inactive that are employed in the processing of traditional medicines and health supplements.
5.1.8 registered product

A product currently registered in accordance with the provisions of Control of Drugs and Cosmetics Regulations 1984, bearing the MAL number.

5.2 origin

5.2.1 finished herbal products/herbal medicinal products

Products containing as active substances exclusively herbal drugs or herbal drug preparations. They may consist of herbal preparations made from one or more herbs. If more than one herb is used, the term “mixed herbal product” may also be used. They may contain excipients in addition to the active ingredients. In some countries herbal medicines may contain, by tradition, natural organic or inorganic active ingredients, which are not of plant origin (e.g. animal materials and mineral materials). Generally however, finished products or mixed products to which chemically defined active substances have been added, including synthetic compounds and/or isolated constituents from herbal materials, are not considered to be herbal.

5.2.2 herbs

Herbs include crude plant material such as leaves, flowers, fruit, seeds, stems, wood, bark, roots, rhizomes or other plant parts, which may be entire, fragmented or powdered.

5.2.3 herbal medicines

Herbal medicines include herbs, herbal materials, herbal preparations and finished herbal products.

5.2.4 herbal materials

Herbal materials are either whole plants or parts of medicinal plants in the crude state. They include herbs, fresh juices, gums, fixed oils, essential oils, resins and dry powders of herbs. In some countries, these materials may be processed by various local procedures, such as steaming, roasting, or stir baking with honey, alcoholic beverages or other materials.

5.2.5 herbal preparations

The basis for finished herbal products and may include comminuted or powdered herbal materials, or extracts, tinctures and fatty oils, expressed juices and processed exudates of herbal materials. They are produced with the aid of extraction, distillation, expression, fractionation, purification, concentration, fermentation or other physical or biological processes. They also include preparations made by steeping or heating herbal materials in alcoholic beverages and/or honey, or in other materials.

5.2.6 traditional medicine

Any product employed in the practice of indigenous medicine to treat, mitigate, cure and prevent disease in human and to maintain human health, whereby the drug used only consists of one or more naturally occurring substances of plant, animal and mineral or part thereof, or in extracted form or non-extracted form, and any homeopathic medicine.
5.3 quality control

All measures undertaken during manufacturing designed to ensure the uniform output of traditional medicines and health supplements that conform to established specifications of identity, purity, strength, safety, and indication of use.

5.3.1 contaminants

Adulterant impurities such as heavy metals, pesticides, mycotoxins, fumigants as well as microbial contamination, including those arising from extraneous sources, and radioactive substances, if relevant.

5.3.2 foreign matter

Material consisting of any or all of the following adulterants:

a) parts of the herbal material or materials other than those named with the limits specified for the herbal material concerned;

b) any organism, part or product of an organism, other than that named in the specification and description of the herbal material concerned;

c) mineral admixtures such as soil, stones, sand, and dust; and glass, metal and plastics or any other extraneous materials. These may be loose or adhering to these herbal materials.

5.3.3 macroscopic examination

Identification of herbal materials based on shape, size, colour, surface characteristics, texture, fracture characteristics and appearance of the cut surface.

5.3.4 microscopic examination

Identification of broken or powdered herbal materials by microscopic technique.

5.3.5 phytochemical characterisation

Analytical data on constituents including constituents with known therapeutic activity as well as compounds suitable as active markers or analytical markers. Includes chromatographic fingerprinting.

5.3.6 reference standard or reference material

A substance prepared for use as the standard in an assay, identification, or purity test. In the case of herbal medicinal products, the reference standard may be a botanical sample of the herbal substance, a sample of the herbal preparation e.g. extract or tincture or a chemically defined substance e.g. a constituent with known therapeutic activity, an active marker or an analytical marker or a known impurity. The reference standard has a quality appropriate to its use. The composition of reference standards of herbal substances and herbal preparations intended for use in assays should be adequately controlled and the purity of a standard should be measured by validated quantitative procedures.
5.3.7 specification

A list of tests, references to analytical procedures, and appropriate acceptance criteria which are numerical limits, ranges, or other criteria for the tests described. It establishes the set of criteria to which a herbal substance/preparation or herbal medicinal product should conform to be considered acceptable for its intended use. "Conformance to specifications" means that the herbal substance/preparation and/or herbal medicinal product, when tested according to the listed analytical procedures, will meet the listed acceptance criteria. Specifications are binding quality standards that are agreed to between the appropriate governmental regulatory agency and the applicant.

