



Research Article

**A CROSS-SECTIONAL SURVEY ON THE CHALLENGES FACED BY THE AYURVEDIC DRUG
MANUFACTURING INDUSTRY IN KERALA**

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ABSTRACT

Ayurveda is the traditional system of medicine in India. As an alternative system of medicine, it is getting global acceptance in the present decade especially in the post Covid scenario. Rising health consciousness among the people, increasing prevalence of epidemics and lifestyle diseases, evidence-based Ayurveda practices and the tremendous changes in the global trade happened in the past few years can be considered as the reason for the same. The annual turnover of Indian market of Ayurveda medicine industry in the year 1998 was 25 billion which was reached a size of INR 626 billion in the year 2022. As per the current researches it is expected to grow at a Compound Annual Growth rate of 12% from 2022 to 2028. Out of the small, medium, and large manufacturing units situated in India, 12% are situated in the state Kerala. Being a small state with such a considerable share in the market a survey has been conducted among 15 Ayurveda drug manufacturing units in the state. The paper expects to assess the possible challenges faced by the industry currently, analyze the methods to resolve them by which improve the productivity without compromising the quality of medicines. The study may also help to check the difficulties faced by the industry at the levels of collection of raw drugs, processing, manufacturing, pacing and marketing and also to suggest the necessary policy shifting if needed.

INTRODUCTION

Ayurveda as a branch of medical science is getting greater acceptance in the present decade when compared to the previous decades. In the year 2023, market size of herbal medicines in the world was calculated as 216.4 USD and is expected to grow up to 437 billion USD by the year 2032^[1]. The growth of the industry is estimated with a CAGR of 27.2% in the year 2024-2030^[2]. Development of newer research methodologies, rapid rise in the occurrence of life style diseases, expansion of scope of global marketing etc. can be considered as the reason for the same. Even though Ayurvedic medicines and modern medicine are running parallel in the Indian market the share of

Ayurvedic medicines in the market are very less on comparison with the modern medicines. The share of Ayurvedic medicine in the market is 70% in the formal medicine market in India^[3].

The size of Ayurvedic medicines market in India has reached 748.5 billion in 2023 and is expected to grow to reach 3207.6 billion by 2032 with a CAGR of 17% during 2024-2032^[4]. Currently Ayurvedic medicine manufacturing industry is undergoing a tremendous transition. The raised demand of herbal products in the global market, strong support by the regulatory authority, infrastructure provided by the AYUSH ministry might have been the reasons for the tremendous growth of Ayurvedic medicine manufacturing industry occurred in the last few years. The Ayurvedic raw drugs showed a raised growth value of 20% in 2005-2006 to 25% in 2019-2020. Along with this, two to three fold increase in value were noted between January and September of 2020 due to Covid-19^[4].

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Pharmaceuticals including poly-herbal and mineral formulations, plant materials, plant extracts, derivatives, cosmetic products, nutraceuticals are the major bulk of Ayurveda^[5]. Even though all these components have showed greater performance in the market both domestically and globally, for to uplifting the potential as an industry, the sector is yet address a lot more problems, assess the challenges, and actions has to be taken for solving the downfalls and policy shifting has to be done if found necessary.

According to the ministry of AYUSH, there are 7435 Ayurvedic drug manufacturing industries in India, most of which are small scale and medium scale^[5]. Of all the companies 12% of total companies are situated in Kerala^[6]. Kerala being known as the hub of Ayurvedic medicines in the country, it was the curiosity to assess the challenges faced by the industry in the state which paved a way for this study. With this back drop this paper is a report of survey conducted among the selected Ayurvedic drug manufacturing industries in Kerala for the challenges faced by the industry at various aspects.

Methodology

For the study, 17 different Ayurvedic medicine manufacturing accessible companies in different parts of the state were selected. A survey was conducted both offline and online with selected questions. The survey was comprised of 31 questions classified under four major domains. Among the 17 companies, 15 were responded to the questions and 2 were didn't respond.

