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ORIGINAL RESEARCH ARTICLE

Accelerated Stability Study of Gojihvadi Kwath Granules

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ABSTRACT

Saviryata avadhi (shelf life) of Ayurvedic preparations is a burning problem specifically with Panchvidha Kashaya Kalpana (Primary preparations) apart from their difficult handling; poor palatability and odour etc. Gojihvadi kwath is one such preparation which is widely used in the treatment of fever. Saviryata avadhi (Self life) of kwath preparation is merely one day as mentioned in our classical texts and it has been reported that conversion of kwath into granules can accelerates its shelf life upto one year. So, in the present study fabrication of Gojihvadi Kwath into granules was done and the dosage form so obtained was trialed for accelerated stability study upto 6 month using organoleptic characters as well as physico chemical parameters mentioned in Ayurvedic pharmacopeia including microbial contamination. The results of this study showed no marked changes in organoleptic as well as in physico chemical parameters indicating accelerated shelf life of granules over kwath preparation up to a period of six months. Thus it proves that shelf life of Gojihvadi Kwath can be increased upto one year in Granules form.

Key words: Gojihvadi Kwath, Gojihvadi granules, Saviryata avadhi, Self life, Multitech chamber.

INTRODUCTION

The scientific research provides us the grounds to reach the truth, to know the spheres and its limitations & finally to know its applied aspects. The research work is the integral part of the science dealing with health and diseases. As a science of Life and Health, the different branches of Ayurveda have evolved over the long period as health being mainly concerned with keeping the body fit and preventing as well as curing the diseases, which was its main objective. Logically therefore, there has been a constant research on therapeutic agents that keeps the body fit, increase its capacity to fight a disease and bring it back to normal. These therapeutic agents are termed as Drugs. The success of a physician lies in identifying the disease in the most appropriate way and prescribing the most effective drug. Herbs, minerals and metals were used for medicinal purpose.

In the present work Gojihvadi kwath has been selected which is described by Acharya Yadav ji Trikam ji first time under jwar rogaadhikara.[1] As we all know that jwar is foremost among all diseases in which various kwath preparations has been advocated at initial stage. But preparation and use of kwath is a tedious job in today's metropolitans life style. Moreover due to poor palatability, odour and short shelf life these are nearly becoming out fashioned medicine.

Therefore, it is the need of time to formulate the dosage forms which are convenient in handling, uniformity in dosing, mask bad taste, odour etc. along with easy administration to human beings. That's why the task is undertaken to convert the Gojihvadi kwath in granules form.

Method of preparation ultimately affects the therapeutic efficacy of a formulation. Hence in the present study of Gojihvadi kwath and its granules a trial has been made to get standard method of preparation of these two dosage forms & Gojihvadi granules thus prepared have been assessed for their shelf life. ICH and WHO have taken conclusive steps regarding various aspects of estimation of shelf life of various formulas existing throughout the world.

The guidelines are framed on the concept of derived storage conditions of temperature and %

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relative humidity in the various climatic zones around the world .The globe is divided into four zones. The measured and calculated data in different zones are based on specific storage conditions. Various parameters to analysis stability period for different formulations are given in various guidelines.

Material & Methods

In the present study Gojihvadi granules have been prepared from Gojihvadi kwath through Gojihvadi kwath churna by using standard operating procedures (SOP) technique as per the method mentioned in Siddha yoga Samgraha[1] and Ayurvedic formulary of India Part– II.[2] **(Table No. 1)**The following steps have been carried out for the preparation of Gojihvadi kwath and Granules.

Step- 1.The Gojihvadi kwath has been prepared from following four types of kwath churna:

- Group A-From kwath churna(8 mesh size)
- Group B-From Kwath Churna (Coarse powder, 10mesh size)
- Group C-From Kwath Churna (Moderately Coarse powder, 44mesh size)
- Group D-From Kwath Churna (Fine powder, 85 mesh size)

Each sample has been prepared thrice and they named as Batch I, Batch II, and Batch III. In this way total twelve samples have been prepared.

Step-2. Four types of Gojihvadi granules have been prepared by four types of kwatha. Kwath and sugar mixed in equal quantity and allowed to boiling continuously till becomes solid. Then passed through the sieves of 10 mesh size and granules are formed.

Each sample was prepared thrice and they named as Batch I, II, and III. In these way total twelve samples of Gojihvadi granules have been prepared.

