

DIFFERENCE IN METHOD OF MANUFACTURING OF CHYAVANAPRASA AMONG GMP CERTIFIED COMPANIES IN KERALA

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ABSTRACT

Background: *Chyavanaprasa* is one among the popular *Ayurvedic* preparations grouped under *Rasayana*, which incorporates more than forty botanicals. In order to ensure quality, safety and efficacy of *Ayurvedic* formulations available in the market like *Chyavanaprasa*, uniform method of preparation must be adopted by different GMP certified companies. **Aim:** The present study was carried out to find out the variations adopted in the method of preparation of *Chyavanaprasa* by various GMP certified companies in the state of Kerala. **Methodology:** The study comprises a survey in eight GMP Certified companies having production above 4000 kg per annum for the formulation. Data collection was carried out by interview using a questionnaire given to specific personnel in the companies and direct

observation of the various processes associated with and related to the

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production of *Chyavanaprasa*. **Results:** The survey reveals the existence of difference in method of preparation of *Chyavanaprasa* among GMP Certified companies and this is also different from API recommendations for the preparation of *Chyavanaprasa*. **Conclusion:** The result confirms the existence of non-uniformity in the production of *Chyavanaprasa* among various companies. Hence development of standard operating procedures in the production of *Chyavanaprasa* by considering the recommendation of API is necessary for quality assurance of the formulation in the Kerala market.

KEYWORDS: *Avaleha*, *Chyavanaprasa*, Good Manufacturing Practices, *Rasayana*, Quality assurance.

INTRODUCTION

Avaleha is a semisolid preparation of drugs prepared with the addition of jaggery, sugar or sugar candy and boiled with prescribed drug juice or decoction.^[1] According to Ayurvedic Pharmacopoeia of India (API), *Chyavanaprasa* is a polyherbal formulation with semisolid and sticky in nature. It is a chocolate brown coloured compound having sweet taste with non-specific pleasant odour.^[2] *Chyavanaprasa* is classified under the group of *Rasayana*, where the main purpose is to maintain the body's integrity for delaying the ageing process, enhance longevity and improves digestion.

The preparation of *Chyavanaprasa* was originally described in the first chapter of *Chikitsa Sthana* in *Charaka Samhita*^[3] entitled *Abhayamalakiya Rasayana pada*. Both *Ashtanga Hridaya*^[4] and *Ashtanga Sangraha*^[5] have described the same formula of *Chyavanaprasa* in the chapter of *Rasayana*. *Susruta* has not mentioned *Chyavanaprasa Rasayana*. In *Sarngadhara Samhita*^[6], *Chyavanaprasa* has been described under *Avaleha Prakarana* in *Madhyama Khanda*, with some variations in the ingredients. In *Bhaishajyaratnavali*^[7], the *Chyavanaprasa* has been mentioned in *Rajayakshma Prakarana* with the same formula and the procedures as described in *Charaka Samhita*. It has been suggested that *Sita* (sugar) may be used instead of *Matsyandika* and *Amalaki Majja* should be fried in mild heat.

According to W.H.O, Quality assurance^[8] is a wide-ranging concept covering all aspects that individually or collectively influence the quality of a product. With regard to pharmaceuticals, quality assurance can be divided into major areas: the development, quality control, production, distribution and inspections. Good manufacturing practice (GMP) is that part of quality assurance which ensures that products are consistently produced and

controlled to the quality standards appropriate to their intended use and as required by the marketing authorization.^[9] GMP is aimed primarily at diminishing the risks inherent in any pharmaceutical production. There is a growing need to apply these methods to standardize the herbs and their formulations to find global acceptability.

Manufacturing of *Chyavanaprasa* is affected by scarcity of some of the major ingredients of its formula. Difficulty in the processing method and issues relating to maintain shelf life of the finished product are some of the major challenges in the production of *Chyavanaprasa*. Variations in the manufacturing process of *Chyavanaprasa* may change the final consistency, taste, odour and efficacy of the finished products despite from taking the same formula and proportions of ingredients in different batches of *Chyavanaprasa*. Here, an attempt is made to identify the specific steps adopted for quality assurance by different GMP certified companies during *Chyavanaprasa* production. The study also enquires into the common problems encountered during the production of *Chyavanaprasa* and corrective measures adopted, if any. The objective of the study is to collect data on different procedures adopted by various GMP certified companies (GCC's) in Kerala for the production of *Chyavanaprasa*.

MATERIALS AND METHODS

The data on various aspects related to and associated with the manufacturing of *Chyavanaprasa* were collected through interview with Head of Department of Research and Development and person-in-charge of production of *avaleha* by the investigator using a questionnaire. Direct observation of the various processes in the manufacturing of *Chyavanaprasa* in eight GMP certified companies having *Chyavanaprasa* production equal or more than 4000 kg per annum was also made. The survey was intended to identify the difference in the method of manufacturing of *Chyavanaprasa* among the major GCC's in Kerala and also it identify the variations from API recommendations for the production of *Chyavanaprasa* adopted by GCC.

