

A COMPARATIVE PHARMACEUTICO-CHEMICAL STUDY OF GOJIHVADI KWATHA AND ITS GRANULES W.S.R. TO STABILITY PROFILE

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Abstract

Gojihvadi Kwatha is a poly herbal drug formulation widely used in the treatment of Jwara (fever) was always burning issue due to its less Saviryata avadhi (Shelf life) as per mentioned in Ayurvedic text books , its method of administration and its taste as well as palatability. The present study was conducted to increase shelf life of Gojihvadi Kwatha by changing its dosage form into the granules. Gojihvadi granules were studied for accelerated stability study for six month as per mentioned organoleptic as well as physicochemical parameters and microbial contamination in Ayurvedic Pharmacopoeia. Study proved that no demarcation found in organoleptic as well as physicochemical parameters and microbial contamination (>10 cfu/mm). This verified the superiority of Gojihvadi granular form over Gojihvadi Kwatha with its increased shelf life up to one year.

Key words: Gojihvadi Kwatha; Gojihvadi granules; Saviryata avadhi; Shelf life; cfu-colony forming unit

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INTRODUCTION

Gojihvadi Kwatha^[1] is described by Acharya Yadavji Trikamji first time under jwara rogaadhikara has been selected for the present. But here is a problem to take Gojihvadi Kwatha's in prescribed Kwatha form because it is very tedious job due to lack of time in present era, also person does not like because of its bad taste, odour etc. It is spoiled due to its less shelf life. Due to commercialization now a days men are more and more dependent on the readymade preparation. Therefore, it is the need of time to formulate the dosage forms which is convenience in handling, uniformity of dose, masking of bad taste, odour etc along with easy administration. That's why the task was undertaken to convert the Gojihvadi Kwatha into granule form.

Aims and objectives

The present study was planned with the following aims and objectives.

- To change the dosage form of Gojihvadi Kwatha into Gojihvadi Granules.
- To fix a standard method of preparation of Gojihvadi Kwatha and its granules.
- To study the shelf life of Gojihvadi granules

MATERIAL AND METHODS

In the present study Gojihvadi granules have been prepared from Gojihvadi Kwatha through Gojihvadi Kwatha 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] (Table1)

The following steps have been carried out for the preparation of Gojihvadi Kwatha and Granules.

Step- 1

The Gojihvadi Kwatha has been prepared from following four types of Kwatha Churna:

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

Each sample was prepared thrice and was named as Batch I, Batch II, and Batch III. In these way total twelve samples was prepared.

Step-2

Four types of Gojihvadi granules were prepared by four types of Kwatha. Kwatha and sugar mixed in equal quantity and allowed to boil continuously till becomes solid. Then passed through the sieve of 10 mesh size and granules are formed. Each sample was prepared thrice and they named as Batch I, II, and III. Totally twelve samples of Gojihvadi granules were prepared.

Preparation of Gojihvadi Kwatha Churna

Each and every ingredient was collected from market after proper identification by pharmacognosist. These ingredients were cleaned, dried properly and taken in prescribed amount. After that these dravyas were coarsely powdered separately with the help of Pulverizor. Then equal quantity of each dravya was weighed and transformed to the set of sieves from no. 10, 44 and 85. The sieves were shaken in a sieve shaker for about 30 minutes and the residue on each sieve was weighed separately as well as kept in air tight containers. In this way total twenty four samples were prepared, twelve for Kwatha and twelve for granules.

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

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

Table 2: Details of ingredients used in Gojihvadi Kwatha Churna preparation

Ingredient	Original amount (g)	Powder obtained (g)	Percent loss (%)	Powder (mesh #08) (g)	Powder (mesh #10) (g)	Powder (mesh #44) (g)	Powder (Mesh #85) (g)
Gojihva	1000	995	0.5	160	200	186	162
Mulethi	1000	905	9.5	90	540	200	100
Misreya	1000	995	0.5	541	153	118	92
Draksa	1000	-	-	-	-	-	-
Anjir	1000	-	-	-	-	-	-
Unnava	1000	990	1	410	240	180	110
Vasa	1000	980	2	195	246	270	154
Jupha	1000	970	3	90	425	252	96
Slesmataka	1000	970	3	144	196	115	150
Khubkalan	1000	945	5.5	100	261	316	148
Hamsraja	1000	905	9.5	220	357	146	112
Gulavanaphsa	1000	900	10	108	200	400	180
Atasi	1000	955	4.5	220	320	230	92
Khatami	1000	950	5	278	181	217	160
Kantkari	1000	985	1.5	220	268	278	106
Kali Marich	500	490	2	86	110	84	80