Details of the preparation of Gojihvadi granules

All ingredients used in the preparation of Gojihvadi granules were cleaned, dried and taken in known amount **(Table 1)** were coarsely powdered separately with the help of pulverizer & transformed to the set of sieves from no.8, 10, 44 and 85. The sieves are shaken in a sieve shaker for about 30 minutes and the residue on each sieve is weighed separately and kept in air tight containers. In this way total twelve samples of Gojihvadi kwath powder has been prepared. Gojihvadi kwath was prepared by Gojihvadi kwath powder (1 part) boiled with 10 times water & reduced till two fifth. Then in this prepared Gojihvadi kwath equivalent amount of sugar were mixed & again heated up to solidification of material up to paka siddhi lakshana of avaleha mentioned in Sharangdhar Samhita[3] which was again allowed to paka till acquired soft solid consistency then this solid material was passed through sieve no. 10 & prepared Gojihvadi granules were dried and packed into plastic container of food grade quality. **(Table 2, 3, 4, 5)**

Accelerated study of Gojihvadi granules

All the samples of Gojihvadi granules were evaluated for organoleptic & physico-chemical parameters (mentioned below) at zero months, one month, three month and six month for accelerated stability study.

Organoleptic character mentioned in our classical textbooks for evaluating the qualities of preparation by colour, taste, odour and consistency etc were noticed through jyanendriya in all samples.

Physico chemical parameters including specific Gravity, pH, total solid content, specific gravity, viscosity at 25^{o}C, pH of aqueous suspension (w/v), loss on drying, water soluble extractive, alcohol soluble extractive, total ash content, acid insoluble ash, microbial contamination has been carried out.

RESULTS

Table 6 & 7 respectively showed organoleptic & physico-chemical character of different samples of Gojihvadi granules at zero, after one month, after three month & after six month accelerated stability study while **Table 8** showed microbial overload.

DISCUSSION

Accelerated Stability Study of Organoleptic and physicochemical characters of the samples:

From the **Table 7 & 8** can be inferred that in all the preparations of all batches and the groups, no remarkable change in colour, odour, taste and consistency was observed. The brown colour may be due to the crude drug as well as the presence of sugar in granules which may impart brown colour to the preparations after fabrication into granular form. The sweet taste of the granules up to the limit of the study indicated the stability of sugar as it is also supported by hardness of the preparations. Hardness also indicated no moisture absorbance at 75% RH of the stability study. The remarkable hardness of the granules will impart the aesthetic value as well the therapeutic value to the granules. It was observed in case of kwath that it was pleasant in taste but in the fabrication of granules and in stability study, no identified smell was recognized. But in all the cases, sweet taste

and hardness was maintained up to the six month which is the good indication of stability for solid dosage form. Due to hardness, if required, these granules can be formulated into tablet form and this formulation may also have good therapeutic effect.

The parameters studied for the accelerated stability study such as pH, loss on drying, water soluble extractives, alcohol soluble extractives, total ash, water soluble ash and acid insoluble ash were not statistically significant when the samples were studied at one month, three month and six month as analyzed by one way ANOVA. Up to the last of the study, the pH of suspension prepared by granules shown acidic pH which was also observed in case of samples of granules at normal stage. It may be due to the addition of sugar and the processing temperature of the granules. As on higher temperature, some of the sugar part may convert into acidic part in presence of water e.g. glucose can convert into gluconic acid. These acidic components formed after hydrolysis of sugar may impart the acidic nature to the formulations. Some of the microbial fermentation as assessed by total microbial load can also have its impact on acidic nature of the suspension prepared from granules. In all of these, the amount of water soluble extractives and alcohol soluble extractives was changed to a major extent in comparison to other parameters. These values shown decrement as the time for study was increased. Here, it seems that these extractives are formed at high temperature and hence may lose the moisture to a greater extent. Due to change in temperature and humidity in the stability chamber (Multitech stability chamber) used for accelerated stability study (e.g.40^0C and 75% RH respectively), these extractives lost the total moisture to attain the equilibrium condition of the chamber and hence decreased their weights. In comparison to all values, the amount of water soluble extractive is higher that indicated much more amount of water soluble active components in the crude drug. Also, these components were so much soluble that these did not increase the viscosity as observed in case of Kwath. Their higher solubility may result quick disintegration and dissolution in gastrointestinal fluid from the granules if administered by oral route. This property of enhanced release will promote the quick response of the active components present in the crude drug after administration. Consequently, it will result in marked bioavailability of the drug. These granules may work as a conventional dosage form for prompt effect. Besides these, the hardness as physical parameter will also impart the ease of fabrication in the solid dosage form of the drug. As it was analyzed by previous studies that all batches maintained their hardness to a remark, the granules prepared by any sieve number will have good aesthetic and therapeutic effect.