5.4 standardisation

Adjusting the herbal substance/preparation to a defined content of a constituent or a group of constituents with known therapeutic activity respectively either by adding excipients or by blending batches of the herbal substance and/or herbal preparation (e.g. standardized extracts). The process ensures consistency and repeatability of product quality.

5.4.1 excipients

Generally defined as constituents of the medicinal product other than the active substance(s). However, in the context of this guideline only two categories of excipients are addressed:

5.4.1.1 excipients for adjustment

Excipients used for standardisation of herbal substances/preparations.

5.4.1.2 other excipients

Technological excipients (e.g. carrier substances) which may be part of herbal preparations.

5.4.2 markers

Chemically defined constituents or groups of constituents of a herbal substance, a herbal preparation or a herbal medicinal product which are of interest for control purposes independent of whether they have any therapeutic activity. Markers serve to calculate the quantity of herbal substance(s) or herbal preparation(s) in the herbal medicinal product if the marker has been quantitatively determined in the herbal substance or herbal preparation. There are two categories of markers:

5.4.2.1 active markers

 Constituents or groups of constituents which are generally accepted to contribute to the therapeutic activity.

5.4.2.2 analytical markers

 Constituents or groups of constituents that serve for analytical purposes.
6 Classification of terminology on phytochemistry

6.1 active ingredients

The therapeutically active component in a herbal medicine's final formulation that is responsible for its physiological action. In cases where it is not possible to identify the active ingredients, the whole herbal medicine may be considered as one active ingredient.

NOTE. In herbal medicines where the active ingredients have been identified, the preparation of these medicines should be standardised to contain a defined amount of the active ingredients if adequate analytical methods are available.

6.2 analytical methods

Chemical constituents of a herbal plant can be identified by the use of spectral methods: FTIR, UV-VIS, GCMS, LCMS and NMR. For complete identification, compounds need to be isolated and purified.

6.2.1 spectroscopic

A technique to investigate the nature of herbal materials using FTIR, IR, UV and NMR. The data obtained may give indication of the functional groups of compounds present in the herbal materials.

6.2.1.1 Fourier Transform Infra-Red (FTIR)

An infra-red spectral fingerprinting technique to profile herbal materials within a spectral wavelength range of 600 to 4000 nm for the purpose of authentication and quality control.

6.2.1.2 Nuclear Magnetic Resonance (NMR)

A technique to analyse the chemical nature of compounds for the purpose of elucidating the chemical structure and its hydrogen (H) and carbon (C) interaction in a defined magnetic field.

6.2.1.3 Ultra Violet-visible (UV-VIS)

A technique to profile soluble phytochemical compound qualitative and quantitatively within a spectral wavelength range of 200 to 400 nm.

6.3 chemical method

Qualitative or quantitative determination of active substances as directed in monographs.

6.4 chromatographic separation methods

The separation and purification of chemical constituents from plants is mainly carried out by chromatographic tools ie thin layer chromatography (TLC), column chromatography, gas chromatography (GC) and high performance liquid chromatography (HPLC).

6.4.1 chromatographic

A technique for separating and identifying the chemical compounds components present in a mixture herbal extracts based on physicochemical properties of compound.
6.4.1.1 Thin Layer Chromatography (TLC)
A chromatographic technique to separate non-volatile components in a mixture. This technique is used to identify components based on differential affinities of solutes between two immiscible phases; one of which is a stationary phase while the other, mobile phase, migrates across a planar surface by capillary action.

6.4.1.2 High Performance Thin Layer Chromatography (HPTLC)
An advanced TLC method used for separation, profiling and quantitative estimation of phytochemicals present in herbal extracts.

6.4.1.3 High Performance Liquid Chromatography (HPLC)
A technique in analytical chemistry used to separate the non-volatile components in a mixture, to identify and quantify each component based on differential affinities between two liquid phases using a stationary column consisting of selected packing materials.

