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Evaluation and standarisation of Shatavaryadi Churna

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Abstract--Introduction-The Ayurvedic medical system has recently got a lot of medical and healthcare services in India. To evaluate the

quality, safety, and effectiveness of the medicine, standards and purity of herbal formulation are crucial. However, pharmacopoeia testing is the protocol that all medicines must follow in order to be accepted globally. A compound herbal formulation called *Shatavaryadi Churna* is suggested for the treatment of a number of diseases. For the treatment of *Timira Vyadhi*, *patal vyadhi*, *kancha vyadhi* and many other *raktaj vikara* the formulation was documented in the Ayurvedic classic *Yoga Ratnakar*. Materials & methods- *Shatavaryadi Churna* was made by using the standard procedure with all aseptic precautions and as described in the Ayurvedic Pharmacopoeia for *Churna Kalpana* (Powder Preparation). The manufactured medication has been standardised by adhering to the approved pharmacopoeial protocol for quality control procedures. Results- Organoleptic parameters, physiochemical evaluation, and microbiological load test was done these analytical values were within the expected limits.

Keywords---evaluation, standardisation, Shatavaryadi Churna.

Introduction

According to the World Health Organization (WHO) 70–95 percent of the world's population, especially in developing nations, uses traditional, complementary, alternative, or non-conventional medicines for their healthcare,. Additionally, the usage of herbal remedies has significantly expanded in accordance with the global trend of people going back to natural cures. The public's increasing usage of botanicals (drugs and other items derived from plants) is driving efforts to evaluate the medicinal value of these agents and create manufacturing and quality standards. The process of prescribing a set of standards or intrinsic properties, constant parameters, and clear qualitative and quantitative values that carry an assurance of quality, efficacy, and safety is known as drug analysis. An herbal product cannot be considered scientifically valid if the drug tested has not been authenticated and characterized in order to ensure reproducibility in the processing of the formulation. In this background, drug analysis is an essential step for the establishment of consistent biological activity, a consistent chemical profile, or simply a quality assurance program for the production and manufacturing of an herbal drug.¹ Shatavaryadi Churna has six contents viz *Shatavari* (Asparagus), *Ela* (Cardamom), *Amalaki* (Emblicmyrobalan), *Vidang* (False black pepper), *Maricha* (Black pepper), *Pippali* (Indian long pepper). Collectively, it consists primarily of *Madhura* (50%)², *Katu* (33%)³ *Rasa*(Taste), *Ruksha* (29%)⁴, *Laghu* (22%) *Gunas*⁵ (Ayurvedic pharmacological parameters), *SheetaVirya* (67%)⁶ and *Madhura Vipaka* (67%)⁷. All six ingredients have got *Balya* (strength improver)^{[8] [9] [10] [11] [12] [13]} and *Rasayan* (Rejuvenator) properties. Out of six drugs *Shatavari*¹⁴ have got *Chakshushya*, is brain tonic-gives energy to brain and nerve, enhance digestion, Cardio tonic, fetal tonic.

*Amalaki*¹⁵ is *rasayana* and have got *Chakshushya* (Vision improver) effect, strengthens nervous system, bone marrow & sense organ. Improves taste & appetite, *Deepana- Pachana* property useful in all skin disorder. *Ela*¹⁶ *Deepana- Pachana* property Urinary system: Seeds are diuretic, *Pippali*¹⁷ is a brain tonic

and alleviates *vata*. It is *tikshna* and acts on the *rakta dhatu*, Marich¹⁸ is *ushna*, anti-inflammatory, and scraping agent. On Respiratory system- acts on *pranavaha strotas* & reduce the mucosa secretion. It also stimulates the action of other drugs due to its strength. It opens up all the *strotas*, opening up even the narrow channels, with removal of even the deep rooted *kapha dosha*. Vidang¹⁹ It is a nervine tonic. have got *Deepana- Pachana- anuloman*, Circulator system: It is useful in diseases due to blood impurities and in diseases caused by vitiation of *meda*. It purifies blood by optimizing its *agni* and is very useful in disorders of *rasa dhatu* and oedema. Diuretic. *Satmikaran: Vidang* is the greatest *rasayan dravya*. It reduces the rigidity of the body, improves circulation, texture of the skin.

Materials and Methods

Shatavaryadi churna

Process of Drug Preparation:[20]

Identification and Collection of drug

All the drugs were procured from the Abhyankar Ayurvedic Products Pvt. Ltd. Pharmacy, Jambhulpada, Tal. Sudhagad, Dist. Raigad Maharashtra in crude form and were identified by the same. Pharmacognostical authentication of all the raw drugs was done based on the morphological features, organoleptic characters.

