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Research Article

PHARMACEUTICAL STANDARDIZATION AND PRELIMINARY ANALYSIS OF *VISHATINDUKADI VATI* PREPARED BY TWO REFERENCES

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ABSTRACT

Standardization of herbo-mineral drugs is essential to certify their quality, purity and reproducibility. *Vishatindukadi Vati* is a herbo-mineral formulation mentioned in Rasatantrasaara and Siddhaprayoga Sangraha (RTSSPS) with two references and different ingredients. The formulation mentioned in *Gutika Prakarana* contains *Kupilu* (*Strychnos nux- vomica* Linn), *Maricha* (*Piper nigrum* Linn.), *Puga Phala* (*Araca catechu* Linn.) and *Chincha Beeja* (*Tamarindus indica* Linn). while the formulation mentioned in *Vatavyadhi Prakarana* contains *Kupilu* (*Strychnos nux-vomica* Linn.) and *Maricha* (*Piper nigrum* Linn.) with *Bhavana* of *Nagavalli* (*Piper betel* Linn.) *Patra Svarasa*. It is mentioned in context of various diseases i.e., *Jirna Vatavyadhi* (chronic disorders due to *Vata*), *Jirna Jvara* (chronic fever), *Ajirna* (indigestion), *Mandagni* (subdued digestive power) and many more. In pharmaceutical process; 3 batches of *Kupilu Shodhana* and using both references three batches of *Vishatindukadi Vati* were prepared and its organoleptic and physico-chemical analysis were performed. Organoleptic and physicochemical analysis of raw materials, in-process and finished products were done. In physico-chemical pH, loss on drying at 105°C, total ash (%w/w), acid insoluble ash (%w/w), water-soluble extractive (%w/w), alcohol soluble extractive (%w/w), uniformity of weight (mg), friability (%), hardness (kg/cm^2) and disintegration time (min.) were carried out for VTV1 and VTV2. An average value of VTV1 and VTV2 were 5.3, 6.48%, 1.55%, 0.24%, 22.5%, 6.96%, 124.3mg, 0.16%, 4.6kg/cm^2, 37.6min and 5.05, 7.24%, 2.39%, 0.26%, 23.7%, 6.69%, 124mg, 0.14%, 3.63kg/cm^2 and 32 min. respectively. It needs further preclinical and clinical studies to prove its safety profile and therapeutic efficacy.

INTRODUCTION

In Rasashastra many minerals, metals and poisonous plant-based compounds involved in the preparation of formulations. The poisonous plants categorized in *Visha* (poison) and *Upavisha* (mild potency poisons) in many Ayurvedic classics. In Rasatarangini 11 types of *Upavisha* are mentioned,[1] like *Vishatinduka Beeja* (*Strychnos nux-vomica* Linn.), *Ahiphena* (*Papaver somnifera* Linn.), *Jayapala Beeja* (*Croton tiglium* Linn.), *Dhattura Beeja* (*Datura metel* Linn.), *Vijaya* (*Cannabis sativa* Linn.), *Gunja* (*Abrus Precatorius.* Linn.), *Bhallataka* (*Semecarpus anacardium* Linn.), *Arka Kshira* (*Calotropis Procera* (Ait) R. Br.), *Snuhi Kshira* (*Euphorbia neriifolia* Linn.) *Langali* (*Gloriosa Superba* Linn.) and *Karavira* (*Nerium indicum* Mill.). These *Upvisha Dravya* are used in various Ayurvedic formulations. There are many formulations in which *Vishatinduka Beeja* is used as an ingredient, *Vishatindukadi Vati* is one among them.

Rasatantrasaara and Siddhaprayoga Sangraha (RTSSPS) have mentioned two different references with different ingredients for the preparation of *Vishatindukadi Vati*. The formulation mentioned in *Gutika Prakarana* contains *Kupilu Maricha*, *Puga Phala* and *Chincha Beeja*[2] while the formulation mentioned in *Vatavyadhi Prakarana* contains *Kupilu* and *Maricha* with *Bhavana* of *Nagavalli Patra Svarasa.*[3]

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Vishatindukadi Vati is widely used by Ayurvedic physicians for various diseases like *Jirna Vatavyadhi, Jirna Jvara*, *Ajirna*, *Mandagni* and many more. In market survey GMP certified Ayurvedic pharmaceutical companies are preparing and marketing *Vishatindukadi Vati* but some preparing as per *Gutika Prakarana* and others are preparing as per the reference of *Vatavyadhi Prakarana*. So, two different formulations of *Vishatindukadi Vati* with both references were taken for this study.