Method of preparation as per API^[10]

Ripe fresh *amalakis* are bundled in a piece of cloth. Ingredients 1 to 38 are coarsely powdered and put in a vessel. Water is added and the bundle of amalaki is immersed in the vessel and boiled till the water is reduced to one-fourth. The bundle is then removed, and the decoction is strained and kept separately. The seeds of the boiled amalaki are removed and the pulp is made into a paste, which is then filtered through a piece of cloth or sieve of 40

mesh over a wide mouthed vessel. After the fibers are removed, the pulp is fried with cow's ghee and sesame oil (ingredient 39- to 40) till the moisture evaporates. *Matsyandika* (a variety of jaggery) is added to the decoction and cooked to a specific consistency termed as *avaleha paka* and at this stage the fried pulp is added. Fine powders of ingredients 43 to 48 are added to the *avaleha*, stirred well, and allowed to cool; and *madhu* (honey) is added.

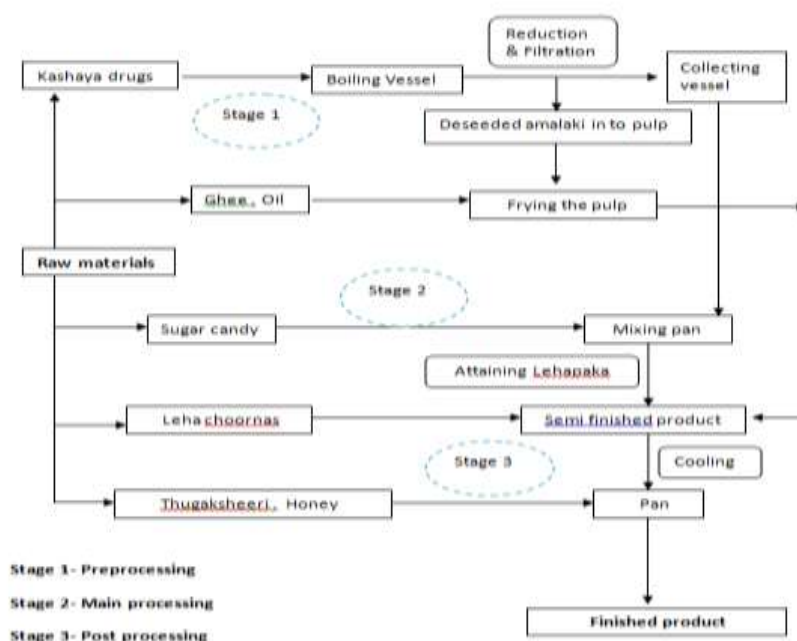


Figure no: 1 Flow chart for production of Chyavanaprasa

Survey questionnaire

The survey questionnaire was prepared on the basis of thorough literature review of Ayurvedic treatises and preliminary discussions with the experts from the academy and industry. The questionnaire contained both closed ended and open ended questions. The questionnaire gives priority to the areas such as processing techniques like preparation of *kashaya*, removal of *amalaki* seeds, frying of grinded *amalaki* paste, mixing of sugar candy with *kashaya*, assessment of *avaleha paka*, mixing of *prakshepa churna* etc.

RESULTS

The data collected through questionnaire and direct observation of the various processes associated with and related to the production of *Chyavanaprasa avaleha* from various GMP Certified Companies were listed below.

General data

- The present study revealed that the GMP certified companies (GCC) in Kerala were producing *Chyavanaprasa* throughout the year according to the market demand and all the GCC's have quality control section for raw material standardization, in-process checking and quality control of finished products.

Pre-processing

- Washing is usually done by using sprayers and large sieves and after that it was dried in shade. 100 % of GCC's follow this process before production and used as first-in first-out manner.
- The disintegration method was adopted by 75% of GCC's and shredding was adopted by 25% of GCC's for size reduction of *Kashaya* drugs.
- Pulverizer was used by all GCC's for making fine powder of *prakshepa churna* used in *Chyavanaprasa* production.

Processing Techniques

- As per API, fresh *amalaki* was made into bundle, boiled along with other *kashaya* drugs and after that, it was deseeded and was made in to a pulp which is used in the production of *Chyavanaprasa*. But 87.5% of GCC's were deviating from this step and they were using *amalaki* powder due to scarcity of fresh *amalaki* throughout the year. 12.5% of GCC's were boiling dry *amalaki* rinds as separate *kashaya*.

