Standard Operating Procedures

Regulation of Ayurveda Products

by

Ayurveda Formulary Committee

Version 1 (December 2021)

Department of Ayurveda

Ministry of Health

Democratic Socialist Republic of Sri Lanka

CONTENTS

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Regulation of Ayurveda Products

Standard Operating Procedures

1. Background

1.1. The Ayurveda Formulary Committee

The Ayurveda Formulary Committee (as specified in the sections of 21 (1), (2) of the *Ayurvedic Pharmacies Regulations 1973* published in the Gazette extra ordinary no. 229/3 dated 06.09.1976, according to the sections of 10 & 82 of the no. 31 of 1961 Ayurveda act), which is appointed by the Minister in charge of the subject of Indigenous Medicine, is the principal regulatory authority for regulation of Ayurveda products in Sri Lanka.

1.2. Legal Requirement of Pre-marketing license

As specified in the sections 21 (1), (2) of the *Ayurvedic Pharmacies Regulations 1973* (published in the Gazette extra ordinary no. 229/3 dated 06.09.1976), every formula of the Ayurveda product shall be approved by the Ayurveda Formulary Committee, prior to issuance to the market for public consumption (pre-marketing license). Accordingly, the Ayurveda products are registered by the Department of Ayurveda, on approval of the same Committee.

"Every formula for the preparation of any drug to be sold to the public shall be first approved by the Formulary Committee set up for the purpose. Any alteration or addition made to or any omission from any formulae already approved shall require the approval of such Formulary Committee" (the *Ayurvedic Pharmacies Regulations 1973,* sections 21 (1), (2)).

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1.3.Objective of this document

The Standard Operating Procedures (SOP) document aims to provide clear guidance and information on the procedure to be followed in submission of application for registration of Ayurveda products by individuals / organizations, evaluation of application, approving and issuing license, approving advertisements of Ayurveda products, and any other related functions assigned to the Ayurveda Formulary Committee.

1.4.Responsibility

The Ayurveda Formulary Committee or any other authority which would replace the Ayurveda Formulary Committee in future is the responsible body for regulation of Ayurveda products in the country.

1.5.Accountability

The Commissioner of Ayurveda

2. Ayurveda Products

2.1. The term *Ayurveda* is defined as, according to the no. 31 of 1961 Ayurveda act, "Ayurveda includes the Siddha and Unani and *Deshiya Chikitsa* systems of medicine and surgery and any other system of medicine indigenous to Asian countries and recognized as such by their respective Governments".

Footnote:

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2.2.Definition of Ayurveda products

For the purpose of these SOPs, an Ayurveda product is defined as a medicinal extract / fraction / item / formulation, a healthy food, a health supplement, a food supplement, a nutraceutical, a cosmeceutical, or a medical device (locally manufactured or imported to the country):

i. made by the use of one or more of ingredients or medicinal items contained in

a) Ayurveda Pharmacopoeia published by the Department of Ayurveda, Sri Lanka,
b) Siddha Pharmacopoeia published by the Department of Ayurveda, Sri Lanka
c) Unani Pharmacopoeia published by the Department of Ayurveda, Sri Lanka
d) Pharmacopoeias of Ayurveda, Siddha and Unani approved by the Government of India
e) Indigenous/ Traditional medicines contained in the Pharmacopeias in other Asian Countries as approved by the respective governments

And / or

ii. made by the use of one or more of the pharmaceuticals considered as a botanical, mineral or zoological item traditionally used in the Indigenous Traditional medical (*Deshiya Chikitsa*) system of Sri Lanka

And / or

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iii. referred to in the original (classical[#]) books accepted in the systems of Ayurveda, Siddha, Unani, and Indigenous Traditional medicine (*Deshiya Chikitsa*) recognized by the Department of Ayurveda

And / or

iv. Evaluated by criteria, published by the World Health Organization (WHO), for evaluation of Traditional / Herbal Medicine (produced by means of any botanical, mineral or zoological substance), not specified in i, ii, iii above (value added products are also included in this category).

Everything that is contained in the above definition shall not be produced to market for human consumption or advertised by the use of electronic or print media or social media, without the approval of the Ayurveda Formulary Committee (pre-marketing license is required).

2.3.Categories of products (both locally manufactured and imported)

A medicinal extract/fraction/item/formulation, a healthy food, a health supplement, a food supplement, a nutraceutical, a cosmeceutical, a medical device which has been approved by the Ayurveda Formulary Committee is categorized into one of the following schedules:

i. Schedule 1

The products (external applications and herbal drinks) which could be sold over the counter and advertised through mass media are incorporated in this schedule.

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ii. Schedule 2

The products (orally administered excluding herbal drinks) which could be sold over the counter and advertised through mass media are incorporated in this schedule.

iii. Schedule 3

The products (which are modern dosage forms / modified classical# medicine developed through scientific methods by using proprietary blends and clinically tested for appropriate evidence-based data, or locally manufactured modified Ayurveda products which have been evaluated, satisfied & approved by the Ayurveda Formulary Committee) which shall only be administered according to a prescription of a Registered Ayurveda Practitioner and shall not be advertised through mass media are incorporated in this schedule.

iv. Schedule 4

The products that are regarded as essential and, exclusively classical# and/or incorporated in a recognized pharmacopoeia (Ayurveda/ Siddha/ Unani pharmacopoeia recognized by the Government of Sri Lanka) are categorized under this schedule. These products shall only be administered according to a prescription of a Registered Ayurveda Practitioner and shall not be advertised through mass media.

v. Others

Any other Ayurveda products that could not be incorporated in the above schedules are categorized under this schedule.

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3. Registration Procedure of products

3.1.Registration of locally manufactured products

3.1.1. Application process and dossier submission

The application form (see appendix 5.1) and relevant documents could be downloaded from the website of the Department of Ayurveda (www.ayurveda.gov.lk) or could be obtained from the technical branch of the Department of Ayurveda. The duly completed application, properly prepared dossier (according to the check list specified in the appendix 5.2), and necessary number of samples shall be handed over to the technical branch of the Department of Ayurveda on fixed days allocated for this purpose by the Department of Ayurveda or shall submit by online. The Ayurveda Practitioner who serves as the advisor of the applicant shall hand over all the documents in person, on behalf of the applicant, and shall take full responsibility for the accuracy and completeness of the application (even it is submitted through online platform). It will be checked by the receiving officer according to the check list, if is it satisfactory, specified processing fee will be accepted, and an acknowledgement receipt including an electronic acknowledgement will be issued to the applicant.

3.1.2. Review process

The safety, efficacy and quality of the products are assessed based on Ayurveda/ Siddha/ Unani/ Indigenous Traditional medical principles and modern scientific principles by the technical subcommittee which is appointed by the Formulary committee.

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3.1.2.1. **Safety**

The safety of the product is evaluated by the technical subcommittee taking into consideration of the type of product, quantity of use or maximum level of use, target population (adult, children etc.), method of application, history of traditional use and scientific evidence as described in the table 1.

Table 1: Level of evidence required to establish safety of the local products

Category of product	Minimum requirements of evidence
Cosmeceuticals	Evidence of traditional use of each **Ayurveda / herbal ingredient** (supported by pharmacopoeias, monographs, authentic texts, *Ola* leaf manuscripts, any acceptable document / proof) **And** safety profile / documentary proof of approval for human use of **other ingredients** which do not fall under the above category of Ayurveda / herbal ingredients **And** Appropriate **safety assessment** report (e.g., local tolerance assessment such as skin irritation test, carried out under the supervision of qualified person in-house or in a reputed laboratory acceptable by the Ayurveda Formulary Committee) (refer Appendix B of the SLS 1708 Sri Lanka Standard Guideline for Herbal Cosmetics) (Note: The cosmeceutical should be formulated in such a manner that the concentrations of all ingredients including Ayurveda / herbal ingredients ensure freedom from any harmful effect due to interaction among each other)

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Nutraceuticals / dietary supplements / health supplements / healthy food	Evidence of traditional use of each **Ayurveda / herbal ingredient** (supported by pharmacopoeias, monographs, authentic texts, *Ola* leaf manuscripts, any acceptable document / proof) **And** safety profile / documentary proof of approval for human use of **other ingredients** which do not fall under the above category of Ayurveda / herbal ingredients
Classical[#] / pharmacopeial over-the-counter medicines (exact formula mentioned in authentic texts / pharmacopoeias/ traditional practice, without any modifications, intended for mild disorders)	Evidence of traditional safe use of the **formula** (supported by pharmacopoeias, authentic texts, *Ola* leaf manuscripts, any acceptable document / proof)
Proprietary over-the-counter medicines (novel formulation made up of Ayurveda ingredients or modified classical[#] / pharmacopeial formula / dosage/ indication, intended for mild disorders)	Evidence of traditional safe use of each **Ayurveda / herbal ingredient** (supported by pharmacopoeias, authentic texts, *Ola* leaf manuscripts, any acceptable document / proof) **And** safety profile/ documentary proof of approval for human use of **other ingredients** which do not fall under the above category of Ayurveda / herbal ingredients
Classical[#] / pharmacopeial Prescription medicines (exact formula of authentic texts / pharmacopoeias/ traditional practice, without any modifications)	Evidence of traditional safe use of the **formula** (supported by pharmacopoeias, authentic texts, *Ola* leaf manuscripts, any acceptable document / proof)

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Proprietary prescription medicines (novel formulation made up of Ayurveda ingredients or modified classical# / pharmacopeial formula / dosage/ indication)	Evidence of traditional safe use of each **Ayurveda / herbal ingredient** (supported by pharmacopoeias, authentic texts, *Ola* leaf manuscripts, any acceptable document / proof), **And** safety profile / documentary proof of approval for human use of **other ingredients** which do not fall under the above category of Ayurveda / herbal ingredients **And** acceptable report of an appropriate clinical research (as evidence of safety of the **finished product** for human use) or the Ayurveda Formulary Committee may seek expert opinion to decide on safety of a formula (which is developed from a classical# / pharmacopoeia / indigenous traditional medical formula with minor modification); the decision to rely on expert opinion and/or research data will be the discretion of the Ayurveda Formulary Committee. (Note: An expert opinion shall be obtained from a relevant registered Ayurveda practitioner in the format specified in appendix 5.15)
Medical devices	Shall satisfy the requirements determined by the Ayurveda Formulary Committee based on nature of device, intended use, Ayurveda/traditional principles, and modern scientific knowledge

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3.1.2.2. **Efficacy**

The efficacy of the product is evaluated by taking into consideration of the type of the product, route of administration, history of traditional use and scientific research evidence as specified in the table 2.