6.4.1.4 Preparative High Performance Liquid Chromatography (Prep HPLC)
A similar analytical technique as HPLC but is usually associated with the use of large column and high flow rate. It is used for isolation and purification of substances from plant extract.

6.4.1.5 Gas Chromatography (GC)
A technique in analytical chemistry used to separate volatile components in a mixture to identify and quantify each component based on differential affinities between liquid and gas phases by using a capillary column consisting of selected packing materials.

6.5 extraction
A process to separate herbal ingredients using various solvents for example water.

6.5.1 decoction
A method of extraction of dissolve substances by boiling plant materials.

6.5.2 distillation
A process of separating volatile substances from solid-liquid or liquid mixtures through vaporization and condensation, based on different volatility (vaporization point) of components in the mixture.

6.5.3 maceration
A method of extract preparation in the herbs soaked with an appropriate solvent and allowed to stand in a closed container for a desired time.

6.5.4 percolation
A slow passage of a liquid through a filtering medium uses boiling water in a similar way to distillation.
6.5.5 reflux

A herbal extraction technique involving the boiling and condensation of solvent vapors and the return of this condensate to the system from which it originated. Solvents used are usually alcohols and water.

6.5.6 Supercritical Fluid Extraction (SFE)

A process of extracting substances from plant materials using pressurize carbon dioxide (CO₂) as the extracting solvent. Co-solvents may also be used such as ethanol or methanol.

6.5.7 Soxhlet extraction

A continuous cycle of extraction technique of substances from plant materials using Soxhlet extractor and organic solvent through the process of reflux.

6.5.8 sonication

Application of sound energy to agitate particles in a plant sample, to facilitate the process of extraction.

6.6 phytochemistry

Study of phytochemical referring to a wide variety of compounds synthesised by plants mainly use for human health.

6.7 primary metabolite

Primary compounds that is directly involved in normal growth, development, and reproduction of plants.

6.7.1 carbohydrate

A primary compound consisting of carbon (C), hydrogen (H), and oxygen (O) atoms, found throughout the plant kingdom in the form of sugars, starches, cellulose, and others.

6.7.2 lipid

A primary compound consisting of fats, waxes, sterols, fat-soluble vitamins (such as vitamins A, D, E, and K), monoglycerides, diglycerides, triglycerides, phospholipids, and others in plants.

6.7.3 protein

A primary compound consisting of one or more long chains of amino acid residues.

6.8 secondary metabolite

Secondary organic compounds derived from specific pathways for defense and protection of the plants that are of benefit for medicinal purpose.
6.8.1 alkaloid
A group of organic bases containing nitrogen and usually oxygen that occur in the form of salts.

6.8.2 antioxidant
A molecule that inhibits the oxidation by removing free radical intermediates, and inhibits other oxidation reactions of other molecules. Antioxidants are often reducing agents such as polyphenols, ascorbic acid or tocopherol. They prevent oxidative damage in living cells and tissues.

6.8.3 oxidant
A chemical that transfers electrons or hydrogen from a substance to an oxidizing agent resulting in free radicals and oxidative damage.

6.8.4 cathecin
A subclass of flavonoids found in tea.

6.8.5 coumarin
A class of widely occurring phenolic compounds, especially abundant in citrus fruits, which may help the enzymes that fend off cancer.

6.8.6 essential oils
A volatile product obtained from plants by steam or water distillation

6.8.7 flavonoids
Water soluble phenolic compound usually found in fruits, vegetables, wine and tea, especially green tea.

6.8.8 lignans
A group of natural products (dimers) derived from condensation of 2 phenylpropane units. Lignans are another class of phenolic compounds. Found in almost all fruits, vegetables and grains, phenolic compounds affect the quality, appeal and stability of foods with antioxidant action, flavour and colour.

6.8.9 phenolic
Phenol compounds which have an aromatic ring with an alcoholic ring attached to it. Examples; ellagic acid, hydroxycinnamic acid derivatives (caffeic, chlorogenic and ferulic acids, curcumin, coumarins).