Table no: 1 Usage of *amalaki* in the production of *Chyavanaprasa*

Sl.No.	Details of the process	Percentage of GMP certified companies following the process
1	<i>Amalaki</i> made into bundle and boiled along with <i>Kashaya</i>	0 %
2	Dry <i>Amalaki</i> rinds were boiled as separate <i>Kashaya</i>	12.5 %
3	No boiling of <i>Amalaki</i>	87.5 %

- As per classical textbooks and API, *amalaki* pulp should be fried in ghee and oil before adding to *avaleha* at *avaleha paka*. But, 87% of GCC's were directly frying *amalaki* powder and 13% were avoiding the frying process.
- 75% of GCC's consider black colour and rough touch as the endpoint for frying of *amalaki* where as 25% companies stop frying when it attains a golden brown colour.

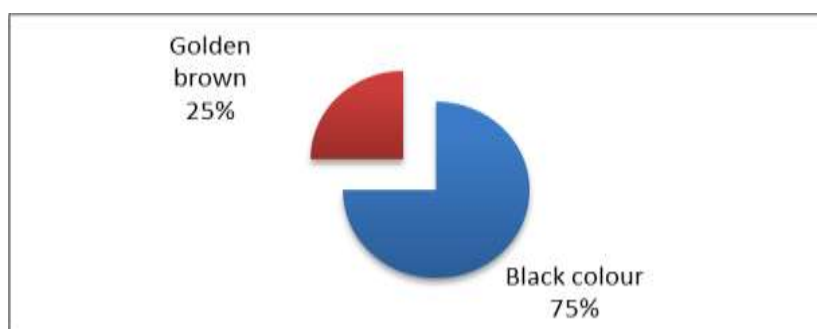


Figure no: 2 Endpoint of frying of *amalaki*

- The parameters such as total suspended solids (TSS), specific gravity and pH were assessed by 75% of GCC's as in-process check for *kashaya* in *Chyavanaprasa* production while 12% of GCC's assess Brix parameter only. 13% of the companies were not doing the in-process quality control check for *kashaya*.
- The features of *avaleha paka* according to classical textbooks are *tantumatva* (thread like appearance), *apsumajjana* (sinks in water), *kharatva* (hard to touch), *pidithomudra* (finger prints seen when pressed) and *gandavarnarasotpatthi* (attainment of proper smell, colour and taste). 50% of GCC's check the parameters such as *tantumatva*, TSS, specific gravity and Brix value for the quality control assessment of *avaleha paka* while 50% of GCC's checks Brix and *tantumatva* only.
- According to API, the time of addition of *thugaksheeri* is during *avaleha paka*. 63% of GCC's were adding *thugaksheeri* while attaining *avaleha paka*, while 38% were adding *thugaksheeri* only after cooling.
- All of the companies were adding honey after cooling and it was mixed homogenously.
- 75% of GCC's were using preservatives and 25 % were not adding any preservatives. The main preservatives used were potassium metabisulphate/ sodium metabisulphate, sodium benzoate and sorbitol.
- 100% of GCC were relying primarily on *avaleha paka* and organoleptic characters of finished *Chyavanaprasa* while physicochemical characters considered were varying as Shown in table no. 2 and 3.

Table no: 2 Quality control parameters of *Chyavanaprasa* as per API^[11]

Parameters	Value
Loss on drying	Not more than 9 %
Total solids	
Water soluble extractives	Not less than 50 %
Alcohol soluble extractives	Not less than 50 %

Total ash	Not more than 2 %
Acid insoluble ash	Not more than 2 %
pH (1% aqueous solution)	3.82 –4.23
Microbial analysis ^[12]	Total microbial count
	Total fungal count
	10 ⁵ c.f.u/ml
	10 ³ c.f.u/ml

Table no: 3 Quality control parameters of *Chyavanaprasa* checked by GCC's

Sl. No.	Parameters checked by GCC's	Percentage of GCC's checking
1	Loss on drying, pH, Alcohol soluble extractive, Water soluble extractive, Total ash, Acid insoluble ash Microbial limit, total sugar	62.5 %
2	Loss on drying, pH, total ash, reducing sugar	37.5 %

- All of GCC were using food grade colour less pet bottle for packing and Shelf life was three years as per API.

DISCUSSION

Ayurveda, is now recognized not only in India, but also in the western world. With the growing need for safer drugs, attention has been drawn to the efficacy and standards of Ayurvedic formulations. In the present era, Ayurvedic physicians mainly depend on pharmaceutical industries, for prepared medicines. Physician prescribing the medicine with a particular diagnosis in the mind, but sometimes he fails to observe expected outcome. That may be due to the lack of quality of medicine. The increasing needs of the population and the chronic shortage of authentic raw materials have made it incumbent that some sort of uniformity in the manufacture of Ayurvedic medicines should be brought about.