Twelve samples of Kwatha Churna were prepared by mixing ingredients in given ratio. (Table 2)

Preparation of Gojihvadi Kwatha

For the preparation of Kwatha all ingredient (155 g) and water (1550 ml) were taken in 1: 10 ratio. The amount of water was taken as per

w/v concept. The temperature observed throughout the Kwatha preparation was in between 90-100⁰c while average duration was 1.5 to 2.0 hrs. The total yields of each sample of Gojihvadi Kwatha of different batches were 620 ml as shown in the tables. Thus total twelve samples were prepared in this method. (Table-3)

Table 3: Details of different samples of Gojihvadi Kwatha preparation

Parameters	Gojihvadi Kwatha A (yavkuta)			Gojihvadi Kwatha B (Mesh #10)			Gojihvadi Kwatha C (Mesh #44)			Gojihvadi Kwatha D (Mesh #85)		
	Batch I	Batch II	Batch III	Batch I	Batch II	Batch III	Batch I	Batch II	Batch III	Batch I	Batch II	Batch III
Amount of Kwatha Churna (g)	155	155	155	155	155	155	155	155	155	155	155	155
Water (ml)	1550	1550	1550	1550	1550	1550	1550	1550	1550	1550	1550	1550
Temp. during watha preparation (⁰ C)	95	94	98	96	98	98	98	96	95	100	98	97
Total yield (g)	620	620	620	620	620	620	620	620	620	620	620	620
Duration (hrs)	1.45	1.55	1.45	1.50	1.45	1.55	2.0	1.55	1.45	1.50	1.45	1.55

Table 4: Details of different samples of Gojihvadi granules preparation

Parameters	Gojihvadi granules A (yavkuta)			Gojihvadi granules B (Mesh #10)			Gojihvadi granules C (Mesh #44)			Gojihvadi granules D (Mesh #85)		
	Batch I	Batch II	Batch III	Batch I	Batch II	Batch III	Batch I	Batch II	Batch III	Batch I	Batch II	Batch III
Amount of Kwatha (ml)	620	620	620	620	620	620	620	620	620	620	620	620
Temp. (at sugar added) (⁰ C)	84	82	84	86	82	85	88	82	85	87	82	83
Temp. at the end (⁰ C)	92	90	92	90	91	92	92	98	90	87	82	83
Total yield (g)	125	140	136	130	145	135	130	140	142	146	145	150
Duration (min.)	170	185	175	160	180	175	160	125	165	150	185	155

Preparation Gojihvadi Granules

Gojihvadi Granules were prepared from concentrated Gojihvadi Kwatha by mixing equal part of sugar. After adding sugar to Gojihvadi Kwatha, heat was applied till patite na shiryate stage. The average temperature observed throughout the granule formation was 110-120⁰c while average duration was 3.55 hrs to 5.05 hrs.

After eliciting the paka lakshana mentioned in Sharangdhara Samhita^[3] further heating was stopped and then passed through the sieve and instantly cooled. The decrease in temperature in turn decrease the kinetic energy of molecule which leads to coalesces of sugar to each other and thus whole mass was converted in to granular form. Thus four types of granules were prepared by four types of Kwatha. Each sample was prepared thrice. In this way total twelve samples were prepared. (Table 4)

Analytical study

Prepared drug Gojihvadi Kwatha Churna, Gojihvadi Kwatha and Gojihvadi granules were evaluated for organoleptic as well as physicochemical parameters. 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. Organoleptic character were same for all three preparation however Physicochemical parameters were different for Gojihvadi Kwatha Churna as included pH, total solid content, specific gravity, wt/ml and viscosity at 25⁰C. Physicochemical parameters for Gojihvadi Kwatha and Gojihvadi granules including specific Gravity, pH, total solid content, specific gravity, viscosity at 25⁰C, 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.

The observations made were tabulated in the table 5-15.

DISCUSSION

Organoleptic characters of different samples of Gojihvadi Kwatha

All the batches prepared from different sieves were of dark brown colour that may be due to presence of different constituents. (Table-5) The colour indicated the water soluble extract from crude drug in Kwatha. Sweet taste indicates the presence of carbohydrate moieties in the preparation. Unpleasant smell may be considered due to presence of flavonoids and terpenoids that may be simple as well complex in nature. Some of these may be extracted during the process imparting colour to the preparation.

Watery consistency indicated the presence of mainly non-oily components in the drug.