6.8.10 saponins
Naturally occurring compounds found in most vegetables and herbs, but especially abundant in soybeans and other beans and legumes.
6.9 physical method

The application of physical parameters (i.e. solubility, specific gravity, melting point, water content and other physical characteristics) to evaluate plant herbs.

6.10 physico-chemical method

Method of purification of miscellae (solution containing extracted substance) involving adsorption, precipitation and ion-exchange techniques.

7 Classification of terminology on pharmacology and toxicology

7.1 adverse effect

Change in the morphology, physiology, growth, development, reproduction or life span of an organism, system or (sub) population that result in an impairment of the functional capacity, an impairment of the capacity to compensate for additional stress or an increase susceptibility to other influences.

7.2 blinding/masking

A procedure in which one or more parties to the trial are kept unaware of the treatment assignment(s). Single-blinding usually refers to the subject(s) being unaware, and double-blinding usually refers to the subject(s), investigator(s), monitor, and, in some cases, data analyst(s) being unaware of the treatment assignment(s).

7.3 Case Report Form (CRF)

A printed, optical, or electronic document designed to record all of the protocol required information to be reported to the sponsor on each trial subject.

7.4 clinical study

Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamics effects of an investigational herbal product(s) and/or to identify any adverse reactions to an investigational herbal product(s) and/or to study the pharmacokinetics of an investigational herbal product(s) with the object of ascertaining its safety and/or efficacy.

7.5 clinical trial

Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamics effects of an investigational herbal product(s) and/or to identify any adverse reactions to an investigational herbal product(s) and/or to study the pharmacokinetics of an investigational herbal product(s) with the object of ascertaining its safety and/or efficacy.

7.6 comparator (product)

An investigational or marketed product (i.e. active control), or placebo, used as a reference in a clinical trial.
7.7 compliance
Adherence to all requirements related to the trial, Good Clinical Practice (GCP) and the applicable regulations.

7.8 confidentiality
Prevention of disclosure, to other than authorized individuals, of a sponsor's proprietary information or of a subject's identity.

7.9 dose
The amount of herbal material administered. Dose is expressed as weight of herbal material substance per unit weight of test human/animal (e.g. mg/kg) or as constant dietary concentrations (ppm).

7.9.1 lethal dose
The dose of a herbal material that is likely to cause death.

7.9.2 Median Lethal Dose (LD50)
A statistically derived single dose of a substance that can be expected to cause death in 50% of animals when administered by the oral route. The LD50 value is expressed in terms of weight of test substance per unit weight of test animal (mg/kg).

7.9.3 therapeutic dose
The amount of herbal material required to produce the desired effect.

7.10 double-blind studies
A study in which neither the subject nor the investigator nor the research team interacting with the subject or data during the trial knows what treatment a subject is receiving (e.g., active or placebo).

7.11 experimental protocol
A document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial.

7.12 efficacy
Refers to the maximum response achievable from herbal material to produce a beneficial effect.

7.13 Good Laboratory Practice (GLP)
The organizational process and the conditions under which laboratory studies are planned, performed, monitored, recorded, archived and repeated in conformance with the recognized GLP guidelines.
7.14 **Good Clinical Practice (GCP)**

A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected in conformance with international practice.

7.15 **Investigator**

A GCP certified personnel responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator.

7.16 **Independent Ethics Committee (IEC)**

An independent body (a review board or a committee, institutional, regional, national, or supranational), constituted of medical/scientific professionals and non-medical/non-scientific members, whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial and to provide public assurance of that protection, by, among other things, reviewing and approving/providing favorable opinion on the trial protocol, the suitability of the investigator(s), facilities, and the methods and material to be used in obtaining and documenting informed consent of the trial subjects. This committee is under the purview of Ministry of Health, known as Medical Research Ethics Committee (MREC).

7.17 **Investigational herbal medicine**

A pharmaceutical form of herbal medicine or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication (off-label use), or when used to gain further information about an approved use.

7.18 **Investigator’s brochure**

A compilation of the clinical and nonclinical data on the investigational herbal medicine which is relevant to the study of the investigational herbal product(s) in human subjects.

7.19 **Informed consent**

A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject’s decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form.

7.20 **No-observed-adverse-effect Level (NOAEL)**

The highest dose level where no adverse treatment-related findings are observed.