Table 2: Level of evidence required to establish efficacy of the local products

Category of product	Minimum requirements of evidence
Cosmeceuticals	Evidence of traditional therapeutic use of each **Ayurveda / herbal ingredient** (pharmacological actions supported by pharmacopoeias, monographs, authentic texts, *Ola* leaf manuscripts, any accepted document / proof) (Note: A cosmeceutical should contain sufficient amount of Ayurveda / herbal ingredients for to be considered as an Ayurveda product, which is determined by the Ayurveda Formulary Committee)
Nutraceuticals / dietary supplements / health supplements / healthy food	Evidence of traditional therapeutic use of each **Ayurveda / herbal ingredient** (pharmacological / nutrition / health enhancing actions supported by pharmacopoeias, monographs, authentic texts, *O*la leaf manuscripts, any acceptable document / proof) (Note: A product should contain sufficient amount of Ayurveda / herbal ingredients for to be considered as an Ayurveda product, which is determined by the Ayurveda Formulary Committee)

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Classical[#] / pharmacopeial over-the-counter medicines (exact formula mentioned in authentic texts / pharmacopoeias/ traditional practice, without any modifications, intended for mild disorders)	**Evidence of traditional medicinal use** of the **formula** (supported by pharmacopoeias, authentic texts, *Ola* leaf manuscripts, any acceptable document / proof)
Proprietary over-the-counter medicines (novel formulation made up of Ayurveda ingredients or modified classical[#] / pharmacopeial formula / dosage/ indication, intended for mild disorders)	**Evidence of traditional medicinal use** of each **Ayurveda / herbal ingredient** (supported by pharmacopoeias, monographs, authentic texts, *O*la leaf manuscripts, any acceptable document / proof) **And** **acceptable clinical research evidence** for the **formula** (case series of appropriate number of patients / phase II clinical trial, with evidence of publication) **and/or** the Ayurveda Formulary Committee may seek **expert opinion** (the applicant shall obtain this from five suitably qualified registered Ayurveda practitioners in the format specified in appendix 5.15) to decide on therapeutic use of a formula (which is developed from a classical/pharmacopoeia/indigenous traditional medical formula with minor modification); the decision to rely on expert opinion and/or research data will be the discretion of the Ayurveda Formulary Committee.
Classical[#] / pharmacopeial Prescription medicines (exact formula of authentic texts / pharmacopoeias/ traditional practice, without any modifications)	**Evidence of traditional medicinal use** of the **formula** (supported by pharmacopoeias, authentic texts, *Ola* leaf manuscripts, any acceptable document/ proof)

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Proprietary prescription medicines (novel formulation made up of Ayurveda ingredients or modified classical[#] / pharmacopeial formula / dosage/ indication)	**Evidence of traditional medicinal use** of each **Ayurveda / herbal ingredient** (supported by pharmacopoeias, monographs, authentic texts, *Ola* leaf manuscripts, any acceptable document/ proof) **And** acceptable **report of a phase II/ III clinical trial** conducted, **for the finished product,** according to high quality, scientific & ethical principles (supported by evidence of ethical clearance, clinical trial registration and publication), **and/or** the Ayurveda Formulary Committee may seek **expert opinion** (the applicant shall obtain this from five suitably qualified registered Ayurveda practitioners in the format specified in appendix 5.11) to decide on therapeutic use of a formula (which is developed by minor modification of a classical / pharmacopoeia / indigenous traditional medical formula); the decision to rely on expert opinion and/or research data will be the discretion of the Ayurveda Formulary Committee. The expert opinion should be followed by appropriate clinical research evidence (conducted in an institution recognized by the Ayurveda Formulary Committee) within three years.
Medical devices	Shall satisfy the requirements determined by the Ayurveda Formulary Committee based on nature of device, intended use, Ayurveda/traditional principles, and modern scientific knowledge

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3.1.2.3. **Quality**

The quality of the product is assessed by traditional and modern quality parameters as specified in recognized pharmacopoeias, monographs, WHO guidelines, Sri Lanka Standards (SLS) and any other recognized standards acceptable by the Committee (appendix 5.7).

The products shall be tested for quality in any independent laboratory accredited for that purpose by the Sri Lanka Accreditation Board (SLAB) or any other independent laboratory approved by the Ayurveda Formulary Committee.

3.1.2.4. **Labeling and marking**

The label / package insert of a product shall contain the information legibly and indelibly as specified in appendix 5.13.

3.1.3. Registration for the first time and issuance of license

Based on the decision of the Ayurveda Formulary Committee, the Commissioner of Ayurveda issues a registration certificate / letter, within a specified predetermined reasonable time period (however, applications could be expedite processed on urgent basis with additional charges) (see appendix 5.8). If the application / dossier needs further clarification, it is the responsibility of the applicant to provide required information within a specified reasonable time period, to the Department, and then it will be reviewed again. A Free Sale Certificate (for export purpose) could also be obtained on request of the applicant by paying a specified fee.

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3.1.4. Extension of registration

A product registration is valid for three years. The registration could be extended for another three years (see appendix 5.9). At the completion of six years, a fresh application and dossier with appropriate post-marketing report / post-marketing research report (issued / recognized by an appropriate local authority / institution) shall be submitted (see appendix 5.8).

3.1.5. Permission to import ingredients / blends / extracts for manufacture of Ayurveda products

A prior permission shall be sought from the Ayurveda Formulary Committee, by submitting the documents specified in the appendix 5.14, for import any ingredient / finished Ayurveda formulation / blend / extract for the purpose of manufacture of Ayurveda products. This permission shall not be misused to sell or to utilize for any other purpose than the manufacture of Ayurveda products.

3.2.Registration of Import Products

3.2.1. Prior Permission to import product samples

A prior permission shall be obtained from the Department of Ayurveda before import any products to the country, by producing a request letter by the local agent along with detail of the formula (ingredients with quantity, indication) and the necessity for import duly justified by the Ayurveda Practitioner who serves as the advisor of the local agent (see appendix 5.10).

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3.2.2. Application process and dossier submission

The application form (appendix 5.4) and relevant documents could be downloaded from the website of the Department of Ayurveda (www.ayurveda.gov.lk) or could be obtained from the technical branch of the Department of Ayurveda. The duly completed application, properly prepared dossier (according to the check list specified in the appendix 5.5), and necessary number of samples (identical to the market sample) shall be handed over to the technical branch of the Department of Ayurveda on fixed days allocated for this purpose by the Department of Ayurveda or shall submit by online. The Ayurveda Practitioner who serves as the advisor of the importer shall submit the application in person and/or shall take full responsibility for the accuracy and completeness of the application even it is submitted through online platform. It will be checked by the receiving officer according to the check list, if is it satisfactory, a specified processing fee will be accepted, and an acknowledgement receipt (including an electronic acknowledgement) will be issued to the applicant.

3.2.3. Review process

The need / necessity of the product to the country is assessed and the safety, efficacy and quality are evaluated based on Ayurveda / Siddha / Unani / Indigenous Traditional medical principles and modern scientific principles.

3.2.3.1. **Safety**

The safety of the product is evaluated by taking into consideration of the type of product, history of traditional use and scientific studies as described in the table 3.

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Table 3: Level of evidence required to establish safety of the imported products

Category of product	Minimum requirements of evidence
Cosmeceuticals	**Evidence of traditional use** of each Ayurveda / herbal ingredient (supported by pharmacopoeias, monographs, authentic texts, *Ola* leaf manuscripts, any other reliable & acceptable document) **And** **safety profile** / documentary proof of approval for human use of other ingredients which do not fall under the above category of Ayurveda / herbal ingredients **And** Appropriate **safety assessment** report (e.g., local tolerance assessment such as skin irritation test, carried out under the supervision of a suitably qualified person in in-house or reputed laboratory acceptable by the Ayurveda Formulary Committee) (refer Appendix B of the SLS 1708 Sri Lanka Standard Guideline for Herbal Cosmetics) (Note: The cosmeceutical should be formulated in such a manner that the concentrations of all ingredients including Ayurveda / herbal ingredients ensure freedom from any harmful effect due to interaction among each other in the product)
Nutraceuticals / dietary supplements / health supplements / healthy food	**Evidence of traditional use** of each Ayurveda / herbal ingredient (supported by pharmacopoeias, monographs, authentic texts, *Ola* leaf manuscripts, any other reliable & acceptable document) **And** **safety profile** / documentary proof of approval for human use of other ingredients which do not fall under the above category of Ayurveda / herbal ingredients

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Classical[#] / pharmacopeial over-the-counter medicines (exact formula mentioned in authentic texts / pharmacopoeias, without any modifications, intended for mild disorders)	**Evidence of traditional safe use** of the **formula** (supported by pharmacopoeias, authentic texts, *Ola* leaf manuscripts, any acceptable document)
Proprietary over-the-counter medicines (novel formulation made up of Ayurveda ingredients or modified classical[#] / pharmacopeial formula / dosage/ indication, intended for mild disorders)	**Evidence of traditional safe use** of each Ayurveda / herbal ingredient (supported by pharmacopoeias, authentic texts, *Ola* leaf manuscripts, any acceptable document) **And** **safety profile** / documentary proof of approval for human use of other ingredients which do not fall under the above category of Ayurveda / herbal ingredients
Classical[#] / pharmacopeial prescription medicines (exact formula mentioned in authentic texts / pharmacopoeias, without any modifications)	**Evidence of traditional safe use** of the formula (supported by documentary proof of acceptable pharmacopoeias, authentic texts) In addition to that, **for *Rasa* medicines,** an appropriate **toxicological (preclinical) study report** for the formula (generated/issued by an approved independent institution or published in a reputed indexed journal) is required
Proprietary prescription medicines (novel formulation made up of Ayurveda ingredients or modified classical[#] / pharmacopeial formula / dosage/ indication)	**Evidence of traditional safe use** of each Ayurveda / herbal ingredient (supported by pharmacopoeias, authentic texts), **and** safety profile/documentary proof of approval for human use of other ingredients which do not fall under the above category of Ayurveda / herbal ingredients **And** An acceptable **report of a phase I/II clinical trial** to prove safe human use of the formula (with evidence of publication in a reputed indexed journal) **In addition** to that, **for *Rasa* medicines,** an appropriate **toxicological (preclinical) study report** for the formula (generated/issued by an approved independent institution or published in a reputed indexed journal) is required

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Medical devices	Shall satisfy the requirements determined by the Ayurveda Formulary Committee based on nature of device, intended use, Ayurveda/traditional principles, and modern scientific knowledge

3.2.3.2. **Efficacy**

The efficacy of the product is evaluated by taking into consideration of the type of product, history of traditional use and scientific studies as described in the table 4.

Table 4: Level of evidence required to establish efficacy of the imported products

Category of product	Minimum requirements of evidence
Cosmeceuticals	**Evidence of traditional use** of each Ayurveda / herbal ingredient (pharmacological actions supported by pharmacopoeias, monographs, authentic texts, *Ola* leaf manuscripts, any accepted document) (Note: A cosmeceutical should contain sufficient amount of Ayurveda/herbal ingredients for to be considered as an Ayurveda product, which is determined by the Ayurveda Formulary Committee)
Nutraceuticals / dietary supplements/ health supplements / healthy food	**Evidence of traditional use** of each Ayurveda / herbal ingredient (pharmacological/ nutrition/ health enhancing actions supported by pharmacopoeias, monographs, authentic texts, *Ola* leaf manuscripts, any acceptable document) (Note: A product should contain sufficient amount of Ayurveda/herbal ingredients for to be considered as an Ayurveda product, which is determined by the Ayurveda Formulary Committee)

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Classical[#] / pharmacopeial over-the-counter medicines (exact formula mentioned in authentic texts / pharmacopoeias, without any modifications, intended for mild disorders)	**Evidence of traditional medicinal use** of the **formula** (supported by documentary proof of pharmacopoeias, authentic texts)
Proprietary over-the-counter medicines (novel formulation made up of Ayurveda ingredients or modified classical[#]/pharmacopeial formula/dosage/indication, intended for mild disorders)	**Evidence of traditional medicinal use** of each Ayurveda/herbal ingredient (supported by pharmacopoeias, monographs, authentic texts, *Ola* leaf manuscripts, any acceptable document) **And** Acceptable clinical research evidence for the **formula** (**case series/phase II clinical trial** supported by documentary proof of publication in a reputed indexed journal)
Classical[#] / pharmacopeial prescription medicines (exact formula mentioned in authentic texts / pharmacopoeias, without any modifications)	**Evidence of traditional medicinal use** of the **formula** (supported by documentary proof of acceptable pharmacopoeias, authentic texts)
Proprietary prescription medicines (novel formulation made up of Ayurveda ingredients or modified classical[#] / pharmacopeial formula / dosage/ indication)	**Evidence of traditional medicinal use** of each Ayurveda/herbal ingredient of the formula (supported by documentary proof of pharmacopoeias, monographs, authentic texts) **And** Acceptable **report of a phase II/ III clinical trial**, **for the formula**, conducted according to high quality, scientific & ethical principles (supported by documentary evidence of ethical clearance, clinical trial registration and publication in a national/ international reputed peer reviewed index journal)

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Medical devices	Shall satisfy the requirements determined by the Ayurveda Formulary Committee based on nature of device, intended use, Ayurveda/traditional principles, and modern scientific knowledge

3.2.3.3. **Quality**

The quality of the product is assessed by traditional and modern quality parameters as specified in recognized pharmacopoeias, monographs, WHO guidelines, Sri Lanka Standards (SLS) or any other recognized standards acceptable by the Ayurveda Formulary Committee (appendix 5.7).