Standardization of a compound Ayurvedic formulation is essential for establishing the authenticity, quality, safety and efficacy of Ayurvedic medicine. Some of Ayurvedic practitioners use self-made classical medicines to treat the patients. So, it is necessary to develop certain quality control parameters to cover the safety and efficacy issue. So, there is need of standardization of formulation.

Considering all this, the study was undertaken to develop a pharmaceutical standardization of *Vishatindukadi Vati* prepared by two references.

MATERIALS AND METHODS

The whole pharmaceutical study was carried out in following steps;

- Procurement and authentication of the raw material.
- Preparation of drug.

Procurement and authentication of the raw materials

Kupilu, *Maricha* and *Puga Phala* were procured from the Government Ayurved Pharmacy, Rajpipala, Gujarat, India. *Chincha Beeja* and *Nagavalli* were procured from the local market of Vadodara, Gujarat. *Eranda Taila* was procured from the local market of Vadodara, Gujarat as per *fssai* standards. The samples were identified at Pharmacognosy laboratory of the Upgraded Department of Dravyaguna, Government Ayurved College, Vadodara, Gujarat.

Preparation of drug

All the batches of *Vishatindukadi Vati* 1 and *Vishatindukadi Vati* 2 were prepared in pharmaceutical laboratory of Upgraded Department of Rasashastra and Bhaishajya Kalpana, Government Ayurved College, Vadodara, Gujarat. To develop S.M.P. three batches of *Vishatindukadi Vati* 1 and *Vishatindukadi Vati* 2 were carried out in the following steps entitled with headings;

1. *Kupilu Shodhana*
2. Preparation of *Churna* of *Shuddha Kupilu, Maricha, Puga Phala* and *Chincha Beeja*
3. Preparation of *Nagavalli Patra Svarasa*
4. Preparation of *Vishatindukadi Vati* 1
5. Preparation of *Vishatindukadi Vati* 2

Samples are labeled as

Vishatindukadi Vati 1- VTV1

Vishatindukadi Vati 2-VTV2

First pilot batch was prepared as per the prepared proforma and findings obtained from that pilot batch; main batches were prepared by the adopting the same method to attain the reproducibility of that method.

1. *Kupilu Shodhana* [4]

Eranda Taila was taken in s. s. vessel and heated slightly. *Ashuddha Kupilu* was added and *Bharjana* was done in *Eranda Taila* till it puffed up. After that, it was taken out from the vessel; the testa and embryo were removed with the knife. *Shuddha Kupilu* was collected and stored in airtight container. [Figure 1]

2. Preparation of *Churna* [5] **of *Shuddha Kupilu, Maricha, Puga Phala* and *Chincha Beeja***

Shuddha. Kupilu, Maricha, Puga Phala and Chincha Beeja were crushed in mortar and pestle individually and ground in the mixer grinder. *Maricha, Puga Phala and Chincha Beeja* were sieved through #120 while *Shuddha Kupilu* sieved through #60. Sieved fine powders were collected and packed in air tight container.

3. Preparation of *Nagavalli Patra Svarasa* [6]

Fresh *Nagavalli* was taken in the above-mentioned quantity, washed with water and cleaned well. Then leaves were cut into small pieces with the help of a knife. After those small pieces were taken into a mixer grinder paste was prepared. *Svarasa* was obtained by squeezing the paste through the cotton cloth and measured. Collected *Svarasa* was used for further process. [Figure 2]

4. Preparation of *Vishatindukadi Vati* 1

Shuddha. Kupilu, Maricha, Puga Phala and Chincha Beeja were taken in the mortar pestle above mentioned quantity, trituration was carried out until it became a homogenous mixture. After proper mixing, water was added little by little and levigated well till became a doughy mass. After that, 240mg of *Vati* was prepared. *Vati* was shade-dried, weighted, labeled and stored in an airtight container. [Figure 3]