7.21 **Pre-clinical study**

A stage of research that determines the safety profile of a herbal material before introduction into clinical study.
7.22 pharmacokinetics
Qualitative and quantitative study of the time course of absorption, distribution, metabolism and excretion of herbal material in an organism.

7.23 pharmacodynamics
Studies on the relationships between herbal material concentrations around the organs/tissues and the pharmacological effects that it induces by the modification of biological functions.

7.24 pharmacogenetics
A study of how the actions of and reactions to herbal products vary with the patient’s genes.

7.25 randomisation
The process of assigning trial subjects to treatment or control groups to reduce bias by using an element of chance to determine the assignments.

7.26 safety
The condition of being safe from the risk of experiencing the adverse effects.

7.27 sponsor
An individual, company, institution, or organisation which takes responsibility for the initiation, management, and/or financing of a clinical trial.

7.28 Standard Operating Procedures (SOPs)
Detailed, written instructions to achieve uniformity of the performance of a specific function.

7.29 Serious Adverse Event (SAE)
Any untoward medical occurrence that at any dose results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity or results in a congenital anomaly/birth defect.

7.30 source data
All information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial.

7.31 toxic
Herbal materials that cause death, disease and/or birth defects in the organism that ingest or absorb them.

7.32 toxicity
The ability of herbal materials to cause poisonous effects resulting in severe biological harm or death after exposure to, or contamination with herbal materials.
7.32.1 acute toxicity

Refers to possible adverse effects occurring following administration of a single dose of herbal materials or multiple doses given within 24 hours.

7.32.2 chronic toxicity

Refers to the possible adverse effects likely to arise from repeated exposure/administration of the herbal materials over a considerable part of the lifespan of the organism.

7.32.3 sub-chronic toxicity

Refers to the possible adverse effects likely to arise from repeated exposure/administration of the herbal materials (90 days) over prolonged period of time covering post-weaning maturation and growth well into adulthood.

7.32.4 sub-acute toxicity

Refers to possible adverse effects likely to arise from repeated exposure/administration of the herbal materials (28 days) of the herbal materials.

7.33 toxicology

Study of the adverse effects of chemicals, physical or biological agents on living organism and ecosystem, including the prevention and improvement of such adverse effect.

7.33.1 genetic toxicology

The study of the deleterious of herbal materials on genetic materials, deoxyribonucleic acid (DNA) which may affect the integrity of the cell.

7.33.2 prenatal developmental toxicology

Any adverse effect on the developing organism that may result from teratogen exposure which can be medications, drugs, chemicals, maternal conditions or diseases prior to conception, during prenatal development or postnatally to the time of maturation.

7.33.3 reproductive toxicology

The study of the occurrence, causes, manifestation and development of adverse effects of herbal materials on reproduction.

7.34 trial subject

An individual who participates in a clinical trial, either as a recipient of the investigational product(s) or as a control.

7.35 trial site

The location(s) where trial-related activities are actually conducted.
7.36 protocol
A document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial, including amendments made during the course of the trial in accordance to International Committee of Harmonization (ICH) GCP Guidelines.

8 Classification of terminology on food and pharmaceutical technology

8.1 absolute
A highly concentrated alcoholic extract of a concrete which contains only alcohol soluble materials.

8.2 concentration
A process to increase the strength of a herbal solution by evaporation, filtration or vacuum-drying.

8.3 concrete
An extract of plant parts by the use of a hydrocarbon solvent.

8.4 drying
Removal of moisture or liquid from a herbal material to a level as stipulated in the monograph using various drying methods. For example sun-drying, hot air drying and freeze drying.

8.5 extracts
Concentrated herbal mixtures obtained by extraction methods.

8.6 essential oil
Volatile component responsible for the odour or taste of a plant.

8.7 formulation studies
Studies to evaluate the choice of other components (for examples, choice and types of ingredients, container closure system, devices etc) and manufacturing process.

8.8 fractionation
A method to isolate chemical compounds or extracts from herbs usually by distillation.

8.9 galenicals
Liquid medicines for oral administration containing tinctures or other preparations derived by the extraction of crude drugs of plant with a suitable solvent.

