



Kharaliya Rassayana: Checking the Possibilities of a Short Cut for Large Scale Production

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Abstract

Processing time of Ayurveda medicines is a big challenge. Many of Kharaliya Rasayana take days for the process. How to shorten the processing time is big challenge for the industry. An attempt was made to prepare Kharaliya Rasayana Named Gandhakadi Yoga by a new method without violating the basic principles. In one batch Gandhakadi yoga was prepared by following classical method of Kharaliya Rasayana e.g. by adding Bhavana Drava into Gandhaka one by one until it gets dry, total 3 batches were prepared by this method. It took approximately 67 to 125 days depending upon the season. Another batch was prepared with modification. Rasakriya of all Bhavana Drava was prepared, additional watery portion was evaporated. Total Solid contents of all the Bhavana Drava (in the form of Rasakriya) were triturated with Gandhaka. The entire process of this method was completed in 10 days. Samples were analyzed physico chemically. Study revealed that there was no major change in the selected parameters whether it is prepared in 10 days or 70 days. This modified method might be useful for bulk production, as it takes less time in the trituration process when Ghana (Rasakriya) of all Bhavana Drava is added at the same time.

Keywords: Gandhakadi Yoga; Classical Method; Modified Method; Bhavana; Large Scale Production

Introduction

Drug Dosage

Herbal Drugs are rarely administered in their raw form, and more often than not, they have to be necessarily admixed with various kinds of adjuncts resulting in their transformation into the 'dosage forms' or 'drug delivery systems'. To design new formulation is a very responsible job for a pharmaceutical scientist. There are several factors that constitute an ideal dosage form, which should be considered in the development process. Not only must the dosage form perform optimally, so that the drug product is therapeutically effective and the formulation is manufacturable at scale, but also the end-user requirements must be taken into account.

"An ideal dosage form is designed by selecting the most appropriate route of administration to ensure adequate bioavailability and exposure to allow the drug to have the intended therapeutic effect in the body," says Steven Winling, product development technical specialist, Catalent. "At the same time, the dosage form should be designed to facilitate patient adherence and ease of administration by offering the least invasive route possible, limiting the number of daily administrations, and allowing for a simple dosing regimen."

There are many factors which play key roll to design a new formulation as follow [1]:

- A 'convenient' dosage form.
- As likable taste, good flavor, attractive color, etc.
- Continuity of the chemical compositions & physical

structures until their use by the Patients.

- Cost effectiveness.
- Easier mechanical handling, storage under varying temperatures, etc.
- Easily availability of raw materials for the large scale production.
- Easy packing and transportation
- Fast acting
- Maximum shelf life.
- Minimum dose
- Minimum effect of environmental changes.
- Minimum utility of men power, energy and time.
- Multi utility or wide therapeutic range.
- Organo-leptically amicable, agreeable appearance, desirable sensual characteristics such
- Suitable for large scale production
- The prevention of interactions of drugs in poly herbal or Herbo-mineral formulations.
- The stability against microbial action or oxidative degradation.

Need of the Study

To prepare Kharaliya Rasayana by following the traditional method is very time consuming and it takes months to prepare if prepared by following classical methods. The

industrial production is time bound and sometimes require to gear up the process to match the demand in emergency conditions like pandemic. It is the need of hour to find the solution for this problem. As there is no such work has been carried out in the past, a specific method was developed to accelerate the production. In the present study, Gandhakadi Yoga was formulated, based on Gandhaka Rasayana and was prepared by classical method of Bhavana and the method of Bhavna was modified to check its utility for bulk production at industrial level.

Aims and Objectives

- To prepare and compare the Gandhakadi yoga by following classical and modified methods of Kharaliya Rasayana.
- To analyze the samples by utilizing suitable parameters.

Materials and Methods

To prepare Gandhakadi yoga, the raw materials (except Bhringaraja and Guduchi) were procured (Table 1) from the pharmacy attached to I.P.G.T. & R.A., G.Ay.U, Jamnagar. Guduchi and Bhringraja Panchanga were collected near from bank of Rangamati River and were authenticated by the experts.

