

APPENDIX 7

GUIDELINE ON REGISTRATION OF NATURAL PRODUCTS

IMPORTANT NOTES:

1. This part shall be read in conjunction with the relevant sections of the main DRGD.
2. Natural products shall be evaluated based on the criteria for safety and quality of the product, and where appropriate, efficacy/ claimed benefits.
3. This document is intended to provide guidance for the registration of natural products. However, this is a living document that is continually updated/ revised in the line with progress in scientific knowledge and experience.
4. The lists presented are by no means exhaustive. It may be reviewed as and when it is deemed necessary.

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1. GENERAL INFORMATION

1.1 DEFINITIONS

Natural products include traditional medicines, herbal products, homeopathic medicines, natural products with modern claim and natural products with therapeutic claim.

1.1.1 Traditional medicine

As defined under the CDCR 1984, traditional medicine refers to any product used in the practice of indigenous medicine in which the drug consists 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 homeopathic medicine. It shall not include any sterile preparation, vaccine, any substance derived human parts, any isolated and characterized chemical substances.

1.1.2 Finished Herbal Product

Finished herbal products consist of herbal preparations made from one or more herbs. If more than one herb is used, the term “mixture herbal product” can also be used. Finished herbal products and mixture herbal products may contain excipients in addition to the active ingredients. However, finished products or mixture herbal products to which chemically defined active substance have been added, including synthetic compounds and/ isolated constituents from herbal materials, are not considered to be herbal.

1.1.3 Herbal Remedy

Herbal remedy refers to 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.

1.1.4 Homeopathic Medicine

Homeopathic medicine refers to any pharmaceutical dosage form used in the homeopathic therapeutic system where diseases are treated by the use of minute amounts in which such substances are capable of producing in healthy persons symptoms similar to those of the disease being treated. Refer [Appendix 7A: Homeopathic Medicine](#)

1.1.5 Natural Products with Modern Claim

Refer to [Appendix 7B: Guideline on Natural Products with Modern Claim](#)

1.1.6 Natural Products with Therapeutic Claim

Refer to [Appendix 7C: Guideline on Natural Products with Therapeutic Claim](#)

1.2 EXEMPTIONS FROM PRODUCT REGISTRATION

The following preparations do not require registration with the Authority:

- a) Extemporaneous preparation prepared and given directly to the patient by any traditional practitioner during the course of treatment;
- b) Traditional preparation containing plants, animal parts or mineral substance or a mixture of these substances of natural origin that is produced only through drying, without any treatment/process involved. E.g. raw herbs;
- c) Traditional preparation containing plants, animal parts, mineral substance/ extracts or a mixture of these substances of natural origin traditionally used as food, spices or flavouring of food that do not have any medicinal claim;
- d) Traditional preparations used for cosmetic purposes, such as to whiten or improve the appearance of skin, hair, teeth, etc., have to be notified as cosmetic product.

1.3 PREPARATIONS NOT ALLOWED TO BE REGISTERED

- a) Traditional preparation with the indication listed in “List of Non-Permissible Indications for Natural Product”
- b) Traditional preparation containing herbal ingredients listed under Poisons Act 1952, except for those exempted for homeopathic preparation. Refer to Section 3.3 - General guidelines for the registration of homeopathic products.
- c) Traditional preparation containing ingredient known or reported to cause any adverse effect on humans.

Refer to List of Botanicals (& botanical ingredients) which are banned due to reported adverse event.
- d) Traditional preparation containing combination of plants, animal parts or mineral substance of natural origin with chemical/ synthetic substance with therapeutic effect.
- e) Traditional preparation containing combination of plants, animal parts or mineral substance of natural origin with vitamins and amino acids.
- f) Traditional products are prohibited from containing ingredients derived from human origin. E.g.:
 - i) CRINIS CARBONISATUS = Carbonised human hair
(Reference: *Pharmacopoeia of The People's Republic Of China: English Edition 1992*)
 - ii) HUMAN PLACENTA

1.4 CLASSIFICATION FOR SPECIFIC ACTIVE INGREDIENTS

1.4.1 PRODUCTS CONTAINING CASSIA/ SENNA:

Finished products containing cassia/ senna as an active ingredient with a daily dose of less than 0.5g of the crude drug or 20mg sennoside (standardized preparation) shall be classified as traditional products and restricted to traditional claims. Active ingredient consumed more than this daily limit will be classified as pharmaceutical product, depending on the product formulation.

1.4.2 PRODUCTS CONTAINING PSYLLIUM HUSK/ PLANTAGO OVATA

Finished products containing psyllium husk as an active ingredient and with a total daily consumption of less than 3.5g per day shall be classified as a non-drug. However, daily doses above this amount and up to 6.9g will require this product to be registered under the traditional product category.

Reference: Circular [Bil. \(24\) dlm.BPFIK/PPP/07/11 Jld.5](#) *Pengkelasan Produk Mengandung Psyllium Husk* (14 May 2010)

2. GENERAL REQUIREMENTS FOR REGISTRATION OF NATURAL PRODUCTS

2.1 PRODUCT NAME

- a) If the product owner wishes to use a *formulary name, any amendments made to the product formulation such as the addition of active ingredients, removal of active ingredients or change in strength of active ingredients will not be permitted.
* The name of the Chinese/ Ayurvedic proprietary medicine as stipulated in the reference such as Taiwan Pharmacopoeia, The Chinese Herbal Medicine Materia Medica, and Ayurvedic Pharmacopeia
- b) A brand name added in front of the formulary name shall be required, in order to differentiate the product from products with the same formulary name.
- c) Any product name that is the same or similar either in writing or pronunciation with the product name of an adulterated product is prohibited.
- d) For a product name that is the name of active ingredient or a common name, e.g. *Kapsul Kacip Fatimah; Misal Kucing Tea; Orthosiphon Capsule; Herbal Rub; Natural Herb Capsule*, a brand name shall be added to the product name in order to differentiate and identify this specific product.

- e) For single-ingredient products, in cases where the product name bears the name of the active ingredient, the strength should be added to the product name. E.g.: Sunsky Tongkat Ali 500 mg Capsule.
- f) The dosage form is required to be added to the product name in the system (i.e in section A1)
- g) Justification will be required to prove the “claim” made in the product name. E.g.: “Double Strength/ Acticoat/ WaterSol”.
- h) Product name supported by a registered trademark certificate will not be accepted if deemed inappropriate by the Authority or if it does not follow the regulations stated in this Appendix.
- i) The replacement product may use the same product name as a previously registered product provided that the formulation (strength of active ingredient), product registration holder and dosage form of the product remain the same.
- j) The name of the active ingredient is not allowed to be used as brand name.
- k) The name of active ingredient combined with the product indication are not allowed to be used as product name.
- l) Product names not permitted to be registered are specified in **Table 1** below:

Table 1: Non-Permissible Product Names

| No. | Non-Permissible Product Names | Example |
|-----|---|---|
| 1. | Prohibited use of disease names as stated in the Medicines (Advertisement and Sale) Act 1956 (Revised 1983) | Example: Diabetes, Asthma, Cancer |
| 2. | Prohibited use of a single active ingredient as a product name in products containing more than one active ingredient unless product name contains words such as ‘Plus, Compound, Complex, Herbanika | Example: Tongkat Ali Capsule ---- But product contains tongkat ali, ginseng, etc. |
| 3. | Prohibited use of superlative - Names that indicates superiority in efficacy | Example: Power/ Kuasa, Superior, Pure, Mustajab, Safe, Healthy/ Sihat, Penawar/ Shifa, VIP, Good, Heal/ Sembuh, Premium, Mustajab, Men/ Women/ Children Complete, Men/ Women/ Children Enriched, Paradise/ Syurga, Menawan, Booster |

| No. | Non-Permissible Product Names | Example |
|-----|--|---|
| 4. | <p>Prohibited use of spelling of words that may cause confusion</p> <p>Words that involve names of/ part thereof:</p> <ul style="list-style-type: none"> i) 20 disease names prohibited in the Medicines (Advertisement and Sale) Act 1956 (Revised 1983) ii) Diseases without scientific evidence of efficacy/ prescription medication to treat diseases/ parameters that indicate certain diseases (e.g. insulin, glucose) iii) Prohibited indication (e.g. to detoxify body) | <p>Example:</p> <ul style="list-style-type: none"> a) Go Out = GOUT b) UTix = Urinary Tract Infection c) Diabecine = Diabetes d) Metformon = Metformin e) Insuprem = Insulin f) Glucosey = Glucose g) DetoxB = Detox body |
| 5. | <p>Prohibited use of names that may cause ambiguity</p> <p>Ambiguous product name</p> | <p>Example:</p> <p>B For Energy?</p> |
| 6. | <p>Prohibited use of names that may be offensive or indecent</p> | <p>Example:</p> <p>SENXBIG=SEnXBIG(label), Sexy, Enjoy, Paradise, Heavenly, Blue boy, Casanova, Desire (<i>Dezire</i>), <i>Sensual (Xensual)</i>, Asmara, Syok</p> |
| 7. | <p>Prohibited use of product names incoherent with the approved indication</p> <p>Name containing a product claim whereas product is indicated for more than the approved indication</p> | <p>Example:</p> <p>Cough Syrup X= Approved indication for cough, dizziness, flu and itch</p> |
| 8. | <p>Prohibited use of product names that have elements of ludicrous belief</p> <p>Statements referring to ancient believe/ negative spirits/ supernatural power</p> | <p>Example:</p> <p>Words such as miracle, magic, magical, miraculous, saintly, heavenly</p> |
| 9. | <p>Prohibited use of product names similar to the existing approved product names</p> <p>Product names similar to the spelling and pronunciation of words of the existing product names</p> | <p>Example:</p> <p>Tenormin vs Tenormine vs Tenormy Re-Liv vs Re-Lif</p> |

| No. | Non-Permissible Product Names | Example |
|-----|--|---|
| 10. | Prohibited use of product names that may cause ambiguity in the nature of product (drug/ food/ beverage) Product names similar to a food/ beverage product | Example: Juice, Health drink, Beverage, Kooky |
| 11. | Prohibited use of product names that represent professional advice or opinion or referring to the profession | Example: Dr Sunny, Dr Noortier Rooibose Tea, Professor, Herbalist, Doctor |
| 12. | Prohibited use of product names that represent weight loss/ slimming properties/ names that can be associated with weight loss/ slim | Example: Slim, Langsing, Trim, Trimnfit, <i>Sleen</i> , <i>Kurus</i> , <i>Susut perut</i> , <i>Xlim</i> , <i>Weight watcher</i> , <i>Burn</i> |
| 13. | Prohibited use of product names referring to any religious content | Example: Maksum, Mahmudah, Arifbillah |
| 14. | Name of internal organ | Example: Liver, Brain, Kidney, etc. |
| 15. | Use of abbreviation as a product name unless it carries no meaning | Example: TB, UTI, HB, etc. |
| 16. | Other prohibited product names | Example: Minda, IQ, Smart, Genius, Ultra Mega, Detox, Immune, Phase 2, Defense, Prime |

Note:

1. This list is not meant to be exhaustive and will be reviewed from time to time.
2. The Authority reserves the right to disallow any other words or phrases for product names, which in its opinion, is misleading, improper or not factual.

2.2 INGREDIENTS

2.2.1 Active Ingredients

- a) Active ingredients are substances that have a therapeutic role in the formulation. Substances included in the formulation as active ingredients must make a contribution to the proposed indications for the product. Where a claim links the presence of an ingredient to the product indication, that ingredient must contribute to that indication. The evidence may be scientific and or traditional.