Contains of *shatavaryadi churna* :- [21]

Dravya	Latin name	Family	Proportion	Part used
Shatavari	Asparagus racemosus	Liliaceae	12parts	Roots
Elabeej	Elettaria cardamomum	Zingiberaceae	10parts	Seeds
Vidang	Embelia ribes	Myrsinaceae	8parts	Seeds
Amlaki	Emblica officinalis	Euphorbiaceae	6parts	Fruit pulp
Marich	Piper longum	Piperaceae	4parts	Seeds
Pipali	Piper longum	Piperaceae	3parts	Fruit

Table 1: Contents of Shatavaryadi Churna

Process of formulation:-

All the raw drugs were dried separately in try dryer except for *Ela*. *Ela* was kept under shaded portion for air-drying at 32°C to 35°C. The ingredients with the botanical source and parts used are mentioned above. Then dried drugs were disintegrated by the disintegrator separately in aseptic conditions. After that all the disintegrated drugs were then ground by the pulverizer. Then all the ground drugs were made to pass through the sieve separately. All the drugs were then thoroughly mixed together in the prescribed ratio to form a powder. This powder was made to pass through the 85 number sieves to get a fine powder, and the *Churna* was ready for use.

Analytical study

Prepared final formulation i.e. *Shatavaryadi Churna* was analyzed by employing various analytical parameters

Organoleptic characteristics for various sensory characters like appearance, color, taste, odor etc and were carefully noted down.

S. no.	Parameters	Result
1	Texture	Fine powder
2	Color	Greenish brown
3	Odor	Sweetest pungent
4	Taste	Sweet astringent

Table 2: Organoleptic study

Table 3: Physico-Chemical Parameters Of Shatavaryadi Churna (Individual drug)

A) Shatavari

Sr no.	Test parameter	Specification	Observation	Method reference
1	pH		5.9%	Visual
2	Total Ash	NMT 10%	6.317%	API
3	Acid Soluble Ash	NMT 2%	1.022%	API
4	Alcohol Soluble Extractive	NLT 8%	10.674%	API
5	Water Soluble Extractive	NLT 8%	10.328%	API

B) Amalaki

Sr no.	Test parameter	Specification	Observation	Method reference
1	pH		4.9%	Visual
2	Total Ash	NMT 7%	3.783%	API
3	Acid Soluble Ash	NMT 2%	0.538%	API
4	Alcohol Soluble Extractive	NLT 40%	51.769%	API
5	Water Soluble Extractive	NLT 50%	61.258%	API

C) Ela

Sr no.	Test parameter	Specification	Observation	Method reference
1	pH		6.5%	Visual
2	Vegetable oil content	NMT 4%	5.742%	API
3	Total Ash	NMT 6%	3.814%	API
4	Acid Soluble Ash	NMT 4%	1.643%	API
5	Alcohol Soluble Extractive	NLT 2%	3.876%	API
6	Water Soluble Extractive	NLT 10%	13.716%	API

D) Vidanga

Sr no.	Test parameter	Specification	Observation	Method reference
1	pH		7.3%	Visual
3	Total Ash	NMT 6%	3.537%	API
4	Acid Soluble Ash	NMT 1.5%	0.853%	API
5	Alcohol Soluble Extractive	NLT 10%	14.351%	API
6	Water Soluble Extractive	NLT 9%	12.853%	API

E) Marich

Sr no.	Test parameter	Specification	Observation	Method reference
1	pH		7.2%	Visual
2	Moisture content	NMT 3%	1.861%	API
3	Total Ash	NMT 7%	3.256%	API
4	Acid Soluble Ash	NMT 2%	1.148%	API
5	Alcohol Soluble Extractive	NLT 6%	8.962%	API
6	Water Soluble Extractive	NLT 6%	8.874%	API

F) Pippali

Sr no.	Test parameter	Specification	Observation	Method reference
1	pH		6.4%	Visual
2	Moisture content	NMT 3%	1.427%	API
3	Total Ash	NMT 7%	4.734%	API
4	Acid Soluble Ash	NMT 2%	1.488%	API
5	Alcohol Soluble Extractive	NLT 6%	8.058%	API
6	Water Soluble Extractive	NLT 6%	18.694%	API

