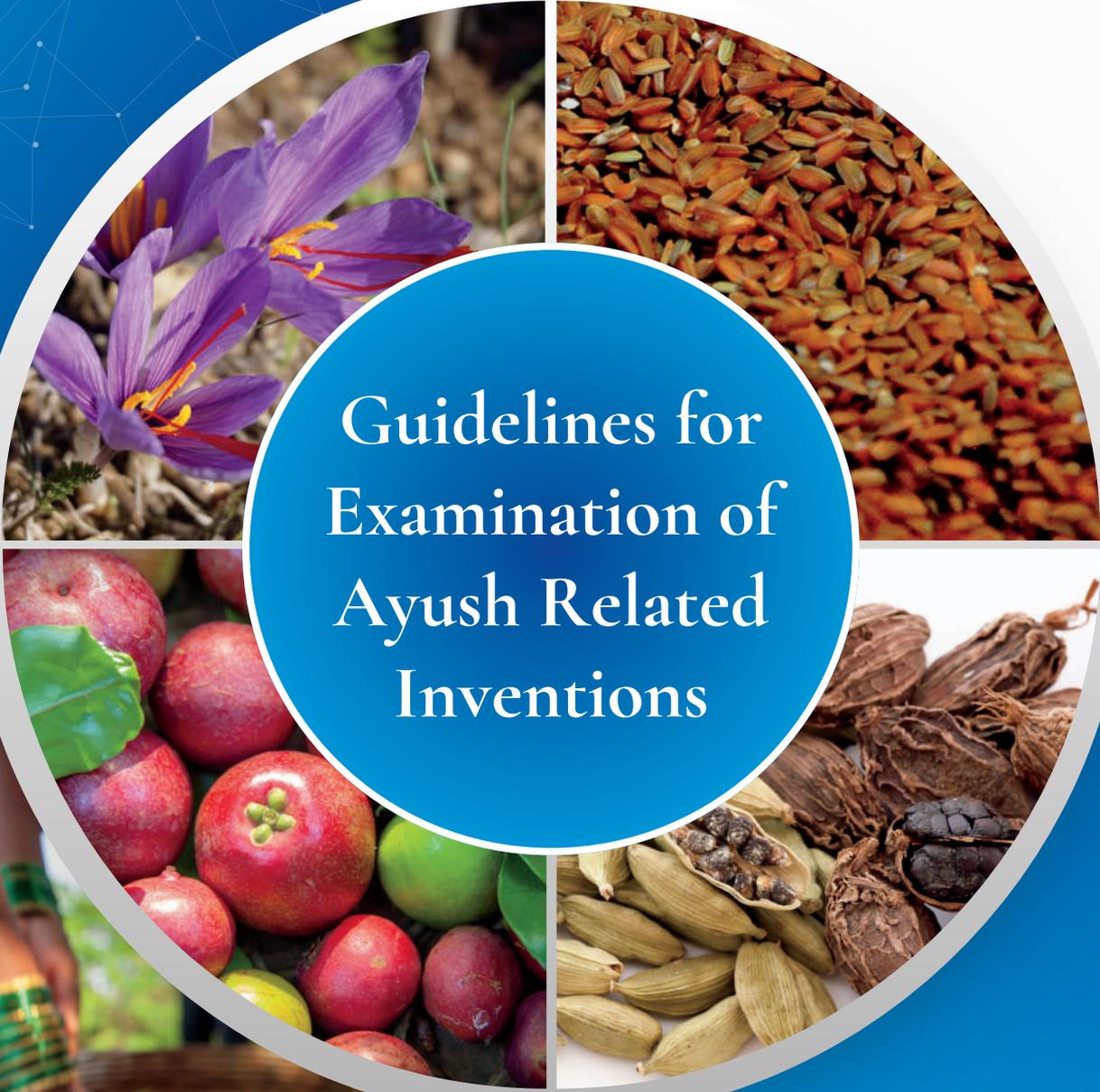




| 2025



Guidelines for
Examination of
Ayush Related
Inventions

Office of the Controller General of
Patents, Designs and Trade Marks





Smart Wearable device and method for estimating traditional medicine system parameters