- b) Overages of active ingredient
Overages may be used during manufacture. An overage is where the amount of an ingredient added during manufacturing is greater than the nominated on the product label. Details of the overage used must be available.
- c) Listed active ingredients can be checked through <https://www.npra.gov.my/> through “Product Search”. Ingredients not listed will require safety and/or efficacy data evaluation prior to addition to this list.
- d) For new active ingredients or new combination products, the following information shall be required:
- Product containing new single ingredient:
 - i) **Extract form**
 - Information on the taxonomy of the ingredient;
 - Techniques and methods in preparing/ processing the extract and subsequently the product;
 - Information on the use and safety of the ingredient and the product quality standard.
 - ii) **Powder/ Granules**
 - Information on the taxonomy of the ingredient;
 - Techniques and methods in preparing/ processing the extract and subsequently the product;
 - Information on the use and safety of the ingredient and the product.
 - Product containing multiple ingredients (contains ingredients known to be used traditionally):
 - The source of the product formulation;
e.g. Chinese Pharmacopoeia
 - Proof or evidence of the traditional use
 - Product containing multiple ingredients (contains ingredients not known to be used traditionally):
 - Information on the use and safety of every new ingredient;
 - Safety data on the new formulation;
 - Regulatory status in other countries.

2.2.2 Premix

Effective from 1 December 2007, premixed ingredient(s) shall not be used in natural product (traditional) formulation,

Reference: [Bil. \(71\) dlm. BPFK/02/5/1.3](#): Keputusan Mesyuarat PBKD: Larangan Penggunaan Bahan 'Premix' dalam Formulasi Produk Semulajadi (Tradisional) (1 June 2007)

2.2.3 Prohibited/ Banned Ingredients

The following lists present prohibited/banned ingredients not allowed in the formulation of natural products registered by the Authority:

- A. [Table 2](#) : Botanicals (and botanical ingredients) containing scheduled poisons listed under the Poisons Act 1952
- B. [Table 3](#) : Botanicals (and botanical ingredients) banned due to reported adverse event
- C. [Table 6](#) : Ingredients (botanicals and substance derived from animals) banned due to safety reasons

Table 2: Botanicals (and botanical ingredients) containing scheduled poisons listed under the Poisons Act 1952

| Genus | Species | Common/ Local Name | Part of plant prohibited (whole plant unless otherwise specified) | Constituent(s) of concern |
|---|--------------------|--------------------|---|---|
| <i>Aconitum</i> | <i>All species</i> | | | Aconite |
| <i>Asidosperma</i> | <i>quebracho</i> | White quebracho | | Asidospermine, yohimbine |
| <i>Atropa</i> | <i>belladonna</i> | Deadly nightshade | | Atropine, hyoscine (scopolamine), hyoscyamine |
| <i>Cabola</i> | <i>albarrane</i> | Squill | | Glycoside |
| <i>Cannabis</i> (controlled under Dangerous Drug Act 1952) | <i>All species</i> | Marijuana | | Cannabinoids |

| Genus | Species | Common/ Local Name | Part of plant prohibited (whole plant unless otherwise specified) | Constituent(s) of concern |
|----------------------|---------------------|--|---|------------------------------------|
| <i>Catharanthus</i> | <i>roseus</i> | Periwinkle Madagascar, Old Maid, <i>Vinca rosea</i> , Myrtle Syn: <i>Vinca balcanica</i>, <i>Vinca difformis</i>, <i>Vinca heracea</i>, <i>Vinca major</i>, <i>Vinca minor</i>, <i>Vincae minoris</i> herba | | Vinca, Vincristine, Vinblastine |
| <i>Chondodendron</i> | <i>tomentosum</i> | Curare, Velvet leaf, Ice Vine, | | Tubocurarine |
| <i>Claviceps</i> | <i>purpurea</i> | Ergot | | Ergometrine |
| <i>Colchicum</i> | <i>autumnale</i> | Autumn Crocus/ Meadow Saffron/ Naked Lady) | | Colchicine |
| <i>Datura</i> | <i>metel</i> | Devil's Trumpet, Metel, J California Jimson Weed Syn.: <i>Datura wrightii</i> | | Atropine, Scopolamine |
| <i>Datura</i> | <i>stramonium</i> | Jimson Weed/ Gypsum Weed, Loco Weed | | Atropine, Hyoscyamine, Scopolamine |
| <i>Delphinium</i> | <i>staphysagria</i> | Lice bane, Stavesacre | | Delphinine |

| Genus | Species | Common/ Local Name | Part of plant prohibited (whole plant unless otherwise specified) | Constituent(s) of concern |
|-------------------|-----------------------|--|---|----------------------------|
| <i>Digitalis</i> | <i>purpurea</i> | Common Foxglove, Purple Foxglove, Kecubung | Leaf | Glycoside |
| <i>Drimia</i> | <i>maritima</i> | Squill Syn.: <i>Urginea maritima</i> , <i>Scilla maritima</i> Related substance: <i>Urginea indica</i> , <i>Urginea pancreatum</i> , <i>Urginea scilla</i> | | Glycoside |
| <i>Ephedra</i> | All species | Ma Huang | | Ephedrine, Pseudoephedrine |
| <i>Gelsemium</i> | <i>sempervirens</i> | Yellow Jessamine, Evening Trumpet, Carolina Jessamine | | Gelsemine |
| <i>Hyoscyamus</i> | <i>muticus</i> | Egyptian henbane | | Hyoscyamine |
| <i>Hyoscyamus</i> | <i>niger</i> | Black henbane | | Hyoscyamine-atropine |
| <i>Lobelia</i> | <i>inflata</i> | Lobelia, pokeweed, Indian tobacco, gagroot, asthma weed, vomitwort, bladderpod, rapuntium inflatum. | | Lobeline |
| <i>Lobelia</i> | <i>nicotianifolia</i> | Wild Tobacco | | Lobeline |

| Genus | Species | Common/ Local Name | Part of plant prohibited (whole plant unless otherwise specified) | Constituent(s) of concern |
|----------------------|---------------------|--|---|---|
| <i>Mitragyna</i> | <i>speciosa</i> | Daun Ketum | | Mitragynine |
| <i>Nicotiana</i> | <i>tabacum</i> | Common tobacco | | Nicotine |
| <i>Papaver</i> | <i>somniferum</i> | Opium poppy | | Morphine, codeine, hydrocodone, meperidine, methadone, papaverine |
| <i>Pausinystalia</i> | <i>yohimbe</i> | Yohimbe, Johimbe Syn. <i>Corynanthe johimbi</i> , <i>Corynanthe yohimbi</i> | | Yohimbine |
| <i>Physostigma</i> | <i>venenosum</i> | Calabar bean | | Physostigmine |
| <i>Pilocarpus</i> | <i>microphyllus</i> | Pilocarpus jaborandi, jaborandi | | Pilocarpine |
| <i>Punica</i> | <i>granatum</i> | Pomegranate | Bark | Iso-Pellatrierine |
| <i>Rauwolfia</i> | <i>serpentina</i> | Indian snakeroot, Serpentine root | | Reserpine |
| <i>Rauwolfia</i> | <i>vomitoria</i> | African serpentwood | | Reserpine |
| <i>Schoenocaulon</i> | <i>officinale</i> | Veratrum officinale | | Sabadilla, Veratrine |
| <i>Scillae</i> | <i>bulbus</i> | Sea onion, Squill | | |
| <i>Solanum</i> | <i>nigrum</i> | Black nightshade | | Solanine |

| Genus | Species | Common/ Local Name | Part of plant prohibited (whole plant unless otherwise specified) | Constituent(s) of concern |
|------------------|-------------------|---|---|---|
| <i>Strychnos</i> | <i>nux-vomica</i> | Poison nut, Quaker button, strychnine tree, ma qian zi/maqianzi | | Strychnine |
| <i>Valerian</i> | All species | | All parts except for root part | Valepotriates |
| <i>Veratrum</i> | All species | | | |
| <i>Vinca</i> | All species | Including <i>Catharanthus roseus</i> | | Vinca, Vincristine, Vinblastine, Vinpocetin |

Table 3: Botanicals (and botanical ingredients) banned due to reported adverse event

| Genus | Species | Common/ Local Name | Part of plant prohibited | Reason for prohibition |
|---------------------|--------------------|--------------------|--------------------------|---|
| <i>Aristolochia</i> | <i>All species</i> | | | Contain Aristolochic Acid reported to cause kidney toxicity (**Please refer to footnote below) |

| Genus | Species | Common/ Local Name | Part of plant prohibited | Reason for prohibition |
|---------------------|--------------------|--|--------------------------------|---|
| <i>Berberis</i> | <i>All species</i> | | | <p>Berberine</p> <p>*Other herbs containing naturally-occurring berberine are allowed to be registered with specific requirements. Please refer to Appendix 20.</p> <p>Notes: Only prohibited for oral preparation.</p> |
| <i>Borneolum</i> | <i>syntheticum</i> | Bingpian, borneol | | Contain borneol- not allowed for oral preparation |
| <i>Dioscorea</i> | <i>hispida</i> | Ubi gadong, Gadong, Gadog, Gadong Lilin, Gadong Mabok, Ubi Arak, Ubi Akas, Taring Pelanduk, Susur Gadong, Gadongan, Kedut dan Ubi Bekoi | All parts | <p>Contain dioscorine and dioscorinine reported to cause burning sensation in the throat, giddiness, followed by haematemesis, sensation of suffocation, drowsiness and exhaustion</p> <p>Not allowed for oral preparation</p> |
| <i>Dryobalanops</i> | <i>aromatica</i> | Borneo/ Malay/ Sumatra Camphor, Pokok Kapur | Whole herb | Contain camphor- not allowed for oral preparation |
| <i>Hydrastis</i> | <i>canadensis</i> | Goldenseal, Eye Balm, Indian Dye | | Reported to cause disturbance of the nervous system |

| Genus | Species | Common/ Local Name | Part of plant prohibited | Reason for prohibition |
|------------------------------|--|--|--------------------------------|--------------------------------------|
| <i>Larrea</i> | <i>tridenata</i> | Chapparal | | Reported to cause liver toxicity |
| | <i>mexicana</i> | | | |
| <i>Piper methysticum</i> | | Kava-kava | | Reported to cause liver toxicity |
| <i>Symphytum</i> | <i>officinale</i> | Comfrey | | |
| | <i>asperum</i> | | | |
| | <i>x. uplandicum</i> | | | |
| <i>Senecio</i> | <i>aureus</i> | Life root | | |
| | <i>jacobaea</i> | Tansy ragwort, Tansy Butterweed | | |
| | <i>bicolor</i> | Silver ragwort | | |
| | <i>nemorensis</i> | Alpane ragwort, Wood ragwort | | |
| | <i>vulgaris</i> | Common groundsel, Groundsel, Old- man-in the- spring | | |
| | <i>longilobus</i> -syn .with <i>douglasii</i> , <i>filifolius</i> | Threadleaf groundsel, Threadleaf ragwort | | |
| | <i>Scandens Buch.- Ham</i> | German/African /Cape Ivy, Climbing Groundsel | | |
| <i>Stephania</i> | <i>tetrandra</i> | | | Reported to cause kidney toxicity |

- **** To identify the botanicals that may contain Aristolochic Acid besides the Aristolochia genus, refer to:
- a. List A - Botanicals Known or Suspected to contain Aristolochic Acid ([Table 4](#))**
 - b. List B - Botanicals that may be Adulterated with Aristolochic Acid ([Table 5](#))**

Notes:

Products containing any of the listed herbs (EXCEPT for Aristolochia spp. that is totally banned) will have to be sent to any governmental doping centre for testing and the result shall be attached with the registration form.