The products shall be tested for quality in any independent laboratory accredited for that purpose by the Sri Lanka Accreditation Board (SLAB) or any other laboratory approved by the Ayurveda Formulary Committee.

3.2.3.4. **Labeling and marking**

The label / package insert of a product shall contain the information legibly and indelibly as specified in appendix 5.13.

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3.2.4. Registration for the first time and issuance of license

Based on the decision of the Ayurveda Formulary Committee, the Commissioner of Ayurveda issues a registration certificate / letter (valid for a period of three years), within a specified predetermined time period, from the receipt of application. If the application / dossier needs further clarification, it is the responsibility of the applicant to provide required information within a specified time period to the Department, and then it will be reviewed again (see appendix 5.11).

3.2.5. Extension of registration

The product registration could be extended for another three years at the completion of three years from the first registration, on applicant's request (see appendix 5.12). When submit an application for a renewal of registration of an import medicine, an appropriate clinical research report (of a research which evaluates safety and efficacy of the medicine for its therapeutic claims, conducted in a recognized institution in Sri Lanka and published in a reputed peer reviewed indexed journal) shall be submitted. At the completion of extended three years, a fresh application, dossier and, an appropriate post-marketing report (for Cosmeceuticals, Nutraceuticals, and health supplements) or a published report in a reputed peer reviewed indexed journal of a post-marketing clinical research (for medicines) conducted in Sri Lanka, shall be submitted (see appendix 5.11).

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4. Obtaining prior permission for advertisement of Ayurveda products

Only the products categorized under schedule 1 or schedule 2 could be advertised through mass media (print / electronic / social media or any other media which could be used to reach general public). A prior approval shall be sought from the Ayurveda Formulary Committee for this purpose.

A duly completed application along with the sample of intended advertisement (in CD / DVD / print materials or any other appropriate medium) shall be submitted to the technical branch of the Department of Ayurveda (a specified fee will be charged for processing the application). Based on the recommendation of the Media Sub-Committee, the Ayurveda Formulary Committee takes decision regarding approval. The Commissioner of Ayurveda conveys the decision to the applicant. The permission is granted until the validity period of registration of the particular product. Once the approval obtained, it is the responsibility of the applicant to adhere to the instructions given by the Department and shall seek prior approval for any changes made to the advertisement.

Footnote:

#*Classical Medicine* means any medicine formulated exclusively according to a formula and method which are mentioned in any original / classical text of *Ayurveda/ Siddha/ Unani /Deshiya Chikitsa*, recognized by the Department of Ayurveda

5. Appendices

APPENDIX 5.1: Application form for the first-time registration of local products

APPENDIX 5.2: Checklists for submission of dossiers for local products

APPENDIX 5.3: Application form for the extension of registration of local products

APPENDIX 5.4: Application form for the first-time registration of imported products

APPENDIX 5.5: Checklist for submission of dossiers for imported products

APPENDIX 5.6: Application form for extension of registration of imported products

APPENDIX 5.7: List of quality parameters used for the review of products

APPENDIX 5.8: Timeline of the process of first-time registration of local products

APPENDIX 5.9: Timeline of the process of extension of registration of local products

APPENDIX 5.10: Timeline of the application process for sample import permit

APPENDIX 5.11: Timeline of first-time registration of import products

APPENDIX 5.12: Timeline of the process of extension of registration of import products

APPENDIX 5.13: Information to be contained in the label/ package insert of a product

APPENDIX 5.14: Check list for submission of application to import raw materials

APPENDIX 5.15: Format of expert opinion regarding locally manufactured products

Footnote:

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APPENDIX 5.1: Application form for the first-time registration of local products

File /dossier no. :
Receipt no. :
Issue date:
Signature:

Department of Ayurveda

Application for Registration of Locally Manufactured Ayurveda Products

1. Particulars of the Applicant:

1.1.	Name of the applicant:
1.2.	Address:
1.3.	NIC/Passport/Driving license no. :
1.4.	Profession:
1.5.	Position / designation of the applicant in the institution:
1.6.	Telephone:
1.7.	Email:

2. Particulars of the Company / Institution:

2.1.	Name of the company / institution:
2.2.	Address:
2.3.	Telephone:
2.4.	Registration no. provided by the Department of Ayurveda: Date of registration:
2.5.	Business registration certificate's No: Date of registration:

Footnote:

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3. Particulars of the Drug Manufactory:

3.1.	Name of the Drug Manufactory:
3.2.	Address:
3.3.	Province: District: Division:
3.4.	Registration no. provided by the Department of Ayurveda: Date of registration: Date of first-time registration:

4. Particulars of the Advisory Ayurveda Practitioner:

4.1.	Name:
4.2.	Ayurveda Medical Council Registration no. : General: Special: Date of registration: Date of renewal:
4.3.	Section of registration (General / Special): If special, specify:
4.4.	Address:
4.5.	Telephone:
4.6.	Email:

5. Particulars of the Product:

5.1.	Name of the product:
5.2.	Category: (Cosmeceutical/food & dietary supplement/medicine/device etc.) If it is a medicine, please specify whether classical/pharmacopeial or proprietary medicine:
5.3.	Use/ therapeutic indications:
5.4.	Dosage:
5.5.	Mode of administration (external/oral etc.):

Footnote:

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6. Particulars of Export (if any):

6.1.	Is this product intended for export? (Yes/No)
6.2.	If yes, Name of the country:
6.3.	Name of the company / institution intends to import in the respective country:
6.4.	Address:

7. Particulars of Imported materials used in the Manufacture of the Product (if any):

7.1.	Is any material imported for manufacture of the product? (Yes/No)
7.2.	If yes,
7.2.1.	Materials import license no. : Date:
7.2.2.	Country of import:
7.2.3.	Name of manufacturer of the materials in the respective country:
7.2.4.	Address of the manufacturer:
7.2.5.	List of import materials: (Attach additional sheet/s if necessary)
7.2.6.	Is any finished product imported, to be used as an ingredient of the product? (Yes/No)
7.2.7.	If yes,
7.2.7.1.	Name/s of finished product/s imported as an ingredient:
7.2.7.2.	Whether a separate approval has been obtained from the Department of Ayurveda to import such a product? (Yes/No)

Footnote:

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8. Particulars of ingredients which are restricted by any law of Sri Lanka (if any):

8.1.	List of restricted ingredients: (Attach additional sheet/s if necessary)
8.2.	Source / place of supply: Province: District: Division: (Attach a copy of invoice)
8.3.	Detail of approval from relevant authority: (Attach a copy of approval)

9. Particulars of preservatives / excipients included in the product (if any):

(Attach additional sheet/s if necessary)

Name of preservative / excipient	Quantity / percentage

10. Particulars of Previous Registration (if any) of the Product:

10.1.	Was this product previously registered in the Department of Ayurveda? (Yes/No)	
10.2.	If yes, first time registration no. :	Date:
	last registration no. :	Date:

Footnote:

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11. Declaration of the Advisory Ayurveda Practitioner :

I do hereby declare that the particulars given above, and the information provided in the dossier of the product (name of the product) …… are true and correct according to my professional knowledge, I act in accordance with the Ayurveda Act no. 31 of 1961 and the Registered Ayurvedic Medical Practitioners (Professional Conduct) Rules no. 01 of 2014, and I am aware that I am personally responsible and accountable for the accuracy of all the information submitted herewith.

Signature: Date:

Professional seal:

12. Declaration of the Applicant :

I do hereby certify that the particulars provided in the application are true and correct.

Signature: Date:

Official seal:

For office use only
Money order no:
Receipt no:
Date of dossier submission:
Remarks: Completed / Incomplete / Forged document / Complaints
Name & Signature of the receiver:

Note: Along with this application, a completed check list, a dossier containing all the necessary documents and required number of market identical samples shall be handed over by the Advisory Ayurveda Practitioner to the technical branch of the Department of Ayurveda on fixed days allocated for this purpose.

Footnote:

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APPENDIX 5.2: Checklist for Submission of Dossiers (Local Products)

Name of the product: Name of the Institution:

No.	Required Documents	Completed by the Advisory Ayurveda Practitioner		Checked by the receiving officer (mark √) otherwise strike off
		Attached (mark √) otherwise strike off	Page number in the dossier	
1.	Application form-completed & signed			
2.	An Affidavit stating that all the submitted documents are true and correct			
3.	Pharmacy Registration Certificate (copy)			
4.	Business Registration Certificate (copy)			
5.	Good Manufacturing Practices (GMP) certificate / ISO certificate (copy) (optional)			
6.	Advisory Ayurveda Practitioner's Ayurveda Medical Council Registration & Renewal Certificates (copies)			
7.	List of ingredients (with scientific names & quantity)			
8.	Method of preparation of the product			
9.	Ayurveda reference for each Ayurveda ingredients (copy of relevant documents)			
10.	Safety profile of each non-Ayurveda ingredients (copy of documents with CAS number mentioned)			
11.	Clinical research report / Ayurveda reference for the formula (copy of relevant documents)			
12.	Label/ leaflet (trilingual copy)			
13.	Quality parameters **(appropriate reports as specified in appendix 5.7):**			
	i. TLC/ GC/ HPLC/ ICPMS/ LCMS (anyone)			
	ii. Microbiological purity (appropriate reports):			
	Total Plate Count			
	Total Coliform Count			
	Total Aerobic Bacteria			
	Yeast & Mould Count			
	E.coli			
	S.aureus			
	Candida albicans			
	Pseudomonas			
	Salmonella			
	iii. Heavy metals (appropriate reports):			
	Mercury			
	Arsenic			
	Cadmium			
	Lead			
	Antimony (Sb)			

Footnote:

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	Tin (Sn)			
	Copper			
	iv. pH			
	v. Acid value			
	vi. Relative density			
	vii. Saponification value			
	viii. Water content			
	ix. Non-volatile matter			
	x. Total non-aqueous content			
	xi. Alcohol content			
	xii. Diethylene glycol content			
	xiii. Total fatty matter			
	xiv. Rosin acids content			
	xv. Matter insoluble in ethanol			
	xvi. Matter insoluble in water			
	xvii. Acid insoluble ash			
	xviii. Free caustic alkali			
	xix. Total free alkali			
	xx. Free fatty acids			
	xxi. Reducing sugars, Sucrose			
	xxii. Fat			
	xxiii. Chlorides			
	xxiv. Lather			
	xxv. Mush			
	xxvi. Consistency			
	xxvii. Cohesiveness			
	xxviii. Peroxide value			
	xxix. Coloring matter			
	xxx. Moisture content			
	xxxi. Boric acid / Benzoic acid / Sorbic acid content			
	xxxii. Active synthetic anionic ingredient content			
	xxxiii. Inorganic salts			
	xxxiv. Thermal stability			
	xxxv. Fineness			
	xxxvi. Total fluoride			
	xxvii. Abrasion			
	xxviii. Grit			
	xxxix. Solid content			
	xl. Ash content			
	xli. Active matter as PPD			
	xlii. Dye ingredients			
	xliii. Assay (as H_2O_2)			
	xliv. Microbiological efficacy			
	xlv. Pesticide residue			
	xlvi. Aflatoxins			