Applicant: AYUR.AI (OPC) PRIVATE LIMITED
Patent No: 416499, Date of Grant: 02/01/2023
inventor: BALA PESALA

Integrative system and method for performing medical Diagnosis using Artificial Intelligence

Applicant: Ayur.AI (OPC) Private Limited
Patent No.: 429737, Date of Grant: 24/04/2023
Inventor: Balasubrahmanyam Pesala



Herbal cigarette and process of preparation thereof

Applicant: RAJAS UDAY NITSURE, UDAY ANANT NITSURE
Patent No: 379565, Date of Grant: 21/10/2021
Inventor: Rajas Uday Nitsure, Uday Anant Nitsure

Vaginal douche composition based on herbal extracts

Applicant: VEE EXCEL DRUGS & PHARMACEUTICALS PVT. LTD.
Patent No: 377408, Date of Grant: 21/09/2021
Inventor: Bansal Vipin, Kushwaha Ashok Kumar



Herbal incense formulation

Applicant: GLOBAL CONSUMER PRODUCTS LIMITED
Patent No: 421133, Date of Grant: 10/02/2023
Inventor: Ashish Bhobe, Sridhar Srinivasan, Pavana Nair, Jitendra Pandeyji

Herbal sanitary pad

Applicant: Poonam Bhatt
Patent No: 436895, Date of Grant: 03/07/2023
Inventor: Poonam Bhatt, Krishi Bhatt



Herbal soap

Applicant: Khumujam Jina
Patent No: 319506, Date of Grant: 30/08/2019
Inventor: Khumujam Jina



सत्यमेव जयते

Guidelines for Examination of Ayush Related Inventions



Office of the Controller General of Patents, Designs and Trade Marks
Department for Promotion of Industry and Internal Trade
Ministry of Commerce and Industry
Government of India

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1. Introduction

Ayush is traditional and non-conventional systems of healthcare and healing including Ayurveda, Siddha, Unani, Sowa-Rigpa, Homoeopathy and Yoga & Naturopathy. The scope of these guidelines covers inventions related to Ayush systems of healthcare and other codified/non codified system of Ayush related invention.

India is rich in traditional medicinal bio-resources and possesses centuries old associated traditional knowledge. The traditional medicinal systems are well established, and further undergoing state of the art research resulting in new products/processes. These guidelines are intended to provide clarity to the filing and processing of patent applications claiming Ayush related inventions. These guidelines are complementary to the already issued “Guidelines for processing of patent applications relating to traditional knowledge and biological material” by the Indian Patent Office in 2012 and are more focused on providing guidance to Ayush stakeholders regarding filing and examination of patent applications on Ayush related inventions.

Ayush related inventions include areas such as –

- Ayush product(s) and Equipment(s) / Device(s)
- Value added products related to Food recipes/ Nutraceuticals based on Ayush systems

Thus, the inventions claiming above said scope of research can be granted IP protection subject to fulfilment of the provisions related to patentability under the Patents Act 1970 (as amended) and corresponding rules as notified thereunder.

2. Legal Provisions

2.1 The Provisions and Procedure as per the Patents Act, 1970 (as amended) and the Patents Rules 2003 (as amended):

The following sections of the Patents Act, 1970 are emphasized in the context of examination of applications based on Ayush related inventions:

S. No.	Sections of the Patents Act, 1970	Details
1.	Section 2	Section 2(1)(ac): "capable of industrial application", in relation

		<p>to an invention, means that the invention is capable of being made or used in an industry;</p> <p>Section 2(1)(j): "invention" means a new product or process involving an inventive step and capable of industrial application;</p> <p>Section 2(1)(ja): "inventive step" means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art</p> <p>Section 2(1)(l): "new invention" means any invention or technology which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing of patent application with complete specification, i.e. the subject matter has not fallen in public domain or that it does not form part of the state of the art;</p>
2.	Section 3 (Inventions not patentable)	<p>Section 3(a): an invention which is frivolous or which claims anything obviously contrary to well established natural laws;</p> <p>Section 3(b): an invention the primary or intended use or commercial exploitation of which could be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment;</p> <p>Section 3(c): the mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living thing or non-living substance occurring in nature;</p> <p>Section 3(d): the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.</p> <p>Explanation.—For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and</p>