Table 4: Microbial limit test of Shatavaryadi churna

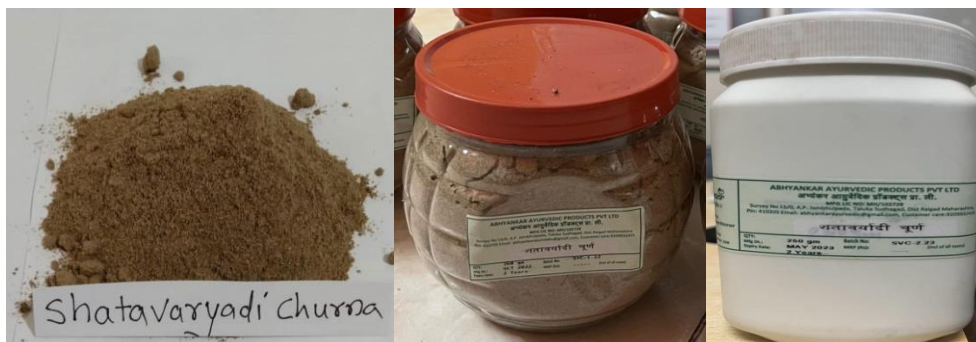
Sr No:	Name of drug	Microbial parameters	Results
1.	Shatavari Root	Total Bacterial count (NMT 100cfu/g) Yeast and mount (NMT 100 cfu/g) E.coli S.aureus P.aeruginosa Salmonella sp.	Complies Complies Absent Absent Absent Absent
2.	Ela Fruit	Total Bacterial count (NMT 100cfu/g)	Complies

		Yeast and mount (NMT 100 cfu/g) E.coli S.aureus P.aeruginosa Salmonella sp.	Complies Absent Absent Absent Absent
3.	Vidanga Fruit	Total Bacterial count (NMT 100cfu/g) Yeast and mount (NMT 100 cfu/g) E.coli S.aureus P.aeruginosa Salmonella sp.	Complies Complies Absent Absent Absent Absent
4.	Amalaki Fruit	Total Bacterial count (NMT 100cfu/g) Yeast and mount (NMT 100 cfu/g) E.coli S.aureus P.aeruginosa Salmonella sp.	Complies Complies Absent Absent Absent Absent
5.	Marich Fruit	Total Bacterial count (NMT 100cfu/g) Yeast and mount (NMT 100 cfu/g) E.coli S.aureus P.aeruginosa Salmonella sp.	Complies Complies Absent Absent Absent Absent
6.	Pippali Fruit	Total Bacterial count (NMT 100cfu/g) Yeast and mount (NMT 100 cfu/g) E.coli S.aureus P.aeruginosa Salmonella sp.	Complies Complies Absent Absent Absent Absent

Table 5:- Physico-Chemical Parameters Of *Shatavaryadi Churna*

Sr no.	Test parameter	Specification	Observation	Method reference
1	pH 5%		4.39%	Visual
2	Loss on drying	@ 110*c	3.32%	API
3	Total Ash	NMT 6%	7.97%	API
4	Acid Insoluble Ash	NMT 1.5%	0.003%	API
5	Alcohol Soluble Extractive	NLT 10%	25.13 %	API

6	Water Soluble Extractive	NLT 9%	36.03%	API
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pH Value ^[22] :- The pH value of an aqueous medium may be defined as the common logarithm of the reciprocal of the hydrogen ion concentration expressed in gram per liter. It was done by digital pH meter. The pH meter was stabilized for 15-30 min. Now the electrode has been immersed in a standard buffer solution of pH 4.0 and stabilized for 1 min. and reading was adjusted at pH 4.0. The electrode was rinsed and immersed in the sample.

Determination of total ash ^[23] : - 2gms of accurately weighed ground drug was incinerated in a tarred platinum or silica dish at a temperature not exceeding 450⁰ C until free from carbon. It was then cooled and weighed. By adding the filtrate, it was evaporated to dryness, and ignited at a temperature not exceeding 450⁰ C. The value of total ash is determined by calculating the percentage of ash with reference to the air-dried drug.

Acid insoluble ash ^[24] : - To the crucible containing total ash, 25ml of dil. HCl was added. The insoluble matter on an ash less filter paper was collected and washed with hot water. Filter paper containing the insoluble matter transferred to the original crucible dry on a hot plate and ignites to constant weight. The residue was allowed to cool in suitable desiccators for 30 minutes and weigh without delay. The content of acid insoluble ash was calculated with reference to the air-dried drug.