…… ……

Advisory Ayurveda Practitioner Receiving Officer

Footnote:

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APPENDIX 5.3: Application form for the extension of registration of local products

File /dossier no. :
Receipt no. :
Issue date:
Signature:

Department of Ayurveda

Application for Renewal of Registration
Locally Manufactured Ayurveda Products

1. Particulars of the Applicant:

1.1.	Name of the applicant:
1.2.	Address:
1.3.	NIC/Passport/Driving license no. :
1.4.	Profession:
1.5.	Position / designation of the applicant in the institution:
1.6.	Telephone:
1.7.	Email:

2. Particulars of the Company / Institution:

2.1.	Name of the company / institution:
2.2.	Address:
2.3.	Telephone:
2.4.	Registration No. provided by the Department of Ayurveda: Date of registration:
2.5.	Business registration certificate No: Date of registration:

Footnote:

#*Classical Medicine* means any medicine formulated exclusively according to a formula and method which are mentioned in any original / classical text of *Ayurveda/ Siddha/ Unani /Deshiya Chikitsa*, recognized by the Department of Ayurveda

3. Particulars of the Drug Manufactory:

3.1.	Name of the Drug Manufactory:
3.2.	Address:
3.3.	Province: District: Division:
3.4.	Registration No. provided by the Department of Ayurveda: Date of registration: Date of first-time registration:

4. Particulars of the Advisory Ayurveda Practitioner:

4.1.	Name:
4.2.	Ayurveda Medical Council Registration No. : General: Special: Date of registration: Date of renewal:
4.3.	Section of registration (General / Special): If special, specify:
4.4.	Address:
4.5.	Telephone:
4.6.	Email:

5. Particulars of the Product:

5.1.	Name of the product:
5.2.	Category: (Cosmeceutical/food & dietary supplement/medicine/device etc.) If it is a medicine, please specify whether classical/pharmacopeial or proprietary medicine:
5.3.	Use/ therapeutic indications:
5.4.	Dosage:
5.5.	Mode of administration (external/oral etc.):

Footnote:

#*Classical Medicine* means any medicine formulated exclusively according to a formula and method which are mentioned in any original / classical text of *Ayurveda/ Siddha/ Unani /Deshiya Chikitsa*, recognized by the Department of Ayurveda

6. Particulars of Export (if any):

6.1.	Is this product intended for export? (Yes/No)
6.2.	If yes, Name of the country:
6.3.	Name of the company / institution intends to import in the respective country:
6.4.	Address:

7. Particulars of Imported materials used in the Manufacture of the Product (if any):

7.1.	Is any material imported for manufacture of the product? (Yes/No)
7.2.	If yes,

7.2.1.	Materials import license no. : Date:
7.2.2.	Country of import:
7.2.3.	Name of manufacturer of the materials in the respective country:
7.2.4.	Address of the manufacturer:
7.2.5.	List of import raw materials: (Attach additional sheet/s if necessary)
7.2.6.	Is any finished product imported, to be used as an ingredient of the product? (Yes/No)
7.2.7.	If yes,

7.2.7.1.	Name/s of finished product/s imported as an ingredient:
7.2.7.2.	Whether a separate approval has been obtained from the Department of Ayurveda to import such a product? (Yes/No)

Footnote:

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8. Particulars of ingredients which are restricted by any law of Sri Lanka (if any):

8.1.	List of restricted ingredients: (Attach additional sheet/s if necessary)
8.2.	Source / place of supply: Province: District: Division: (Attach a copy of invoice)
8.3.	Detail of approval from relevant authority: (Attach a copy of approval)

9. Particulars of preservatives / excipients included in the product (if any):

(Attach additional sheet/s if necessary)

Name of preservative / excipient	Quantity / percentage

10. Particulars of Previous Registration of the Product:

10.1.	First time registration no. : Date: Date/s of previous renewal/s of registration:

Footnote:

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11. Post marketing particulars of the Product:

11.1. Were any adverse effects reported regarding the product? (Yes/No)

If yes, please describe briefly (attach additional sheet/s if necessary)

11.2. Was any research done on the product after obtaining the first-time registration? (Yes/No)

If yes, briefly describe the results

(attach a copy of the report /publication/s)

12. Declaration of the Advisory Ayurveda Practitioner :

I do hereby declare that the particulars given above, and the information provided in the dossier of the product (name of the product)…… are true and correct according to my professional knowledge, I act in accordance with the Ayurveda Act no. 31 of 1961 and the Registered Ayurvedic Medical Practitioners (Professional Conduct) Rules no. 01 of 2014, and I am aware that I am personally responsible and accountable for the accuracy of all the information submitted herewith.

Signature: Date:

Professional seal:

Footnote:

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13. Declaration of the Applicant :

I do hereby certify that the particulars provided in the application are true and correct.

Signature: Date:

Official seal:

For office use only
Money order no:
Receipt no:
Date of dossier submission:
Remarks: Completed / Incomplete / Forged document / Complaints
Name & Signature of the receiver:

Footnote:

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APPENDIX 5.4: Application form for the first-time registration of imported products

File /dossier no. :
Receipt no. :
Issue date:
Signature:

Department of Ayurveda

Application for Registration of Import Ayurveda Products

1. Particulars of the Applicant:

1.1.	Name of the applicant:
1.2.	Address:
1.3.	NIC/Passport/Driving License No. :
1.4.	Profession:
1.5.	Position / designation of the applicant:
1.6.	Telephone:
1.7.	Email:

2. Particulars of the Import Institution:

2.1.	Name of the import company / institution:
2.2.	Address:
2.3.	Telephone:
2.4.	Registration No. provided by the Department of Ayurveda: Date of registration:
2.5.	Business Registration Certificate No. : Date of registration:
2.6.	Is it a BOI approved institution? (Yes / No): (If yes, please attach a copy of the BOI certificate)

Footnote:

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3. Particulars of Advisory Ayurveda Practitioner:

3.1.	Name:
3.2.	Ayurveda Medical Council Registration No. : General: Special: Date of registration: Date of renewal:
3.3.	Section of registration (General / Special): If special, specify:
3.4.	Address:
3.5.	Telephone:
3.6.	Email:

4. Particulars of the Export Company / Institution:

4.1.	Name:
4.2.	Address:
4.3.	Country:
4.4.	Telephone:
4.5.	Email:
4.6.	Registration No. with the regulatory authority in the respective country: Date of registration: (Please attach a copy of the certificate)

Footnote:

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5. Particulars of the Product:

5.1.	Name of the product:
5.2.	Category: (Cosmeceutical/food & dietary supplement/medicine/device etc.) If it is a medicine, please specify whether classical/pharmacopeial or proprietary medicine:
5.3.	Use/ therapeutic indications:
5.4.	Dosage:
5.5.	Mode of administration (external/oral etc.):

6. Particulars of Sample Import License:

6.1.	License No. issued by the Department of Ayurveda: Date of issue:

7. Particulars of Previous Registration (if any) of the Product:

7.1.	Was this product previously registered in the Department of Ayurveda? (Yes/No)	
7.2.	If yes, first time registration no. : last registration no. :	Date: Date:

Footnote:

#*Classical Medicine* means any medicine formulated exclusively according to a formula and method which are mentioned in any original / classical text of *Ayurveda/ Siddha/ Unani /Deshiya Chikitsa*, recognized by the Department of Ayurveda

8. Declaration of the Advisory Ayurveda Practitioner :

I do hereby declare that the particulars given above, and the information provided in the dossier of the product (name of the product) …… are true and correct according to my professional knowledge, I act in accordance with the Ayurveda Act no. 31 of 1961 and the Registered Ayurvedic Medical Practitioners (Professional Conduct) Rules no. 01 of 2014, and I am aware that I am personally responsible and accountable for the accuracy of all the information submitted herewith.

Signature: Date:

Professional seal:

9. Declaration of the Applicant :

I do hereby certify that the particulars provided in the application are true and correct.

Signature: Date:

Official seal:

For office use only
Money order no:
Receipt no:
Date of dossier submission:
Remarks: Completed / Incomplete / Forged document / Complaints
Name & Signature of the receiver:

Note: Along with this application, a completed check list, a dossier containing all the necessary documents and required number of market identical samples shall be handed over by the Advisory Ayurveda Practitioner to the technical branch of the Department of Ayurveda on fixed days allocated for this purpose.

Footnote:

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APPENDIX 5.5: Checklist for Submission of Dossiers (Imported Products)

Name of the product: Name of the Institution:

No.	Required Documents	Completed by the Advisory Ayurveda Practitioner			Checked by the receiving officer (mark √) otherwise strike off
		Attached (mark √) or strike off	Not applicable	Page no. in the dossier	
1.	Application form-completed & signed				
2.	An Affidavit stating that all the submitted documents are true and accurate				
3.	Certificate of Registration as an Ayurveda Products Importer (copy)				
4.	Business Registration Certificate (copy)				
5.	Foreign Sales Agreement (copy)				
6.	Good Manufacturing Practices (GMP) certificate (copy)				
7.	ISO certificate (copy)				
8.	Advisory Ayurveda Practitioner's Ay.MC Registration Certificate (copy) & registration renewal letter (copy)				
9.	Letter of the Advisory Ayurveda Practitioner certifying the necessity of the product				
10.	Free Sale Certificate (copy)				
11.	Product (Sample) Import License (copy)				
12.	List of ingredients (with scientific names & quantity)				
13.	Method of preparation of the product				
14.	Ayurveda reference for each Ayurveda ingredients				
15.	Safety profile of non-Ayurveda ingredients (CAS number mentioned)				
16.	Clinical research report / Ayurveda reference for the formula (copy of the reference page to be provided)				
17.	Label/ leaflet (trilingual for over-the-counter product)				
18.	Quality parameters **(appropriate technical reports specified in appendix 5.7)**				
	i. TLC/ GC/ HPLC/ ICPMS/ LCMS (anyone)				
	ii. Microbiological purity (appropriate reports):				
	Total Plate Count				
	Total Coliform Count				
	Total Aerobic Bacteria				
	Yeast & Mould Count				
	E.coli				
	S.aureus				
	Candida albicans				
	Pseudomonas				
	Salmonella				
	iii. Heavy metals (appropriate reports):				
	Mercury				
	Arsenic				

Footnote:

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		Cadmium				
		Lead				
		Antimony (Sb)				
		Tin (Sn)				
		Copper				
	iv.	pH				
	v.	Acid value				
	vi.	Saponification value				
	vii.	Water content				
	viii.	Non-volatile matter				
	xi.	Total non-aqueous content				
	xii.	Alcohol content				
	xiii.	Diethylene glycol content				
	xiv.	Extrusive content				
	xv.	Total fatty matter				
	xvi.	Rosin acids content				
	xvii.	Matter insoluble in ethanol				
	xviii.	Matter insoluble in water				
	xix.	Acid insoluble ash				
	xx.	Free caustic alkali				
	xxi.	Total free alkali				
	xxii.	Free fatty acids				
	xxiii.	Reducing sugars, Sucrose				
	xxiv.	Fat				
	xxv.	Chlorides				
	xxvi.	Lather				
	xxvii.	Mush				
	xxviii.	Consistency				
	xxix.	Cohesiveness				
	xxx.	Peroxide value				
	xxxi.	Coloring matter				
	xxxii.	Moisture content				
	xxxiii.	Boric acid / Benzoic acid / Sorbic acid content				
	xxxiv.	Active synthetic anionic ingredient content				
	xxxv.	Inorganic salts				
	xxxvi.	Thermal stability				
	xxvii.	Fineness				
	xxviii.	Total fluoride				
	xxxix.	Abrasion				
	xl.	Grit				
	xli.	Solid content				
	xlii.	Ash content				
	xliii.	Active matter as PPD				
	xliv.	Dye ingredients				
	xlv.	Assay (as H_2O_2)				
	xlvi.	Microbiological efficacy				
	xlvii.	Pesticide residue				
	xlviii.	Aflatoxins				