Drug	Latin name	Part used	Proportion
Shuddha Gandhaka	Sulphurion	Mineral	1 part
Aamalaki	<i>Emblica officinalis</i>	Fruit	Q.S. for Bhavana
Arjuna	<i>Terminalia arjuna</i>	Stem	Q.S. for Bhavana
Aaragvadh	<i>Cassia fistula</i>	Fruit pulp	Q.S. for Bhavana
Guduchi	<i>Tinospora cordifolia</i>	Leaves & stem	Q.S. for Bhavana
Haritaki	<i>Terminalia chebula</i>	Fruit	Q.S. for Bhavana
Katuki	<i>Picrorhiza kurroa</i>	Rhizomes	Q.S. for Bhavana
Rohitaka	<i>Tecoma undulata</i>	Bark	Q.S. for Bhavana
Punarnava	<i>Boerhavia diffusa</i>	Whole part	Q.S. for Bhavana

Table 1: The Ingredients of Gandhakadi yoga.

Gandhaka Shodhana

- For Gandhaka Shodhana, Bhringaraja Swarasa was used as liquid media. To prepare Swarasa fresh drug was cut into small pieces and crushed by hammer and was made into paste with the help of mixer then the paste was kept into 2 folded non reacting cloths and squeezed firmly and Swarasa was collected. Each time fresh Swarasa was prepared as per requirement, during the Dhalana procedure of Gandhaka [2].
- For Gandhaka Shodhana, Ashuddha Gandhaka was powdered with the help of mortar and pestle and

was taken in a steel vessel and heated on Mandagni. Bhringraja Swarasa was taken in a steel vessel and the piece of cloth was tide on the mouth of steel vessel. It was slight smeared with Ghee to avoid the adhering of melted Gandhaka. When Gandhaka was totally melted it was poured into the vessel containing Bhringraja Swarasa through the cloth. A solid mass and some granule parts of Gandhaka were taken out from Bhringraja Swarasa. Then procured Gandhaka washed with hot water. The whole procedure was repeated for three times. After it got dried it was powdered and kept in an air tight jar.

Gandhakadi yoga Nirmana

Gandhakadi yoga was prepared by following unit Operations

- Preparation of Kwatha
- Amalaki, Katuki, Arjuna, Haritaki, & Punarnava [3]
- Preparation of Guduchi Swarasa [4]
- Preparation Aaragvadh Heema
- Procedure of Bhavana (wet trituration) [5]

For preparing Gandhakadi yoga as per Classical method, Swarasa of Guduchi; Heema of Aaragwadha and Kwatha of Amalaki, Arjuna, Haritaki Katuki and Punarnava were used as separate Bhavana Drava. While preparing Gandhakadi yoga by modified method (GyM), all liquids were prepared classically and then were converted to Rasakriya and then Bhavana of that Rasakriya was given. For Bhavana of Guduchi, Swarasa of Guduchi was prepared similar to method as explained above for Bhringaraja Swarasa. to prepare Aaragvadh heema, the equal size of legumes of Aaragvadh was cut vertically into two parts and the pulp was scrapped. Pulp was collected along with seeds; Water was added into the pulp and it was soaked for overnight. Next day, the mixture was properly mixed and strained with the cotton cloth.

To prepare Kwatha, Yavakuta Churna (coarse powder) of Kwathya Dravya was taken in a stainless steel vessel. The material was soaked for overnight in the potable water. Next day, Kwatha was prepared by reducing water to 1/8th, as per method described in the standard text. It was strained with double layered cotton cloth and measured. To prepare Gandhakadi Yoga classically (GyA), Shuddha Gandhaka was taken in granite mortar and it was powdered with the help of pestle and was made into fine powder and Bhavana Drava was added into the powder of Gandhaka and trituration was done and made the paste dried. Total three Bhavana were given by each liquid. After drying of the previous Bhavana, next was given. First Bhavana of Aamalaki Kwatha was given followed by Arjuna Kwatha, Haritaki Kwatha, Katuki Kwatha, Guduchi Swarasa, Aaragwadha Heema, Rohitaka Kwatha and Punarnava Kwatha. Finally, after whole procedure the mass was powdered and was sieved through 80 no. mesh the powder was stored in a non reacting glass bottle.