		<p>other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy;</p> <p>Section 3(e): a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance;</p> <p>Section 3(f): the mere arrangement or re-arrangement or duplication of known devices each functioning independently of one another in a known way</p> <p>Section 3(h): a method of agriculture or horticulture;</p> <p>Section 3(i): any process for the medicinal, surgical, curative, prophylactic diagnostic, therapeutic or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products.</p> <p>Section 3(j): plants and animals in whole or any part thereof other than micro- organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals;</p> <p>Section 3(k): a mathematical or business method or a computer programme per se or algorithms;</p> <p>Section 3(p): an invention which in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components.</p>
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2.2 Additional information related to Biological Diversity Act, 2002 for the applicants:

In addition to the requirements under the Patents Act, 1970 and the rules thereunder, the applicants are also required to abide with the provisions of the Biological Diversity Act, 2002 and rules thereunder for applications for patents for inventions based on biological resources, in particular the Section 6 of the Biological Diversity Act, 2002 and the rules thereunder.

2.3 Implications for non- disclosure or wrong mention of the source or geographical origin of biological material under the Patents Act, 1970:

Applications for patents based on TK and/or biological material can be refused under section 15 if not complying with the provisions of the Patents Act or as an outcome of pre-grant opposition under Section 25(1), and granted patents can be revoked in post-grant opposition under Section 25(2) of the Patents Act, 1970. Granted patents may be revoked under Section 64(1) as well.

Non-disclosure or wrong mention of the source or geographical origin of biological material used in an invention in the complete specification is one among the grounds for pre- and post- grant oppositions as well as revocation under Sections 25(1), 25(2) and 64(1) respectively of the Patents Act, 1970.

3. Guidelines to offer understanding on processing of patent applications of Ayush related invention(s):

3.1 Filing of patent application:

- An application for a patent for an invention may be made by any of the following persons either alone or jointly with any other person:
 - True and first inventor
 - True and first inventor's assignee
 - Legal representative of any deceased true and first inventor or his/her assignee
- A patent application can be submitted through online or physical mode at four locations of Indian Patent Office viz. Kolkata, Delhi, Chennai and Mumbai.
- For more details, "Manual of Patent Office Practice And Procedure" may be referred (available at https://ipindia.gov.in/writereaddata/Portal/Images/pdf/Manual_for_Patent_Office_Practice_and_Procedure_.pdf)

3.2 Screening and classification:

All inventions including those relating to Ayush systems are screened into different subjects and also assigned patent classification codes. The patent applications are published after 18 months, or earlier if requested by the applicant for early publication.

3.3 Examination:

The invention should qualify the patentability criteria of novelty, inventive step (non-obviousness) and industrial applicability as per the provisions of the Patent Act 1970

(as amended) and The Patent Rules 2003 (as amended). The Patent office conducts prior art search to evaluate the novelty and inventive step using the Traditional Knowledge Digital Library (TKDL) which allows search on Indian Systems of Medicines like Ayurveda, Siddha, Unani and Sowa-Rigpa as well as Yoga and other available databases. List of some databases to be referred for Ayush systems and traditional knowledge is given in Annexure-I.

3.4 Guiding principles for assessment of patent applications:

The different types of Ayush related inventions that are commonly received by the Indian Patent office have been compiled and the principles that may be adopted for evaluation of patentability in different categories have been listed as guiding principles 1-6 that are presented below. These are not exhaustive to cover all possible scope of inventions related to Ayush but considering the fact that each invention being unique, the patentability of each application will depend on the individual merit of the invention examined as per the provisions of the Patent Act 1970 (as amended) and the Patent Rules 2003 (as amended).

<p>Guiding Principle 1</p>	<p>If the claims are for extracts/alkaloids and/or isolated active ingredients of plants, which are naturally/inherently present in plants, such claims cannot be considered as novel and/or inventive when use of such plants is known in prior art. However, processes for obtaining such extracts/isolates may be considered patentable, subject to the requirements of patentability.</p>
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When the subject-matter of claimed invention is referring to extracts of plant materials as product claims containing undefined active ingredients, such claims cannot be said to be novel if the use of such plants or specific plant part is known / published prior art in Ayush systems.