Organoleptic characterization of different samples of Gojihvadi Kwatha Churna

The results obtained indicates that no marked changes were obtained in colour, odour, taste and consistency in between different samples prepared by using different sieves numbers as well as amongst batches prepared for each group. The carbohydrates along with some fatty acids, triglycerides may impart sweet and unpleasant taste. As the crude drug was micronized in small particles, the large surface area of the crude drug may be responsible for sweet taste when much more amount of the drug comes into contact of taste buds to be soluble in oral saliva. (Table 6)

Organoleptic characters of different samples of Gojihvadi Granules

In case of granules prepared by using different sieves numbers as showing in Table 7 that all the batches and as well as groups were of similar colour brown. It seems that at the time of heating the sucrose may be hydrolyzed to its monosaccharide components as glucose and fructose. But in the preparation of granules the sugar was used to impart the hardness to facilitate the granule formation.

In these preparations, the formed fructose may intensify the taste of the granules resulting sweet taste which is due to conversion of monosaccharide into Carmel at the time of heating. This Carmel is known a burnt sugar. In all the preparations the odour was almost unidentified but it is unpleasant in case of Churna and Kwatha formulations. It is because of the volatile components responsible for the smell such as flavonoids and terpenoids was lost on heating while non-volatile components might be degraded at high temperature in to other smell less components.

Table 5: Organoleptic characters of Gojihvadi Kwatha

Group A (Sieve no.8)			
Characteristics	Batch I	Batch II	Batch III
Colour	Dark brown	Dark brown	Dark brown
Odour	Unpleasant	Unpleasant	Unpleasant
Taste	Slightly sweet	Slightly sweet	Slightly sweet
Consistency	Watery	Watery	Watery
Group B (Sieve no.10)			
Characteristics	Batch I	Batch II	Batch III
Colour	Dark brown	Dark brown	Dark brown
Odour	Unpleasant	Unpleasant	Unpleasant
Taste	Slightly sweet	Slightly sweet	Slightly sweet
Consistency	Watery	Watery	Watery
Group C (Sieve no.44)			
Characteristics	Batch I	Batch II	Batch III
Colour	Dark brown	Dark brown	Dark brown
Odour	Unpleasant	Unpleasant	Unpleasant
Taste	Slightly sweet	Slightly sweet	Slightly sweet
Consistency	Watery	Watery	Watery
Group D (Sieve no.85)			
Characteristics	Batch I	Batch II	Batch III
Colour	Dark brown	Dark brown	Dark brown
Odour	Unpleasant	Unpleasant	Unpleasant
Taste	Slightly sweet	Slightly sweet	Slightly sweet
Consistency	Partially thick	Partially thick	Partially thick

Table 6: Organoleptic characterization of Gojihvadi Kwatha Churna

Group A (Sieve no.8)			
Characteristics	Batch I	Batch II	Batch III
Colour	Greenish brown	Greenish brown	Greenish brown
Odour	Unpleasant	Unpleasant	Unpleasant
Taste	Slightly sweet	Slightly sweet	Slightly sweet
Consistency	Soft	Soft	Soft
Group B (Sieve no.10)			
Characteristics	Batch I	Batch II	Batch III
Colour	Greenish brown	Greenish brown	Greenish brown
Odour	Unpleasant	Unpleasant	Unpleasant
Taste	Slightly sweet	Slightly sweet	Slightly sweet
Consistency	Soft	Soft	Soft
Group C (Sieve no.44)			
Characteristics	Batch I	Batch II	Batch III
Colour	Greenish brown	Greenish brown	Greenish brown
Odour	Unpleasant	Unpleasant	Unpleasant
Taste	Slightly sweet	Slightly sweet	Slightly sweet
Consistency	Soft	Soft	Soft
Group D (Sieve no.85)			
Characteristics	Batch I	Batch II	Batch III
Colour	Greenish brown	Greenish brown	Greenish brown
Odour	Unpleasant	Unpleasant	Unpleasant
Taste	Slightly sweet	Slightly sweet	Slightly sweet
Consistency	Soft	Soft	Soft

Table 7: Organoleptic characters of Gojihvadi Granules

Group A (Sieve no.8)			
Characteristics	Batch I	Batch II	Batch III
Colour	Brown	Brown	Brown
Odour	Unidentified	Unidentified	Unidentified
Taste	Sweet	Sweet	Sweet
Consistency	Hard Solid	Hard Solid	Hard Solid
Group B (Sieve no.10)			
Characteristics	Batch I	Batch II	Batch III
Colour	Brown	Brown	Brown
Odour	Unidentified	Unidentified	Unidentified
Taste	Sweet	Sweet	Sweet
Consistency	Hard Solid	Hard Solid	Hard Solid
Group C (Sieve no.44)			
Characteristics	Batch I	Batch II	Batch III
Colour	Brown	Brown	Brown
Odour	Unidentified	Unidentified	Unidentified
Taste	Sweet	Sweet	Sweet
Consistency	Hard Solid	Hard Solid	Hard Solid
Group D (Sieve no.85)			
Characteristics	Batch I	Batch II	Batch III
Colour	Brown	Brown	Brown
Odour	Unidentified	Unidentified	Unidentified
Taste	Sweet	Sweet	Sweet
Consistency	Hard Solid	Hard Solid	Hard Solid

Table 8: Percentage of Foreign Organic Matter (F.O.M.)