…… ……

Advisory Ayurveda Practitioner Receiving Officer

Footnote:

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APPENDIX 5.6: Application form for the extension of registration of imported products

File /dossier no. :
Receipt no. :
Issue date:
Signature:

Department of Ayurveda

Application for Extension of Registration of Import Ayurveda Products

1. Particulars of the Applicant:

1.1.	Name of the applicant:
1.2.	Address:
1.3.	NIC/Passport/Driving license no. :
1.4.	Profession:
1.5.	Position / designation of the applicant:
1.6.	Telephone:
1.7.	Email:

2. Particulars of the Import Institution:

2.1.	Name of the import company / institution:
2.2.	Address:
2.3.	Telephone:
2.4.	Registration no. provided by the Department of Ayurveda: Date of registration:
2.5.	No. of the Business Registration Certificate: Date of registration:
2.6.	Is it a BOI approved institution? (Yes / No): (If yes, please attach a copy of the BOI certificate)

Footnote:

#*Classical Medicine* means any medicine formulated exclusively according to a formula and method which are mentioned in any original / classical text of *Ayurveda/ Siddha/ Unani /Deshiya Chikitsa*, recognized by the Department of Ayurveda

3. Particulars of the Advisory Ayurveda Practitioner:

3.1.	Name:
3.2.	Ayurveda Medical Council registration no. : General: Special: Date of registration: Date of renewal:
3.3.	Section of registration (General / Special): If special, specify:
3.4.	Address:
3.5.	Telephone:
3.6.	Email:

4. Particulars of the Export Company / Institution:

4.1.	Name:
4.2.	Address:
4.3.	Country:
4.4.	Telephone:
4.5.	Email:
4.6.	Registration number with the regulatory authority in the respective country: Date of registration: (Please attach a copy of the certificate)

Footnote:

#*Classical Medicine* means any medicine formulated exclusively according to a formula and method which are mentioned in any original / classical text of *Ayurveda/ Siddha/ Unani /Deshiya Chikitsa*, recognized by the Department of Ayurveda

5. Particulars of the Product:

5.1.	Name of the product:
5.2.	Category: (Cosmeceutical/food & dietary supplement/medicine/device etc.) If it is a medicine, please specify whether classical/pharmacopeial or proprietary medicine:
5.3.	Use/ therapeutic indications:
5.4.	Dosage:
5.5.	Mode of administration (external/oral etc.):

6. Particulars of Sample Import License:

6.1.	License No. issued by the Department of Ayurveda: Date of issue:

7. Particulars of Previous Registration of the Product:

7.1.	First time registration no. :	Date:
	Last registration no. :	Date:

Footnote:

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8. Post marketing particulars of the Product:

8.1.	Were any adverse effects reported regarding the product? (Yes/No) If yes, please describe briefly (attach additional sheets if necessary)
8.2.	Was any research done on the product in Sri Lanka after obtaining the first-time registration? (Yes/No) If yes, briefly describe the results (attach a copy of the report /publication)

9. Declaration of the Advisory Ayurveda Practitioner :

I do hereby declare that the particulars given above, and the information provided in the dossier of the product (name of the product) …… are true and correct according to my professional knowledge, I act in accordance with the Ayurveda Act no. 31 of 1961 and the Registered Ayurvedic Medical Practitioners (Professional Conduct) Rules no. 01 of 2014, and I am aware that I am personally responsible and accountable for the accuracy of all the information submitted herewith.

Signature: Date:

Professional seal:

Footnote:

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10. Declaration of the Applicant :

I do hereby certify that the particulars provided in the application are true and correct.

Signature: Date:

Official seal:

For office use only
Money order no:
Receipt no:
Date of dossier submission:
Remarks: Completed / Incomplete / Forged document / Complaints
Name & Signature of the receiver:

Footnote:

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APPENDIX 5.7: List of quality parameters for the review of products

i. The parameters for assessment of quality of Ayurveda Cosmeceuticals, Nutraceuticals, and health supplements

(It is based on SLS, and other requirements determined by the Ayurveda Formulary Committee)

Skin cream & lotion (Moisturizing cream/ Day & Night cream/ lotions/ Hair cream) (SLS 743)

1) General: consistency, homogeneity, odour
2) Identification of herbal ingredients – TLC / HPLC / GC (as appropriate)
3) Thermal stability
4) pH
5) Non-volatile matter
6) Water content
7) Peroxide value
8) Microbiological purity (total aerobic mesophilic microorganisms, *E. coli, S. aureus, Candida albicans, Pseudomonas*)
9) Heavy metals (Hg, As, Cd, Pb)
10) Total formaldehyde (if applicable)

Skin cream & lotion for babies (SLS 742)

1) General: homogeneity, odour
2) Identification of herbal ingredients – TLC / HPLC / GC (as appropriate)
3) Thermal stability
4) pH
5) Non-volatile matter
6) Water content
7) Peroxide value
8) Microbiological purity (total aerobic mesophilic microorganisms, *E. coli, S. aureus, Candida albicans, Pseudomonas*)
9) Heavy metals (Hg, As, Cd, Pb)
10) Total formaldehyde (if applicable)

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Aftershave lotion (SLS 1031)

1) General: free from sediments
2) Identification of herbal ingredients – TLC / HPLC / GC (as appropriate)
3) Alcohol content
4) Heavy metals (Hg, As, Cd, Pb)

Toothpaste (SLS 275)

1) Identification of ingredients – TLC / HPLC / GC (as appropriate)
2) Compliance of dyes, colors, pigments (if applicable)
3) Diethylene glycol content
4) Extrusive content
5) Consistency
6) Cohesiveness
7) Stability
8) Tube/ sachet inertness
9) Microbiological purity (total aerobic bacteria, *E. coli, Salmonella*)
10) Heavy metals (Hg, As, Cd, Pb, Antimony-Sb)
11) Moisture and volatile matter
12) fineness
13) pH of aqueous suspension
14) Total fluoride (if applicable)
15) Abrasion

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Tooth powder (SLS 281)

1) General: odour
2) Identification of ingredients – TLC / HPLC / GC (as appropriate)
3) Irritation
4) Consistency
5) Heavy metals (As, Pb)
6) Microbiological contamination (total aerobic mesophilic microorganisms, *E. Coli, S. aureus, Candida albicans, Pseudomonas*)
7) Moisture and volatile matter
8) Fineness
9) pH of aqueous suspension
10) Abrasion
11) Shelf life

Skin Powders (SLS 389)

1) General: fineness, free flow
2) Identification of ingredients – TLC / HPLC / GC (as appropriate)
3) Grit
4) Boric acid content
5) Matter insoluble in boiling water
6) Fineness
7) Moisture and volatile matter
8) pH of aqueous suspension
9) Microbiological purity (total aerobic mesophilic microorganisms, *E. Coli, S. aureus, Candida albicans, Pseudomonas*)
10) Heavy metals (Hg, As, Cd, Pb)
11) Shelf life

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Skin Powder for babies (SLS 187)

1) General: fineness, free flow
2) Identification of ingredients – TLC / HPLC / GC (as appropriate)
3) Grit
4) Coloring matter
5) Boric acid content
6) Matter insoluble in boiling water
7) Fineness
8) Moisture and volatile matter
9) pH of aqueous suspension
10) Microbiological purity (Total microbial count, *S. aureus, Pseudomonas*)
11) Heavy metals (As, Pb)
12) Shelf life

Hair Shampoo (SLS 1346)

1) General: free from sediments, homogeneity, free from agglomerated particles
2) Identification of herbal ingredients – TLC / HPLC / GC (as appropriate)
3) Active synthetic anionic ingredient content
4) Total (anionic or combination of anionic and non-ionic) active synthetic ingredient content
5) pH
6) Inorganic salts
7) Heavy metals (Hg, As, Cd, Pb)
8) Microbiological purity (total aerobic mesophilic microorganisms, *E. Coli, S. aureus, Candida albicans, Pseudomonas*)

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Hair Shampoo for babies (SLS 1342)

1) General: free from sediments, homogeneity, free from agglomerated particles
2) Identification of herbal ingredients – TLC / HPLC / GC (as appropriate)
3) Active synthetic anionic ingredient content
4) pH
5) Inorganic salts
6) Heavy metals (Hg, As, Cd, Pb)
7) Microbiological purity (total aerobic mesophilic microorganisms, *E. Coli, S. aureus, Candida albicans, Pseudomonas*)

Hair Dyes (SLS 1439)

1) Identification of herbal ingredients – TLC / HPLC / GC (as appropriate)
2) Active matter as PPD content
3) Dye ingredients
4) pH of aqueous suspension
5) Heavy metals (Hg, As, Cd, Pb)
6) Microbiological purity: aerobic plate count, *S. aureus, Pseudomonas*
7) Assay (as H_2O_2) (for developer)
8) pH (for developer)
9) Shelf life

Hair Dye powder (SLS 1440)

1) General: fineness, free flow
2) Identification of herbal ingredients – TLC / HPLC / GC (as appropriate)
3) Synthetic material such as PPD , Paraben content if applicable
4) Dye ingredients
5) pH of aqueous suspension
6) Heavy metals (Hg, As, Cd, Pb)
7) Microbiological purity: aerobic plate count, *S. aureus, Pseudomonas*
8) Shelf life

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Hair oil (non-therapeutic) (SLS 1341)

1) General: odour, colour, free from sediments
2) Identification of herbal ingredients – TLC / HPLC / GC (as appropriate)
3) Acid value
4) Peroxide value
5) Dyes and colorants (if applicable)
6) Heavy metals (Hg, As, Cd, Pb)
7) Microbiological purity: aerobic plate count, *S. aureus, Pseudomonas*
8) Stability

Hair cream

1) Identification of herbal ingredients – TLC / HPLC / GC (as appropriate)
2) Thermal stability
3) pH of aqueous suspension
4) Total non-aqueous content
5) Water content
6) Peroxide value
7) Heavy metals (Hg, As, Cd, Pb)
8) Microbiological purity (total aerobic mesophilic microorganisms, *S. aureus, Candida albicans, Pseudomonas*)

Baby oil (SLS 1191)

1) General: clear, colour less, odour, free from foreign matter & sediment
2) Identification of herbal ingredients – TLC / HPLC / GC (as appropriate)
3) Acid value
4) Peroxide value
5) Sulfur and sulfides
6) Heavy metals (Hg, As, Cd, Pb)
7) Microbiological purity (aerobic plate count, *S. aureus*, *Pseudomonas*)
8) Stability

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Face pack

1) Identification of ingredients – TLC / HPLC / GC (as appropriate)
2) Microbiological purity (total plate count, *E. coli, S. aureus, Salmonella, Pseudomonas*)
3) Heavy metals (Hg, As, Cd, Pb)
4) Moisture content
5) Ash content
6) pH of aqueous suspension
7) Solid content

Toilet soap (SLS 34)