Further, if the claimed invention refers to alkaloids and/or active principles obtained from the plants or specific plant part, and structures of the said alkaloids and/or active principles are characterized and claimed as product, which do not form part of the prior art, such claims cannot be said to involve an inventive step if adequate human intellect is not involved in deriving the said product beyond the reported use in the literature, if the use of said plant materials and their therapeutic effects are known / reported in Ayush systems.

Thus, it is considered that the prior art motivates the person skilled in the art to isolate the individual ingredients such as alkaloids, flavonoids, phyto-steroids, etc.

Illustration 1: The claims relate to an aqueous extract of *Withania somnifera* plant for the management of stress.

Prior art: Discloses use of Ashwagandha (*Withania somnifera*) for the treatment of stress related disorders in Ayurveda and Unani systems of medicine.

Analysis: The claims of alleged invention relate to an extract of *Withania somnifera* plant. Based on the prior art, it can be objected that the aqueous extract of *Withania somnifera* would be useful in treatment of chronic stress disorders such as insomnia, gastric ulcers, hyperacidity, restlessness and depression. Therefore, the subject-matter of claims is not considered as novel over the description in Ayush systems.

Illustration 2: The claims relate to glycoside, Chamaemeloside, derived from Roman or German chamomile for the treatment of Cancer, Diabetes mellitus, Arthritis, Acne vulgaris, Eczema and for wound healing.

Prior art: Discloses use of German chamomile (from which Chamaemeloside is derived) in wound healing and for the treatment of cancer, diabetes mellitus, arthritis, acne vulgaris and eczema in Ayurveda and Unani systems of medicine. The prior art does not disclose the Chamaemeloside.

Analysis: The claims of alleged invention relate to Chamaemeloside derived from Roman or German chamomile. Based on the prior art, it can be objected that German or Roman chamomile (from which Chamaemeloside is derived) has already been used alone or in combination with other ingredients for afore-mentioned indications and therefore, the prior art motivates the person skilled in the art to isolate and identify the active ingredient such as Chamaemeloside, which has the same therapeutic effects. Hence, the product arrived at by isolation and characterization cannot be considered to involve an inventive step in the light of prior art. However, the process of isolation (which is not claimed in this illustration) could have been considered as inventive and patentable, subject to the patentability criteria. The fact that a product claim is not patentable due to existence of prior art does not necessarily mean that a process for isolation of the product is not patentable. Such processes could be patentable if they satisfy the provisions of the Patents Act.

Illustration 3: The claims relate to process for the extraction of berberine from leaves of *Cosciniium fenestratum*, wherein an improved yield of berberine is obtained.

Prior art: The process of isolation of berberine from stem is disclosed in the prior art.

Analysis: In the process as disclosed in this invention, the yield of berberine per gram of leaves and the purity of berberine obtained is significantly higher as compared to the prior art. Further, the present invention uses low temperature and minimum chemicals to obtain high purity berberine, which is not disclosed in the prior art. Thus the process could be patentable.

Guiding Principle 2	In case a combination of ingredients from plants/minerals/animal origin/ existing formulations is already known for the treatment of a disease as a part of Traditional Knowledge, a combination product comprising these known ingredients with further ingredients from plants/minerals/animal origin/ existing formulations with the same known therapeutic effect would obviously be more effective than each of the ingredient when applied separately (additive effect). However, specific ratios leading to unexpected technical effect of such combinations may be considered to establish non-obviousness.
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Illustration 1: The claims relate to a composition comprising of *Calendula officinalis*, *Aloe vera* and *Centella asiatica* as healing agent and for treatment of wound.

Prior art: Discloses independent use of *Calendula officinalis*, *Aloe vera* and *Centella asiatica* for the treatment of wound and as a Cicatrizant/ healing agent in Ayurveda and Unani systems of medicine.

Analysis: The claims of alleged invention were for a composition. Based on the prior art, the combination of these plants would be obvious for the treatment of skin diseases and healing of wounds. The combination of a plant with a known therapeutic effect with further plants with the same known therapeutic effect, wherein all plants are previously known for treating the same disease is considered to be an obvious combination. It would normally be expected that such combinations of medicinal plants would be more effective than each of the medicinal plants when applied separately (additive effect). However, if such combination demonstrates unexpected synergistic effect, it may be considered to establish non-obviousness.