S.No.	Name of Drug	% of F.O.M. (As per API)	% of FOM
1	Gojihva	2	16.60
2	Mulethi	5	08.00
3	Misreya	2	05.33
4	Draksha	2	06.66
5	Anjir	1	03.33
6	Unnava	2	10.00
7	Vasa,	1	10.00
8	Jupha,	2.5	13.30
9	Slesmataka	2	12.30
10	Khubkalan	2	16.60
11	Hamsraja,	1	06.66
12	Gulavanaphsa	1	02.00
13	Atasi	1	10.00
14	Khatami	1.5	10.00
15	Kantkari	1.5	10.00
16	Kali Marich	1	06.00

Table 9: Physicochemical analysis of Gojihvadi Kwatha

Group A						
S.No.	Parameters	Batch I	Batch II	Batch III	Average	S.D.
1.	pH	7.36	7.38	7.30	7.35	0.04163
2.	Total solid content (%)	5.12	5.10	5.00	5.07	0.06429
3.	Specific gravity	0.9812	0.9800	0.9815	0.9809	0.00079
4.	Viscosity at 25°C	0.02075	0.02070	0.02072	0.02072	2.5166
Group B						
	Parameters	Batch I	Batch II	Batch III	Average	S.D.
1	pH	7.35	7.32	7.33	7.34	0.01525
2.	Total solid content (%)	5.57	5.55	5.54	5.55	0.01525
3.	Specific gravity	0.9836	0.9830	0.9832	0.9832	0.0003
4.	Viscosity at 25°C	0.03393	0.03390	0.03391	0.03391	1.5300
Group C						
	Parameters	Batch I	Batch II	Batch III	Average	S.D.
1.	pH	7.34	7.36	7.35	7.35	0.0100
2.	Total solid content (%)	6.69	6.65	6.66	6.67	0.02081
3.	Specific gravity	0.9812	0.9818	0.9815	0.9815	0.0003
4.	Viscosity at 25°C	0.0393	0.0395	0.0390	0.0393	0.0002
Group D						
	Parameters	Batch I	Batch II	Batch III	Average	S.D.
1.	pH	7.30	7.32	7.33	7.32	0.0152
2.	Total solid content (%)	10.38	10.36	10.32	10.35	0.03055
3.	Specific gravity	0.9818	0.9815	0.9812	0.9815	0.0003
4.	Viscosity at 25°C	0.05062	0.0506	0.0564	0.0562	0.0033

Table 10: Physicochemical analysis of Gojihvadi Kwatha Churna

Group A						
	Parameters	Batch I	Batch II	Batch III	Average	S.D.
	pH of 10 % w/v aqueous suspension	6.66	6.58	6.67	6.66	0.0493
	Loss on drying (% w/w)	0.360	0.358	0.361	0.359	0.0015
	Water soluble Extractives (% w/w)	58.2	58.8	58.6	58.5	0.3055
	Alcohol soluble extractives(% w/w)	76.5	76.8	76.2	76.5	0.3000
	Total ash	7.60	7.62	7.63	7.2	0.0153
	Acid insoluble ash	32.30	32.50	32.40	32.30	0.1000
Group B						
	pH of 10 % w/v aqueous suspension	6.16	6.11	6.18	6.25	0.0360
	Loss on drying (% w/w)	0.372	0.370	0.374	0.372	0.0020
	Water soluble Extractives (% w/w)	61.4	60.8	61.0	61.06	0.3055
	Alcohol soluble extractives(% w/w)	77.7	77.1	77.4	77.4	0.3000
	Total ash	8.78	8.74	8.72	8.75	0.0305
	Acid insoluble ash	34.33	34.30	34.00	34.21	0.1824
Group C						
	pH of 10 % w/v aqueous suspension	6.16	6.15	6.12	6.14	0.02081
	Loss on drying (% w/w)	0.372	0.370	0.370	0.370	0.0012
	Water soluble Extractives (% w/w)	61.4	61.2	61.4	61.3	0.1154
	Alcohol soluble extractives(% w/w)	77.7	77.5	77.6	77.6	0.1000
	Total ash	8.78	8.74	8.75	8.75	0.0208
	Acid insoluble ash	34.33	34.30	34.31	34.31	0.0153
Group D						
	pH of 10 % w/v aqueous suspension	6.16	6.12	6.11	6.13	0.0264
	Loss on drying (% w/w)	0.372	0.371	0.370	0.371	0.0010
	Water soluble Extractives (% w/w)	61.4	61.2	61.1	61.2	0.1527
	Alcohol soluble extractives (% w/w)	77.7	77.4	77.5	77.5	0.1528
	Total ash	8.78	8.74	8.72	8.75	0.0306
	Acid insoluble ash	34.33	34.30	34.28	34.30	0.0251