Microbial contamination of different samples of Gojihvadi Granules during accelerated study inferred that total microbial counts as well as total fungal count in different samples of Gojihvadi Granules in accelerated conditions were observed below than the maximum limit defined in API part II volume I 10^5 per gram & 10^3 per gram respectively[4]. This indicated that we can store granules for a longer duration without affecting their constituent which indicates its long shelf life (**Table 8**).

Table 1: Details of ingredients used in the preparation of Gojihvadi Granules

S No	Drug Name	Botanical Name	Part Used	Proportion (%)
1	Gojihva	*Onosma bracteatum*	Whole Plant	6.45
2	Kantakari	*Solanum surattance*	Root	6.45
3	Vasa	*Adhatoda vasica*	Whole Plant	6.45
4	Marich	*Piper nigrum*	Fruit	3.23
5	Yestimadhu	*Glycerrhiza glabra*	Root	6.45
6	Draksha	*Vitis vinefera*	Dry fruit	6.45
7	Hansraj	*Adiantum lanulatum*	Whole Plant	6.45
8	Mishreya	*Foniculum vulgare*	Fruit	6.45
9	Gulavanaphsa	*Viola odorata*	Flower	6.45
10	Khubkalam	*Sisymbrium irio*	Seed	6.45
11	Atasi	*Linum usitatissimum*	Seed	6.45
12	Jufa	*Hyssopus officinalis*	Whole Plant	6.45
13	Sapistan	*Cordia latifolia*	Fruit	6.45
14	Anjir	*Ficus carica*	Dry Fruit	6.45
15	Unnav	*Zizyphus sativa*	Fruit	6.45
16	Khatmi	*Althoea officinalis*	Seed	6.45

Table 2: Details of Three samples of Gojihvadi granules of Group A

Parameter	Kwath Preparation			Parameter	Granules Preparation		
	B - I	B- II	B- III		B- I	B- II	B- III
Kwath churna (gm)	155	155	155	Kwath (ml)	620	620	620
Water (ml)	1550	1550	1550	Temp. when sugar is added (^{0}C)	84	82	84

Temperature (^{0}C)	95	98	94	Temp. at the end (^{0}C)	92	90	92
Total yield (ml)	620	620	620	Total yield (gm)	125	140	136
Duration (min)	90	110	95	Duration (min)	170	185	175

(Note: B – I –Batch I, B- II, Batch II & B-III – Batch III)

Table 3: Details of Three samples of Gojihvadi Granules of Group B

Parameter	Kwath Preparation			Parameter	Granules Preparation		
	B-I	B-II	B-III		B-I	B-II	B-III
Kwath churna (gm)	155	155	155	Kwath (ml)	620	620	620
Water (ml)	1550	1550	1550	Temp. when sugar is added (^{0}C)	86	82	85
Temperature (^{0}C)	92	95	94	Temp. at the end (^{0}C)	90	91	92
Total yield (ml)	620	620	620	Total yield (gm)	130	145	135
Duration (min)	100	110	90	Duration (min)	160	180	175

Table 4: Details of Three samples of Gojihvadi Granules of Group C

Parameter	Kwath Preparation			Parameter	Granules Preparation		
	B-I	B-II	B-III		B-I	B-II	B-III
Kwath churna (gm)	155	155	155	Kwath (ml)	620	620	620
Water (ml)	1550	1550	1550	Temp. when sugar is added (^{0}C)	88	82	85
Temperature(^{0}C)	98	99	94	Temp. at the end (^{0}C)	92	98	90
Total yield (ml)	620	620	620	Total yield (gm)	130	140	142
Duration (min)	90	100	120	Duration (min)	160	125	165

Table 5: Details of Three samples of Gojihvadi granules of Group D

Parameter	Kwath Preparation			Parameter	Granules Preparation		
	B-I	B-II	B-III		B-I	B-I I	B-III
Kwath churna (gm)	155	155	155	Kwath (ml)	620	620	620
Water (ml)	1550	1550	1550	Temp. when sugar is added (^{0}C)	87	82	83
Temperature(^{0}C)	99	98	93	Temp. at the end (^{0}C)	91	90	93
Total yield (ml)	620	620	620	Total yield (gm)	146	145	150
Duration (min)	100	110	95	Duration (min)	150	185	155

Table 6: Accelerated Stability study of organoleptic characters of different samples of Gojihvadi Granules

At zero months

Characteristics	Sample 1	Sample 2	Sample 3
Colour	Brown	Brown	Brown
Odour	Odourless	Odourless	Odourless
Taste	Sweet	Sweet	Sweet
Consistency	Hard	Hard	Hard