(Note- “Synergism” is the interaction of two or more substances to produce a combined effect greater than the sum of their individual effects. Experimental results should prove that the combined action of all the given ingredients is greater than the sum of their individual

effects. A brief about synergism along with illustrations on synergistic data is given at Annexure II).

Illustration 2: The claims relate to synergistic anti-acne topical composition comprising of extracts of *Symplocos racemose* 0.5 gm, *Salmalia malabarica* 0.5 gm, *Picrorhiza kurroa* 0.5 gm, *Vitex negundo* 0.5 gm, *Embelia ribes* 3 gm, *Terminalia chebula* 3 gm, and *Terminalia bellerica* 2 gm.

Prior art: Discloses formulations comprising one or more of the ingredients selected from *Symplocos racemosa*, *Salmalia malabarica*, *Picrorhiza kurroa*, *Vitex negundo*, *Embelia ribes*, *Terminalia chebula*, and *Terminalia bellerica* for different uses including skin disorders.

Analysis: The cited prior art, though disclosing the different ingredients recited in the claims for the treatment of the same indication, do not disclose the exact combination of the ingredients in the claimed ratio. In view of the synergistic data provided in the description, the inventive step could be established distinguishing the invention from the prior art.

Guiding Principle 3	In case an ingredient is already known for the treatment of a disease, then it creates a presumption of obviousness that a combination product comprising this known ingredient would be effective for the treatment of the same disease. However, unexpected technical effect of such combinations may be considered to establish non-obviousness.
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Illustration 1: The claims relate to a combination of two constituents of watery extract of *Cucumis melo*, along with *Citrus aurantifolia*, for the treatment of vitiligo.

Prior art: Discloses usefulness of only one of the constituents, watery extract of *Cucumis melo* for its anti-vitiligo property in the Unani system of medicine.

Analysis: The claim of alleged invention relates to a composition comprising two constituents and not on a single constituent, the watery extract *Cucumis melo* for its anti-vitiligo property. Based on said cited documents, it can be objected that if one ingredient here, *Cucumis melo*, was already known for the treatment of vitiligo, then it is necessarily expected that a combination comprising this known active ingredient must be effective for treating vitiligo. As long as no unexpected technical effect of the claimed combination vis-a-vis the already known product comprising *Cucumis melo*, is established, inventive step cannot be acknowledged.

Illustration 2: The claims relate to a combination of three constituents containing Maghz-e-Karanjwa (*Caesalpinia bonduc* Tinn.), Gaozaban (*Onsoma bracteatum* Wall.) and Kasni (*Cinchorium intybus*) for the treatment of worm infestation and anemia.

Prior art: Maghz-e-Karanjwa (*Caesalpinia bonduc* Tinn.) is already known for the treatment for worm infestation only.

Analysis: The combination of three constituents has shown unexpected and synergistic effect in the treatment of worm infestation and anemia. In view of the data provided in respect of unexpected and synergistic effect, the inventive step may be considered for acknowledging patentability.

Guiding Principle 4	Discovering the Optimum or Workable range of traditionally known ingredients by routine experimentation may be considered inventive only if it is not obvious to the person skilled in the art.
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In case of inventions relating to selection of optimum or workable range of ingredients, such selection of a particular range of known ingredients is not inventive since the selection of optimum or workable range is generally considered to be well within the expectation of the person skilled in the art.

Illustration 1: The claims relate to a formulation comprising at least two of the following: an extract of *Pongamia pinnata* (in the range of 2 to 20%), an extract of *Lawsonia alba* (in the range of 5 to 15%), an extract of *Dhatura alba* (in the range of 2 to 20%) and an extract of *Cocos nucifera* (in the range of 20 to 60%) for the management of chronic ulcer, diabetes ulcer, and the management of bleeding in cuts and wounds.

Prior art: Discloses use of said plants for the treatment of ulcer/wound in Ayurveda, Unani and Siddha systems of medicine.