Table 11: Physicochemical analysis of Gojihvadi Granules

Parameters	Group A			Average	S.D.
	Batch I	Batch II	Batch III		
pH of 10 % w/v aqueous suspension	6.21	6.20	6.24	6.24	0.0208
Loss on drying (% w/w)	3.32	3.30	3.29	3.30	0.0152
Water soluble Extractives (% w/w)	96.61	96.60	96.58	96.60	0.0153
Alcohol soluble extractives(% w/w)	28.60	28.54	28.58	28.54	0.03056
Total ash	5.02	5.01	5.04	5.02	0.01527
Acid insoluble ash	63.14	63.10	63.11	63.12	0.02081
Group B					
pH of 10 % w/v aqueous suspension	6.26	6.22	6.24	6.24	0.0200
Loss on drying (% w/w)	4.12	4.10	4.15	4.12	0.0252
Water soluble Extractives (% w/w)	79.2	80.2	80.0	79.8	0.5291
Alcohol soluble extractives (% w/w)	18.9	19.8	19.2	19.3	0.4582
Total ash	16.7	16.5	16.4	16.53	0.1527
Acid insoluble ash	79.7	79.5	79.4	79.53	0.1527
Group C					
pH of 10 % w/v aqueous suspension	6.19	6.18	6.14	6.17	0.0264
Loss on drying (% w/w)	2.94	2.92	2.90	2.92	0.0200
Water soluble Extractives (% w/w)	92.29	92.27	92.22	92.26	0.0360
Alcohol soluble extractives(% w/w)	34.99	34.88	34.92	34.93	0.0556
Total ash	12.8	12.6	12.4	12.6	0.2000
Acid insoluble ash	60.3	60.2	60.1	60.2	0.1000
Group D					
pH of 10 % w/v aqueous suspension	6.25	6.23	6.21	6.29	0.0200
Loss on drying (% w/w)	4.06	4.02	4.01	4.03	0.0264
Water soluble Extractives (% w/w)	92.29	92.24	92.22	92.25	0.0360
Alcohol soluble extractives(% w/w)	34.19	34.14	34.18	34.17	0.0264
Total ash	9.23	9.21	9.20	9.21	0.0152
Acid insoluble ash	65.4	65.2	65.1	65.2	0.1573

Table 12: Microbial contamination of Gojihvadi Kwatha Churna & Gojihvadi granules

S.No.	Group	Batch	Gojihvadi Kwatha Churna		Gojihvadi granules	
			Total Bacterial count (cfu/gm)	Total fungal count (cfu/gms)	Total Bacterial count (cfu/gm)	Total fungal count (cfu/gms)
1	A	I	62	<10	83	<10
2		II	61	<10	83	<10
3		III	60	<10	83	<10
4	B	I	74	<10	78	<10
5		II	75	<10	78	<10
6		III	74	<10	110	<10
7	C	I	75	<10	110	<10
8		II	77	<10	110	<10
9		III	76	<10	81	<10
10	D	I	80	<10	81	<10
11		II	80	<10	81	<10
12		III	82	<10	81	<10

Table 13: Accelerated Stability study of Organoleptic characters of different samples

At zero months			
Characteristics	Sample 1	Sample 2	Sample 3
Colour	Brown	Brown	Brown
Odour	Odorless	Odorless	Odorless
Taste	Sweet	Sweet	Sweet
Consistency	Hard	Hard	Hard
After three month			
Characteristics	Sample 1	Sample 2	Sample 3
Colour	Brown	Brown	Brown
Odour	Odorless	Odorless	Odorless
Taste	Sweet	Sweet	Sweet
Consistency	Hard	Hard	Hard
After six month			
Characteristics	Sample 1	Sample 2	Sample 3
Colour	Brown	Brown	Brown
Odour	Odorless	Odorless	Odorless
Taste	Sweet	Sweet	Sweet
Consistency	Hard	Hard	Hard