Determination of Alcohol Soluble Extractive ^[25] : - 5 gms of the air-dried drug coarsely powdered was macerate with 100 ml of alcohol of the specified strength in a closed flask for twenty-four hours, shaking frequently during six hours and allow it to stand for eighteen hours. After that it was filtered rapidly, taking precautions against loss of solvent. Now 25 ml of the filtrate was evaporated to dryness in a tarred flat bottomed shallow dish, and allow drying at 105⁰C to constant weight and weigh. The percentage of alcohol soluble extractive was calculated with reference to the air-dried drug.

Water soluble extractive ^[26] : - 5 gms of the air-dried coarsely powdered air dried drug was macerate with 100 ml of distilled water in a closed flask for twenty-four hours, shaking frequently during six hours and allowing it to stand for eighteen hours. After that, it was filtered, taking precautions against loss of water. Then 25

ml of the filtrate was evaporated to dryness in a tarred flat bottomed shallow dish and dry at 105°C, to constant weight and weigh. The percentage of water soluble extractive was calculated with reference to the air-dried drug.

Microbial Examination [27] :- The development of microbiology as a scientific discipline dates from Lewis Pasteur (1822-55). The microbial test is designed to perform the qualitative estimation of specific viable microorganism present in the samples. This test is used for the estimation of the number of the viable aerobic microorganisms present and for detecting the presence of designated microbial species in the sample. The test provides a determination of whether the drug harbor designated microbial species that are pathogenic in nature.

TLC Profile:- attached in.

Result

Basic physicochemical parameters were observed to be within the prescribed limit as per *Churna kalpana* provided by Ayurvedic Pharmacopia of India(API).

pH value :- The pH results indicate that the 5% (w/v) aqueous solutions of each material were slightly acidic in composition(ph- 4.39). The finished product's acidic pH could be caused by acidic phytochemicals contained in the formulation. The metabolism and absorption of *Churna* is likely to get starts from the oral cavity and a significant quantity may get metabolized, and absorbed from upper GIT. The mouth cavity's acidic environment helps keep the *Churna's* natural ingredients intact. The mildly acidic nature of *Churna* favours digestion.

Total Ash value:- Ash value depends upon the total inorganic substance present in a particular drug; this parameter has importance in quality control and standardization of the drugs. The Total Ash value was 7.97%.This suggests that just about 5% of the *Churna* samples are inorganic and that the majority of the samples are approximately 95% organic. The formulation is more bio-absorbable to human biological systems when it has more organic character.

Acid soluble ash: - The formulation's 0.003%(w/v) acid insoluble ash value suggests that less Churna was absorbed by the oral mucosa. The majority of drugs are acid soluble, making them better absorbed in acidic conditions, i.e., gastric fluids. As a result, the formulation had a very high bioavailability.

Water soluble extractive: - The evaluation of unprocessed medicines heavily relies on water soluble extractives. The addition of hazardous substances, adulteration, improper processing during drying, storage, or formulation are all indicated by a lower extractive value. The value of the water-soluble extractive in the current formulation was 36.03%(w/v), which is quite high than the value of the alcohol-soluble extractive 34.5%(w/v). Comparatively more value suggests that the unadulterated crude medications are more likely to dissolve in the upper GIT, which is the optimum setting for subsequent action.

Microbial study:- There were no fungi, yeast, bacteria, or mould in the formulation. The total bacterial count (40 cfu/g) was significantly lower than the

Churna Kalpana peroral intake limit. In light of recognized microbial allergens and the allergic reaction to these microorganisms' metabolites, regulated microbial development may therefore be advantageous.

Discussion

Shatvaryadi Churna's pharmacognostical evaluation highlighted the unique qualities of this remedy. Numerous standardization parameters were used in this examination, including physical characteristics, physiochemical study, organoleptic study, and chromatographic evaluation. The pH value of 4.39, Loss on Drying at 110° 3.32%, Total Ash value 7.97%, Acid insoluble Ash 0.003%, Water Soluble Extract 36.03% and Alcohol soluble Extract 25.13%. The formulation was free from pathogenic microbial contaminations.

Conclusion

For the quality assured herbal product, the standardization is required. On the basis of the result obtained in the present study the above mentioned parameters i.e. authenticity, biological parameter, chemical parameter, physical parameter and analytical profiling shows the quality assured herbal product. On the basis of result outcome of the research product i.e. *Shatavaryadhi churna* is ideal. The result of this study may be used as the reference standard in further research under taking of its kind.

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