1) General: homogeneity, free from objectionable odour
2) Identification of herbal ingredients – TLC / HPLC / GC (as appropriate)
3) Total Fatty Matter (TFM)
4) Rosin acids content
5) Matter insoluble in ethanol
6) Free caustic alkali, as NaOH
7) Total free alkali, as NaOH
8) Chlorides, as NaCl
9) Lather
10) Shelf life

Bathing bar (SLS 1220)

1) General: firm, smooth without any lumps/cracks
2) Identification of herbal ingredients – TLC / HPLC / GC (as appropriate)
3) Total Fatty Matter (TFM)
4) pH of aqueous suspension
5) synthetic surface-active agent
6) Free caustic alkali, as NaOH
7) Mush
8) Shelf life

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Liquid toilet soap

1) Identification of herbal ingredients – TLC / HPLC / GC (as appropriate)
2) Total Fatty Matter (TFM)
3) pH of aqueous suspension
4) Matter insoluble in ethanol
5) Total free alkali, as NaOH
6) Microbiological purity (aerobic plate count, *S. aureus, Pseudomonas*)

Baby Soap (SLS 547)

1) General: well saponified, homogenized, free from objectionable odour
2) Identification of herbal ingredients – TLC / HPLC / GC (as appropriate)
3) Total Fatty Matter (TFM)
4) Freedom from rosin
5) Matter insoluble in ethanol
6) Free caustic alkali, as NaOH
7) Total free alkali, as NaOH
8) Chlorides, as NaCl
9) Shelf life

Soft Soap (SLS 37)

1) General: shall be jelly like texture, free from objectionable odour
2) Identification of herbal ingredients – TLC / HPLC / GC (as appropriate)
3) Total Fatty Matter (TFM)
4) Matter insoluble in ethanol
5) Free caustic alkali, as KOH
6) Total free alkali, as KOH
7) Shelf life

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Shaving Soap (SLS 36)

1) General: well saponified, homogenized, free from objectionable odour,
2) Identification of herbal ingredients – TLC / HPLC / GC (as appropriate)
3) Total Fatty Matter (TFM)
4) Matter insoluble in ethanol
5) Total free alkali as KOH
6) Free fatty acids
7) Matter insoluble in water
8) Shelf life

Alcohol Based Hand Sanitizers (SLS 1657)

1) General: shall be clear, acceptable odour
2) Identification of herbal ingredients – TLC / HPLC / GC (as appropriate)
3) Alcohol content
4) pH
5) Microbiological efficacy (percent reduction)
6) Visible impurities

Herbal capsule

1) Identification of ingredients – TLC / HPLC / GC (any one appropriate method)
2) Microbiological purity (total plate count, *E. coli, S. aureus, Salmonella, Pseudomonas*)
3) Heavy metals (Hg, As, Cd, Pb)
4) Moisture content
5) Coloring matter
6) Pesticide residue: Organochlorine pesticides, Organophosphorus pesticides, Pyrethroids
7) Test for Aflatoxins (B_1, B_2, G_1, G_2)

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Herbal Tea

1) Identification of ingredients – TLC / HPLC / GC (any one appropriate method)
2) Microbiological purity (*E. coli, S. aureus, Salmonella, Pseudomonas*)
3) Heavy metals (Hg, As, Cd, Pb)
4) Moisture content
5) Coloring matter
6) Pesticide residue: Organochlorine pesticides, Organophosphorus pesticides, Pyrethroids
7) Test for Aflatoxins (B_1, B_2, G_1, G_2)

Soft candy (toffees and jelly-based candy) (SLS 1575)

1) General: appearance, colour, odour, free from dirt, shall not stick to wrappers
2) Identification of ingredients – TLC / HPLC / GC (any one appropriate method)
3) Heavy metals (As, Cd, Pb, Sn, Cu)
4) Microbiological purity (total plate count, *E. coli, S. aureus, Salmonella, Pseudomonas*)
5) Moisture content
6) Ash, sulphated
7) Acid insoluble ash
8) Reducing sugars
9) Sucrose
10) Fat
11) Sulphur dioxide

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Herbal-fruit drinks / Herbal-fruit juices (SLS 729, SLS 1328)

1) Identification of ingredients – TLC / HPLC / GC (any one appropriate method)
2) Total soluble solids content
3) Acidity
4) Sulphur dioxide content
5) Benzoic acid content
6) Sorbic acid content
7) Microbiological purity (total plate count, yeasts & moulds count, total coliform count)
8) Pesticide residues
9) Heavy metals (As, Cd, Pb, Tin-Sn)

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ii. The parameters for assessment of quality of Ayurveda medicines

(** It is based on the PROTOCOL FOR TESTING of Ayurvedic, Siddha & Unani Medicines published by the Pharmacopeial Laboratory for Indian Medicines, Ghaziabad, Department of AYUSH, Government of India, the General Guidelines for Drug Development of Ayurvedic Formulations published by the Central Council for Research in Ayurvedic sciences, Ministry of AYUSH, India, and other relevant documents. The parameters are adopted to suit the country context.)

The quality parameters (except description, colour, odour, taste, stability/shelf life, consistency, foreign matter; these could be checked in an in-house laboratory under supervision of a suitably qualified person) shall be tested in any independent laboratory accredited for that purpose by the Sri Lanka Accreditation Board (SLAB) or any other independent laboratory approved by the Ayurveda Formulary Committee.

Asava / Arishta (Fermented liquids) **

1) Description, colour, odour
2) pH
3) Viscosity
4) Total solids
5) Alcohol content
6) Sugar content
7) TLC/HPTLC/ GC-MS (any one of the appropriate method)
8) Test for methanol
9) Test for heavy/toxic metals (Lead, Cadmium, Mercury, Arsenic)
10) Microbial contamination (Total viable aerobic count, Enterobacteriaceae, Total fungal count)
11) Test for specific pathogen (*Escherichia coli*, *Salmonella* spp., *Staphylococcus aureus*, *Pseudomonas aeruginosa*)
12) Aflatoxins (B1, B2, G1, G2)
13) Stability (Shelf life)

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Kalkaya / Avaleha / Leham / Modak / Kayam / Ilagam / Majoonath (Confections / Semi solid)**

1) Description, colour, odour, taste, consistency
2) Loss on drying at 105^0 C / Moisture content
3) Total ash
4) Total acidity
5) Total sugars
6) Identification: TLC / GC / HPLC (any one of the appropriate method)
7) Test for heavy metals: Lead, Cadmium, Mercury, Arsenic
8) Microbial contamination: Total bacterial count, Total fungal count, test for specific pathogen: *E.coli, Salmonella spp., S.aureus, Pseudomonas aeruginosa*
9) Test for Aflatoxins (B_1, B_2, G_1, G_2)
10) Shelf life

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Chewing candy**

1) Description, colour, taste, odour, identification
2) Loss on drying at 105°C /Moisture content
3) Friability
4) Hardness
5) Uniformity of weight (single dose does not exceed more than 5g)
6) Disintegration time (More than 30 minutes)
7) Total ash
8) Salt content
9) Total sugars
10) TLC / HPTLC (any one of the appropriate method)
11) Test for heavy/toxic metals (Lead, Cadmium, Mercury, and Arsenic)
12) Microbial contamination (Total bacterial count, Total fungal count, Enterobacteriaceae, *Salmonella* spp.)
13) Aflatoxins (B1, B2, G1, G2)
14) Shelf life

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Churna / Choornam / Kvatha churna / Kudinir choornam / Safoof **

1) Description, colour, odour, foreign matters
2) Loss on drying at 105^0 C / Moisture content
3) Particle size (80-100 mesh for churna; 40-60 mesh for Kvatha churna)
4) pH (5% aqueous extract)
5) Identification: TLC / HPTLC / HPLC (any one of the appropriate method)
6) Test for heavy metals: Lead, Cadmium, Mercury, Arsenic
7) Microbial contamination: Total viable aerobic count, Enterobacteriaceae, Total fungal count
8) Test for specific pathogen: *E.coli, Salmonella spp., S.aureus, Pseudomonas aeruginosa*
9) Test for Aflatoxins (B_1, B_2, G_1, G_2)
10) Shelf life

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Pattuwa / Lepa / Malhara / Kalimbu / Pasai / Zimad (medicated wax / cream / poultice / Paste)**

1) Description, colour, odour, uniformity of content
2) Peroxide value (if applicable)
3) Loss on drying at 105^0 C / Moisture content
4) pH (5% aqueous extract) (if applicable)
5) Particle size
6) Spreadability
7) Identification: TLC / HPLC / GC (any one of the appropriate method)
8) Test for heavy metals: Lead, Cadmium, Mercury, Arsenic
9) Microbial contamination: Total viable aerobic count, Total fungal count
10) Test for specific pathogen: *E.coli, Salmonella spp., S.aureus, Pseudomonas aeruginosa*
11) Test for Aflatoxins (B_1, B_2, G_1, G_2)
12) Shelf life

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Netrabindu / Kan Chottu Marunthu (Eye Drops) **

1) Description, colour, odour
2) pH
3) Clarity test (suspended particles)
4) TLC/ HPTLC / GC/ HPLC (as appropriate)
5) Test for heavy/toxic metals (Lead, Cadmium, Mercury, and Arsenic)
6) Pesticide residue (Organochlorine pesticides, Organophosphorus pesticides, Pyrethroids)
7) Microbial contamination (Total viable aerobic count, Enterobacteriaceae, Total fungal count)
8) Test for specific pathogen (*Escherichia coli*, *Salmonella* spp., *Staphylococcus aureus*, *and Pseudomonas aeruginosa*)
9) Aflatoxins (B1, B2, G1, G2)
10) Shelf life

Suppositories**

1) Description, colour, uniformity of content
2) Melting range (°C)
3) Viscosity
4) Iodine value
5) Saponification value
6) Unsaponifiable matter (percentage of)
7) pH (5% of aqueous solution)
8) Identification: HPTLC/GC/HPLC/GC-MS (as appropriate)
9) Free fatty acids (percentage of)
10) Total fatty matter (percentage of)
11) Microbial contamination (Total viable aerobic count, Total fungal count)
12) Test for specific pathogen (*Escherichia coli*, *Salmonella* spp., *Staphylococcus aureus*, *and Pseudomonas aeruginosa*)
13) Dissolution test
14) Test for heavy metals: Lead, Cadmium, Mercury, and Arsenic
15) Shelf life

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Tailas / Ghritas / Thylam / Nei / Roghan (Medicated Oils And Ghee)**

1) Description, colour, odour
2) Rancidity
3) Loss on drying at 105^{o} C/ Moisture content
4) Viscosity
5) Refractive index
6) Saponification value
7) Unsaponifiable matter (percentage of)
8) Acid value
9) Peroxide value
10) Free fatty acids (%)
11) Total fatty matter (%)
12) Mineral oil test
13) Identification: TLC / HPLC / GC (as appropriate)
14) Test for heavy metals: Lead, Cadmium, Mercury, Arsenic
15) Microbial contamination: Total viable aerobic count, Total fungal count
16) Test for specific pathogen: *E.coli*, *Salmonella spp.*, *S.aureus*, *Pseudomonas aeruginosa*
17) Test for Aflatoxins (B_1, B_2, G_1, G_2)
18) Shelf life

Footnote:

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Guggulu**

1) Description, colour, odour & taste
2) Loss on drying at 105^0 C
3) Total ash
4) pH (5% of aqueous solution)
5) Disintegration time
6) Uniformity of weight
7) Identification: TLC / HPLC / GC (as appropriate)
8) Test for heavy metals: Lead, Cadmium, Mercury, Arsenic
9) Microbial contamination: Total bacterial count, Total fungal count
10) Test for specific pathogen: *E.coli, Salmonella spp., S.aureus, Pseudomonas aeruginosa*
11) Test for Aflatoxins (B_1, B_2, G_1, G_2)
12) Shelf life