Table 14: Accelerated stability study of physicochemical parameters of Granules

At zero months						
S.No.	Parameters	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 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 15: Microbial contamination of different samples of Gojihvadi Granules during accelerated study

Sample	At Month	Total Bacterial count (cfu/g)	Total fungal count (cfu/g)
I	Zero	78	<10
	Three	85	<10
	Six	136	<10
II	Zero	48	<10
	Three	72	<10
	Six	80	<10
III	Zero	60	<10
	Three	90	<10
	Six	95	<10

In solid formulations, the main characteristics are the consistency as hardness. Number of factors can affect this property and this attribute of solid dosage forms can directly or indirectly affect various parameters related to formulations such as friability during shipping and transport, disintegration and dissolution profile, solubilization in gastrointestinal fluid, absorption and ultimately the bioavailability (rate and extent of the drug absorbed in the blood) of the active components for the formulation responsible for the therapeutic effect. Hence, it can be realized that Hardness of the formulations should be optimal. In all the preparations by using different sieve numbers, the hardness was satisfactory. It may be due to the addition of sugar at the time of granule fabrication. Besides hardness, sugar imparted the sweet taste to the granules and hence masked any other taste and flavors.

Characterization of various physicochemical parameters

Percentage of foreign organic matter (F.O.M.)

The percentage of FOM found in the drugs was much more than expected level that shows the substandard drug due to commercialization of Ayurvedic crude drugs. (Table 8)

Physicochemical analysis of Gojihvadi Kwatha

Various physicochemical parameters as pH, total solid content, specific gravity and viscosity studied for Gojihvadi Kwatha are shown in Table 9 for all the batches and groups are similar and no statically significant difference is observed as seen by applying One Way ANOVA. From the table, it is clear that all the preparations were slightly alkaline in nature that indicated the presence of alkaline components in the crude drug. As total solid content was similar in all the preparations, it indicated no effect of sieving process on the parameter. The liquid nature similar to water will also facilitate the mixing of Kwatha with another dug with homogenous distribution.

Physicochemical analysis of Gojihvadi Kwatha Churna

Form the Table 10, it is indicated that pH of all the preparations as Churna was decreased and entered into acidic range. The pH of all the preparations was measured by making suspension in water. It indicated the marked effect of Churna processing on the range of pH. Similarly, the amount of acid insoluble ash was higher than total ash value. Higher amount of acid soluble ash indicated the more acidic components as due to common ion

effect acidic moieties might be insoluble in acidic media resulting higher value of acid insoluble ash. These higher acidic components may be responsible for acidic nature of the formulation Churna and acidic pH. (Graph 1)

Physicochemical analysis of Gojihvadi Granules

It is clear from the Table 11 that the pH of the suspension of the granules was also acidic in nature. It indicated that addition of sugar for fabrication of granules did not have any remarkable effect on pH. In the pH of granules and Churna, no significant difference was observed as analyzed by t-test. It indicated no remarkable effect of sugar addition, heating and processing on granule nature. Amongst all the tests performed for the physicochemical characterization of granules, no significant difference was observed between batches as well as in groups as analyzed by one way ANOVA. It was observed that the amount of water soluble extractives, alcohol soluble extractives, and total ash was comparatively higher than of Churna. In these parameters, it can be concluded that sugar addition may have its effect on these parameters as sugar is soluble in water and up to some extent in alcohol-water mixture. Also, being organic in nature, it may affect the ash quantity. But in overall case, no remarkable effect of granule fabrication was observed on the formulation's Physicochemical characters. Hence, the active constituents will remain same after granule formation and should show the same therapeutic effect of the crude drug which is main motive to formulate the crude drug. (Graph 2)

But the pH analysis amongst Kwatha, Churna and granules indicated the significant effect as analyzed by one way ANOVA. Here, the effect of processing of Churna and granules can be considered significant. In case of Churna fabrication after micronized and then after from Churna to granules, larger surface

area may increase direct contact solvent system with the crude drug resulting in much more extraction from the drug. These extracted active constituents might be responsible for change in pH nature.