Analysis: The claims of alleged invention relate to a composition comprising plant parts in a specified ratio. The claims can be objected as not patentable in so far as the alleged invention is obvious over *Agasthiyar* (TK) which taught a composition of extracts of two of the claimed plants, *Karanj* and *Henna* formulated as oil for topical treatment of ulcers and wounds. Although, cited art does not specifically teach adding the ingredients in the percentages claimed by the applicant, the amount of specific ingredient in a composition is clearly a result affecting variable, which a person skilled in the art would routinely optimize.

Guiding Principle 5	In case a multi-ingredient formulation is known to have a specific therapeutic activity as per the prior art, merely selecting one or more ingredient for the same said therapeutic activity cannot be considered as inventive.
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Illustration 1: The claims relate to an extract of *Zingiber zerumbet* (bitter ginger) for inflammation and also for allergic disorder like Asthma.

Prior art: Discloses use of *Zingiber zerumbet* (bitter ginger) along with few other ingredients for the treatment of inflammation and Asthma in Unani system of medicine.

Analysis: The claims of alleged invention relate to an extract of *Zingiber zerumbet*. As per the prior art disclosure, the multi-component formulation comprising *Zingiber zerumbet* has the same therapeutic activity (i.e. anti-bronchial asthmatic), and therefore it is obvious that one single component namely *Zingiber zerumbet* taken out of them would have the same therapeutic activity. Hence, the person skilled in the art would have been motivated to arrive at the invention and thus, the claims of alleged invention can be objected for lacking inventive step.

Guiding Principle 6	If the subject matter of the claims relates to inventions regarding equipment / device used for known procedure in Ayush systems or related fields, then such inventions may be patentable if the claims qualify the patentability criteria as per the provisions of the Act.
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Illustration 1: Advanced automated system or device for Therapeutic Emesis (*Vamana Karma*) comprising a frame holding primary and secondary sinks connected with sensing elements for pH, temperature, weight, volume & a display unit along with vomitus collecting bag and its method for fabrication.

Prior art: Procedure for performing *Vamana Karma* is disclosed in Ayurveda but it does not disclose any device along with sensors, for doing such procedure.

Analysis: The claims relate to advanced automated system or device for Therapeutic Emesis (*Vamana Karma*) and its method for fabrication. As per the prior art (Ayurveda), the procedure for performing *Vamana Karma* is well documented however, an automated device for conducting *Vaman Karma*, comprising pH, temperature, and volume sensors for analyzing the vomitus and hygienically conducting the said *karma* was not known and can be considered patentable.

List of some databases and relevant Acts to be referred for Ayush systems and related inventions:

1. Ayush Research Portal (<https://ayushportal.nic.in>)
2. Database of Ayurvedic, Unani, Siddha and Sowaigpa Formulations (<https://www.tkd.res.in>)
3. Foundation for Revitalisation of Local Health Traditions (FRLHT) Indian Medicinal Plant Database (<https://www.medicinalplants.in>)
4. e-Charak portal has been jointly developed by the National Medicinal Plants Board (NMPB), Ministry of Ayush, Government of India and Centre for Development of Advanced Computing (C-DAC) (<https://echarak.in/echarak/main.do>). It is an e-Channel for Herbs, Aromatic, Raw material and Knowledge and a platform to enable information exchange between various stakeholders involved in the medicinal plants sector.
5. Tribal Digital Document Repository by Ministry of Tribal Affairs, Govt. of India. (<https://repository.tribal.gov.in>)
6. The Biological Diversity (Amendment) Act, 2023, <https://egazette.gov.in/WriteReadData/2023/247815.pdf>
7. The Patent Act, 1970. <https://ipindia.gov.in/writereaddata/Portal/ev/sections-index.html>
8. The Patent Rules, 2003. <https://ipindia.gov.in/writereaddata/Portal/ev/rules-index.html>

Brief about synergism along with illustrations on synergistic data.

Section 3(e) precludes patenting of "a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance". In order to assess whether the invention falls under Section 3(e), it is examined whether there is synergistic effect of claimed composition which is more than the combined effect of each component of the composition when used individually.