Developing the survey items

Keeping the aim of the study in mind, a discussion has been carried out with five faculties, seven P G Scholars in the department of *Rasasasthra* and *Bhaishajyakalpana*, Govt. Ayurveda College, Thiruvananthapuram, and one person who is a part of

the concerned industry. Various sessions of the Ayurvedic drug manufacturing industry and the probable challenges have been discussed in the session. The sessions being dealt were, raw drug collection, storage and processing, pre-procedures, quality control and analysis, manufacturing, post production and marketing.

From the discussion, the whole sessions have been divided into four major domains, including, pre-production, production, post-production and miscellaneous. A total of 18 probable areas of challenges were observed from the four domains.

Pre-production was concerned with issues related to raw material unavailability, seasonal variations, substituents, storage issues, quality assurance, microbial contamination of raw drugs. Production session was included with issues pertaining with stages of production, standard operative procedures, etc machineries used in the preparation etc. The session of postproduction was concerned with problems related with market complaints, and marketing sources, packing, batch variation, microbial contamination of finished products etc. Miscellaneous was concerned with other miscellaneous issues including waste management, laboratory setting, waste management systems used etc.

From the 18 major areas of the domains sorted, 31 direct questions have been framed for the survey. Out of the 31 questions, 16 questions were having a probability of being responded as "Yes or No" to show the agreement and disagreement of the respondent towards the question and 15 were subjective questions expecting an elaborate reply. Subsequently the framed questions were validated by the higher faculty in the department and sent for the survey. (The questions for the survey are attached in the supplementary file)

Table 1: Major domains of the survey

Pre-production	Production	Post-production	Miscellaneous
1. Raw material unavailability	7. <i>Paka</i> analysis	10. Market complaints	15. Waste management
2. Seasonal variation of raw drugs	8. Machineries used	11. Marketing	16. Factors affecting rate of production
3. Substituents	9. Change in characteristics of finished products as per the climate	12. Packing	17. Actions against rodent attack
4. Storage of raw drugs		13. Batch variation	18. In-house laboratory
5. Quality assurance of raw drugs		14. Microbial contamination of finished product	
6. Microbial contamination of raw drugs			

Conduction of the Survey

Approval of the Study

As the study does not involve interventions, ethical clearance from the institutional ethical committee has not been sought. All the participants of the survey were informed about the purpose of the study, and after getting consent from the participants,

they were included in the study. Among the 17 selected manufacturing companies, two weren't responded.

Method of Data Collection

The data collection was carried out both offline and online over phone call. Out of the 17 companies the four were enquired with offline survey and 13

were responded via online survey. Data collection was carried out from 04/08/2023 to 20/11/2024.

AIM

To review the major problems faced by the Ayurveda manufacturing industries in Kerala.

RESULTS AND DISCUSSION

OBJECTIVES

To conduct a survey among selected Ayurveda drug manufacturing units in Kerala.

To review the major problems faced by the Ayurveda drug manufacturing industries in Kerala

Table 2: Response to questions to show agreement and disagreement

S.No	Domain	Yes	No
1	Affected by unavailability of raw drugs	15	0
2	Stoppage of medicine manufacturing due to absence of raw materials	11	4
3	Satisfied with the current packing system	6	9
4	Microbial contamination of raw drugs	11	4
5	<i>Paka lakshana</i> by conventional methods	15	0
6	Own laboratory	11	4
7	Rodent attack of packing and storage area	15	0
8	Change in organoleptic characteristics of medicine as per climate	15	0
9	Manufacturing affected negatively due to raised price of raw drugs	15	0
10	Whether forced to stop medicine production during times of financial crisis of nation lie covid-19 pandemic	5	10
11	Being unable to manufacture certain medicine as per the need of the market	9	6
12	Equipped with newer instruments in production, pre-production and packing	12	3
13	Increased production of <i>Kashaya sachete/ Gutika</i> in place of <i>Kashaya</i>	6	9
14	Online marketing	9	6
15	Online marketing helps upto a great extend in the marketing	6	9
16	Affected by recent licensed or non-licensed manufacturing units spread through social media	7	8