5. Preparation of *Vishatindukadi Vati* 2

Shuddha. Kupilu and *Maricha* were taken in the mortar pestle as per above mentioned quantity, trituration was carried out until it became a homogenous mixture. After proper mixing, *Nagavalli Svarasa* was added little by little and continue levigated for 12 hours. After that, 240mg of *Vati* was prepared. *Vati* was shade-dried, weighted, labeled, and stored in an airtight container. [Figure 4]

Organoleptic characters and physico-chemical evaluation

VTV1 and VTV2 were analysed by using different organoleptic characters i.e., colour, odour, taste, texture and appearance; physico-chemical parameters i.e., pH,[7] loss on drying,[8] total ash,[9] acid insoluble ash,[10] water soluble extractive,[11] and alcohol soluble extractive,[12] total solid content[13], uniformity of weight[14], friability test[15], hardness test[16], disintegration time,[17] organoleptic and preliminary physico-chemical analysis were conducted at Quality Testing Laboratory, Upgraded Department of Rasasashtra and Bhaishjya Kalpana, Government Ayurved College, Vadodara, Gujarat.

OBSERVATIONS AND RESULTS

1. *Kupilu Shodhana*

Table 1: Details of observations during *Shodhana* procedure of *Kupilu*

Duration (min: sec)	Temperature (^{0} C)		Observation
	Flame	Materials	
B-1			
00:00	47.4	33.3	-
05:00	64.0	59.4	Black colour of *Kupilu,* characteristic smell of *Eranda Taila*
10:00	151.4	95.3	Characteristic smell of *Eranda Taila* persists
15:00	166.6	116.9	Characteristic smell of *Eranda Taila* persists
17:00	189.2	142.6	*Kupilu* were slightly puffed, Characteristic smell of *Eranda Taila* persists
20:00	190.6	147.2	*Kupilu* were slightly puffed, characteristic smell of *Eranda Taila* persists
25:00	215.3	155.1	*Kupilu* were slightly puffed, characteristic smell of *Eranda Taila* persists
30:00	242.2	161.3	Puffed *Kupilu*, characteristic smell of *Eranda Taila* persists
35:00	261.4	168.3	Puffed *Kupilu*, characteristic smell of *Eranda Taila* persists
40:00	265.9	179.8	Puffed *Kupilu*, Dark Brown in colour, characteristic smell of *Eranda Taila*
B-2			
00:00	48.4	33.5	-
05:00	65.3	56.3	Black colour of *Kupilu,* characteristic smell of *Eranda Taila*
10:00	153.4	96.3	Characteristic smell of *Eranda Taila*
15:00	167.1	113.3	Characteristic smell of *Eranda Taila*
20:00	187.7	139.5	*Kupilu* were slightly puffed, characteristic smell of *Eranda Taila* persists
25:00	211.3	151.1	*Kupilu* were slightly puffed, characteristic smell of *Eranda Taila* persists
30:00	243.8	163.4	Puffed *Kupilu*, characteristic smell of *Eranda Taila* persists
35:00	263.6	171.8	Puffed *Kupilu*, characteristic smell of *Eranda Taila* persists
40:00	267.8	181.2	Puffed *Kupilu*, Dark Brown in colour, characteristic smell of *Eranda Taila*
B-3			
00:00	51.3	33.9	-
05:00	64.3	54.3	Black colour of *Kupilu,* characteristic smell of *Eranda Taila*
10:00	150.2	95.3	Characteristic smell of *Eranda Taila*
15:00	165.2	110.2	Characteristic smell of *Eranda Taila*
20:00	184.6	141.5	*Kupilu* were slightly puffed, characteristic smell of *Eranda Taila* persists
25:00	213.3	153.2	*Kupilu* were slightly puffed, characteristic smell of *Eranda Taila* persists
30:00	244.5	164.5	Puffed *Kupilu*, characteristic smell of *Eranda Taila* persists
35:00	264.8	173.6	Puffed *Kupilu*, characteristic smell of *Eranda Taila* persists
40:00	269.9	183.1	Puffed *Kupilu*, Dark Brown in colour, characteristic smell of *Eranda Taila*