After one month

Characteristics	Sample 1	Sample 2	Sample 3
Colour	Brown	Brown	Brown
Odour	Odourless	Odourless	Odourless
Taste	Sweet	Sweet	Sweet
Consistency	Hard	Hard	Hard

After three month

Characteristics	Sample 1	Sample 2	Sample 3
Colour	Brown	Brown	Brown
Odour	Odourless	Odourless	Odourless
Taste	Sweet	Sweet	Sweet
Consistency	Hard	Hard	Hard

After six month

Characteristics	Sample 1	Sample 2	Sample 3
Colour	Brown	Brown	Brown
Odour	Odourless	Odourless	Odourless
Taste	Sweet	Sweet	Sweet
Consistency	Hard	Hard	Hard

Table 7: Accelerated stability study of physiochemical parameters of Gojihvadi Granules

At zero months

S.No.	Parameter	Sample I	Sample II	Sample III	Average	S.D.
1	pH of 10% w/v aqueous suspension	6.26	6.05	6.11	6.14	0.1081
2	Loss on drying (%w/w)	4.12	3.12	3.77	3.67	0.5074
3	Water soluble extractives (%w/w)	79.2	76.2	78.3	77.9	1.539
4	Alcohol soluble extractives (%w/w)	18.9	20.6	17.3	18.9	1.6502
5	Total ash (%w/w)	9.7	11.6	10.22	10.5	0.9819
6	Water soluble ash(%w/w)	37.8	40.8	35.6	38.06	2.6102
7	Acid insoluble ash (%w/w)	19.8	15.7	18.2	17.9	2.0663

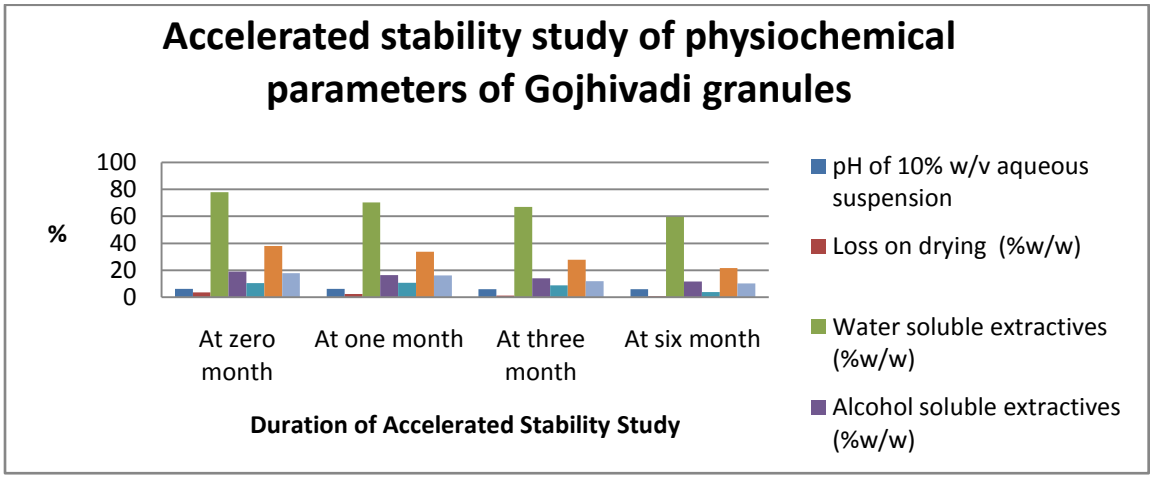
After 1 month

S.No.	Parameter	Sample I	Sample II	Sample III	Average	S.D.
1	pH of 10 % w/v aqueous suspension	6.16	6.01	6.08	6.08	0.07505
2	Loss on drying (%w/w)	2.12	2.92	2.06	2.36	0.4801
3	Water soluble extractives (%w/w)	71.36	71.36	68.36	70.36	1.7320
4	Alcohol soluble extractives (%w/w)	15.76	16.76	14.76	16.42	1.0000
5	Total ash (%w/w)	10.7	10.7	10.7	10.7	5.5598