Table 3: Responses with descriptive answers

S.No	Query	Response
1	Affected by seasonal changes	1- Yield, transportation 12- Quality of fresh drugs are getting affected
2	Options availed during scarcity of herbal drugs	<ul style="list-style-type: none"> • Substituents: 9 • Drugs with similar quality- 2 • Dry instead of fresh- 1 • Some other parts of the plant instead of the prescribed part- 1 • Doubling of some other ingredient- 2
3	Common packing issues	<ul style="list-style-type: none"> • <i>Churna</i>- 3 • <i>Gutika</i>- 4 • <i>Taila</i>- 3 • <i>Arishta</i>- 2 • <i>Lehya</i>- 3
4	Suggestions on alternative packing method	<ul style="list-style-type: none"> • Glass bottle for <i>Kashaya</i> and <i>Taila</i>- 3 • Aluminum foils-<i>Churna</i>- 1 • Glass bottle for <i>Churna</i> with salt and sugar- 4

		<ul style="list-style-type: none"> Increased bottle cap thickness- 1
5	Climate change	<ul style="list-style-type: none"> More during June, lesser during April and May-1 Summer- More oil and <i>Ghritha</i> production Rainy seasons- Pain relief balm, tablets, allergic medicine and cough syrup
6	More batch variation found among;	<ul style="list-style-type: none"> <i>Arishtam</i>- 4 <i>Tailam</i>- 4 <i>Ghritham</i>- 4 <i>Ashaya</i>- 2 <i>Lehya</i>- 1
7	Deterioration of medicine after packing before going out to market	<ul style="list-style-type: none"> <i>Arishta, Asava</i>- 5 <i>Lehya</i>- 4
8	Preservation of raw drugs	<ul style="list-style-type: none"> Washing, chopping and drying- 15 Steam dryer- 1 Isolated drying area- 1 Special solution of potassium permanganate for washing- 1
9	Waste management	<ul style="list-style-type: none"> Boiler- 15 Reuse as fuel- 1 Reuse as fuel for other company- 1 Recycle of meat waste as cattle feed, cutlet etc- 1 Open space burning- 1 Fertilizer- 1
10	Dealing of market complaints	<ul style="list-style-type: none"> Through phone, batch recall, sample collection, analysis and replacement- 6 Surveillance cell- 1 Separate wing- 2 No market complaints- 6
11	Quality assurance of raw drugs	<ul style="list-style-type: none"> Extractive values- 1 TLC for high-cost drugs- 1 Special committee- 3 Botanist- 2 Laboratory assessment and physical examination- 8
12	Measures to make drying yard and storage area rodent free	<ul style="list-style-type: none"> Conventional pest control methods- 10 Repellents- 1 Rodent free mesh- 1 Fumigation- 1 Organic spray- 1 Gum stick- 1
13	Change in organoleptic characteristics of finished products in accordance with the climate	<ul style="list-style-type: none"> <i>Taila</i>- 7 <i>Ghritha</i>- 3 <i>Lehya</i>- 2 <i>Arishta</i>- 3
14	Marketing strategy	<ul style="list-style-type: none"> Sales executive- 15 Advertisement in TV and other social media platforms- 9
15	Major share of production	<ul style="list-style-type: none"> <i>Taila</i>: 15

Out of the 17 companies, only 15 were responded to the survey. Out of the 15, 8 were large scale manufacturers and 7 were small scale manufacturers.

Pre-production

Out of 15 companies, all the companies face issues in medicine manufacturing due to unavailability of raw materials. Of which 73.3% of companies had opined that they were forced to stop production of certain formulations during the period of severe scarcity of certain raw drugs. As Kerala is not cultivating much herbal drugs as per the need of the industry, manufacturers are forced to depend on nearby states for the same which are providing with a comparatively higher cost and it is not feasible for small scale industries.