Total three batches were prepared in different season to evaluate the quantity of Bhavana Dravya and the time taken for drying after Bhavana to evaluate the role of humidity and atmosphere in the process of Bhavana. To prepare Gandhakadi Yoga modified way(GyM), Measured Kwatha (decoction) of the all drugs, Guduchi Swarasa and Aaragvadh Heema were mixed and taken in stainless steel vessel and constant mild heat was applied to the vessel sufficient to facilitate the evaporation on continuous stirring up to the

semi solid (70% water was evaporated approximately) form of the initial quantity. After desirable reduction in volume, the Rasakriya (semi solid status) was collected in a separate vessel and it was mixed with Shuddha Gandhaka and Bhavana was given until the mixture was dried. Finally, after whole procedure the mass was powdered. It was sieved through 80 no. mesh. The powder was stored in a non reacting glass bottle. Analysis of Gandhakadi Yoga was carried out, Organoleptic characteristic like Sparsh (consistency), Rupa (Color), Rasa (Taste) and Gandha (Odor) of the samples were perceived by the Gnanendriya (sensory organs). While the physico-chemical parameters e.g. pH, Specific gravity, total solid content, alcohol content were done as per standards.

Observations and Results

Gandhaka Shodhana

- First time it was difficult to churn Bhringaraja in the mixer. So initially they were crushed manually for easy procedure, from the next mixing previously squeezed Swarasa was added.
- The color of Bhringaraja was dark green.
- Initially Gandhaka melted quickly in Ghee, but after 1st processing, it took slightly more time.
- On melting, Gandhaka acquired yellowish orange in color.
- Bhringaraja Swarasa was taken in double quantity than Gandhaka.
- After 1st processing, black burnt matter of Bhringaraja appeared in the Gandhaka at the end of melting stage of Gandhaka.
- Color of the Gandhaka initially was crystalline yellow after Shodhana it became greenish yellow.
- Bhringaraja Swarasa became darker in color with globules of ghee formed on the surface of liquid.
- Typical odor of Gandhaka was smelt during whole procedure.

Gandhakadi Yoga A Nirmana

Yavakuta Churna (coarse powder) of Kwathya Dravya was used. Mild heat around 70-75 degree Celsius was applied during whole procedure to avoid the chances of degradation of the some of the active constituents. Change in color of water was observed immediately after adding water in Kwathya Dravyas. Initially, some part of Yavakuta floated, gradually it sunk. Typical pleasant smell was felt during boiling of Kwatha. Aaragvadh Heema was prepared by legumes of Aaragwadha. The legumes were cut and the pulp was scrapped with the help of scrapper from it. The legumes of Aaragvadh were examined properly as insects like the sweet pulp. As a result 75% of legumes were not proper and has to be omitted. As an out put of observation

it was found that to prepare Guduchi Swarasa only fresh raw material should be used for maximum yield. Paste should be done perfectly for proper squeezing. More energy is needed to squeeze the paste of Guduchi as it has more intro cellular

binding capacity.

In nut shell, the Organo-leptic properties of the each Bhavana drug were as per (Table 2).

Drug	Color	Taste	Smell	Consistency
Aamalaki	translucent brown	Amlapradhan pancharasa	Specific sour	Thick & sticky
Arjuna	Brownish	Kashaya	Typical	Thick
Haritaki	Brownish	Kashaya	Typical bitter	Thick
Katuki	Blackish Brown	Tikta Kashaya	Typical	Thick & sticky
Punarnava	Greenish Brown	Kashaya	Specific	Thick & sticky
Rohitaka	Reddish	Kashaya	No Specific	Thick
Aaragvadh	Dark brown	Madhura	Specific sweet	Thick & sticky
Guduchi	Dark green	Tikta Kashaya	Typical	Thick & sticky

Table 2: The Organo-leptic properties of the each Bhavana drug.

Bhavana Process

- The Kwatha / Swarasa/ Heema (Bhavya material) was triturated / mixed up to the properly until drugs became Pankwata in appearance (semi solid form)
- The Bhavya Dravya was mixed with Gandhaka within 3 to 4 minutes.
- Each Bhavana is being repeated 3 times and the total time for process is prolonging for one day to 7 days.
- Particles of Gandhaka were becoming more and more soft and smaller.
- Color of the semisolid paste was converting yellow to greenish in color.
- Initially the smell of Gandhaka was there but after several

Bhavana the taste was according to the Bhavana Dravya.

- The weight of dried Gandhaka was increasing after each Bhavana.
- Initially the Bhavana Dravya was needed very less to get Pankwata (mud like) state.
- After the Bhavana of Aamalaki pestle was running very easily in the mortar and the drug was dried very easily but it became harder and harder after each Bhavana.
- The drug absorbs the moist after the Bhavana of Haritaki. And easily converted in to semi solid state.
- Manual Mardana is hard due to many factors. I.e. it is more time consuming 67 to 125 days.
- The data of material used for 3 Bhavana in 3 batches is given in (Table 3).

