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Pharmaceutical Standardization of an Ayurvedic Polyherbal Formulation- *Adityapak Guggulu*

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ABSTRACT

Adityapak Guggulu is a polyherbal formulation, prepared according to the method as described in *Chakradatta*. It is the only *Guggulu Kalpana* which is prepared by giving *bhavana* of *dashamoola kwatha* and dried in the heat of the Sun. The present study deals with development of preliminary pharmaceutical and analytical profile of *Adityapak Guggulu* which is not available. To set the standard operating procedure, three batches of the drug was prepared. To standardize and to develop the quality parameters of the drug organoleptic characters, physicochemical analysis, chromatographic patterns, microbial screening and heavy metal analysis was done. The result of physicochemical analysis were found more or less similar for all the three samples. TLC has showed identical R_f values indicating that same type of compounds are present in the samples. As per microbial overload test results, total plate count and total fungal count were within the normal range in all drug samples and the pathogens found absent. The heavy metals were within the permissible limits as per API. The obtained values of physical and chemical parameters for the finish product can be adopted to lay down new pharmacopoeial standards.

KEYWORDS

Standardization, Adityapak Guggulu, Pharmaceutical, Physicochemical

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INTRODUCTION

Pharmaceutical study means the different process involve in the manufacturing of drug. Like healing, drug manufacturing too is an art. The significance of drug has been rightly established in Ayurveda. Looking to the importance of *dravya* (drug), *Acharya* Charaka placed it at second position in *Chikitsa Chatuspada*[1]. The drug should have four properties i.e. to be dispensable in multiple dosage forms, to be available in abundance, with all pharmaceutical properties and suitability[2]. Therefore, while treating an ailment the first and foremost thing is the selection of the drug which is prepared in a proper way.

Adityapak Guggulu, which was described by Sri Chakrapanidatta in his treatise *Chakradatta* for treatment of various *vatavyadhi*, is widely used by the practitioners of Ayurveda. But, due to dearth of standard operating procedures for processing of *Adityapak Guggulu* and also pharmacopoeial standards for the medicine, the preparation which were done using traditional methods may not have the desired quality and batch-to-batch uniformity. Hence, there is need for standardization of *Adityapak Guggulu* following scientific parameters including organoleptic characters, physicochemical analysis, chromatographic patterns, microbial screening and heavy metal analysis. The planning of the present work was to standardize and to develop the quality parameters of the drug.

MATERIALS AND METHODS

Adityapak Guggulu is a polyherbal formulation consisting of 19 ingredients which was mentioned in *Chakradutta, Vatavyadhi*/66-68[3]. The chief ingredient of the formulation is *Guggulu*. Here, '*Aditya'* means the Sun and '*paka'* means method of preparation i.e. it is mainly processed under the direct heat of the Sun. The raw materials should be taken and impregnated in the decoction of *dashamoola*. Later, the contents are kept in the heat of the Sun and left to stay until the ingredients get saturated with the *kwatha* and get dry. The process of impregnating the ingredients in *dashamoola kwatha* and drying it in the heat of the Sun is repeated for 7 times. Later *vati* is prepared out of the ingredients and dried in Sun heat.

Table 1 Ingredients of *Adiytapak Guggulu*

Sl. No.	Ingredients	Latin name	Part used	Proportion
1.	*Guggulu*	*Commiphora wightii* (Arn) Bhandari	Exudate	10 part
2.	*Haritaki*	*Terminalia chebula* Retz.	Pericarp	2 part
3.	*Bibhitaki*	*Terminalia belerica* Roxb	Pericarp	2 part
4.	*Amalaki*	*Phyllanthus emblica* Linn	Pericarp	2 part

5.	*Pippali*	*Piper longum* Linn.	Fruit	2 part
6.	*Dalcini*	*Cinnamomum zeylanicum* Blume	Stem Bark	1 part
7.	*Elachi*	*Elettaria cardamomum* (Linn.)Matom.	Fruit	1 part
8.	*Bilva*	*Aegle marmelos* (Linn.) Correa ex Roxb.	Root bark	2 part
9.	*Syonaka*	*Oroxylum indicum* (L.) Vent.	Root bark	2 part
10.	*Gambhari*	*Gmelina arborea* Roxb.	Root bark	2 part
11.	*Patala*	*Stereospermum suaveolens* (Roxb.)DC	Root bark	2 part
12.	*Agnimantha*	*Clarodandrum phlomidis* (Burm. f.) O. Ktze.	Root bark	2 part
13.	*Salaparni*	*Desmodium gangeticum* (L.) DC.	Root	2 part
14.	*Prisniparni*	*Uraria picta* (Jacq.) Desv. Ex DC	Root	2 part
15.	*Brihati*	*Solanum indicum* Linn.	Root	2 part
16.	*Kantakari*	*Solanum xanthocarpum* Burm.f.	Root	2 part
17.	*Gokshur*	*Tribulus terrestris* Linn.	Root	2 part