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Sharkara Sikta / Siruthugalgal (Granules) **

1) Description, colour, taste, odour
2) Compressibility
3) Flow property
4) pH (5% of aqueous solution)
5) Total sugars
6) TLC/HPTLC/HPLC/LC-MS (as appropriate)
7) Test for heavy/toxic metals (Lead, Cadmium, Mercury, Arsenic)
8) Microbial contamination (Total viable aerobic count, Enterobacteriaceae, Total fungal count)
9) Test for specific pathogen (*Escherichia coli*, *Salmonella* spp., *Staphylococcus aureus*, *Pseudomonas aeruginosa*)
10) Aflatoxins (B1, B2, G1, G2)
11) Shelf life

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Guli / Vati / Gutika / Kuligai / Marthirai / Vadagam / Habb / Qurs

(Tablet including herbo mineral tablet / Pills)**

1) Description, colour, taste, odour
2) pH (5% aqueous extract)
3) Loss on drying at 105^{o}C / Moisture content
4) Friability
5) Hardness
6) Weight variation (uniformity of weight)
7) Disintegration time (not more than 35 minutes except guggulu)
8) Total sugar (if added)
9) Identification: TLC / HPLC /GC (as appropriate)
10) Test for heavy metals: Lead, Cadmium, Mercury, Arsenic
11) Microbial contamination: Total viable aerobic count, Total fungal count
12) Test for specific pathogen: *E.coli, Salmonella spp., S.aureus, Pseudomonas aeruginosa*
13) Test for Aflatoxins (B_1, B_2, G_1, G_2)
14) Shelf life

Footnote:

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Vartti, Netra Vartti**

1) Description, colour, odour
2) pH (5% of aqueous solution)
3) Friability
4) Hardness
5) Dissolution time
6) Uniformity of weight
7) Loss on drying at 105^{o}C / Moisture content
8) TLC/HPTLC/HPLC/ GC (as appropriate)
9) Test for heavy/toxic metals (Lead, Cadmium, Mercury, and Arsenic)
10) Microbial contamination (Total viable aerobic count, Total fungal count
11) Test for specific pathogen (*Escherichia coli*, *Salmonella* spp., *Staphylococcus aureus*, *Pseudomonas aeruginosa*)
12) Aflatoxins (B1, B2, G1, G2)
13) Shelf life

Footnote:

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Shaarkar / Sharbat / Manappagu / Syrup**

1) Description, colour, odour, taste
2) pH
3) Viscosity
4) Total solids
5) Total sugar content
6) Identification: TLC / HPLC / GC (as appropriate)
7) Test for heavy metals: Lead, Cadmium, Mercury, Arsenic
8) Microbial contamination: Total bacterial count, Total fungal count
9) Test for specific pathogen: *E.coli*, *Salmonella spp.*, *S.aureus*, *Pseudomonas aeruginosa*
10) Test for Aflatoxins (B_1, B_2, G_1, G_2)
11) Shelf life

Footnote:

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Pishti / Bhasma / Parpam / Kushta / Sindur / Chenduram (Processed fine powder, Calyx)**

1) Description, colour, odour
2) pH (1% aqueous extract)
3) Loss on drying at 105^0 C / Moisture content
4) Total ash
5) Acid – insoluble ash
6) Sulphated ash (if applicable)
7) Particle size (mesh size 200 – 300)
8) Test for heavy metals: Lead, Cadmium, Mercury, Arsenic
9) Microbial contamination: Total viable aerobic count, Enterobacteriaceae, Total fungal count
10) Test for specific pathogen: *E.coli, Salmonella spp., S.aureus, Pseudomonas aeruginosa*
11) Shelf life

Footnote:

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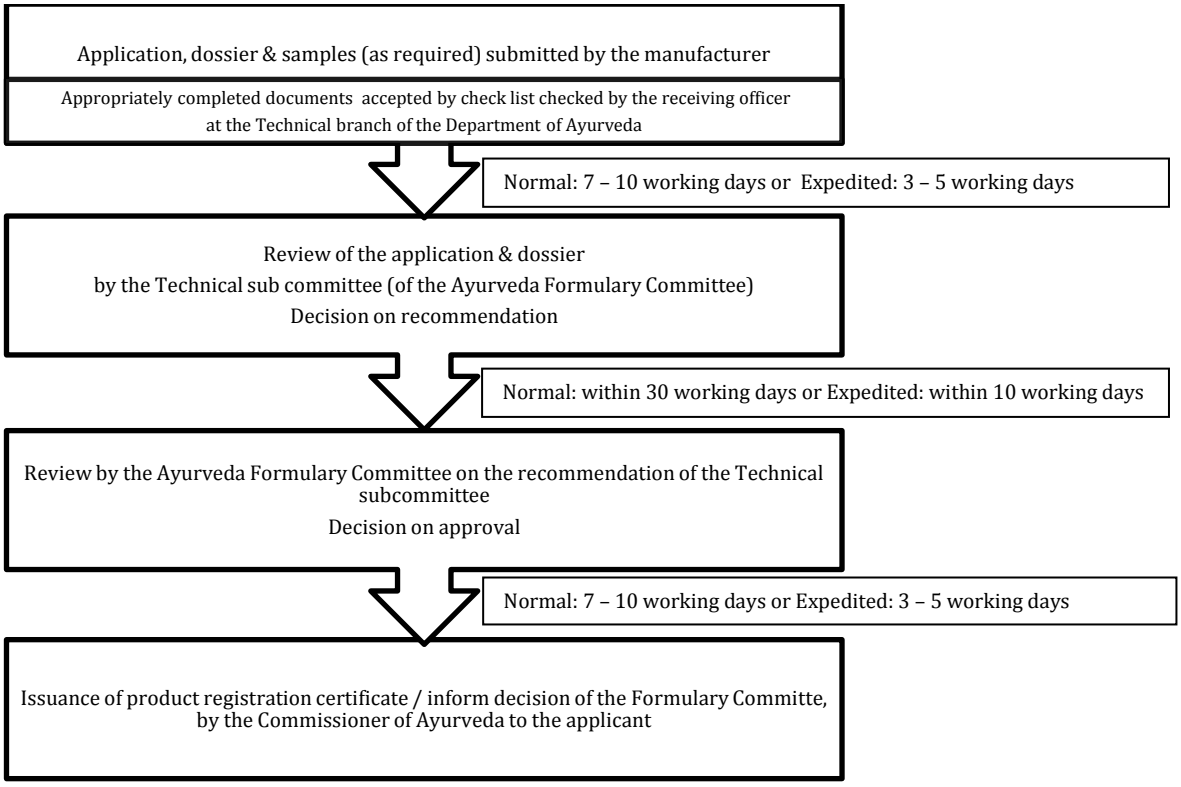
APPENDIX 5.8: Timeline of the process of first-time registration of local products



The above flow chart describes the process of registration (for the first time) / renewal of registration after three years of locally manufactured products.

Within 60 and 21 working days the decision is conveyed to the applicant in normal and expedited processes respectively. But this time period is subjected to change by the Department of Ayurveda on prior notice.

Footnote:

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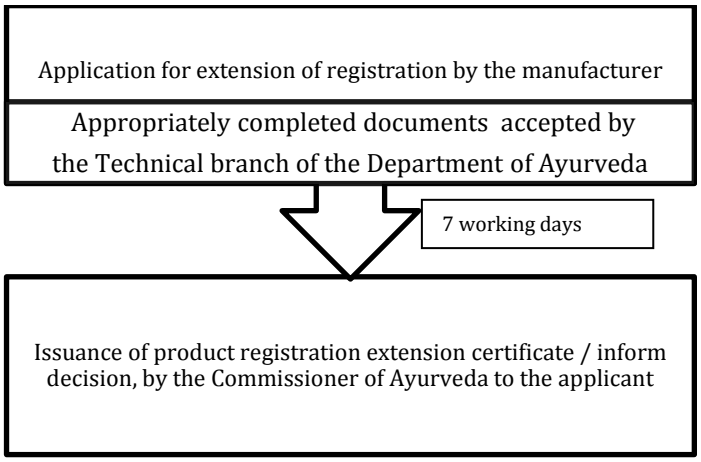
APPENDIX 5.9: Timeline of the process of extension of registration of local products



The above flow chart depicts the process of extension of registration at the end of three years of registered locally manufactured products.

Footnote:

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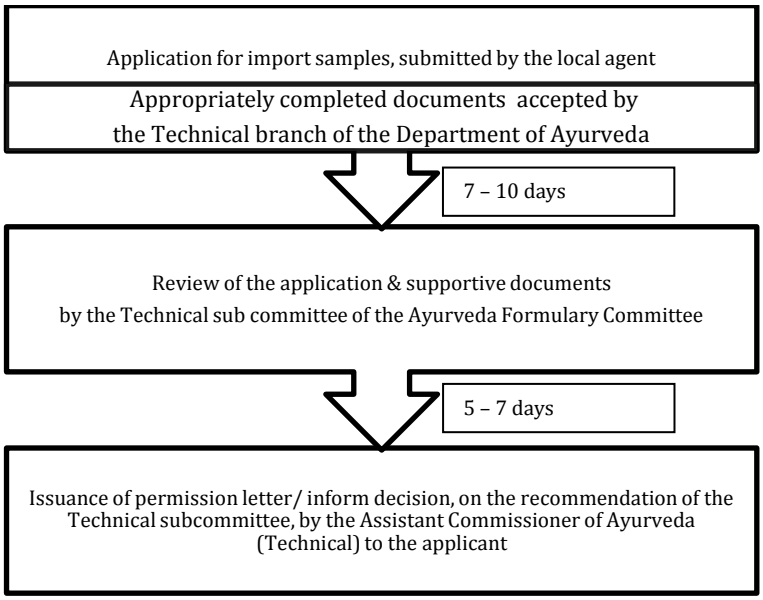
APPENDIX 5.10: Timeline of the application process for sample import permit



The above flow chart depicts the process of application for import samples of the products intended to import

Footnote:

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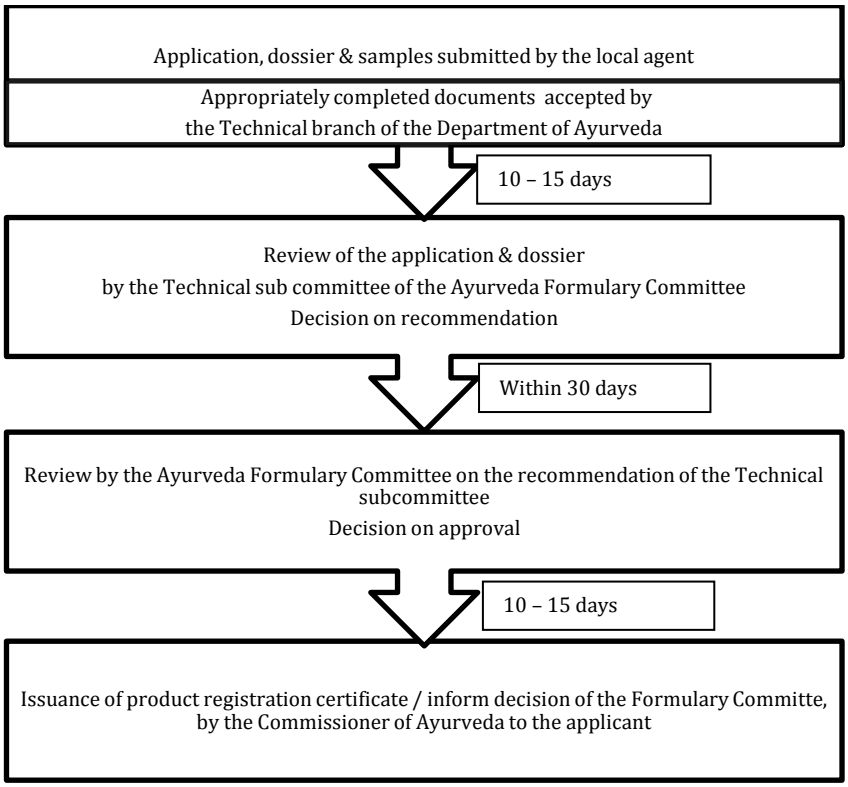
APPENDIX 5.11: Timeline of the process of first-time registration of import products