Material	Batch1	Time taken for 3 Bhavana	Batch2	Time taken for 3 Bhavana	Batch3	Time taken 3 Bhavana
		August to Nov (in days)		Dec to February (in days)		March to May (in days)
Gandhaka(in Kg)	1		1		1	
Aamalaki Kwatha(in ml)	700	6	660	6	620	5
Katuki Kwatha (in ml)	630	9	640	8	640	5
Arjuna Kwatha (in ml)	650	10	665	7	650	6
Haritaki Kwatha (in ml)	640	10	650	7	640	5
Guduchi Swarasa (in ml)	680	21	600	15	610	10
Aaragvadh Heema (in ml)	680	21	600	17	630	10
Rohitaka Kwatha (in ml)	630	27	630	18	600	11
Punarnava kwatha (in ml)	650	21	640	16	600	15
Total	5260	125	5085	94	4990	67

Table 3: The data of material used for 3 Bhavana in 3 batches.

- The data of increase in weight of Gandhaka after Bhavana is given in Table 4.

Liquid media of	Batch 1		Batch 2		Batch 3		
Bhavana Dravya	Initial (in g)	Final (in g)	Initial (in g)	Final (in g)	Initial (in g)	Final (in g)	Average (in g)
Aamalaki	1000	1025	1000	1015	1000	1010	1016.66
Katuki	1025	1043	1015	1035	1010	1025	1033.33
Arjuna	1043	1073	1035	1050	1025	1035	1052.33
Haritaki	1073	1104	1050	1060	1035	1050	1071.33
Guduchi	1104	1132	1060	1080	1050	1065	1092.33
Aaragvadh	1132	1189	1080	1110	1065	1075	1124.66
Rohitaka	1189	1211	1110	1110	1075	1085	1135.33
Punarnava	1211	1245	1110	1125	1085	1095	1155

Table 4: The data of increase in weight of Gandhaka after Bhavana.

- Final weight of Gandhakadi yoga A is given as (Table 5).

Material	Batch 1	Batch 2	Batch 3	Average
Initial wt. of Gandhaka (in g)	1000	1000	1000	1000
Final wt. of Gandhakadi yoga A (in g)	1245	1125	1095	1155

Table 5: Final weight of Gandhakadi yoga A: *(classical).

Preparation of Modified Gandhakadi yoga-GmY) was divided in to two parts:

- Preparation of Rasakriya
- Bhavana

Observation of preparing Rasakriya

- The froth gradually diminished to the edges after attaining the peak temperature (86 °C).
- Evaporation started to appear at temperature above 70 °C which was aggravated on stirring.
- The color of the mixture of liquids were light greenish

brown initially, it became dark brown of final product Rasakriya (semi solid status).

Bhavana of Rasakriya to Gandhaka

- Immediately, Gandhaka got mixed with the liquid material.
- Gandhaka appeared like Pankwata.
- The color immediately changed after mixing of semisolid liquids.
- Gandhaka stick to the machine at the completion of process.
- The relate data is shown in (Tables 6 & 7).

Initial volume of the mixture (in ml)	Rasakriya (semi solid status) (in ml)	Loss (in ml)	% loss
6000	2000	4000	66.66

Table 6: Preparation of Rasakriya.

Gandhaka (in g)	Liquid (in ml)	Weight of Gandhaka after Bhavana (in g)	Increase (In g)	% increase	Time taken for whole process
1000	2000	2100	1100	110	7 days

Table 7: The data of increase in weight of Gandhaka after Bhavana (Modified).

- Comparative physicochemical analysis of Gandhakadi Yoga prepared by traditional method and modified method areas given in (Table 8).

Parameter	Samples				
	GyA1	GyA2	GyA3	Average	GyM
pH	4.37	3.79	3.91	4.02	4.06
Loss on drying	34.24	37.82	27.66	33.24	34.2717
Ash value	11.35	13.27	11.3	11.97	12.86
Acid insoluble ash	0.38	0.36	0.28	0.34	0.28
Water soluble extract	35.36	30.22	30.86	32.14	36.7
Alcohol soluble extractives	23.84	24.56	24.65	24.35	21.1

Table 8: Analytical results of various samples.