Seasonal climatic changes affect the availability of raw drugs for all the companies and not to a greater extend to large scale manufacturers as they depend on wholesale dealers and but storage of seasonal drugs in the concerned seasons. In the absence of certain herbal drugs, 60% of companies relays on the substituents, 13.3% of the companies opined that they double the quantity of some other drug in the formulations, 13.3% of the companies are forced to add drugs with the similar quality of the unavailable drug, 6% each of the companies adopt the method of adding dry drug in place of fresh drug, and adding some other part of the plant instead of the prescribed part in the yoga.

For assuring quality of raw drugs, 6% of companies rely on extractive values of certain drugs lie *Guggulu*, *Silajathu* etc. 6% companies are doing TLC of high-cost drugs. 20% companies are having a special committee for assuring the quality of raw drugs. 13.3% companies are having a special Botanist for quality analysis. 53.3% companies rely on analytical parameters and physical examination of raw drugs.

73.3% of companies face issues pertaining with microbial contamination of stored raw drugs before production. Specific procedures for storing the raw drugs are adopted including chopping, washing, drying and storing in racks, sacks and large air tight containers. Fungal infestation is common and efficient ways to prevent it is not available till date. 6% of companies are having an isolated area for cleaning and drying of the raw drugs. One company is having a special solution for cleaning and washing the raw drugs. One company uses electric steam dryer for drying the raw drugs and all the other companies follow proper washing, chopping and drying of raw drugs. 26.6% of companies doesn't face the issue of microbial contamination of raw drugs in the stored place before taken out for preparation, all the other companies face the issue and they reuse these drugs after proper washing. The most common drugs are *Vacha*, *Ashwagandha*, and *Harithaki*.

Production

All the companies assess *Pakalakshanas* by conventional techniques. All the companies face the issue of change in organoleptic characteristic of finished products in accordance with the change in climate. 80% of companies are equipped with newer equipment for production, packing and pre-production. The major share of the production of all the companies was *Taila*.

Miscellaneous

The rate of manufacturing is being affected negatively for all the companies due to the raised price of raw drugs. 33.3% of the companies were forced to stop production of medicines during the period of financial crisis in the nation lie covid-19. 60% of companies at times were unable to manufacture certain medicines as per the need of the market due to unavailability of drug, financial crisis and raised price of the raw drugs.

In 40% of companies the production of *Kashaya* sachets/*Gutika* has been increased in the recent years when compared with the production of *Kashaya*. The major challenges due to seasonal changes are quality of certain drugs during certain climates, yield of preparation, transportation of raw drugs and finished products.

Most of the large-scale manufacturers are having specific waste management plants and effluent treatment plants. Small scale manufacturers are not having a proper system of waste management and the mostly adopted way is burning in boilers. 6% of the companies adopt open space burning of solid wastes. Newer innovations are under process in herbal waste management such as, reusing meat waste for making snacks like cutlets, animal feeds, transforming it into fertilizers and making it into pellet form for using as fuels. 6% each of the companies are reusing the solid waste as fuels, recycle of meat waste as cutlet, other solid waste as animal foods, reusing as fertilizers.

In house laboratory facilities are available for 73.3% of the companies but most of them are not properly functioning due to lack of guidelines. 26.6% of companies are not having own laboratory but they depend on other registered laboratories for quality checking of raw drugs and the finished products.

All the companies face the issue of rodent attack of the storage area of prepared and stored medicines. 66.6% of companies use conventional pest control methods, 6.6% each of the companies adopt repellents, rodent free mesh, fumigation methods, organic sprays and gum-stick for rodent control.