(Source for Lists A and B)
U. S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Nutritional Products, Labeling, and
Health Supplements
[Revised April 9, 2001]

Table 4: List A: Botanicals Known or Suspected to Contain Aristolochic Acid

| Botanical Name* | Common or Other Names |
|--|---|
| <p>Asarum canadense Linn. Syn. Asarum acuminatum (Ashe) E.P. Bicknell Syn. Asarum ambiguum (E.P. Bicknell) Daniels Syn. Asarum canadense var. ambiguum (E.P. Bicknell) Farw. Syn. Asarum canadense var. reflexum (E.P. Bicknell) B.L. Rob. Syn. Asarum furcatum Raf. Syn. Asarum medium Raf. Syn. Asarum parvifolium Raf. Syn. Asarum reflexum E.P. Bicknell Syn. Asarum rubrocinctum Peattie</p> | <p>Wild ginger Indian ginger Canada snakeroot False coltsfoot Colic root Heart snakeroot Vermont snakeroot Southern snakeroot</p> |
| <p>Asarum himalaicum Hook. f. & Thomson ex Klotzsch or Asarum himalaycum Hook. f. & Thomson ex Klotzsch</p> | <p>Tanyou-saishin (Japanese)</p> |
| <p>Asarum splendens (F. Maek.) C.Y. Cheng & C.S. Yang</p> | <p>Do-saishin (Japanese)</p> |
| <p>Bragantia wallichii R.Br. Specimen exists at New York Botanical Gardens. Tropicos does not list this species as a synonym for any Thottea species. Kew Gardens Herbarium does not recognize the genera Bragantia. Until additional information is obtained we will use the name as cited in J. Nat. Products 45:657-666 (1982)</p> | |

Table 5: List B: Botanicals that may be Adulterated with Aristolochic Acid

| Botanical Name* | Common or Other Names |
|---|---|
| Akebia spp. | Akebia Mu tong Ku mu tong Zi mutong Bai mu tong Mokutsu (Japanese) Mokt'ong (Korean) |
| Akebia quinata (Houtt.) Decne. Syn. Rajania quinata Houtt. | Chocolate vine Fiveleaf akebia Mu tong Yu zhi zi Mokutsu (Japanese) |
| Akebia trifoliata (Thunb.) Koidz. | Mu tong Three leaf akebia Yu zhi zi |
| Asarum forbesii Maxim. | Batei-saishin (Japanese) |
| Asarum heterotropoides F. Schmidt Syn. Asarum heterotropoides F. Schmidt Syn. Asiasarum heterotropoides (F. Schmidt) F. Maek. | Keirin-saishin (Japanese) Chinese wild ginger Manchurian wild ginger Bei xi xin Xin xin |

| Botanical Name* | Common or Other Names |
|---|--|
| <p>Asarum sieboldii Miq.</p> <p>Syn. Asarum sieboldii fo. seoulense (Nakai) C.Y. Cheng & C.S. Yang</p> <p>Syn. Asarum sieboldii var. seoulensis Nakai</p> <p>Syn. Asiasarum heterotropoides var. seoulense (Nakai) F. Maek.</p> <p>Syn. Asiasarum sieboldii (Miq.) F. Maek.</p> | <p>Usuba-saishin</p> <p>(Japanese)</p> <p>Chinese wild ginger</p> <p>Xi Xin</p> <p>Hua Xi Xin</p> <p>Manchurian wild ginger</p> <p>Siebold's wild ginger</p> |
| Clematis spp. | <p>Clematis</p> <p>Mufangji</p> <p>Clematidis</p> <p>Ireisen (Japanese)</p> <p>Wojoksum (Korean)</p> |
| <p>Clematis armandii Franch.</p> <p>Syn. Clematis armandii fo. farquhariana (W.T. Wang) Rehder & E.H. Wilson</p> <p>Syn. Clematis armandii var. biondiana (Pavol.) Rehder</p> <p>Syn. Clematis biondiana Pavol.</p> <p>Syn. Clematis ornithopus Ulbr.</p> | <p>Armand's clematis</p> <p>Chuan mu tong (stem)</p> <p>Xiao mu tong</p> <p>Armand's virgin bower</p> |
| Clematis chinensis Osbeck. | <p>Chinese clematis</p> <p>Wei ling xian (root)</p> |
| Clematis hexapetala Pall. | |
| <p>Clematis montana Buch.-Ham. ex DC.</p> <p>Syn. Clematis insulari-alpina Hayata</p> | |

| Botanical Name* | Common or Other Names |
|---|-----------------------|
| <p>Clematis uncinata Champ. ex Benth. Syn. Clematis alsomitrifolia Hayata Syn. Clematis chinensis var. uncinata (Champ. ex Benth.) Kuntze Syn. Clematis drakeana H. Lév. & Vaniot Syn. Clematis floribunda (Hayata) Yamam. Syn. Clematis gagnepainiana H. Lév. & Vaniot Syn. Clematis leiocarpa Oliv. Syn. Clematis ovatifolia T. Ito ex Maxim. Syn. Clematis uncinata var. biternata W.T. Wang Syn. Clematis uncinata var. coriacea Pamp. Syn. Clematis uncinata var. floribunda Hayata Syn. Clematis uncinata var. ovatifolia (T. Ito ex Maxim.) Ohwi ex Tamura Syn. Clematis uncinata var. taitongensis Y.C. Liu & C.H. Ou</p> | |
| Cocculus spp. | Cocculus |
| <p>Cocculus carolinus (L.) DC. Syn. Cebatha carolina Britton Syn. Epibaterium carolinum (L.) Britton Syn. Menispermum carolinum L.</p> | |
| <p>Cocculus diversifolius DC. Syn. Cocculus madagascariensis Diels</p> | |
| <p>Cocculus hirsutus (L.) Diels Syn. Cocculus villosus DC. Syn. Menispermum hirsutum L.</p> | |
| <p>Cocculus indicus Royle Syn. Anamirta paniculata Colebr.</p> | Indian cockle |
| <p>Cocculus laurifolius DC. Syn. Cinnamomum esquirolii H. Lév.</p> | |
| Cocculus leaebe DC. | |

| Botanical Name* | Common or Other Names |
|--|-------------------------|
| Cocculus madagascariensis Diels Syn. Cocculus diversifolius DC. | |
| Cocculus orbiculatus DC. Syn. Cissampelos pareira Linn. Cocculus orbiculatus (L.) DC. Syn. Cocculus cuneatus Benth. Syn. Cocculus sarmentosus (Lour.) Diels Syn. Cocculus sarmentosus var. linearis Yamam. Syn. Cocculus sarmentosus var. pauciflorus Y.C. Wu Syn. Cocculus sarmentosus var. stenophyllus Merr. Syn. Cocculus thunbergii DC. Syn. Cocculus trilobus (Thunb.) DC. Syn. Menispermum orbiculatus L. Syn. Menispermum trilobum Thunb. Syn. Nephroia sarmentosa Lour. | Moku-boui (Japanese) |
| Cocculus palmatus (Lam.) DC. | Columba Columbo |
| Cocculus pendulus Diels Syn. Cebatha pendula (J.R. & C. Forst.) Kuntze Syn. Epibaterium pendulus Forst. f. Syn. Cocculus Epibaterium DC. | |
| Cocculus pendulus (Forst. & Forst.) Diels | |
| Cocculus palmatus Hook. Syn. Jateorhiza Miersii Oliver | Colombo |
| Cocculus thunbergii DC. | |
| Diploclisia affinis (Oliv.) Diels Syn. Diploclisia chinensis Merr. Syn. Cocculus affinis Oliv. | |

| Botanical Name* | Common or Other Names |
|--|--|
| Diploclisia chinensis Merrill | Xiangfangchi |
| Menispermum dauricum | |
| Saussurea lappa (Decne.) Sch. Bip. / Aucklandia Lappa | Mokkou (Japanese) |
| <p>Sinomenium acutum (Thunb.) Rehder & E.H. Wilson</p> <p>Syn. Cocculus diversifolius var. cinereus Diels</p> <p>Syn. Cocculus heterophyllus Hemsl. & E.H. Wilson</p> <p>Syn. Menispermum acutum Thunb.</p> <p>Syn. Sinomenium acutum (Thunb.) Rehder & E.H. Wilson</p> <p>var. cinereum (Diels) Rehder & E.H. Wilson</p> <p>Syn. Sinomenium diversifolium (Diels) Diels</p> | <p>Orientvine</p> <p>Xunfengteng</p> <p>Dafengteng</p> <p>Daqingmuxinag</p> <p>Zhuigusan</p> <p>Da ye qingshener</p> <p>Mufangji</p> <p>Hanfangji</p> <p>Tuteng</p> <p>Zhuigufeng</p> <p>Maofangji</p> |
| Stephania spp. (except for Stephania Tetrandra which is banned) | Stephania |
| Vladimiria souliei (Franch.) Ling | Sen-mokkou |

Table 6: Ingredients (Botanicals and Substance Derived from Animals) banned due to safety reasons:

| Genus | Species | Part of Plant/ Animal Prohibited <i>(whole plant/ animal unless otherwise specified)</i> | Constituent of Concern | Reasons for Prohibition |
|--|--------------------|--|---|--|
| <i>Abrus</i> | <i>precatorius</i> | Seed | Abrin, Agrus, Agglutinin | <ul style="list-style-type: none"> - Potent inhibitor of protein and DNA synthesis - Severe diarrhea - Severe stomach cramp - Severe gastroenteritis |
| <i>Adonis</i> | <i>vernalis</i> | | Adonitoxin | Uncontrolled dose can damage heart and cause death |
| Animal parts containing hormones (All species) | | | | |
| <i>Antiaris</i> | <i>toxicaria</i> | Latex, sap | Cardiac glycoside (antiarin), Cardenolides & alkaloids with cardiac arresting potential | <ul style="list-style-type: none"> - Latex is highly poisonous - Paralyze heart muscle and cause death |
| <i>Aristolochia</i> | <i>All species</i> | | Aristolochic acid | Reported to cause kidney toxicity, interstitial nephropathy |
| <i>Calotropis</i> | <i>gigantean</i> | Latex | Cardiac glycosides, calotropin | Severe mucous membrane irritation characterized by vomiting, diarrhea, bradycardia, convulsion and death |
| | <i>procera</i> | | | |
| <i>Catharanthus</i> | <i>roseus</i> | | Vinca alkaloids | Bone marrow depression, central and peripheral (including autonomic) neurotoxicity |

| Genus | Species | Part of Plant/ Animal Prohibited (whole plant/ animal unless otherwise specified) | Constituent of Concern | Reasons for Prohibition |
|-----------------|--------------------|---|--|---|
| <i>Cerbera</i> | <i>manghas</i> | Seed | Digitoxinglycoside, Cerberine, Cerberoside, thevetin | <ul style="list-style-type: none"> - Drastic purgative and emetic - Burning in the stomach sensation, vertigo, nausea, violent purgation and colic - Heart failure |
| | <i>odollam</i> | Seed | Cerberine, Cerberoside, odollin, odolotoxin, thevetin and cerapain | <ul style="list-style-type: none"> - Gastro intestinal symptoms - cardiac toxicity - Nausea, severe retching, vomiting, abdominal pain, blurring of vision - Arterial block and nodal rhythm, hyperkalaemia - Irregular respiration, collapse and death from heart failure |
| <i>Cinchona</i> | <i>All species</i> | | Quinine and derivatives | <ul style="list-style-type: none"> - Resistance of malarial vector - Use of bark is contraindicated in pregnancy and ulcers, intestinal or gastric, and if taken concomitantly with anticoagulants can increased their effects - Can elicit thrombocytopenia with purpura - Cinchona alkaloids are toxic. Can cause symptoms such as blindness, deafness, convulsions and paralysis |

| Genus | Species | Part of Plant/ Animal Prohibited (whole plant/ animal unless otherwise specified) | Constituent of Concern | Reasons for Prohibition |
|-------------------|--------------------|---|--|--|
| <i>Citrullus</i> | <i>Colocynthis</i> | Seed, fructus | Curcubitacin | <ul style="list-style-type: none"> - Carcinogenic effects, induce infertility in both sexes - Enterohepatonephrotoxicity |
| <i>Dryopteris</i> | <i>filix-mas</i> | Rhizome | Filicin, aspidinol | Hepatotoxic and blindness |
| <i>Euphorbia</i> | <i>antiquorum</i> | Latex | Apha euphorbol, Beta amyryn cycloartenol Euphol | Inflammation of the gastrointestinal mucous membrane, irritate skin, difficult respiration, eyes pupil dilated |
| | <i>trigona</i> | | | |
| <i>Excoecaria</i> | <i>agallocha</i> | Latex | Excoecaria phorbol | <ul style="list-style-type: none"> - Highly irritant to skin - Cause blindness if it enters the eye - Biocidal |
| <i>Garcinia</i> | <i>acuminate</i> | Gum resin | Cambogic acid, β -guttiferin, α -1 guttiferin | Vomiting, hypercarthasis, sympathetic irritation of sympathetic nervous system, caused death by gastro-enteritis |
| | <i>hanburyi</i> | | | |
| | <i>morella</i> | | | |
| <i>Gelsemium</i> | <i>elegans</i> | Root, leaf, rhizome | Gelsemine & gelseminine (Gelsemium indole alkaloid) | Paralysis, shortness of breath, muscle stiffeningcoma, hypocyclosis |
| <i>Hyoscyamus</i> | <i>muticus</i> | | Hyoscyamine, atropine, hyoscine | Difficulty in swallowing and talking, transient bradycardia followed by tachycardia with palpitation and arrhythmias, CNS depression, coma |