Synergism is the interaction of two or more substances to produce a combined effect greater than the sum of their individual effects. The Guidelines for examination of patent applications in the field of Pharmaceuticals provides insight that "if the functional interaction between the features achieves a combined technical effect which is greater than the sum of the technical effects of the individual features, it indicates that such a composition is more than a mere aggregation of the features" and does not fall within the ambit of mere aggregation of features. Some illustrations demonstrating the assessment of presence of synergism are as follows:

Illustration 1: Patent application claims relate to a composition comprising tamarind seed polysaccharide (TSP) in combination with an extract of *Helichrysum italicum*. The treatment with TSP according to the said patent application is effective in stimulating the antimicrobial response, especially when administered topically to the skin and to the mucosa.

Analysis: The claims of alleged invention relate to a composition of two active ingredients, namely tamarind seed polysaccharide and extract of *Helichrysum italicum*. The complete specification contained the following experimental data regarding the expression of beta defensin by normal human epidermal keratinocyte. Beta defensin are host defense peptides having the ability to kill a broad range of microorganisms including bacteria, yeast and viruses.

Products	Concentration	DEFB2 expression (pg/ml)
Negative ref. (control)	-	0
Positive ref. (LPS)	5 mcg/ml	12
Tamarind Seed Polysaccharide (TSP)	0.2%	40*
<i>Helichrysum italicum</i> extract (HIE)	0.2%	21
HIE + TSP	0.2% + 0.2%	140*

*p < 0.001 vs. control

It is apparent from the table that the combined effect of *Helichrysum italicum* extract and

Tamarind Seed Polysaccharide (140 pg/ml) is higher than the sum of their individual effects (40 pg/ml + 21 pg/ml), thereby indicating synergism between them.

Illustration 2: Patent application claims relate to a composition comprising *Vaccinium myrtillus* extract and *Echinacea sp.* extract.

Analysis: The claims of alleged invention relate to a composition of two active ingredients, namely *Vaccinium myrtillus* extract and *Echinacea sp.* extract. The complete specification contained the following experimental data regarding the re-epithelialisation of ulcers by the use of *Vaccinium myrtillus* extract and *Echinacea sp.* extract, when used individually and in combination.

Treatment	Re-epithelialisation		
	7 days	14 days	28 days
Placebo	0.02 +/- 0.01	0.01 +/- 0.01	0.03 +/- 0.02
<i>Vaccinium myrtillus</i> 0.3%	0.10 +/- 0.03	0.23 +/- 0.13*	0.50 +/- 0.23*
<i>Echinacea sp.</i> extract 0.3%	0.01 +/- 0.01	0.20 +/- 0.02*	0.35 +/- 0.02*
<i>Vaccinium myrtillus</i> 0.3% + <i>Echinacea sp.</i> extract 0.3%	2.14 +/- 0.73**	4.9 +/- 1.01**	8.30 +/- 1.10**

*P<0.05;

**P<0.001 Student's "t" test

The provided data clearly demonstrates that the re-epithelialisation achieved using the composition comprising *Vaccinium myrtillus* and *Echinacea sp.* extract is much higher than the sum of re-epithelialisation achieved when these two ingredients are used individually, indicating a synergistic effect between them.

Illustration 3: Patent application claims relate to a composition comprising extract of *Andrographis paniculata* and *Ginkgo biloba* extract for the treatment of neurodegenerative disorders.

Analysis: The claims of alleged invention relate to a composition of two active ingredients, namely extract of *Andrographis paniculata* and *Ginkgo biloba* extract. The complete specification contains the following experimental data regarding the comparative effect of the claimed composition and its components when used individually, on Experimental Autoimmune Encephalomyelitis (EAE) in 20 transgenic mice. Clinical signs of the disease are recorded daily on the basis of the following scores:

0 : no signs of EAE

- 1: limp tail
- 2: weakness of hind legs or abnormal gait
- 3: complete paralysis of hind legs
- 4: complete paralysis of hind and fore legs
- 5: death

The mean clinical data are calculated by adding the daily scores of the mice belonging to the same treatment group and dividing by the number of mice.

Group	Incidence	Score (Maximum)	Average of Maximum Scores
Control	20/20 (100%)	5	3.9 +/- 0.1
<i>Andrographis paniculata</i> extract	7/20 (35%)	4	2.9 +/- 0.1*
<i>Ginkgo biloba</i> extract	4/20 (20%)	5	3.3 +/- 0.1
<i>Andrographis paniculata</i> extract + <i>Ginkgo biloba</i> extract	12/20 (60%)	2	2.2 +/- 0.1**

* p<0.05 Student's t-test

** p<0.01 vs. control

Based on the data provided in the above given table, the combination of *Andrographis paniculata* extract and *Ginkgo biloba* extract exhibits no incidence of death and much lower maximum scores indicating less severe clinical signs of disease compared to the scores achieved using *Andrographis paniculata* extract and *Ginkgo biloba* extract when used individually, thereby indicating the presence of synergism between the two components.