Table 2: Results of *Kupilu Shodhana*

No.	Parameters		Results			
			B-1	B-2	B-3	Average
1.	Initial quantity of *Ashuddha Kupilu* (g)		500	500	500	500
2.	Total quantity of *Eranda Taila* used in *Kupilu Shodhana* (g)		~32	~32	~32	32
3.	Final yield of *Shuddha Kupilu*	(g)	419	418	416	417.66
		(%)	83.8	83.06	83.2	83.29
4.	Weight of residue	(g)	81	82	84	82.33
		(%)	16.02	16.04	16.08	16.04
5.	Total ~~gain~~/loss	(g)	81	82	84	82.33
		(%)	16.02	16.04	16.08	16.04
6.	*Kupilu Shodhana* Reason of ~~gain~~/loss		Due to *Bharjana* process and removal of embryo and testa			
7.	Total time taken for *Kupilu Shodhana* (hrs:min)		10:00	10:00	10:00	10:00

Churna* of *Shuddha Kupilu, Maricha, Puga Phala* and *Chincha Beeja

Table 3: Results of *Churna* of *Shuddha Kupilu, Maricha, Puga Phala* and *Chincha Beeja*

S.No	Parameters		Results			
			Shuddha Kupilu	***Maricha***	***Puga Phala***	***Chincha Beeja***
1.	Initial quantity of (g)		1253	600	200	150
2.	Final yield of *Churna*	(g)	1058.33	142	93	93
		(%)	84.46	71	62	62
3.	Total ~~gain~~/loss	(g)	194.67	58	58	57
		(%)	15.53	29	29	38
4.	Reason of ~~gain~~/loss		Due to powdering and sieving	Due to powdering and sieving	Due to powdering and sieving	Due to powdering and sieving
5.	Total time taken for preparation of *Churna* (hrs. min)		8	2.30	2	1.5

3. *Nagavalli Patra Svarasa*

Nagavalli Patra Svarasa was green in colour. Light green-colored residue was obtained after squeezing the *Svarasa* from the paste. The characteristic smell of *Nagavalli Patra Svarasa* was felt during preparation. The results of *Nagavalli Patra Svarasa* were mentioned in Table no.4.

Table 4: Results of *Nagavalli Patra Svarasa*

No.	Parameters		Results			
			B 1	B 2	B 3	Average
1.	Initial quantity of *Nagavalli Patra* (g)		1000	1000	1000	1000
2.	Total quantity of *Svarasa* obtained	(ml)	570	580	573.33	573.33
		(%)	57	58	57.33	57.33
3.	Weight of residue after filtration	(g)	370	365	369	369
		(%)	37	36.5	36.9	36.9
4.	Total ~~gain~~/loss (g)	(g)	370	365	369	369
		(%)	37	36.5	36.9	36.9
5.	Reason of ~~gain~~/loss		Due to filtration and residue of fibrous material			
6.	Total time taken for preparation of *Svarasa* (hrs)		2	2	2	2

4. *Vishatindukadi Vati* 1

For the preparation of VTV1, 5 minutes of trituration was carried out to prepare a homogenous mixture and the material was turned to a light brown color and the characteristic smell of *Maricha* was felt. After addition of water, 10 minutes of levigation was carried out, the material turned to a dark brown color and the characteristic smell of *Kupilu* was felt. After 25 minutes of levigation material became more sticky. Characteristic smell of

ingredients was felt during the process. After 6 hours of levigation, material became a doughy mass. After drying of *Vati*, it was brown in colour.

Table 5: Results of *Vishatindukadi Vati* 1

No.	Parameters		Results			
			B -1	B -2	B- 3	Average
1.	Initial quantity of ingredients of *Vishatindukadi Vati* 1 (g)		147	147	147	147
2.	Initial quantity of water used in *Vishatindukadi Vati* 1 (ml)		390	390	390	390
3.	Final yield of *Vishatindukadi Vati* 1	(g)	141	141	143	141.66
		(%)	95.91	95.91	97.27	96.37
4.	Total ~~gain~~/loss	(g)	6	6	4	5.33
		(%)	4.08	4.08	2.72	3.62

5. *Vishatindukadi Vati* 2

For the preparation of VTV2, 5 minutes of trituration was carried out to prepare a homogenous mixture and the material was turned to a light brown color and the characteristic smell of *Maricha* was felt. After addition of *Svarasa;* 10 minutes of levigation was carried out, the material turned to a greenish-brown color and the characteristic smell of *Nagavalli* was felt. After 25 minutes of trituration material became more sticky. The characteristic smell of *Maricha* was felt during the process. After 12 hours of levigation material became doughy mass. After drying *Vati*, it was black in colour.