| Genus | Species | Part of Plant/ Animal Prohibited (whole plant/ animal unless otherwise specified) | Constituent of Concern | Reasons for Prohibition |
|-----------------|--------------------|---|----------------------------------|--|
| <i>Jatropha</i> | <i>multifida</i> | Fruit, seed | Phytotoxin (toxalbumin - Curcin) | Nausea, vomiting, serious purgative action |
| <i>Lantana</i> | <i>camara</i> | | Lantadene, Lancamaron | Cause toxicity in buffalo, cattle, sheep and goat. Symptoms include photosensitive dermatitis, jaundice and yellowing of mucous membrane and loss of appetite with a decrease in ruminal motility |
| <i>Lobelia</i> | <i>chinensis</i> | | Lobeline | <ul style="list-style-type: none"> - Stimulant and has peripheral and central effects - Excessive use can cause nausea, vomiting and dizziness |
| | <i>tupa</i> | | | <ul style="list-style-type: none"> - Stimulant and has peripheral and central effects - Caused arrhythmias |
| <i>Lytta</i> | <i>vesicatoria</i> | Whole body, tincture | Cantharidin | <ul style="list-style-type: none"> - Excessive salivation, abdominal pain, swelling of kidney and urogenital system, headache, vomiting and diarrhea accompanied by bleeding - Burning of the mouth, dysphagia, nausea, hematemesis, gross hematuria and dysuria - Renal dysfunction and related to acute tubular necrosis and glomerular |

| Genus | Species | Part of Plant/ Animal Prohibited (whole plant/ animal unless otherwise specified) | Constituent of Concern | Reasons for Prohibition |
|--------------------|----------------------|---|-----------------------------------|--|
| | | | | destruction |
| <i>Melaleuca</i> | <i>alternifolia</i> | | Tea tree oil | Skin irritation, respiratory distress, vomiting, diarrhea and cytotoxic for oral administration. * Banned in oral preparation |
| <i>Papaver</i> | <i>All species</i> | | Morphine and derivatives, codeine | <ul style="list-style-type: none"> - Potential abuse - Dependence, palpitation, hallucination, euphoric activities, CNS depression - Nervous system toxicity - Possible death from circulatory and respiratory failure |
| <i>Pilocarpus</i> | <i>pinnatifolius</i> | Bark | Pilocarpine | Bronchospasm, ocular problem, miosis, blurred vision |
| | <i>jaborandi</i> | | | |
| <i>Podophyllum</i> | <i>emodii</i> | Root, leaf | Podophyllin resin | <ul style="list-style-type: none"> - Serious systemic toxicity with excessive amounts (persistent nausea and vomiting, tachypnea, fever, stupor, coma, tachycardia, neuropathy and death) - Renal failure and hepatotoxicity |
| | <i>peltatum</i> | | | |
| <i>Solanum</i> | <i>dulcamara</i> | Leaf, flowering tops | Solanaceous alkaloids | Typical antimuscarinic effect e.g. dry mouth, mydriasis |
| <i>Strophantus</i> | <i>All species</i> | | Strophantus alkaloids | Cardiac effect similar to digoxin |

| Genus | Species | Part of Plant/ Animal Prohibited (whole plant/ animal unless otherwise specified) | Constituent of Concern | Reasons for Prohibition |
|------------------|------------------|---|------------------------|----------------------------------|
| <i>Symphytum</i> | <i>pregrinum</i> | | Pyrrolizidine alkaloid | Reported to cause liver toxicity |

2.2.4 Use of Protected/ Endangered Ingredients

a) Protected/ Endangered Wildlife Species

It is the responsibility of the applicant to ensure that the ingredient(s) derived from wildlife species, its parts and derivatives used in the formulation **COMPLIES** with the Wildlife Conservation Act 2010 (Act 716) and International Trade in Endangered Species Act 2008 (Act 686). Both guidelines can be downloaded through the PERHILITAN website: <http://www.wildlife.gov.my>.

The applicant shall contact the following department to obtain the necessary permit/ license. A copy of the permit/ license shall be attached with the application form for product registration.

Department of Wildlife and National Parks, Peninsular Malaysia
Km. 10, Jalan Cheras,
56100 Kuala Lumpur,
Tel: +603-90866800, Fax: +603-90753873

b) Endangered Botanical Species

It is the responsibility of the applicant to declare the source of the botanical ingredient if it is listed under the International Trade in Endangered Species Act 2008 (Act 686). Please refer to <http://myphyto.gov.my> for the details.

2.3 EXCIPIENTS

- a) Excipients are substances used to assist in the manufacture of active substance into dosage forms suitable for administration. Each excipient ingredient included in a formulation must have a justifiable excipient role and shall be controlled by specifications. The intended use of an excipient shall be appropriate.

- b) New excipient will require safety and/or other additional data to support the function in the product prior to addition into the Quest database.
- c) **LIST OF RESTRICTED EXCIPIENTS:**

| Specific Excipient | Allowable Limits |
|--------------------|--|
| Menthol | <ul style="list-style-type: none"> - Oral (0 to 4mg/kg body weight/day) - External (<10%) |

2.4 INDICATIONS

General note: The indications listed below will serve as a guide for the applicant. For traditional/ homeopathic medicines, only low level claim(s) will be accepted. Other indication with the same level of claims may be considered if supported with traditional/ homeopathic use.

2.4.1 Indications Acceptable for Natural Products

a) General Health Maintenance/ *Kesehatan Am*

“Traditionally used..../ “*Digunakan secara tradisional....*

“Homeopathically used.... / “*Digunakan secara homeopati...*

1. For general health/ for health/ *untuk kesehatan.*
2. For general health maintenance/ for general well-being/ *untuk mengekalkan kesehatan*
3. For health and strengthening the body/ *untuk kesehatan dan menguatkan badan.*
4. For relief of body heatiness/ *untuk melegakan panas badan.*
5. For general debility, weakness after illness or childbirth/ *untuk letih lesu/ kelesuan badan selepas sakit atau selepas bersalin.*
6. For loss of appetite/ *untuk kurang selera makan.*
7. For difficulty in sleep/ *bagi melegakan kesukaran untuk tidur.*
8. For relief of fatigue/ *untuk melegakan kepenatan.*
9. As an aid to overcome fatigue during physical exertion/ *membantu melegakan kepenatan fizikal.*
10. To expel wind and invigorate vital energy/ *untuk membuang angin dan menambah tenaga.*
11. To improve appetite/ *untuk menambah selera makan.*
12. For relieving waist ache and body weakness/ *untuk melegakan sakit pinggang dan lemah anggota badan.*
13. For relieving dizziness, sweating, and difficulty in sleep/ *untuk melegakan pening, berpeluh berlebihan dan sukar untuk tidur.*
14. For reducing body odour/ *untuk mengurangkan bau badan.*
15. For reducing toothache/ *untuk mengurangkan sakit gigi.*
16. To relieve tired eyes/ *untuk melegakan kepenatan mata.*
17. For healthy eyes/ *untuk kesehatan mata.*

b) Blood & Body Fluid/ *Darah & Cecair Badan*

“Traditionally used..../ “*Digunakan secara tradisional....*

“Homeopathically used.... / “*Digunakan secara homeopati...*

1. For improving blood circulation/ *untuk melancarkan perjalanan darah.*
2. To improve urination/ *untuk melawaskan kencing/ buang air kecil.*
3. For improving bowel movement/ *untuk melawaskan buang air besar.*
4. For relieving mild vomiting/ *untuk melegakan muntah ringan.*
5. For reducing minor swelling/ *untuk melegakan bengkak-bengkak ringan.*

c) Bone, Muscle & Joint/ *Tulang, Otot & Sendi*

“Traditionally used..../ “*Digunakan secara tradisional....*

“Homeopathically used.... / “*Digunakan secara homeopati...*

1. For strengthening muscle and bone/ *untuk menguatkan otot dan tulang.*
2. For relieving muscular ache/ *untuk melegakan sakit otot.*
3. For relieving waist ache and backache/ *untuk melegakan sakit pinggang dan sakit belakang.*
4. For relief of joints and muscular pain/ *untuk melegakan sakit sendi dan otot.*
5. For relieving muscles sprain/ *untuk melegakan terseliuh/ terkehel.*

d) Pain & Fever/ *Sakit Am & Demam*

“Traditionally used..../ “*Digunakan secara tradisional....*

“Homeopathically used.... / “*Digunakan secara homeopati...*

1. To relieve/ alleviate pain/ *untuk melegakan kesakitan.*
2. For relieving fever/ *untuk melegakan demam.*
3. For relieving headache/ *untuk melegakan sakit kepala.*
4. For relieving pain and itchiness related to piles/ *untuk melegakan kesakitan dan rasa gatal akibat buasir.*
5. For symptomatic relief of body heatiness/ body heat / *untuk melegakan panas badan.*

e) Cough & Cold/ *Batuk & Selesema*

“Traditionally used...../ “*Digunakan secara tradisional.....*

“Homeopathically used.... / “*Digunakan secara homeopati...*

1. For relief of fever, cough and cold/ *untuk melegakan demam, batuk dan selesema.*
2. For relief of sore throat/ *untuk melegakan sakit tekak.*

3. For reducing phlegm and relief of cough, sore throat and body heatiness/ *untuk mengurangi kahak dan melegakan batuk, sakit tekak dan panas badan.*
4. For relief of throat irritations and cough/ *untuk melegakan sakit tekak dan batuk.*
5. For relief of nasal congestion/ *untuk melegakan hidung tersumbat.*
6. For relief of sore throat and cough/ *untuk melegakan sakit tekak dan batuk.*
7. For relief of mouth ulcers due to heatiness/ *untuk melegakan sakit mulut akibat panas badan.*
8. To relieve sinusitis/ *untuk melegakan resdung.*

f) Digestive System/ Sistem Pencernaan

“Traditionally used..../ “*Digunakan secara tradisional....*

“Homeopathically used.... / “*Digunakan secara homeopati...*

1. For relief of stomach ache, mild diarrhoea/ *untuk melegakan sakit perut, cirit-birit ringan.*
2. For relief of flatulence, stomach ache, mild diarrhoea, and loss of appetite/ *untuk melegakan kembung perut, sakit perut, cirit-birit ringan dan kurang selera makan.*
3. For relief of mild diarrhoea, vomiting and improve appetite/ *untuk melegakan cirit-birit, muntah ringan dan menambah selera makan.*
4. For relief of mild constipation/ *untuk melegakan sembelit ringan.*
5. To improve appetite and digestion/ *untuk menambah selera makan dan pencernaan.*
6. For relieving abdominal pain and flatulence/ *untuk melegakan sakit perut dan kembung perut.*
7. For relief of stomach ache, constipation, mild vomiting and indigestion/ *untuk melegakan sakit perut, sembelit, muntah ringan dan makanan tidak hadam.*
8. Aid in digestion/ *untuk membantu penghadaman.*

g) Women’s Health/ Kesihatan Wanita

“Traditionally used..../ “*Digunakan secara tradisional....*

“Homeopathically used.... / “*Digunakan secara homeopati...*

1. To relieve menstrual pain, headache and to regulate menstruation/ *untuk melegakan senggugut, sakit kepala dan melancarkan perjalanan haid.*
2. To reduce body weight/ *untuk mengurangkan berat badan.*
[Note: For specific active ingredient only supported by established reference, examples: *Cassia species, Garcinia Cambogia and Phaseolus vulgaris*]
3. For relief of vaginal discharge/ *untuk melegakan keputihan.*
4. For women after childbirth/ *untuk wanita lepas bersalin.*
5. For general wellbeing and strengthen the body after childbirth/ *untuk kesihatan dan menguatkan badan wanita selepas bersalin.*
6. For women after childbirth to reduce body weight/ *untuk ibu-ibu selepas bersalin mengurangkan berat badan.*

7. For symptomatic relief of vaginal discharge and mild itch/ *untuk melegakan keputihan dan gatal-gatal ringan.*
8. To improve menstrual flow, for relief of menstrual pain, vaginal discharge and flatulence/ *untuk melancarkan haid, melegakan senggugut, keputihan dan kembung perut.*
9. For strengthening body muscle and reducing body weight/ *untuk menguatkan otot-otot tubuh dan mengurangkan berat badan.*
10. For general health of women after childbirth/ *untuk menyihatkan rahim selepas melahirkan anak.*
11. To relieve symptoms of menopause/ *untuk melegakan simptom menopause.*
[Note: For specific active ingredient only supported by established reference, examples: red clover (*trifolium pratense*) and black cohosh (*cimicifuga racemosa*)]

h) Men's Health/ Kesihatan Lelaki

"Traditionally used..../ "Digunakan secara tradisional....