Disclaimer: These guidelines provide guidance for the situations that are commonly encountered in TK and Ayush related inventions and are not exhaustive to cover all aspects of patentability. Each application will be decided based on the individual merits of the invention. The guidelines are subject to revision from time to time based on interpretations by a Court of Law, statutory amendments and valuable inputs from the stakeholders.



A novel antimicrobial polyherbal composition

Applicant: The Talwar Research Foundation
Patent No: 282906, Date of Grant: 05/05/2017
Inventor: Gursaran Talwar, Mahendra Rai, Kavita Bansal



Improved process for pygeum extraction

Applicant: Goel Pawan Kumar
Patent No: 389375, Date of Grant: 15/02/2022
Inventor: Tewari Kiran, Sharma Ashok

Moringa oleifera based complete feed for goats: chemical composition, production protocol & goat productivity thereof

Applicant: Indian Council of Agricultural Research (ICAR)
Patent No: 412627, Date of Grant: 28/11/2022
Inventor: U. B. Chaudhary, Giriraj Singh

Synergistic herbal hair growth formulation for alopecia

Applicant: 1. H.N.B. GARHWAL UNIVERSITY SRINAGAR (GARHWAL) (A CENTRAL UNIVERSITY), 2. MONA SEMALTY, 3. AJAY SEMALTY, 4. TEJ PRAKASH SEVAK, 5. YUVERAJ SINGH TANWAR, 6. MOHAN SINGH MANIYARI RAWAT
Patent No: 426371, Date of Grant: 22/03/2023
Inventor: Mona Semalty, Ajay Semalty, Tej Sevak, Yuveraj Tanwar, Mohan Rawat

A polyherbal composition and process for preparing the same

Applicant: Dr Ankita Wal & Dr Pranay Wal
Patent No: 442819, Date of Grant: 03/08/2023
Inventor: Dr Ankita Wal, Dr. Abdul Samad, Mohd Nazam Ansari, Dr. Amita Verma, Dr. Mohd Masih Uzzaman Khan, Shahnawaz Sameem, Dhaneshwar Kumar, Somesh Shukla

A herbal based repellent for termites on woody trees

Applicant: Indian Council of Agricultural Research (ICAR)
Patent No: 535555, Date of Grant: 29/04/2024
Inventor: Dr. Abraham Verghese, Dr. T.N. Shivananda, Dr. N. Bakthavatsalam

Herbal composition and ingestable capsule containing the same for accelerated healing and reunion of fractured bones

Applicant: MAHAVIR JAYKUMARJI SHAH
Patent No: 342423, Date of Grant: 24/07/2020
Inventor: Mahavir Jaykumarji Shah

Oat milk based instant soluble (effervescent)

Tea tablets and a method for its production
Applicant: INDIAN INSTITUTE OF TECHNOLOGY, KHARAGPUR
Patent No: 493669, Date of Grant: 03/01/2024
Inventors: Dr. Hari Mishra, Sunil Behra, Aastha Deora



Brief on AYUSH-64

The CCRAS, an apex body for R&D in Ayurveda under the Ministry of Ayush, Govt. of India developed a poly-herbal anti-malarial drug 'AYUSH-64' in 1980 through extensive pharmacological, toxicological and clinical studies. It has been patented by the Central Council for Research in Ayurvedic Sciences CCRAS through National Research and Development Corporation, New Delhi. Its efficacy and safety has already been proven in infective febrile conditions such as malaria, microfilaremia, chikungunya, and flu-like illness. It was repurposed for COVID-19 based on the recommendations of Interdisciplinary Ayush R & D Task Force. A molecular docking study conducted at ICMR-NIN, Hyderabad that revealed 35 phytoconstituents isolated from AYUSH-64 demonstrated anti-viral activity against SARS-CoV-2.