The above flow chart depicts the process of registration (for the first time)/ renewal of registration after six years of imported products

Footnote:

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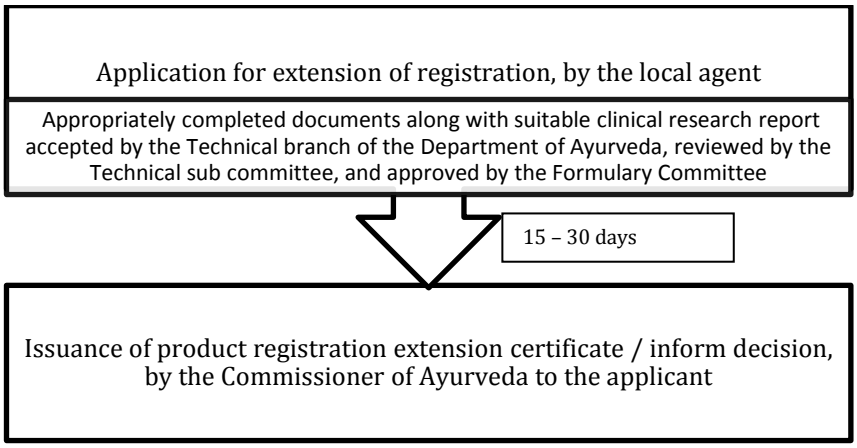
APPENDIX 5.12: Timeline of the process of extension of registration of import products



The above flow chart depicts the process of extension of registration at the completion of three years of imported products

Footnote:

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APPENDIX 5.13: Information to be contained in the label / package insert of a product

Department of Ayurveda

Information to be contained in the label / package insert of a product

The label / package insert shall contain the following in a legible manner for local / imported product. The contents shall appear in a readable font size. It is recommended to refer relevant SLS standards (if applicable) for further information.

<u>Over-the-counter product</u> (cosmeceutical / nutraceutical / dietary supplement / health supplement / healthy food / non-prescription medicine)

The information shall appear in all three languages (Sinhala, Tamil, and English) for name of the product, directions for use and warning statements.

i. Name of the product (true name of the product; it should not mislead or confuse the consumer)
ii. Brand name or trade name
iii. List of ingredients (with scientific names)(shall be visible to the consumer at the point of sale): ingredients present in greater than 1% at the time they are added shall be listed in descending order
iv. Health enhancing action / intended use (claims should be authorized or approved by the Ayurveda Formulary Committee)
v. Additional claims: 'free from' claims/claims with similar meaning should not be made inappropriately to mislead the consumer e.g., regarding ingredients prohibited for use in a particular product. The absence of specific ingredient/s should be proven by adequate and verifiable evidence. If herbal ingredients added are claimed and/or labeled as 'natural', it should have adequate evidence of natural origin.
vi. Net content
vii. Dosage form
viii. Directions for use (indication, dosage, mode of administration, age group categorization when appropriate)
ix. Date of manufacture
x. Date of expiry / shelf life / best before
xi. Lot / batch number
xii. Name of the manufacturer/ importer with address (including country of origin), contact details
xiii. Warning statements (when appropriate, should comply SLS 457)
xiv. Storage conditions (when appropriate)
xv. Product registration number (provided by the Department of Ayurveda; shall not mislead / confuse the consumer by mentioning manufactory license number instead of product registration number)

Footnote:

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Prescription medicine

i. Name of the medicine
ii. Brand name or trade name
iii. Statement of 'prescription only medicine' / 'prescribed only by a registered Ayurveda practitioner' or equivalent statement
iv. List of ingredients (with scientific names) with quantities/ percentages (shall be visible to the consumer at the point of sale)
v. Pharmacological action (Ayurveda/ Siddha/ Unani/ scientific) of the medicine
vi. Net content
vii. Dosage form
viii. Directions for use (indication, dosage, mode of administration, age group limitations)
ix. Date of manufacture
x. Date of expiry / shelf life / best before
xi. Lot / batch number
xii. Name of manufacturer/ importer with address, contact details
xiii. Product registration number (provided by the Department of Ayurveda)
xiv. Interactions (when appropriate)
xv. Adverse effects (when appropriate)
xvi. Overdose (when appropriate)
xvii. Information on whether it can be prescribed for pregnant and lactating mothers
xviii. Warnings
xix. Storage conditions

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APPENDIX 5.14: Check list for application to import ingredients

Application for Permission to import ingredients / blends / formulation / extracts for Ayurveda product manufacturing which comes under the purview of the Formulary Committee

Check List

Name of the institution: Name of the ingredient:

Address:

(Please specify the category by marking ✓in the appropriate box provided below)

Blend	Ayurveda formulation	Extract

	Required Documents	By the applicant			Checked on receiving
		Attached	Not applicable	Page No.	
1.	Request letter for Import Permit (name, scientific name, quantity to be imported, country of origin, manufacturer, exporter, detailed statement on the purpose of import and the intended use/ manufacture detail shall be included)				
2.	For import ingredients /blends/formulation/ extracts: Ayurveda text reference Safety profile / toxicological study report / clinical study report TLC (if applicable) Heavy metals (Pb, Cd, Hg, As) report Microbiology (total plate count, *E.coli*, *Salmonella, S.aureus, Pseudomonas*, total Yeast & Mould) report Pesticide residue report Aflatoxins (B_1, B_2, G_1, G_2) report				
3.	Letter of recommendation & justification by the Advisory Ayurveda Practitioner of the institution				
4.	Certified copy of the Ayurveda Medical Council registration certificate of the Advisory Ayurveda Practitioner				
5.	Certified copy of the Manufacture License issued by the Department of Ayurveda				
6.	Certified copy of Good Manufacturing Practice (GMP) certificate of the manufacturer of the material				
7.	Certified copy of ISO certificate of the manufacturer of the material				
8.	Certified copy of Good Agriculture & Collection Practice (GACP) certificate of the manufacturer of raw material (if applicable)				
9.	Certified copy of any other acceptable Quality Assurance certificate of the manufacturer of the material (if applicable)				
10	Free sale certificate for the material (if applicable)				

……

Receiving Officer

Footnote:

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APPENDIX 5.15: Format of expert opinion regarding locally manufactured products

Expert / Professional Opinion of a Registered Ayurveda Practitioner about a Locally Manufactured Ayurveda Product

(The Ayurveda practitioner shall provide his/her expert opinion regarding safety and efficacy of a product, honestly and competently, complying to medical ethics specified in the Registered Ayurvedic Medical Practitioners (Professional Conduct) Rules no. 01 of 2014, published in the gazette extra ordinary no. 1884/36 dated 2014.10.15, which could be taken into consideration by the Ayurveda Formulary Committee in the evaluation of products for approval. He / She shall provide opinion only relevant to his / her section of registration / stream / speciality. An incomplete form will not be accepted.)

1. Particulars of the Registered Ayurveda Practitioner:

1.1.Full Name:

1.2.Educational / Professional Qualification/s:

1.3.Ayurveda Medical Council Registration No.: General ……., Special …….
(Please attach copies of registration and renewal of registration certificates)

1.4.Section of Registration: (General / Special: ……..)

1.5.Residential Address:

1.6.Official / Dispensary Address:

1.7.Telephone No:

1.8.Email:

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2. Particulars of the Product:

2.1.Name of the Product (including its proprietary/trade name):

2.2.Name of the Manufacturer:

2.3.Claimed Therapeutic Uses:

2.4.Ingredients of the product:
(Please attach additional sheet if necessary)

3. Opinion on Safety and Efficacy of the product:

3.1.Do you think, based on the *Ayurveda/Siddha/Unani/Deshiya Chikitsa* principles, that the product mentioned in 2.1 is **safe** for human consumption in health conditions mentioned in 2.3? Yes/No

3.2.Please briefly justify, by providing responses to the below given questions, on how you arrive to the above (3.1) decision:
(Please attach additional sheet if necessary)

3.2.1. Do you have any experience in your medical practice regarding the safety of ingredient/s used to manufacture this product? Yes / No If yes, please briefly explain with examples.

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3.2.2. Is any adverse reaction reported in your medical practice when using similar products made from the ingredient/s mentioned in 2.4? Yes / No
If yes, please briefly explain.

3.2.3. Can you certify the purification process of the ingredient/s is appropriately followed in manufacturing of this product? Yes / No

3.2.4. Can you assure the proper manufacturing process and quality assurance is implemented to ensure the safety and quality of this product? Yes / No

3.2.5. Can you certify that the product mentioned in 2.1 would not be harmful to humans in health conditions mentioned in 2.3, based on properties of the ingredients according to the *Ayurveda/Siddha/Unani/ Deshiya Chikitsa* principles? Yes / No
Please briefly justify.

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3.3. Do you think, according to the *Ayurveda/Siddha/Unani/ Deshiya Chikitsa* principles, that the product mentioned in 2.1 could be **therapeutically useful** in medical conditions / illness mentioned in 2.3? Yes/No

3.4. Please briefly justify, by responding to the below given questions, on how you arrive to the above (3.3) decision:
(Please attach additional sheet if necessary)

3.4.1. Do you have any clinical experience in your medical practice regarding the medicinal use/s of the ingredient/s of this product mentioned in 2.4, related to the health conditions mentioned in 2.3? Yes / No
If yes, please briefly explain.

3.4.2. Can you certify that the product mentioned in 2.1 would be therapeutically useful in the health conditions mentioned in 2.3, based on the properties of the ingredients according to the *Ayurveda/Siddha/Unani/ Deshiya Chikitsa* principles? Yes / No
Please briefly justify.

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3.5. Do you have any clinical experience with the product mentioned in 2.1, in your professional practice? Yes / No

If yes, please provide information briefly about your clinical experience.
(Number of patients treated, therapeutic indications, dosage, clinical outcomes, adverse effects):

3.6. Are any research reports / publication available regarding the product mentioned in 2.1? Yes / No

If yes, please provide details and attach a copy.

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4. Declaration by the Registered Ayurveda Practitioner:

I, ……bearing NIC/Passport/Driving License No: ……... and Ayurveda Medical Council registration no: (General/Special) ……, do hereby certify that the information provided by me in the sections 1, 2, 3 are accurate, honest and are my professional opinion based on skilled knowledge, I act in accordance with the Ayurveda Act no. 31 of 1961 and the Registered Ayurvedic Medical Practitioners (Professional Conduct) Rules no. 01 of 2014, I am aware that I am personally responsible and accountable for my opinion regarding the safety and efficacy of the product mentioned in 2.1 and I am liable to any consequences including legal flowing from any misrepresentation of facts and/or where my opinion cannot be justified on a professional basis. I further understand and agree that I could be requested by the regulatory authority to provide further information and/or testify on safety and efficacy of the product. I am also aware and agree that any credible research evidence would supersede on any opinion and/or facts/figures put forwarded by me.

…….. ……

Signature Date

Professional seal:

Footnote:

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