"Homeopathically used.... / "Digunakan secara homeopati...

1. For men's health and energy/ for vitality/ *untuk memulihkan tenaga dan kesihatan lelaki.*

i) Skin And External Usage/ Kulit Dan Kegunaan Luar

"Traditionally used...../ "Digunakan secara tradisional...

"Homeopathically used.... / "Digunakan secara homeopati...

1. For symptomatic relief of pain and itch associated with insect bites/ *untuk melegakan sakit dan gatal-gatal digigit serangga.*
2. For relief of minor burns/ *untuk melegakan lecur ringan.*
3. For relief minor cuts/ *untuk melegakan luka-luka ringan.*
4. For relief of minor bruises/ *untuk melegakan lebam yang ringan.*
5. For reducing pimples/ *untuk mengurangkan jerawat.*
6. To help maintaining healthy skin, nail and hair/ *untuk kesihatan kulit, kuku dan rambut.*
7. For reducing pimples and mild itch/ *untuk melegakan jerawat dan gatal-gatal ringan.*

2.4.2 Non-Permissible Indications

Table 7:

| NO. | NON-PERMISSIBLE INDICATIONS |
|-----|--|
| 1. | <i>Penyakit atau kecacatan ginjal / Disease or defects of the kidney</i> |
| 2. | <i>Penyakit atau kecacatan jantung / Disease or defects of the heart</i> |
| 3. | <i>Kencing manis / Diabetes</i> |
| 4. | <i>Epilepsi atau sawan / Epilepsy or fits</i> |
| 5. | <i>Kelumpuhan / Paralysis</i> |
| 6. | <i>Tibi / Tuberculosis</i> |
| 7. | <i>Asma / Asthma</i> |
| 8. | <i>Kusta / Leprosy</i> |
| 9. | <i>Kanser / Cancer</i> |
| 10. | <i>Kepekakan / Deafness</i> |
| 11. | <i>Ketagihan dadah / Drug addiction</i> |
| 12. | <i>Hernia atau pecah / Hernia or rupture</i> |
| 13. | <i>Penyakit mata / Disease of the eye</i> |
| 14. | <i>Hipertensi (Darah Tinggi) / Hypertension</i> |
| 15. | <i>Sakit otak / Mental disorder</i> |
| 16. | <i>Kemandulan / Infertility</i> |
| 17. | <i>Kaku / Frigidity</i> |
| 18. | <i>Lemah fungsi seks atau impoten / Impairment of sexual function or impotency</i> |
| 19. | <i>Penyakit venerus / Venereal disease</i> |
| 20. | <i>Lemah urat saraf atau aduan atau kelemahan lain timbul daripada atau berhubung kait dengan perhubungan seks / Nervous debility or pother complaint of infirmity arising from or relating to sexual intercourse.</i> |

2.5 PARTICULARS OF PACKING

- The maximum pack size allowed for all dosage forms is based on the daily dosing for a quantity not exceeding six (6) months usage. This does not apply to products in blister or strip packaging (with justification).
- Packaging particulars to the listing of packing are:
 - C1: Pack size and fill details by weight, or volume or quantity.
 - C2: Container type
 - C3: Barcode/ serial number (optional)
 - C4: Recommended distributor's price (optional)
 - C5: Recommended retail price (optional)
- Measuring spoon/ device must be provided for all products in bulk powder form, unless if for physician use only.
- Sample pack size should not exceed 20 capsules/ tablets.

2.6 LABELLING REQUIREMENTS

- a) The following information shown in **Table 8** below shall be included in the product label.

| No. | Items | Immediate Label | Outer Label | Package Insert | Blister Pack |
|-----|---|-----------------|-------------|----------------|--------------|
| 1. | Product name | √ | √ | √ | √ |
| 2. | Dosage Form | √ | √ | √ | √ |
| 3. | Name of active ingredients, including part of plant used | √ | √ | √ | |
| 4. | Strength of active ingredient in weight | √ | √ | √ | |
| 5. | Indication | √ | √ | √ | |
| 6. | Batch number | √ | √ | | √ |
| 7. | Manufacturing date | √ | √ | | |
| 8. | Expiry date | √ | √ | | √ |
| 9. | Dosage/ Use instruction | √ | √ | √ | |
| 10. | Storage condition(s) - state temperature used in the stability study - state "Protect from light and moisture" (If product is not packed in moisture resistant container) | √ | √ | √ | |
| 11. | Registration number (MAL) | √ | √ | | √ |
| 12. | Name and address of product registration holder (Example: Product Registration Holder: XXXXX) | √ | √ | √ | |

| No. | Items | Immediate Label | Outer Label | Package Insert | Blister Pack |
|-----|---|--|--|----------------|--------------|
| 13. | Name and address of manufacturer (Example: Manufacturer: XXXXX) | √ At least name of town/ city and country of manufacturer | √ At least name of town/ city and country of manufacturer | √ | |
| 14. | Warning label (if applicable) e.g. Ginseng, Bee Pollen etc. as required under 2.6.2 Specific Labelling Statements/ Warning & Precautions <i>Note: Please refer to Appendix 19: General Labelling Requirements and Appendix 20: Specific Labelling Requirements</i> | √ | √ | √ | |
| 15. | Pack size (unit/ volume) | √ | √ | √ | |
| 16. | Name and strength of preservative | √ | √ | √ | |
| 17. | Name and content of alcohol, where present | √ | √ | √ | |
| 18. | To declare source of ingredients derived from animal origin (active and excipient) including starting materials and gelatine (capsule shell). | √ | √ | | |
| 19. | Additional statement (if applicable) | √ | √ | √ | |
| 20. | Contraindication/ Precaution (if any) | √ | √ | √ | |
| 21. | Security Label (Hologram) # In products without an outer carton, the security label shall be applied onto the immediate label. The security label shall not be applied onto the outer shrink | | √ # | | |

| No. | Items | Immediate Label | Outer Label | Package Insert | Blister Pack |
|-----|----------------------|-----------------|-------------|----------------|--------------|
| | wrap of the product. | | | | |
| 22. | Product Description | | | √ | |
| 23. | Date of Revision | | | √ | |

- b) All labels and package inserts must be in *Bahasa Malaysia* or English. Additional translation to another language will be allowed.
- c) Font size of the product name on the label, including alphabets and numbers, should be equal in size.
- d) For a product containing two (2) or more active ingredients, the font size of each active ingredient highlighted on the inner/ outer carton must be of equal size and equal prominence (Note: This does not refer to the product name, but the statement made on the label). Justification for highlighting certain ingredients only on the product name/ label must be provided and is subject to approval by the Drug Evaluation Committee.
- e) All the following requirements must be stated on the labels and package inserts:
- State the weight per dosage form
 - State the quantity/ content of active ingredients per dosage form
 - For products in liquid form (syrup), content of active ingredients shall be stated as follows:
 “Each ___ml (per dosage) product contains extract of the following ingredients”
 Herb X = ___mg
 Herb Y = ___mg
 - Check and correct all spelling/ grammar and translations.
- f) For products meant for traditional practitioner/ physician use, state its primary use by the related traditional physician/ practitioner on the label.
- E.g.: ‘For Chinese Physician Use Only’ OR
 ‘For Ayurvedic Practitioner Use Only’.
- g) For small label, the labelling requirements may follow that of blister packaging subject to satisfactory justification.
- * Definition of small label: Small label refers to the label on a small primary (immediate) container, where the container is not large enough to accommodate an immediate label that includes all the information and formatting typically required.*

g) Example of label approved by the Authority:

| | | |
|--|---|---|
| This is a traditional medicine | <p>KAPSUL PQR</p> <p>500MG</p> <p>MALXXXXXXXXT</p> <p>50 CAPSULE</p> <div data-bbox="699 741 842 792" style="border: 1px solid black; padding: 2px; text-align: center;">Hologram</div> | Each Capsule (Vegetable capsule) contains : |
| Please consult your pharmacist/ doctor before taking this product | | Folium XX 200mg Fructus QY 300mg |
| Jauhkan daripada capaian kanak-kanak <i>Keep out of reach of children</i> | | Dosage Adult : 2 capsules taken twice a day after food |
| Indication: Traditionally used for women's health | | Product Registration Holder: Syarikat XYZ Sdn Bhd 18, Jalan Utama 47000 Sungai Buloh Selangor |
| Warning: Pregnancy and breastfeeding: Insufficient reliable data | | Manufactured by: Syarikat ABC Sdn Bhd 3, Jalan Universiti 46730 Petaling Jaya Selangor |
| Keep below 30 ° celcius Protect from light and moisture | | |
| Batch No.: Manufacturing date: Expiry date: | | |

2.6.1 Statements to Be Stated on Product Label

The following statements shall also be stated on the product label, where applicable:

- For product with an indication “For general health/ well-being” **or** “*Untuk kesihatan umum*”:
 - “Please consult your pharmacist / doctor before taking this product **or** *Sila merujuk kepada ahli farmasi/ doktor sebelum mengambil produk ini.*”
- For product with an indication “To relieve symptoms for.... (any illness)” **or** “*untuk mengurangkan tanda-tanda/ simptom....*”:
 - “Please consult your pharmacist/ doctor if symptoms persist/ worsen **or** *Sila merujuk kepada ahli farmasi/ doktor jika simptom berlarutan/ bertambah teruk.*”
- For product with indication “To regulate menstruation/ To improve menstrual flow”:

“Contraindicated in pregnant women.”
- For product with indication ‘To reduce body weight’, state these statements, (unless proven otherwise):
 - **“Balanced diet and regular exercise are essential.”**
 - **“Safety on long term use has not been established.”**

- “This is a traditional medicine/ *Ini adalah ubat tradisional.*” **OR** “This is a homeopathy medicine/ *Ini adalah ubat homeopati.*”
- Unless otherwise supported, all natural products label shall state the following general cautionary statement, **EXCEPT** for products with indication for men’s health or product for children use only:

“Pregnancy and breastfeeding: Insufficient reliable data”

- For product with an indication to be taken/ used **specially for women**, refer to **2.6.3 Cautionary Statement for Products Specially Used in Women.**
- “Keep out of reach of children & *Jauhkan daripada capaian kanak-kanak*” (in both *Bahasa Malaysia* and English).
- “Protect from light and moisture.”
- State the storage condition according to the temperature stated in stability data.
- For products containing ingredients as specified below, include the required statements:
 - i) **Animal part(s):**
“This product contains animal part(s).”
 - ii) **Animal origin(s):**
Example: for active ingredients such as pearl, shell of oyster (Concha), etc.
“This product contains substance(s) from animal origin.”
 - iii) **Porcine:**
“This product contains animal part(s) (porcine/ pig).”
 - iv) **Alcohol:**
 - “This product contains alcohol.”
 - Please declare the percentage of alcohol contained in the product.
- For the following dosage forms, include:
 - i) **Topical preparations:** “For external use only.”
 - ii) **Liquids and suspensions:** “Shake well before use”

- Labels with the picture/ graphic of the herb/ animal should not have the picture/ graphic of only one (1) particular active ingredient if the product formulation contains more than one (1) ingredient. For multiple ingredients exceeding two (2), the label should have picture/ graphics of at least two (2) ingredients on the label.
- Any special/ specific name of active ingredient/ extract stated on the label should be positioned away from name of the active ingredient in the product formulation.
- Any picture of the founder placed on the label must be decent and should not exceed 1/10th of the panel.