8.10 herbal standards
Reference used as a comparative material for evaluations and benchmark or specification.
8.11 infusion
An extract obtained by steeping/soaking (herb, tea, part of plant etc.) in liquid to draw out its soluble constituents.

8.12 juice
Liquid part of herbs.

8.13 labeling

8.14 liniment
Solutions or mixtures of various substances in oil, alcoholic solution of soaps and emulsions intended for external application.

8.15 mucilages
Thick, viscid, adhesive liquids produced by dispersing gum in water or by extracting with water the mucilaginous principle from vegetable substances.

8.16 oleoresin
A solvent extract of a dried herbs which is virtually free from the extracting solvent consisting of essential oil and resin.

8.17 processing
Treatment of herbal material by applying a series of procedures, to produce a specific end product.

8.18 packaging
Wrapping of herbal product to facilitate handling, transportation, preservation, optimization of product presentation, dispensing, hygiene and preventing cross-contaminations.

8.19 pecolation
A slow passage of a liquid through a filtering medium uses boiling water in a similar way to distillation.

8.20 poultices
Soft, semi-liquid, external preparations which either stimulate a body surface or alleviate an inflamed area by supplying medicating substances in the presence of heat and moisture.

8.21 pharmacokinetic studies
The study of the absorption, distribution, metabolism and excretion of drugs and other substances in living organisms.
8.22 product development

Development of formulation by identification of critical attributes to the quality of herbal finished products, taking into consideration of intended usage and route of administration by formulation studies.

8.23 pilot and up scaling studies

Studies to evaluate batches that produced by a procedure fully representative of and stimulating that to be applied to a full production scale batch. The batch size is smaller than production batch (e.g. minimal 1/10) but larger than laboratory scale batch.

8.24 storage

Maintenance of herbal raw material, intermediate and finish product under controlled condition.

8.25 shelf life

The time period for which a herbal product remains usable as stated in the expiry date.

8.26 standardised extracts

Extracts can be standardised to different degree or level of requirement, either:

a) chemically standardised, which means extracts shall contain consistent level of marker compound(s) qualitative and quantitatively; or

b) biologically standardised, which means extracts shall expressed consistent pharmacological effect on certain biological method; or

c) chemically and biologically guaranteed, which means guaranteed potency extracts.

8.27 syrup

A concentrated solution of a sugar such as sucrose in water or other aqueous liquid.

8.28 super critical fluid extraction

An extraction technique that uses a dense gas that is maintained above its critical temperature to selectively extract and fractionalise valuable non-polar components from feed stream.

8.29 stability studies

Studies to show ability of Herbal product to retain its chemical, physical, microbiological and biological properties within specified limits throughout its shelf life under specified environmental conditions.

8.30 tincture

An alcoholic or aqueous alcoholic extract of herbs in which the solvent is left in the extract as a diluent.
8.31 tonic
A class of medicinal preparations believed to have the power of restoring normal tone to tissues.

9 Classification of terminology on legislation and registration

9.1 administer
In relation to any product, means:

a) give or apply to a human being or an animal, whether orally, by injection or by introduction into the body in any other way or by external application; and

b) give or apply it either in existing state or it has been dissolved or dispersed in, or diluted or mixed with, some other substance used as vehicle.

9.2 authority
Drug Control Authority established under regulation 3 of Control of Drugs and Cosmetics Regulations 1984.

9.3 contract manufacturer
Any person who manufactures any product on the order of another person to whom a manufacturer's license has been issued under Control of Drugs and Cosmetics Regulations 1984.

9.4 drug
Any substance, product or article intended to be used or capable, or purported or claimed to be capable, of being used on humans or any animal, whether internally or externally for a medicinal purposes.

9.5 herbal remedy
Any drug consisting of a substance or a mixture of substances produced by drying, crushing or comminuting, but without subjecting to any other process, a natural substance or substances of plant, animal or mineral origin, or any part of such substance or substances.

9.6 indigenous medicine
A system of treatment and prevention of disease established through traditional use of naturally occurring substances.

9.7 importer
Includes any person who, whether as owner, consignee, agent or broker, is in possession of, or in anywise entitled to the custody, or control, of the imported article.
9.8 label
A display of information, safety marks or features that is accompanying a product or attached to a container and package in relation to a product.