There is infact a large difference for *Chyavanaprasa* production in industrial scale and academic level. Purely textual method of preparations may not be profitable to the industries and many modifications are adopted according to demand of situations. The industries are facing so many problems related to *Chyavanaprasa* production such as processing time and stability of the product. So, they incorporate many modern techniques and sophisticated machineries to make production easier and profitable. This will reduce the production time and manual labour, which finally leads to reduced cost of production.

The detailed survey on Quality assurance of *Chyavanaprasa* revealed that different methodologies were adopted by various industries in the production of *Chyavanaprasa*. These methodologies were used to decrease the lead time, labour and cost.

Most of the GMP Certified companies were not boiling fresh amalaki along with *kashaya* drugs. As per API, fresh amalaki is made in to a bundle and is boiled along with other drugs of *Kashaya*. But 87.5% of GCC's were deviating from this step due to scarcity of fresh *amalakis* throughout the year. 12.5% were boiling dry *amalaki* rinds as separate *kashaya*, which is also a modification in the preparatory aspect. While boiling, water soluble portion of *amalaki* will be present in the *kashaya*.

Vitamin C, also known as ascorbic acid, is a water-soluble vitamin found in amalaki. It is an antioxidant that is very essential for human nutrition and proper functioning of the body. The human body cannot synthesize vitamin C endogenously, so it is an essential dietary component. At high temperature, in the presence of sunlight and oxygen in the air, vitamin C reacts and it is oxidized. Boiling in high temperature also destroys vitamin C since it easily leaches into the cooking water being a water-soluble vitamin. For high retention of vitamin C while boiling, it is recommended to boil in low heat.

Some of the companies (13%) also avoid frying of amalaki and they are using amalaki powder as *avaleha churna* while 87% of GCC's were frying amalaki powder. As per companies, the endpoint of frying in 75% GCC's were black colour and having roughness on touch. 25% of the GCC's stop frying when it attains a golden brown colour. Sugar candy was used by 62.5 % of GCC's as substrate whereas 25 % were using jaggery as substrate and 12.5 % using mixture of jaggery and sugar candy for production. The type of jaggery used by all GCC's was *unda sarkara*. Jaggery is cheaper compared to sugar candy, which will reduce the cost of production.

Most of the companies were doing in-process checks of parameters like TSS, specific gravity and pH for prepared *Kashaya*. The critical control points of *lehapaka* were *tantummatva*, *apsumajjana*, *kharatva*, *peedithomudra* and *gandavarnarasotpatthi* and modern parameters like TSS, specific gravity and Brix value. But 50% of GCC's checks only Brix and *tantummatva*.

The production of *avaleha* was accelerated by the GCC's by the adoption of modern advanced machineries such as superheated steam jacketed vessels in heating, mechanical sifters in sieving, electrically operated mixing machines for mixing and fluidized bed evaporator to decrease lead time.

The GMP Certified companies were using preservatives like potassium/sodium metabisulphate, sodium benzoate or sorbitol. Even though 100% of GCC were conducting quality checks on organoleptic and physico-chemical parameters like total sugar, moisture of jaggery and it has a deleterious effect on the process of fermentation in *Avaleha*. In such cases, preservatives have to be added to avoid the problem.

As per classical texts shelf life is only one year. But in API, shelf life of *Avaleha* was explained as 3 years. So, the companies are compelled to add preservatives to attain this shelf life. All of GCC were using food grade colour less pet bottle for packing. Interaction of *Avaleha* with packing material has not been studied properly by majority of GCC. A considerable difference can be seen in the cost of *Chyavanaprasa* of same quantity packing prepared by different companies. This may be due to the change in methodology adopted by them.

CONCLUSION

The method of preparation of *Chyavanaprasa* on an industrial scale has considerable difference compared to the textual reference and API. There is non-uniformity in the production of *Chyavanaprasa* among GMP Certified companies. According to API, fresh *amalaki* was used in production of *Chyavanaprasa*. As per API recommendations, fresh *amalaki* should be boiled along with *kashaya*. But due to offseason scarcity of fresh *amalaki*'s, GCC's was forced to use dried *amalaki*'s for the production of *Chyavanaprasa*. Some of the GCC's were using jaggery in the production of *Chyavanaprasa* instead of sugar candy. There was difference found in the percentage of substrate (sweetening agent) used, time of addition of *thugaksheeri*, cost of *Chyavanaprasa* of different companies, type and concentration of preservatives used. Proper quality control in-process checks in all stages of process and microbial analysis for finished products is an inevitable factor for maintaining quality assurance. The shelf life of *Avaleha* as per traditional references was one year but as per API it was 3 years. So, shelf life studies have to be conducted on every *Avaleha* formulations, because shelf life of every *avaleha* depends upon the substrate to *avaleha churna* ratio and *avaleha paka*.

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