2.6.2 Specific Labelling Statements/ Warning & Precautions

- Refer to [Appendix 20: Specific Labelling Requirements](#) for common substance (e.g. alfalfa, bee pollen, black cohosh etc.).
- For products containing the following substances, specific cautionary statement as specified shall be included:

| No. | Substance | Specific Cautionary Statement |
|-----|--|--|
| 1. | For product containing 'Anti-diarrhoea', please state: | "Contraindicated in children below 1 year old" (to be stated for products with children dosing only) |
| 2. | For product containing Benzyl Alcohol/ Phenylmethanol (as preservative) , please state: | <div style="border: 1px solid black; padding: 10px; text-align: center;"> <p>As this preparation contains benzyl alcohol, its use shall be avoided in children under 2 years of age. Not to be used in neonates.</p> </div> |
| 3. | For products containing Camphor : | <p>i) The following <u>warning</u> shall be stated on the <u>label</u>:</p> <p>WARNING:</p> <div style="border: 1px solid black; padding: 10px; text-align: center;"> <p>CAN CAUSE CONVULSION</p> <p>CONTRAINDICATED IN CHILDREN BELOW 2 YEARS OF AGE.</p> <p>CAUTION MUST BE EXERCISED WHEN OLDER CHILDREN ARE TREATED.</p> <p>AVOID DIRECT APPLICATION INTO NOSTRILS</p> </div> <p>PRECAUTION: It is dangerous to place any camphor – containing product into the nostril of children. A small amount applied this way may cause immediate collapse.</p> <ul style="list-style-type: none"> - Avoid contact with the eyes. - Do not apply to wounds or damaged skin. <p>ii) The following <u>warning and precaution</u> shall be stated on <u>product leaflet</u>:</p> <p>WARNING: "This product is contraindicated in children under 2 years of age. Caution must be exercised when older children are treated."</p> |

| No. | Substance | Specific Cautionary Statement |
|-----|---|---|
| | | PRECAUTION: "It is dangerous to place any camphor containing product into the nostrils of children. A small amount applied this way may cause immediate collapse." |
| 4. | For pack size meant as samples, please state: | Sample not for sale |

2.6.3 Cautionary Statements for Products Specifically Used in Women

Special precaution shall be given to ingredients taken during pregnancy. The Authority urges pregnant women to consult their medical/ traditional health care providers prior to taking any natural products.

Unless otherwise supported, all natural products label shall state the following general cautionary statement:

"Pregnancy and breastfeeding: Insufficient reliable data"

However, for products containing any ingredients as listed in the following lists, i.e. List of Prohibited Ingredients in Pregnancy and List of Restricted Ingredients in Pregnancy, the following cautionary statement shall be stated in the product label:

- i) Prohibited Ingredients in Pregnancy:
"Contraindicated in pregnant women. Insufficient reliable data in breastfeeding women"
- ii) Restricted Ingredients in Pregnancy:
"To be used with caution in pregnancy. Insufficient reliable data in breastfeeding women"

The following list has been compiled based on well documented information as an aid to the industry to comply with the labelling requirement for products used during pregnancy.

Table 9: List of Prohibited Ingredients in Pregnancy

| | Latin Compendium Name | Common/ Chinese Name | Remarks |
|----------|---|----------------------|-------------------|
| A | Acorus Calamus | Calamus | |
| | Achillea Millefolium | Yarrow | |
| | Aloe barbadensis | Aloe vera | |
| | Angelica Archangelica | Angelica | |
| | Angelica sinensis | Dong Quai | When taken orally |
| | Artemisia Vulgaris | Mugwort | |
| | Arctostaphylos Uva Ursi | Uva Ursi | |
| | Artemisia Absinthium | Wormwood | |
| | Astragalus gummifer | Tragacanth | |
| B | Bryonia Alba | White Bryony | |
| | Bupleurum chinense, Bupleurum falcatum | Bupleurum | |
| C | Calendula Officinalis | Calendula | |
| | Calomel (mercurous chloride; Hg ₂ Cl ₂) | Qing fen | |
| | Capsella Bursa-Pastoris | Shepherd's Purse | |
| | Cassia Marilandica | Senna | |
| | Caulophyllum Thalictroides | Blue Cohosh | When taken orally |
| | Chamaemelum nobile (Anthemis nobilis) | Roman Chamomile | When taken orally |
| | Chenopodium Ambrosioides | Epazote | |
| | Cichorium intybus | Chicory | |
| | Cimicifuga Racemosa | Black Cohosh | When taken orally |
| | Cnicus Benedictus | Blessed Thistle | |
| | Conium maculatum | Hemlock | |
| | Convalaria Majalis | Lily of the Valley | |
| | Cortex Cinnamomum Cassia | Rou Gui | |
| | Cortex Paeonia suffruticosa (Cortex Moutan Radicis) | Mu Dan Pi | |
| | Crocus Sativus | Saffron | |

| | Latin Compendium Name | Common/ Chinese Name | Remarks |
|----------|---|----------------------|-------------------------------|
| | Croton tiglium | Ba dou | |
| E | Epimedium grandiflorum | Horny goat weed | |
| | Equisetum arvense L. | Horsetail | |
| F | Flos Carthamus Tinctorius | Hong Hua | |
| | Flos Daphne Genkwa | Yuan Hua | |
| | Folium Cassia Angustifolia | Fan Xie Ye | |
| | Fructus Citrus Aurantium | Zhi Ke | |
| | Fructus Citrus Aurantium Immaturus (Fructus Aurantii Immaturus) | Zhi Shi | |
| G | Gentiana lutea | Gentian | |
| | Ginkgo Biloba | Ginkgo | |
| | Glycyrrhiza glabra/ Glycyrrhiza uralensis | Licorice | |
| H | Helleborus spp. | Hellebore | |
| | Hyssopus officinalis | Hissopo | |
| I | Iris Versicolor | Blue Flag | |
| | Ipecac Ipecachuana | Ipecac | |
| J | Juglans Canadensis | Butternut | |
| | Juglans nigra | Black Walnut | |
| | Juniper (<i>Juniperus communis</i>) | Juniper Berries | |
| L | Leonurus Cardiaca | Motherwort | |
| M | Magnolia officinalis | Houpu, Magnolia | |
| | Marrubium Vulgare | Horehound | |
| | Mentha Pulegium | Pennyroyal | When used orally or topically |
| | Monarda didyma | Bee Balm | |
| | Moschus berezovskii Flerov, Moschus sifanicus Przewalski, Moschus moschiferus Linnaeus (Moschus) | She xiang / musk | |

| | Latin Compendium Name | Common/ Chinese Name | Remarks |
|----------|--|-------------------------|-------------------|
| | Mylabris / Radix Sacchari Arundinacei | Ban Mao | |
| N | Natrii Sulfas | Mang Xiao | |
| | Nepeta cataria | Catnip | |
| | Nigella sativa | Black seed/ black cumin | |
| O | Oenothera biennis L. | Evening Primrose | |
| P | Panax Ginseng, Panax Quinquefolius | Ginseng | |
| | Passiflora incarnata L. | Passion Flower | When taken orally |
| | Petroselinum Crispum | Parsley | |
| | Podophyllum Peltatum | American Mandrake | |
| | Polygala Senega | Senega Snakeroot | |
| R | Radix Euphorbiae Pekinensis | Jing Da Ji | |
| | Radix et Rhizoma Rheum Palmatum | Da Huang | |
| | Radix Kansui/ Radix Euphorbiae Kansui | Gan Sui | |
| | Radix Phytolacca actinosa | Shang Lu | |
| | Rhizoma Sparganium Stoloniferum | San Leng | |
| | Resina Toxicodendri/ Resina Rhois Praeparata | Gan Qi | |
| | Rhizome et Radix Veratrum nigrum L. | Li Lu | |
| | Radix Achyranthes bidentata | Niu Xi | |
| | Rhizoma Ligustici Chuanxiong | Chuan Xiong | |
| | Rhizome Curcumae Longae | Jiang Huang | |
| | Rhamnus Purshiana | Cascara Sagrada | |
| | Rhamnus Frangula | Buckthorn | |
| | Rheum Palmatum | Rhubarb Root | |
| | Ruta Graveolens | Rue | |
| | Rheum Australe | Turkey Rhubarb | |

| | Latin Compendium Name | Common/ Chinese Name | Remarks |
|----------|---|----------------------|-------------------|
| S | Sanguinaria Canadensis | Bloodroot | |
| | Semen Pharbitis nil | Qian Niu Zi | |
| | Semen Strychnos nux-vomica. L. | Ma Qian Zi | |
| | Semen Prunus Persica | Tao Ren | |
| | Serenoa repens | Saw Palmetto | When taken orally |
| T | Tabebuia impetiginosa | Pay D' Arco | When taken orally |
| | Tanacetum parthenium | Feverfew | |
| | Tanacetum Vulgare | Tansy | |
| | Thuja Occidentalis | Arbor Vitae | |
| | Turnera Diffusa | Damiana | |
| | Trigonella foenum-graecum | Fenugreek | |
| | Trillium Erectum | Bethroot | |
| | Tussilago Farfara | Coltsfoot | |
| V | Venenum Bufonis | Chan Su | |
| | Viscum Album | European Mistletoe | |
| W | Whitmania pigra Whitman, Hirudo nipponica Whitman, Whitmania acranulata Whitman (Hirudo) | Shui Zhi | |
| X | Xanthoxylum Americanum | Prickley Ash | |

Note: The list is not to be exhaustive and will be reviewed from time to time.

Table 10: Restricted in Pregnancy

| No. | Latin Compendium Name | Common/ Chinese Name | Remarks |
|-----|-----------------------|----------------------|---------------------|
| 1. | Zingiber Officinalis | Ginger | > 1g dry weight/day |

Note: The list is not to be exhaustive and will be reviewed from time to time.

2.6.4 Prohibited Visual/ Graphics/ Statement on Packaging Materials (Label, Box, Package Insert or Consumer Medication Information Leaflet)

General requirements:

- The label should not contain any statement or visual presentation which, whether directly or by implication, is likely to mislead the consumer about any product.
- The graphics printed on the outer and inner labels have to be standardized to avoid confusion to the customers.