Discussion

Conversion of the principles of compounding into formulation is the goal of various procedures. The term Samskara had been denoted by ancient Ayurveda scholars. To achieve small particle size and incorporation of other active material by levigation is known as Bhavana Sanskara. Materials needed for Bhavana are single/compound powdered drug and liquid media. Liquid media is an essential component, contributing to a major role in the outcome of Bhavana apart from mechanical procedures, like grinding and so on. Bhavana can be carried out by adopting two processes: (A) Staged levigation or (B) Nimajjana (saturating with a specified liquid). The amount of liquid added should be sufficient to generate a soft mass and keep the material moist during the grinding process.

To increase the therapeutic efficacy along with some important benefits like smaller dose, increase bioavailability etc. the Bhavana of many drugs has been given to Gandhaka. The result of all three batches of classically prepared GyA were prepared in the monsoon took more time because of humid atmosphere. While the GyA prepared in winter season takes less time than monsoon but more than summer. Here no artificial temperature regulator or humidity controller was used. For the Bhavana, granite mortar and pestle were used to avoid the drug interaction. After the first Bhavana the smell of Gandhaka was observed but after several Bhavana the smell and taste were according to the Bhavana Dravya. The weight of dried Gandhaka was increasing after each Bhavana.

Initially the Bhavana Dravya was needed very less to get Pankvat (mud like) state. After the Bhavana of Aamalaki pestle was running very easily in the mortar and the drug was dried very easily but it became harder and harder after each Bhavana. The drug absorbs the moist after the Bhavana of Haritaki and easily converted in to semi solid state. As Jamnagar is a place near to seashore, humidity level is always very high around 55% to 75%. So manual Bhavana process is very time consuming, as Bhavana Dravya don't get dried till many days if artificial method is not adopted. Especially after Bhavana of sticky drug like Guduchi, it is very hard

to run pestle manually. Bhavana Dravya can be soaked in summer comparatively faster. Labor-intensive Mardana was tough due to many factors, and it was more time consuming. During the study one vital point was observed that to prepare Kharaliya Rasayana at industrial level where the quantity of Gandhaka may be 50kg or even 100kg. Then it would be very hard to prepare it classically as is very time consuming and it may take even up to 105 days.

So, to find out a faster alternative method to prepare Kharaliya Rasayana without violating the classical method, a special batch was prepared a modified way.

- Approximate average volumes of Bhavya Drava were calculated of 3 previous batches. For example: for 1kg Gandhaka on an average 750ml Bhavana Dravya is required for 3 Bhavana.
- There are 8 Bhavana Drava in Gandhakadi Yoga. So 750ml of each Bhavana Drava was mixed and the water part was evaporated at very slow temperature. The 'Rasakriya' state which is semi solid in status was prepared.
- This 'Rasakriya' was mixed with Shuddha Gandhaka and Bhavana was given with the help of electric runner for 3 days.
- It becomes a very tedious and time consuming process for large scale production of Kharaliya Rasayana where Bhavana Dravya or number of Bhavana is many. Some times it may take as many as 100 days.
- Such method can be useful for large scale production at industrial level as the total process took only 1 week instead of 9 to 18 weeks of manual process and individual Bhavana. This method can be useful for preparation of similar drug like Gandhaka Rasayana.
- This sample was also comparatively analyzed with batch no A1 to A3. However this was done as a pharmaceutical experiment and further distinctive research may be done in this direction.

Analytical Study

Evaluation on modern analytical parameters like pH, Loss on drying, Ash value, Acid insoluble ash, Water soluble extract, Alcohol soluble extractives revealed that there are no

major changes in any parameters in both the groups. So e.g. In Classical Gandhakadi Yoga, it was between 30.22 to 35.36, in modified method it was 36.7 and in the preparation of Gandhakadi yoga A, max Kwatha has been used for Bhavana process, which is water extractive, while in modified method, only water extract was used for Bhavana process [6,7].

Conclusion

Looking at the need of the industry for faster production without violating the basic principles. Kharaliya Rasayana may be prepared modified way. To develop Standard Manufacturing Process for such bulk production, it is required to evaluate the total solid content (Rasakriya/Ghana) of every single Bhavana Dravya. Total number of Bhavana Drava and Dravya can be calculated as per the classical reference of numbers of Bhavana (3/7/21 times) for the particular product. Then Bhavana can be given off by adding Rasakriya/Ghana at the same time as per calculation and may be processed at the same time which will not only save the time but also requires less manpower and energy for bulk production.

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