9.9 licensed manufacturer
A person to whom a manufacturer's license has been issued under Control of Drugs and Cosmetics Regulations 1984, and includes a contract manufacturer.

9.10 licensed wholesaler
A person to whom a wholesaler's licence has been issued under Control of Drugs and Cosmetics Regulations 1984.

9.11 manufacture
in relation to any product includes:

a) the making or assembling of the product

b) the enclosing or packing of the product in any container in a form suitable for administration or application, and the labeling of the container; and

c) the carrying out of any process in the course of any of the foregoing activities

9.12 package
Every means by which goods for carriage or for sale are cased, covered, enclosed, contained or packed.

9.13 premises
Any house, shop, store, room, cubicle, shed, conveyance, structure or any place whether open or enclosed.

9.14 possess
In relation to any product, includes keeping, storing, possessing for sale, possessing of or supply, possessing for self administration or administering to any person or animal or causing any person to administer to him.

9.15 product
a) a drug in a dosage unit or otherwise, for use wholly or mainly by being administered to one or more human beings or animals for a medicinal purpose; or

b) a drug to be used as an ingredient of a preparation for a medicinal purpose.

c) alleviating, treating, curing or preventing a disease or a pathological condition or symptoms of a disease;
d) diagnosing a disease or ascertaining the existence, degree or extent of a physiological or pathological condition;

e) contraception;

f) inducing anaesthesia;

g) maintaining, modifying, preventing, restoring, or interfering with, the normal operation of a physiological function;

h) controlling body weight; and

i) general maintenance or promotion of health or wellbeing.

9.16 registered product

A product currently registered in accordance with the provisions of Control of Drugs and Cosmetics Regulations 1984.

9.17 sale or sell

Includes barter and exchange and also includes offering or attempting to sell or causing or allowing to be sold or exposing for sale or receiving or sending or delivering for sale or having in possession any drug knowing that the same is likely to be sold or offered or exposed for sale.

9.18 supply

Includes the supply of commercial samples and dispensed medicine, but does not include the direct administration by or under the immediate personal supervision of a registered medical practitioner or registered dentist of a poison or medicine to his patient in the course of treatment where such administration is authorized under section 19.

9.19 wholesale

A sale to any person who intends to sell again and any sale by a licensed wholesaler authorized by paragraphs (d) to (j) inclusive of section 15(2) of Poison Act 1952.
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Bibliography (Continued)


Acknowledgements

Members of Technical Committee on Herbs and Spices

Prof Dr Zhari Ismail (Chairman)Universiti Sains Malaysia
Ms Siti Sarah Aishah Mohd Azkah/SIRIM Berhad
Ms Nor Azian Durai (Secretary)Biotropics Malaysia Berhad
Mr Yee Kar Ming/Mr Adi Jasmin Mat Sarit/Department of Agriculture
Ms Dee Noo Aiza Hayati Md Noh/Dr Nor Azah Mohamad Ali/Forest Research Institute Malaysia
Dr Rasadah Mat Ali/Dr Zakiah Ismail/Institute for Medical Research
Dr Murizal Zainol/Dr Hussin Muhammad/Malaysian Agricultural Research and Development Institute
Ms Maizatul Hasyima Omar/Ms Maizatul Hasyima Omar/National Pharmaceutical Control Bureau
Dr Normah Ahamad/Mr Chew Seak Seong/Nestle Manufacturing (Malaysia) Sdn Bhd
Mr Kharis Zahid/Mr Noramin Mohd Noor/TPM Biotech Sdn Bhd
Prof Dr Mohd Yazid Abd Manap/Prof Dr Muhammad Shahrim Abd Karim/Universiti Putra Malaysia
Associate Prof Dr Muhammad Shahrim Abd Karim/Institute for Medical Research (Herbal Medicine Research Centre)

Co-opted member

Dr Soobitha Subenthiran/Ass. Prof Dr Jamia Azdina Jamal/Institute for Medical Research (Herbal Medicine Research Centre)
Associate Prof Dr Jamia Azdina Jamal/Universiti Kebangsaan Malaysia