Table 11:

| No. | Subject Matter | Example(s) | Notes |
|-----|---|---|--|
| 1. | Marketing strategy | Example: “Money back guarantee” “Buy 1 free 1” “Backed by RM5 million product Liability Insurance” | Such statements are prohibited on labels for immediate container, outer carton, package insert or Consumer Medication Information Leaflet. |
| 2. | Usage guide that promotes use of other product(s) | Example: “After consumption of this product (Product A), for better results, it is recommended to take Product B” | Not allowed |
| 3. | Consumer testimonial | | Prohibited on product label |

| No. | Subject Matter | Example(s) | Notes |
|-----|--|---|---|
| 4. | Clinical Trial results or any information on clinical trial done on product | Example: "Clinically Tested" "Randomized Double-Blind Placebo Control Clinical Study" | Such statements are prohibited on labels. |
| 5. | Opinion/ Name of prominent figure(s)/ professionals on product or its active ingredient/ content | Example: Opinion of product/ formulation inventor | Prohibited on product label |
| 6. | Label design (graphic and color) similar to labels from another company | | Prohibited on product label |
| 7. | Statement on herbal origin | Example: Source from the Mountains of Alps | Allowed if proven true |
| 8. | Introduction/ description of founder/ manufacturer/ professionals, i.e. elaboration on the identity of the founder or manufacturer | Example: "Manufacturer ABC is a GMP certified manufacturer and has manufactured many products." "Founder Dr. ABC is a world renowned surgeon." | Prohibited on product label |

| No. | Subject Matter | Example(s) | Notes |
|-----|---|---|--|
| 9. | Logo with certification | Example: SIRIM/ ISO / GMP /HACCP | Prohibited on product label because certification renewal is on a yearly basis |
| 10. | Name/ Statement / Logo/ registered trademark that does not satisfy the specifications of the Traditional Unit | Example: “Dr. ABC’s Formula” “Nothing like it” | Prohibited on product label |
| 11. | Special technique used/ superiority in ingredients | Example: Capsule coat | Allowed if proven true |
| 12. | Nutritional claims with analysis certificate attached | Example: Calorie, Fat, Protein and others | Prohibited on product label This is not a food supplement. |
| 13. | Graphics or picture of internal organs | Example: Kidney, Heart, Nerves. | Prohibited on product label |
| 14. | Photograph of celebrities | Example: Artiste, Sports person(s), Politician | Prohibited on product label |
| 15. | Gender symbol (male or female) | (♂ and / or ♀) | Prohibited on product label |

| No. | Subject Matter | Example(s) | Notes |
|-----|---|---|-----------------------------|
| 16. | Indecent photographs/ pornography/ graphics/ images | | Prohibited on product label |
| 17. | Graphics incoherent with the indication | Example: <ul style="list-style-type: none"> - Noted indication is for constipation, but graphics on label shows a slim-looking lady which denotes indication for weight loss - Indication for urination but label graphics contains picture of a water hose. | Prohibited on product label |
| 18. | Highlighting unnecessary body parts | Example: Indication is for general health but graphics on label highlights male and female sexual organ parts | Prohibited on product label |
| 19. | Graphics of plants or animal that may cause confusion | Example: Radix Ginseng which is improvised as a male sexual organ | Prohibited on product label |

| No. | Subject Matter | Example(s) | Notes |
|-----|---|--|---|
| 20. | Statement on sugars in traditional products | Example: - This product contains no added sugar | Allowable on product label provided the product contains no fructose, glucose, sucrose or other kind of sugars with a potential to affect diabetics are not included in the formulation |
| 21. | Negative statements | Example: - No active ingredient - No gluten, yeast, etc. | Prohibited on product label |
| 22. | Other statements | Example: - This product is blended with premium quality - Certified chemical residue free | Prohibited on product label |
| 23. | Label design (graphic/ colour) similar to/ same as an adulterated product | | Prohibited on product label |

Notes:

1. This list is not meant to be exhaustive and will be reviewed from time to time.
2. The Authority reserves the right to disallow any other words, phrases or graphics for product label, which in its opinion, is misleading, improper or not factual.

2.7 QUALITY CONTROL

2.7.1 Quality Testing for Specific Ingredient

- i) For product containing *Aphanizomenon flosaquae*, applicants shall provide certificates of analysis showing that the microcystin-LR or total microcystins content of the raw material does not exceed 1µg/g and the finished product has been tested for microcystin-LR using an acceptable method;
- ii) For products containing Red Yeast Rice (*Monascus purpureus*), applicants shall provide certificates of analysis (for both raw material and finished product) showing the Monacolin-K content. The percentage of Monacolin-K shall not exceed 1% and the Monacolin-K consumed shall not exceed 10 mg per day.

2.7.2 Limit Test for Heavy Metals

Limit for heavy metals:

- i) Lead : NMT 10.0 mg/kg or 10.0 mg/litre (10.0ppm)
- ii) Arsenic : NMT 5.0 mg/kg or 5.0 mg/litre (5.0ppm)
- iii) Mercury : NMT 0.5 mg/kg or 0.5 mg/litre (0.5ppm)
- iv) Cadmium : NMT 0.3 mg/kg or 0.3 mg/litre (0.3ppm)

2.7.3 Disintegration Test

Disintegration time **for tablets, capsules and pills**

- i) Uncoated tablets : NMT 30 minutes
- ii) Film-coated tablets : NMT 30 minutes
- iii) Sugar-coated tablets : NMT 60 minutes
- iv) Enteric-coated tablets : Does not disintegrate for 120 minutes in acid solution but to disintegrate within 60 minutes in buffer solution
- v) Capsules : NMT 30 minutes
- vi) Pills : NMT 120 minutes

2.7.4 Test for Uniformity of Weight (For Tablets and Capsules Only)**i) Tablet**

- For tablet with average weight of 130mg or less: Not more than 2 tablets differ from the average weight by more than 10% AND no tablets differ from the average weight by more than 20%
- For tablet with average weight between 130-324mg: Not more than 2 tablets differ from the average weight by more than 7.5% AND no tablet differs from the average weights by more than 15%
- For tablets with average weight more than 324mg: Not more than 2 tablets differ from the average weight by more than 5% AND no tablet differs from the average weight by more than 10%

ii) Capsule

Individual weight of the capsule to be within the limit of 90 - 110% of the average weight.

2.7.5 Tests for Microbial Contamination

- A. Herbal medicinal products containing herbal drugs, with or without excipients, intended for the preparation of infusions and decoctions using boiling water (e.g. herbal teas, with or without added flavourings)

| Microbiological Quality | Acceptance Criteria |
|-------------------------|---------------------------|
| TAMC | NMT 5×10^7 CFU/g |
| TYMC | NMT 5×10^5 CFU/g |
| <i>Escherichia coli</i> | NMT 1×10^3 CFU/g |
| <i>Salmonella</i> | Absence (25 g) |

- B. Herbal medicinal products containing, e.g. extracts and/or herbal drugs, with or without excipients, where the method of processing (e.g., extraction) or, where appropriate, in the case of herbal drugs, of pre-treatment reduces the levels of organism to below those stated for this category

| Microbiological Quality | Acceptance Criteria |
|--------------------------------------|-------------------------------------|
| TAMC | NMT 5×10^4 CFU/g or CFU/mL |
| TYMC | NMT 5×10^2 CFU/g or CFU/mL |
| Bile-tolerant gram-negative bacteria | NMT 1×10^2 CFU/g or CFU/mL |
| <i>Escherichia coli</i> | Absence (1 g or 1 mL) |
| <i>Salmonella</i> | Absence (25 g or 25 mL) |

- C. Herbal medicinal products containing, e.g. extracts and/or herbal drugs, with or without excipients, where it can be demonstrated that the method of processing (e.g. extraction with low strength ethanol or water that is not at boiling or low temperature concentration) or, in the case of herbal drugs, of pre-treatment, would not reduce the level of organisms sufficiently to reach the criteria required under B.

| Microbiological Quality | Acceptance Criteria |
|--------------------------------------|-------------------------------------|
| TAMC | NMT 5×10^5 CFU/g or CFU/mL |
| TYMC | NMT 5×10^4 CFU/g or CFU/mL |
| Bile-tolerant gram-negative bacteria | NMT 1×10^4 CFU/g or CFU/mL |
| <i>Escherichia coli</i> | Absence (1 g or 1 mL) |
| <i>Salmonella</i> | Absence (25 g or 25 mL) |

- D. Special Ph. Eur. provision for oral dosage forms containing raw materials of natural (animal, vegetal or mineral) origin for which antimicrobial pretreatment is not feasible and for which the competent authority accepts TAMC of the raw material exceeding 10^3 CFU/g or CFU/mL.

| Microbiological Quality | Acceptance Criteria |
|--------------------------------------|-------------------------------------|
| TAMC | NMT 2×10^4 CFU/g or CFU/mL |
| TYMC | NMT 2×10^2 CFU/g or CFU/mL |
| Bile-tolerant gram-negative bacteria | NMT 1×10^2 CFU/g or CFU/mL |
| <i>Salmonella</i> | Absence (10 g or 10 mL) |
| <i>Escherichia coli</i> | Absence (1 g or 1 mL) |
| <i>Staphylococcus aureus</i> | Absence (1 g or 1 mL) |

E. Herbal Medicine for External use

| Route of Administration | TAMC (CFU/g or CFU/ml) | TYMC (CFU/g or CFU/ml) | Specified microorganisms |
|---|---------------------------|---------------------------|---|
| Oromucosal use Gingival use Cutaneous use Nasal use Auricular use | NMT 2×10^2 | NMT 2×10^1 | Absence of <i>Staphylococcus aureus</i> (1 g or 1 ml) Absence of <i>Pseudomonas aeruginosa</i> (1 g or 1 ml) |
| Transdermal patches (limits for one patch including adhesive layer and backing layer) | NMT 2×10^2 | NMT 2×10^1 | Absence of <i>Staphylococcus aureus</i> (1 patch) Absence of <i>Pseudomonas aeruginosa</i> (1 patch) |

Notes:

TAMC : Total Aerobic Microbial Count

TYMC : Total Yeasts & Moulds Count

NMT : Not more than

*[Reference: latest version of British Pharmacopoeia]***2.7.6 Certificate of Analysis (Active Ingredient)**

Certificate of Analysis (COA) for one batch of active ingredient (herbal substance/preparation/quantified extract), issued by both the active ingredient supplier and the product manufacturer, shall be submitted during traditional product registration application. The COA consists of the following tests (as in **Table 1 and Table 2**), shall be submitted for **all active ingredients** in the formulation.

Table 1: List of testing requirements for active ingredients (**herbal substances¹⁾**

| Tests | Specifications | Results |
|---|----------------|---------|
| Appearance/Organoleptic characteristics | | |
| Identification: (should be specific for the herbal substance and are usually a combination of three or more of the following): Macroscopy/Microscopy/ Chromatographic procedures or Chemical tests | | |
| Quantitative assay (for active ingredient compounds that are claimed on label) | | |
| Purity Tests: Foreign Matter Total Ash Content Ash insoluble in hydrochloric acid* Water content | | |
| Extractive Values* Water Soluble extracts Ethanol Soluble extracts Extractable matter | | |
| Microbial Contamination Tests: Total Aerobic Microbial Count (TAMC) Total Yeast and Mould Count (TYMC) Bile tolerant gram-negative bacteria <i>Salmonella</i> <i>Escherichia coli</i> <i>Staphylococcus aureus</i> <i>Pseudomonas aeruginosa</i> | | |
| Heavy metal limit: Arsenic Mercury Lead Cadmium | | |
| Other Tests*: Residual solvents Mycotoxins (Aflatoxin, Ochratoxin A) Pesticides Particle size | | |

Notes:

¹**Herbal substances** refers to 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).

*These tests might not apply to all herbal substances and must be justified by the applicant.

Table 2: List of testing requirements for active ingredients (**herbal preparations²/ quantified extracts³**)

| Tests | Specifications | Results |
|--|----------------|---------|
| Appearance/Organoleptic characteristics | | |
| Identification: Chromatographic procedure (Identification tests should be specific for the herbal preparation, and optimally should be discriminatory with regard to substitutes/adulterants that are likely to occur. Identification solely by chromatographic retention time, for example, is not regarded as being specific; however, a combination of chromatographic tests (e.g. HPLC and TLC-densitometry) or a combination of tests into a single procedure, such as HPLC/UV-diode array, HPLC/MS, or GC/MS may be acceptable.) | | |
| Quantitative assay (for active ingredient compounds that are claimed on label) | | |
| Purity Tests: Water Content | | |
| Microbial Contamination Tests: Total Aerobic Microbial Count (TAMC) Total Yeast and Mould Count (TYMC) Bile tolerant gram- negative bacteria <i>Salmonella</i> <i>Escherichia coli</i> <i>Staphylococcus aureus</i> <i>Pseudomonas aeruginosa</i> | | |

| Tests | Specifications | Results |
|--|----------------|---------|
| Heavy metal limit: Arsenic Mercury Lead Cadmium | | |
| Other Tests**: Residual solvents Mycotoxins (Aflatoxin, Ochratoxin A) Pesticides | | |

Notes:

²**Herbal preparations** are obtained by subjecting herbal substances to treatments such as extraction, distillation, expression, fractionation, purification, concentration or fermentation. These include comminute or powdered herbal substances, tinctures, extracts, essential oils, expressed juices and processed exudates.

³**Quantified extracts** refer to herbal substances/herbal preparations adjusted to one or more active markers, the content of which is controlled within a limited, specified range. Adjustments are made by blending batches of the herbal substance/herbal preparation.