All the samples of collected raw materials were identified and authenticated in the Department of *Dravyaguna Vigyan*, Govt. Ayurvedic College, Guwahati. Various pharmacognostical, physicochemical and phytochemical examination of the drug was carried out in the State Drug Testing Laboratory (AYUSH), Govt. Ayurvedic College, Assam. The materials was assessed through quantitative analysis of standardization parameters such as foreign matter, loss on drying, ash value, acid insoluble ash, water soluble extractive, methanol soluble extractive as per the methods described in the Ayurvedic Pharmacopoeia of India[4].

The whole pharmaceutical study was carried out at the State Ayurvedic Pharmacy of Govt. Ayurvedic College, Guwahati and arranged in the following order-

1. Preparation of *Churna* of herbal ingredients.
2. Preparation of *Dashamoola Kwatha Churna.*
3. *Shodhana* of *Guggulu.*
4. Preparation of *Dashamoola Kwatha.*
5. Preparation of *Adityapak Guggulu*.

Preparation of *Churna* of herbal ingredients

The herbal ingredients from Sl. No. 2 to 7 (Table 1), were washed and dried properly after removing the physical impurities, if any. Later, it was pulverized individually and sieved by 85 mesh to obtain fine powder. Sieved fine powder was collected and packed in air tight container (Table 3).

Preparation of *Dashamoola Kwatha Churna*

The ingredients from Sl. No. 8 to 17(Table 1), which are known as *dashamoola* looked for any physical impurities and removed. After drying properly all the ingredients were mixed in equal quantities and coarse powder was made with the help of disintegrator to pass all the materials through sieve no. 22. Sieved *kwatha churna* was collected and packed in plastic bag (Table 4).

Shodhana* of *Guggulu

Purification of *Guggulu* was done with *gomutra* (ratio 1:4) by *swedana* method. After removing the physical impurities *Guggulu* was shifted into a stainless steel vessel containing *gomutra*. The contents were subjected to mild heat maintaining temperature between 72^0C -80^0C to facilitate gradual dissolution of G*uggulu*. After complete dissolution, the contents in hot condition were filtered through muslin cloth. Contents remained as residue in cloth were discarded. The filtrate was further heated to evaporate the liquid portion maintaining temperature between 65^0C - 72^0C. Heating was given till the contents become semisolid, which was shifted into stainless steel tray smeared with *ghreeta*. The tray was kept in to the oven at the temperature of 70^0C. The sodhana of Guggulu was done in three batches (Table 5).

Preparation of *Dashamoola Kwatha*

Dashamoola kwatha churna was taken from the above practical and soaked in water for overnight (ratio 1:8). Next day, it was boiled on slow heat to reduce the quantity became $1/8^{th}$. Later it was filtered with clean cotton cloth and the liquid was collected as *dashamoola kwatha* (Table 6).

Preparation of *Adityapak Guggulu*

The *Adityapak Guggulu* was prepared in three batches by following the method as mixing, Sun drying and pill making. The quantity of ingredients used in the formulation are shown in Table 2.

Table 2 Quantity of ingredients used in the formulation

Sl. No.	Ingredients	Proportion	Quantity (in g.)
1.	*Sodhita Guggulu*	10 part	450 g.
2.	*Haritaki Churna*	2 part	90 g.
3.	*Bibhitaki Churna*	2 part	90 g.
4.	*Amlaki Churna*	2 part	90 g.
5.	*Pippali Churna*	2 part	90 g.
6.	*Dalcini Churna*	1 part	45 g.
7.	*Elachi Churna*	1 part	45 g.
8.	*Dashamoola kwatha*	900 ml. X 7 times= 6.3 L	

Initially, all the *Churna* (Sl. No. 2 to 7) were taken in prescribed quantity and mixed uniformly with *Guggulu* to prepare a homogenous mixture. After proper mixing, *bhavana* by *dashamoola kwatha* (900 ml.)