Microbial contamination of different samples of Gojihvadi Kwatha Churna & Gojihvadi Granules

Inferred that total microbial count as well as total fungal count in different samples of Gojihvadi Kwatha Churna and Gojihvadi granules were observed below the maximum limit defined in API part II volume I⁴ 10⁵ per gram and 10³ per gram respectively. This indicated that we can use the Churna and granules for a longer duration without affecting their constituent. (Table 12)

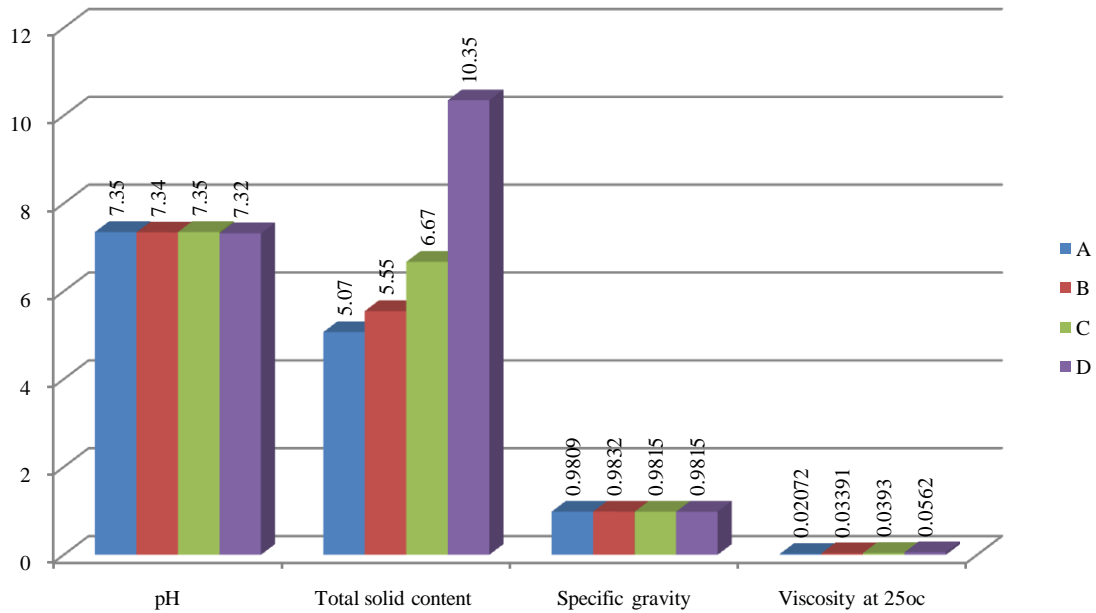
Accelerated Stability Study of Organoleptic characters of the samples

From the Table 13, it can be inferred that in all the preparations of all batches and groups no remarkable change were observed in colour, odour, taste and consistency. 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. 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.

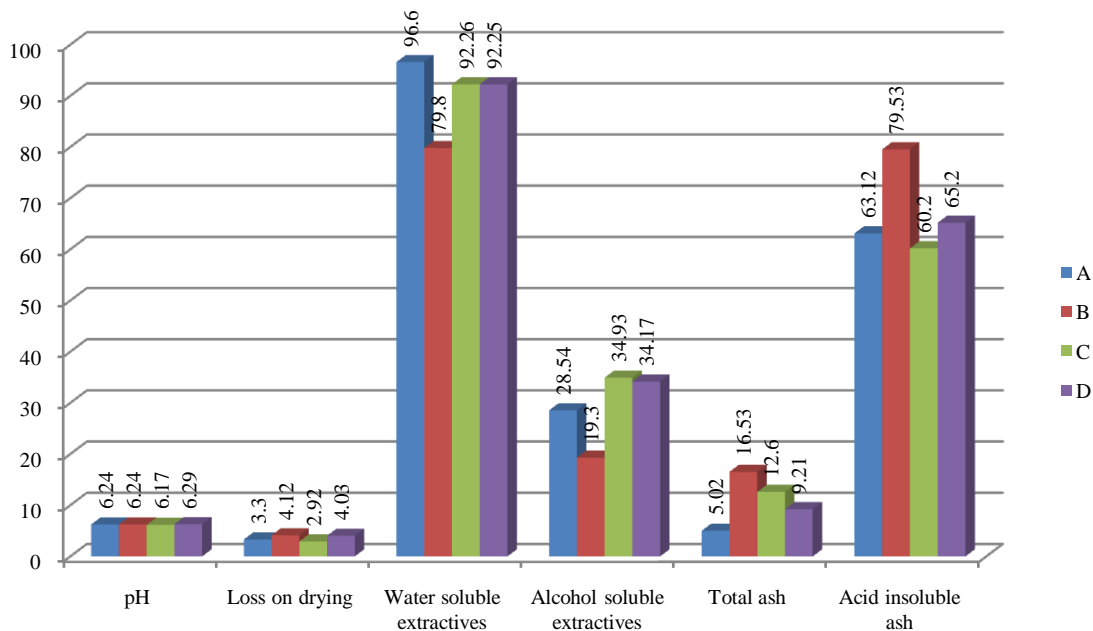
Accelerated stability study of Physicochemical parameters of granules