Post- production

Packing is a major domain as far as Ayurveda is considered, in which new innovations should come into force with time. 40% of companies are satisfied

with the current packing system and 60% of companies suggest further modification in the packing system. Leakage of oils, chances of fermentation in *Lehyas* as it contains large amount of sugar, chances of secondary fermentation in *Arishtas* reminds us the need to make the packing a little better. *Churnas*, especially which contains sugar and salt are also of major concern. 20% of companies face issues in packing of *Churnas* like condensation of *Churnas* due to hygroscopic nature as some of them contains sugar and salt due to which they suggest glass bottles for packing of *Churnas*, 26.6% companies opine issues with packing of *Gutikas*, as there noticed rusting of *Gutikas* containing *Rasa dravyas* over the Aluminium foil and they suggest pouch packing and machine packing for *Gutikas*. 20% faces issues with packing of oils, due to leakage issues, and they prefer glass bottles for the same but it is not found feasible as there will be breakage issues during the transport and handling of the medicines. Another suggestion to resolve the same is increasing the thickness of bottle caps.

60% companies are having online marketing facilities. The marketing of medicines of 46.6% companies affected with the recently popularized licensed and non-licensed manufacturing companies in the social media. All the companies rely on offline marketing rather than online. Although online marketing are available for all the companies, only a few are getting enough profit out of it (40%).

16.6% of the companies opined that climate change not affects the market of medicines and 83.3% of the companies are facing issues related to market demand of certain medicines in relation with climatic changes. Market demand of most of the *Kashasyas* and *Arishtas* are noticed during the month of June and less during may and April. Oil and ghee production is found more during summer season and the production of pain balms, cough syrups, tablets, medicines for allergy, cough syrup are during rainy seasons.

Batch variation is a major issue of Ayurveda medicines when compared to other medicines. Changes in organoleptic characteristics of raw drugs according to climate are the major reason for the same. Mostly affecting in *Arishtas*, *Tailas* and sometimes in *Kashayas*. 26.6% of companies face severe issue of batch variation in *Tailas*, 26.6% in *Ghrithas*, 26.6% in *Arishtas* and 13.3% companies in *Kashaya* and 8.3% in *Lehyas*. 41.6% of companies haven't faced the issue of deterioration of medicine after packing before out for the market. 33.3% companies face problem with *Arishta* and *Asava*, and 26.6% with *Lehya*.

As Ayurvedic medicines are prepared with herbal drugs, the change in characteristic feature of herbs according to each climate will in-turn affect the organoleptic characteristics of the finished product which will create some confusion among the

consumers with medicines of different colour and odour at different climate. 46.6% of companies face the same issue with *Tailas*, 20% with *Ghritha* and *Arishta*, and 13.3% with *Lehyas*.

Most of the companies are not having a proper system to deal, assess and analyze market complaints. 40% of companies are having a system to report market complaints through phone call or mail. Being reported the successive steps like sample collection, comparison with the control samples, analysis and replacement are being done systematically. 1 company is having a separate surveillance cell for assessing and taking proper actions for the reported market complaints. 2 companies are having separate wing for dealing with market complaints. 40% of the companies opined that they haven't got any market complaints yet.

CONCLUSION

Kerala having unique contributions in Ayurveda and Ayurvedic medicines with a considerable share in the market it was the curiosity to analyze the issues faced by the industry in the state which has lead to conduct the study. From the study, it can be concluded that the major issues facing by the Ayurvedic dug manufacturing industries in the state Kerala are issues related due to unavailability of raw drugs, packing issues, batch variation due to variability in organoleptic characteristics of the raw drug, microbial contamination and fungal infestation of raw drugs, and preservation of raw drugs for the manufacture. For uplifting Ayurveda drug manufacturing industry in the state, for improving the annual growth rate of the market without compromising the quality of final products, these issues have to be corrected with proper solutions and new policies. As Ayurveda is getting global acceptance, these issues has to be ruled out by taking proper actions by the government to implement stringent regulations for uniform system at all the steps of medicine manufacturing including raw material collection, processing, manufacture, pacing, sorting market complaints and by which proper standardization of the medicines and also to initiate newer programme in-order to encourage cultivation of herbal medicines in the state and national levels in-order to meet with the cost of production

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