6	Water soluble ash (%w/w)	32.8	34.8	33.5	33.7	1.0148
7	Acid insoluble ash (%w/w)	16.78	14.78	16.66	16.07	1.1216
		After three month				
S.No.	**Parameters**	**Sample I**	**Sample II**	**Sample III**	**Average**	**S.D.**
1	pH of 10 % w/v aqueous suspension	6.02	6.02	5.98	6.0	0.0230
2	Loss on drying (%w/w)	1.12	1.12	1.02	1.08	0.0577
3	Water soluble extractives (%w/w)	67.96	67.92	65.16	67.01	1.6015
4	Alcohol soluble extractives (%w/w)	14.23	14.73	13.23	14.06	0.7637
5	Total ash (%w/w)	8.9	8.91	8.2	8.7	0.4070
6	Water soluble ash (%w/w)	28.48	28.68	26.18	27.78	1.3892
7	Acid insoluble ash (%w/w)	12.3	12.32	11.3	11.9	0.5832
		After six month				
S.No.	**Parameters**	**Sample I**	**Sample II**	**Sample III**	**Average**	**S.D.**
1	pH of 10 % w/v aqueous suspension	5.78	5.88	5.88	5.84	0.0577
2	Loss on drying (%w/w)	0.72	0.88	0.42	0.68	0.2335
3	Water soluble extractives (%w/w)	58.88	58.88	60.88	59.54	1.1547
4	Alcohol soluble extractives (%w/w)	11.14	11.54	11.94	11.54	0.4000
5	Total ash (%w/w)	3.3	3.12	3.9	3.8	0.4084
6	Water soluble ash (% w/w)	21.8	20.6	22.8	21.7	1.1015
7	Acid insoluble ash (%w/w)	9.3	11.3	10.3	10.3	1.0000

Table 8 : Microbial contamination of different samples of Gojihvadi Granules during accelerated study

S.No.	Sample	At Month	Total Bacterial count	Total fungal count
1	I	Zero	78cfu/gm	Less than 10cfu/gm
2		One	78cfu/gm	Less than 10cfu/gm
3		Three	85cfu/gm	Less than 10cfu/gm
4		Six	136cfu/gm	Less than 10cfu/gm
5	II	Zero	48cfu/gm	Less than 10cfu/gm
6		One	54cfu/gm	Less than 10cfu/gm
7		Three	72cfu/gm	Less than 10cfu/gm
8		Six	80cfu/gm	Less than 10cfu/gm
9	III	Zero	60cfu/gm	Less than 10cfu/gm
10		One	72cfu/gm	Less than 10cfu/gm
11		Three	90cfu/gm	Less than 10cfu/gm
12		Six	95cfu/gm	Less than 10cfu/gm



CONCLUSION

Accelerated stability study of different samples of Gojihvadi granules showed insignificant change in organoleptic & physiochemical parameters which indicates that Gojihvadi granule has shelf life up to one year as compared to powder as well as Gojihvadi kwath & provide convenient & palatable dosage form.

गोजिÀादि क्वाथ ग्रेन्युल्स की एक्सीलेरेटीड स्टेबिलिटी स्टडी

*डॉ0नीतू **डॉ0 हरीश कुमार सिंघल ***डॉ0 शुचि मित्रा ****डॉ0 नम्रता जोशी *****डॉ0 खेमचन्द शर्मा

औषध सेवन के संदर्भ में पgचविध कषाय कल्पनाओं की सवीर्यता अवधि अत्यन्त अल्प है। इन मौलिक कल्पनाओं का रखरखाव, स्वादानुकुल न होना, अप्रिय गंध युक्त होना आदि तथ्य इनके निर्माण एवं उपयोग को चिकित्सा में सीमित करते है। गोजिÀादि क्वाथ एक ऐसी ही कल्पना है, जिसका उपयोग ज्वर चिकित्सा हेतु किया जाता है। हमारे शास्त्रीय

ग्रन्थों में क्वाथ कल्पना की सवीर्यता अवधि मात्र एक दिन की कही है। इसको ध्यान में रखते हुए वर्तमान अनुसंधान में गोजिÀादि क्वाथ से गोजिÀादि ग्रेन्युल्स का निर्माण कर उनकी (एक्सीलेरेटीड स्टेबिलिटी स्टडी) सवीर्यता अवधि का अध्ययन किया गया, जिसके सकारात्मक परिणाम देखने को मिले। इस सवीर्यता अध्ययन अवधि में गोजिÀादि क्वाथ ग्रेन्युल्स के ओरगेनोलप्टिक लक्षणों का आयुर्वेदिक फार्मोकोपिया में वर्णित भौतिक रसायन परीक्षणों (माइक्रोविएल कान्टामिनेशन सहित) में कोई विशेष परिवर्तन नहीं देखा गया, जिससे यह सिद्ध होता है कि गोजिÀादि क्वाथ ग्रेन्युल्स का निर्माण कर गोजिÀादि क्वाथ की सवीर्यता अवधि एक वर्ष तक बढ़ायी जा सकती है।

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