was given and the material was transferred to stainless steel tray. The tray was covered with two folded cotton cloth. It was kept in the heat of Sun and left to stay until the water content of the material get evaporated and the ingredients get dry. The process for *bhavana* by the equal quantity *dashamoola kwatha* and drying in the heat of Sun was repeated for 7 times. After proper drying, with the help of pill cutting machine *vati* was prepared. During pill cutting a little amount of talc was sprinkled over it to avoid cohesiveness. The size of *vati* were inspected and malformed were again subjected to the process. *Vati* were allowed to oven dry at the temperature 55^0C for 8 hours and after that it was dried again in the heat of sun for 4 days. After drying, on the next day, *vati* were polished in polishing pan and stored in airtight plastic container.

RESULTS

Table 3 Results of all prepared *Churna*

Sl. No.	Drug name	Quantity taken (in g.)	*Churna* obtained (in g.)	Loss (in g.)	% of yield
1.	*Haritaki*	500	460	40	92.00
2.	*Bibhitaki*	500	455	45	91.00
3.	*Amalaki*	500	447	53	89.40
4.	*Pippali*	500	440	60	88.00
5.	*Dalcini*	500	444	56	88.80
6.	*Elachi*	500	432	68	86.40

Table 4 Results of *Dashamoola Kwatha Churna*

Quantity taken	Quantity obtained	Loss in weight	% of loss
22.00 kg.	20.40 kg.	1.60 kg.	7.3 %

Table 6 Results of *Dashamoola Kwatha*

Quantity of *Dashamoola*	Quantity of water	Quantity obtained
900 g.	6.30 L.	910 ml.

Table 5 Results of all three batches of *Guggulu sodhana*

Batch No.	Wt. of *Guggulu* (in g.)		Wt. loss (in g.)	% of yield	Residue (in g.)
	Before *sodhana*	After *sodhana*			
GS-1	700	510	190	72.9	231
GS-2	700	534	166	76.3	208
GS-3	700	525	175	75.0	222
Average	**700**	**523**	**177**	**74.7**	**220.3**

Table 7: Results of all the three batches of *Adityapak Guggulu*

Batch	Initial Quantity (in g.)	Quantity obtained (in g.)	Duration for preparation (in days)	Gain (in g.)	Gain (in%)
APG-1	900	1350	23	450	50.0
APG-2	900	1388	22	488	54.2
APG-3	900	1372	30	472	52.4
Average	900	1370	25	470	52.2

As a part of standardization procedure, the finished product was tested for relevant physical and chemical parameters and also subjected to microbial screening and heavy metal analysis. While studying organoleptic characters of *Adityapak Guggulu*; the colour is found to be brownish black and odour is g*omutra* with slight balsamic, taste is bitter, slight pungent and touch is smooth.

Table 8 Physico-chemical parameters of *Dashamoola Kwatha*

Sl. No.	Test	Result
1.	pH (10% aqueous)	5.65
2.	Specific gravity	1.02
3.	Viscosity (millipoise)	9.39
4.	Refractive index	1.34
5.	Total solid content (%w/w)	9.67

Table 9 Physico-chemical parameters of *Adityapak Guggulu*

Sl. No.	Parameters	APG-1	APG-2	APG-3
1.	Loss on drying %	4.60	4.60	4.50
2.	Ash Value %	11.23	10.23	12.03
3.	Acid Insoluble ash %	3.23	3.13	3.83
4.	Water Soluble extractive %	67.50	64.62	66.62
5.	Methanol soluble extractive %	49.30	48.39	50.17
6.	Hardness (kg/cm^2)	4.3	4.3	4.5
7.	Average Weight (g.)	0.527	0.521	0.511
8.	Disintegration time (min.)	54	52	56

TLC was done with ethanolic extract of *Adityapak Guggulu*. The solvent system Toluene: acetone (9:1) was used as mobile phase and R_f value was calculated. It showed 4 spots (0.19, 0.27, 0.45, 0.50/ 0.17, 0.30, 0.45, 0.55/ 0.19, 0.29, 0.41, 0.53) for sample no. APG-1, APG-2 and APG-3, respectively. The heavy metal analysis was done for all the three samples by Atomic absorption spectroscopy. Lead, Cadmium and Mercury was not detected for all the three sample. But, Arsenic was found to be 0.82 ppm, 0.42 ppm and 0.64 ppm for APG-1, APG-2 and APG-3, respectively. The microbial limit test was done for all the three samples. As per results, total aerobic count was 40cfu/g., 60cfu/g. and 40cfu/g. and total fungal count 90 cfu/g., 85 cfu/g., and 80 cfu/g. for APG-1, APG-2 and APG-3, respectively. The pathogens *P. aeruginosa*, *E. coli* and *S. typhi* were found to be absent in all the three samples.