** These tests might not apply to all herbal preparations/quantified extracts and must be justified by the applicant.

2.7.7 Certificate of Analysis (Finished Product)

The PRH shall submit a Certificate of Analysis (CoA) for the purpose of product registration evaluation. The CoA submitted to NPRA must meet the following requirements:

- a) CoA from panel laboratories (certified by NPRA) or local manufacturers' laboratories.
 - Only local laboratories can be accepted as a panel laboratory
 - Refer to NPRA website for the list of panel laboratories
 - Local manufacturers are allowed to issue CoA for their own products only
- b) CoA for one (1) batch of local or imported product to be submitted during product evaluation with NPRA's product reference number from QUEST 3+ system.
- c) CoA from multiple laboratories for different tests may be accepted, provided that the same batch of the products is submitted to the laboratories.
- d) The following compulsory testing parameters shall be stated in the CoA:

| Testing parameters | Panel laboratories/ manufacturers' laboratories | Other laboratories |
|--|---|-----------------------|
| Organoleptic | √ | X |
| Disintegration | √ | X |
| Uniformity of weight | √ | X |
| Microbial Contamination Test | √ | X |
| Heavy Metal Contamination | √ | X |
| Lovastatin (product containing Red Yeast Rice; <i>Monascus purpureus</i>) | √ | √ |
| Microcystin (product containing <i>Aphanizomenon flos-aquae</i>) | √ | √ |
| Assay (for all standardize compounds claimed on label) | √ | √ |

- e) For imported products, applicants are required to submit CoA from panel laboratories. Import permit issued by the Centre of Product & Cosmetic Evaluation is required to bring in samples for the purpose of laboratory testing. The applicant should ensure that the import permit is endorsed by the enforcement officer at the entry point.

Reference: Directive No. 8, 2020, [BPFK/PPP/07/25 \(8\) Jld.4](#). *Direktif Penerimaan Keputusan Pengujian Pra-Pendaftaran Produk Semulajadi dari Makmal Swasta yang Telah Diiktiraf oleh Bahagian Regulatori Farmasi Negara (NPRA) dan Makmal Kawalan Kualiti Pengilang Tempatan* (12 May 2020)

- f) All submitted sample test results are deemed final. There is no provision for appeal to submit new or updated results.

Reference: *Pekeliling (25) dlm.BPFK/PPP/01/03 Jld.3. Pekeliling Pemansuhan Sistem Rayuan Pengujian Semula Sampel (Appeal for Sample Retesting) Bagi Sampel Prapendaftaran Produk Tradisional Yang Tidak Lulus Pengujian Makmal Kali Pertama Oleh Pusat Kawalan Kualiti BPFK* (19 January 2015)

- g) Effective from 1 January 2023, Quantification by Input (QBI) of active ingredients may be considered for Traditional Medicine and Health Supplement (TMHS) Products. For details, refer to the *Direktif Berkenaan Pelaksanaan Garis Panduan Guidance on the Acceptance Criteria for Quantification by Input (QBI) of Active Ingredients Claimed on Label of Traditional Medicine and Health Supplement (TMHS) Products*. [NPRA.600-1/9/13\(16\) Jld 1](#). (8 November 2022)

Example of Certificate of Analysis for Finished Product (Natural Product)***Certificate of Analysis*****Company name/ Address :****Product Name :****Batch no. :****Dosage form :****Packaging :****Date of manufacture :****Date of expiry :**

| Test Parameter | Specifications | Results | Method |
|--|--------------------------------|---|---------------|
| Appearance/ Organoleptic: Odour Colour | To describe the characteristic | | |
| Disintegration | DRGD | | |
| Uniformity of weight | | | |
| Assay: All standardized compounds claimed on label | To specify | | |
| Standardized compounds assayed by QBI | To specify | Example: Results and statement 'Not Assayed. Quantified by Input' or words with similar meaning | QBI |
| Microbial Contamination Test TAMC, TYMC, specified microorganism | DRGD | | |
| Heavy Metal Contamination | | | |
| Lead (Pb) | NMT 10 ppm | | |
| Cadmium (Cd) | NMT 0.3 ppm | | |
| Mercury (Hg) | NMT 0.5 ppm | | |
| Arsenic (As) | NMT 5 ppm | | |

NMT = Not More Than

Signature :

Name :

Designation : (At least by Quality Control Manager or equivalent)

Date of signature :

Note: The above parameter are only as an example, other tests may be required for specific product.

2.8 STABILITY DATA

General:

- The stability of the product is important to ensure the quality of natural product (traditional and homeopathic medicines). This is to ensure that the product specifications are maintained throughout the shelf life of product.
- Effective from 27 Nov 2014, a shelf life of two (2) years shall be approved for both local and imported products. Proposed shelf life exceeding this period will have to be supported by stability study data conducted in Malaysia under Zone IVb conditions (30±2 °C, 75±5%). For further information, refer to circular: [Bil \(27\).d/m BPFK/PPP/06/04/Jld.7 Tempoh Hayat Simpanan \(Shelf-Life\) Bagi Produk Tradisional dan Suplemen Kesihatan \(27 November 2014\)](#).
- Should the applicant wish to declare the percentage or content of the isolated compound of a standardized extract, the stability study should state the results of the assay of the isolated compound conducted along the proposed shelf-life. If results of the assay are not provided, the shelf life period approved will not be more than two (2) years.
- Effective from 1 January 2023, Quantification by Input (QBI) of active ingredients may be considered for Traditional Medicine and Health Supplement (TMHS) Products. For details, refer to the *Direktif Berkenaan Pelaksanaan Garis Panduan Guidance on the Acceptance Criteria for Quantification by Input (QBI) of Active Ingredients Claimed on Label of Traditional Medicine and Health Supplement (TMHS) Products*. [NPRA.600-1/9/13\(16\) Jld 1](#). (8 November 2022)
- The testing frequency of the stability data is as described below:

| Storage condition | Testing frequency |
|-------------------|---|
| Real time | Time 0, 3, 6, 9, 12, 18, 24 months and annually there after through |
| Accelerated | 0, 3 and 6 months |

Refer to the ASEAN Guidelines on Stability Study and Shelf Life of Traditional Medicines for further details.

Stability data as shown in the following example shall be submitted for evaluation.

RECOMMENDED PRESENTATION OF THE SUMMARY TABLE OF STABILITY RESULTS

| | | | |
|---------------------|---|----------------------|---|
| Product Name | : | Storage Temperature, | : |
| | | Relative Humidity | : |
| Dosage Form | : | Batch No. | : |
| Strength | : | Manufacturing Date | : |
| Container/Packaging | : | Date of Report | : |
| Pack Size | : | Period of The Study | : |

| Testing Parameters (as applicable) | Specifications | Testing Frequency (Months) | | | | | | | |
|--|---|---|----------------|---|---|----|----|----|----|
| | | 0 | 3 | 6 | 9 | 12 | 18 | 24 | 36 |
| Appearance/ Organoleptic characteristics: Odour Colour | To describe the characteristics | | | | | | | | |
| Disintegration | DRGD | | | | | | | | |
| Uniformity of weight | DRGD | | | | | | | | |
| Assay: (All standardized compounds claimed on label, if applicable) | To specify | | | | | | | | |
| Standardized compounds assayed by QBI | To specify | 'Not Assayed. Quantified by Input' or words with similar meaning | | | | | | | |
| Microbial Contamination Test -Total Aerobic Microbial Count -Total Yeasts & Moulds Count -Test for Specified Microorganisms | DRGD e.g.: -NMT 2 x 10 ⁴ CFU/g or CFU/mL -NMT 2 x 10 ² CFU/g or CFU/mL -NMT 1 x 10 ² CFU of bile-tolerant gram- negative bacteria in 1g or 1mL -Absence of Salmonella in 25g or 25mL -Absence of Escherichia coli in 1g or 1mL -Absence of Staphylococcus aureus in 1g or 1mL | | | | | | | | |
| Heavy Metal Contamination -Lead (Pb) -Cadmium (Cd) -Mercury (Hg) -Arsenic (As) | -NMT 10 ppm -NMT 0.3 ppm -NMT 0.5 ppm -NMT 5 ppm | | _____ NA _____ | | | | | | |

NMT = Not More Than
Conclusion:

Prepared by: (signature)
Name:
Designation:
Date:

Checked by: (signature)
Name:
Designation:
Date:

Approved by: (signature)
Name:
Designation:
Date:

The tabulated list of parameters for each dosage form is presented as a guide for the following types of tests to be included in a stability study.

Tabulated list of stability indicating parameters for natural products

| Testing Parameters Dosage Form | Organoleptic characteristics | Assay | Hardness/ friability | Dissolution/ Disintegration | Water content | Viscosity | pH | Microbial content | Granules/ Particle Size variation | Resuspendability | Adhesiveness |
|--|------------------------------|-------|-------------------------|--------------------------------|---------------|-----------|----|-------------------|--------------------------------------|------------------|--------------|
| Oral powder | √ | √ | | | √ | | | √ | | | |
| Hard capsule | √ | √ | | √ | √ | | | √ | | | |
| Soft capsule | √ | √ | | √ | | | | √ | | | |
| Coated and Uncoated Tablet | √ | √ | √ | √ | √ | | | √ | | | |
| Coated and Uncoated Pill/ Pellet | √ | √ | | √ | √ | | | √ | | | |
| Suspension | √ | √ | | | | √ | √ | √ | √ | √ | |
| Solution | √ | √ | | | | √ | √ | √ | | | |
| Emulsion | √ | √ | | | | √ | √ | √ | | | |
| Semi Solid Preparations (Ointment/ Cream/ Gel/ Lotion/ Paste) | √ | √ | | | | √ | √ | √ | | | |
| Plaster | √ | √ | | | | | | √ | | | √ |
| Granules | √ | √ | | | √ | | | √ | √ | | |
| Herbal Infusion Bag/ Herbal Tea Bag | √ | √ | | | √ | | | √ | | | |
| Pastilles | √ | √ | | | √ | | | √ | | | |

3. PRODUCT SPECIFIC REQUIREMENTS

3.1 FOOT PATCHES

A foot patch that contains herbs with a health claim needs to be registered with the Authority.

Summary of registration for foot patches is described below:

a) Product Indication

- Traditionally used for
 - a) General health;
 - b) Promoting blood circulation;
 - c) Relieve fatigue.
- If there are other indications other than those mentioned above, the applicant is required to submit clinical study data to support the proposed indication.

b) Active ingredient/ Excipient

- The product may only contain active ingredient classified under the category of Natural Products (Traditional).
- Pharmaceutical ingredients with dual function as an active ingredient and excipient, e.g. Vitamin C can be used as excipient.
- However, the maximum allowable amount for the excipient in the traditional product has to follow the pharmacopoeia limits established. If, for example, in the case where the amount of Vitamin C is more than 0.1%, the product shall be classified as an OTC product. The product will then have to fulfill the requirement for the registration of an OTC product.

c) Certificate of Analysis for Finished Product

- It is required with at least one (1) batch data for registration.

d) Certificate of Free Sale (CFS)

- CFS from the regulatory authority of the country of origin of the product depending on the product classification of that product in that country is required.

e) Good Manufacturing Practice (GMP)

- GMP from the governmental issuing body declaring manufacturer adherence to GMP/ ISO or other standards depending on the classification of the product in the country of origin is required.

3.2 HERBAL TEA

Refer to [Bil. \(19\)d/m.BPFIK/PPP/01/03 Jld.3](#). *Pekeliling Kriteria Baru Pengkelasan Produk Food-Drug Interphase (FDI)* (7 August 2014)

3.3 HOMEOPATHIC PRODUCTS

Refer to [Appendix 7A: Homeopathic Products](#)

3.4 NATURAL PRODUCTS WITH MODERN CLAIM

Refer to [Appendix 7B: Guideline on Natural Products with Modern Claim](#)

3.5 NATURAL PRODUCTS WITH THERAPEUTIC CLAIM

Refer to [Appendix 7C: Guideline on Natural Products with Therapeutic Claim](#)