The parameters studied for the stability study such as pH, loss on drying, water soluble extractives, alcohol soluble extractives,

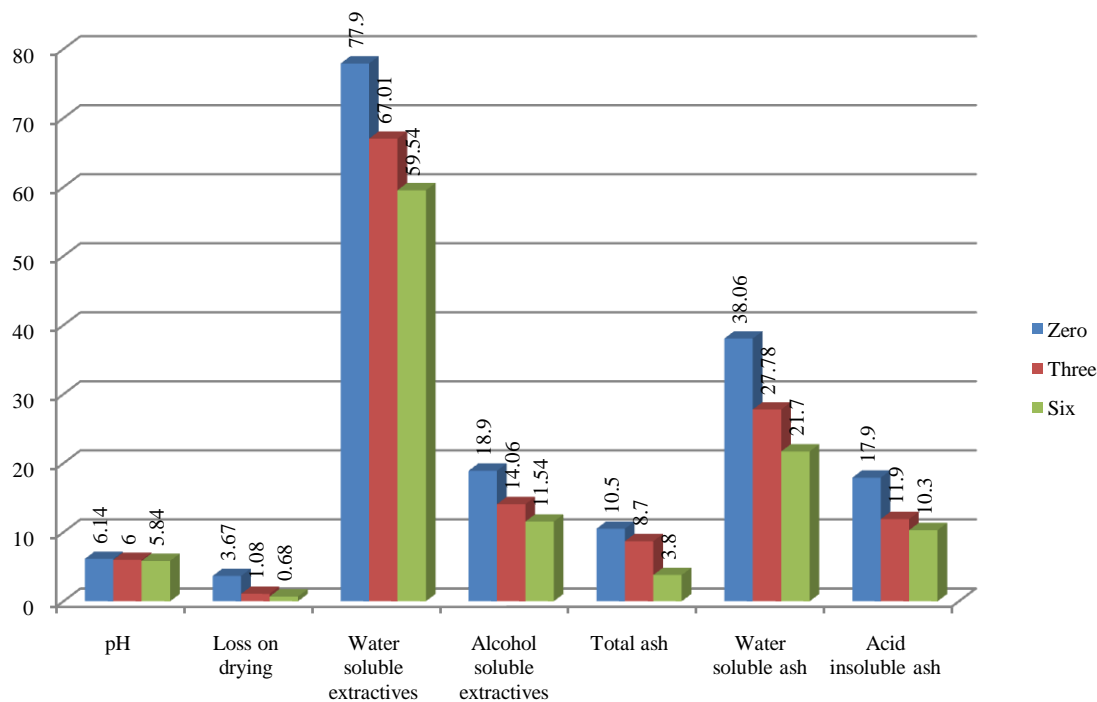
Graph 1: Physicochemical analysis of Gojihvadi Kwatha



Graph 2: Physicochemical analysis of Gojihvadi Granules



Graph 3: Accelerated stability study of physicochemical parameters of Granules



total ash, water soluble ash and acid insoluble ash were not statistically significant when the samples were studied at zero month, three month and six month as analyzed by one way ANOVA. (Graph 3) 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 Churna at normal stage. It indicated that the fabrication of granules and Churna had significant effect on nature of granules. The amount of water soluble extractives and alcohol soluble extractives was changed to a major extent in comparison to other parameters which shown decrement as the time for study was increased. 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.

Their higher solubility may result quick disintegration and dissolution in gastrointestinal fluid from the granules if administered by oral route.^[5] (Table 14)

Microbial contamination of different samples of Gojihvadi Granules during accelerated study

Table 15 inferred that total microbial count as well as total fungal count in different samples of Gojihvadi granules in accelerated condition were observed below than the maximum limit defined in API part II volume I^[4] 10^[5] per gram and 10^[3] per gram respectively. This indicated that we can store granules for a longer duration without affecting their constituent which indicates its long shelf life.

CONCLUSION

From the above study it is concluded that adopted manufacturing procedure of Gojihvadi Kwatha and Gojihvadi Granules may be accepted as S.O.P. (standard operative procedure) due to the repeatedly obtained same analytical data. Organoleptic characters and physicochemical properties of different samples of Gojihvadi Kwatha Churna, Gojihvadi Kwatha and Gojihvadi Granules prepared by using different sieves numbers were same. Accelerated stability study of different samples of Gojihvadi granules showed insignificant change in organoleptic & Physicochemical parameters which indicates that Gojihvadi granule has shelf life up to one year as compared to powder as well as Gojihvadi Kwatha. Granules are convenient and are a palatable dosage form.

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