DISCUSSION

The study was selected to develop the pharmaceutical standardization of the drug. To develop the standard three batches of *Adityapak Guggulu* were prepared and tested for physical and chemical parameters. In preparation of powder of the raw materials 92% yield was found with *Haritaki*, 91% with *Bibhitaki*, 89.4% with *Amalaki*, 88% with *Pippali*, 88.8% with *Dalcini* and 86.4% with *Ela*. During the preparation of *Dashamoola kwatha churna* also 92.7% yield was observed. Loss may be due to the fine particles of powder were spread during grinding and sieving.

Guggulu shodhana by *swedana* method is revalidated in this study. Aim behind the *shodhana* process of *Guggulu* is to separate the liquid soluble and insoluble parts and transfer by virtue of *shodhana* media into it. During this process, temperature was maintained between 60-70^{0}C. More heat leads to excessive frothing and spilling of the material. *Shodhana* of Guggulu was carried out in three batches. For each batch 700 g. of *ashuddha Guggulu* and 2.8*l* of *Gomutra* was taken. The process was completed in 3 days. Results show that average 74.7% yield and 220.3 g. residue was observed.

Adityapak Guggulu was prepared in three batches for each batch of *sodhita Guggulu*. *Dashamoola kwatha* should be freshly prepared for each *bhavana*. Until the water content of the material get evaporated by the heat of Sun and the ingredients get dry, the next *bhavana* should not be given.

The time taken to prepare the sample APG-1, APG-2 and APG-3 were 23 days, 22 days and 30 days respectively. Looking to the condition of weather, variation of time for the preparation was observed. The yield in case of APG-1 was 1350 g., APG-2 was 1388 g. and APG-3 was 1372 g.. An average gain of 470 g. (52.2%) was observed.

After calculating the powder ingredients and *Guggulu* the expected quantity should be around 900 g. The gain was due to the solid content of the *Dashamoola kwatha*. Total 6.3 L (900 ml X 7 times) *kwatha* was used for the preparation of each sample. Hence, the contribution of solid content of the *kwatha* was 7.45%.

The samples were evaluated for organoleptic parameters, physicochemical profiles, TLC profile, microbial limit test and heavy metal analysis. As far as the organoleptic properties are concerned, the samples has showed identical results. All appeared brownish black in colour, odour is of *Gomutra* with slight balsamic. The balsamic odour is due to the presence of *Guggulu* as major ingredients and *sodhana* of *Guggulu* was done by *gomutra*. The taste is bitter and slight pungent, touch is smooth. The loss on drying, ash value, acid insoluble ash, water soluble extractive, alcohol soluble extractive, hardness, uniformity in weight, disintegration time are found more or less similar for all the three samples. Thin layer chromatography has showed 4 spots (0.19, 0.27, 0.45, 0.50/ 0.17, 0.30, 0.45, 0.55/ 0.19, 0.29, 0.41, 0.53) for APG-1, APG-2 and APG-3 respectively. The same Rf values indicating that same type of compounds are present in the samples.

As per microbial overload test results, total plate count and total fungal count were within the normal range in all drug samples

and *P. aeruginosa*, *E. coli* and *S. typhi* were absent. In heavy metal analysis lead, cadmium and mercury were not detected in any sample. But, arsenic was found to be 0.82 ppm, 0.42 ppm and 0.64 ppm for APG-1, APG-2 and APG-3 respectively, which are within the permissible limits as per API. As all the raw materials are plant product and chances of contamination of arsenic may be during storage process and water which was used for *dashamoola kwatha* may also be the cause. The microbial load and heavy metal analysis authenticated the safety aspect of the formulation from the analytical perspective.

CONCLUSION

The scientific analysis for standardization and development of authentic operative procedures for Ayurvedic formulation is highly essential. For the preparation of *Adityapak Guggulu*, the result obtained can be used to develop new set of pharmaceutical standards for getting optimal efficacy of medicine.

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