Table 6: Results of *Vishatindukadi Vati* 2

No	Parameters		Results			
			B-1	B-2	B -3	Average
1.	Initial quantity of ingredients of *Vishatindukadi Vati* 2 (g)		240	240	240	240
2.	Initial quantity *Svarasa* used in *Vishatindukadi Vati* 2 (ml)		570	570	570	570
3.	Final yield of *Vishatindukadi Vati* 2	(g)	230	231	230.66	230.66
		(%)	95.83	96.25	96.11	96.11
4.	Total ~~gain~~/loss (g)	(g)	10	9	9.33	9.33
		(%)	4.16	3.75	3.88	3.88
5.	Reason of ~~gain~~/loss		Due to sticking to the mortar pestle			
6.	Total time taken for preparation of *Vishatindukadi Vati* 2 (days) (for *Vati* preparation + drying)		1 + 3	1 + 3	1 + 3	1 + 3

Organoleptic characters and physico-chemical evaluation

For that, raw materials, in-process materials and finished products were analysed by organoleptic characteristics and physicochemical parameters.

A) Analysis of raw material

1. Organoleptic character

Table 7: Organoleptic characters of raw material

No	Ingredients	Observations				
		Color	Odor	Taste	Touch	Appearance
1.	*Ashuddha Kupilu*	Light brown	Odorless	Not applicable	Smooth	Flat disc
2.	*Maricha*	Black	Aromatic	Pungent	Wrinkled	Round
3.	*Puga Phala*	Reddish brown	Odorless	Astringent, bitter	Hard	Conical, ovoid
4.	*Chincha Beeja*	Brown to Brownish black	Characteristic	Astringent	Hard	Orbicular to rhomboid
5.	*Nagavallipatra*	Yellowish Green	Aromatic	Pungent	Smooth	Ovate broadly cordate to obliquely ovate

2. Physicochemical analysis

Table 8: Physicochemical parameters of raw material

No	Ingredients	Results					
		pH	Loss on Drying (%w/w)	Total Ash (%w/w)	Acid insoluble Ash (%w/w)	Water soluble extractive (%w/w)	Alcohol soluble extractive (%w/w)
1.	*Ashuddha Kupilu*	5.79	3.77	0.79	0.14	18	5.03
	API standard	Not mentioned	Not mentioned	NMT 2	NMT 0.2	NLT 12	NLT 4
2.	*Maricha*	6.59	6.07	3.97	0.34	9.99	15.19
	API standard	Not mentioned	Not mentioned	NMT 5	NMT 0.5	NLT 6	NLT 6
3.	*Puga Phala*	4.78	9.53	1.89	0.29	14.46	26.01
	API standard	Not mentioned	Not mentioned	NMT 3	NMT 0.4	NLT 10	NLT 19
4.	*Chincha Beeja*	6.7	7.3	1.74	0.09	7.85	24.21
	API standard	Not mentioned	Not mentioned	Not mentioned	Not mentioned	Not mentioned	Not mentioned
5.	*Nagavallipatra*	4.55	69.80	11.94	0.79	21.26	14.96
	API standard	Not mentioned	Not mentioned	NMT 17	NMT 3	NLT 10	NLT 20
Total solid content							
6.	*Nagavallipatra Svarasa*	3.75					

* NMT= Not More Than, NLT= Not Less Than

B) Analysis of In-process material

1. Organoleptic character

Table 9: Organoleptic characters of *Shuddha Kupilu*

No	Characteristic		Observations				
			Color	Odor	Taste	Texture	Appearance
1.	*Shuddha Kupilu*	Batch -1	Dark brown	Characteristic smell of *Eranda Taila*	Bitter	Hard	Flat disc
		Batch- 2	Dark brown	Characteristic smell of *Eranda Taila*	Bitter	Hard	Flat disc
		Batch- 3	Dark brown	Characteristic smell of *Eranda Taila*	Bitter	Hard	Flat disc

2. Physicochemical analysis

Table 10: Physico-chemical parameters of *Shuddha Kupilu*

No	Parameters		Results					
			pH	Loss on Drying (%w/w)	Total Ash (%w/w)	Acid insoluble Ash (%w/w)	Water soluble extractive (%w/w)	Alcohol soluble extractive (%w/w)
1.	*Shuddha Kupilu*	B 1	4.23	7.76	0.84	0.11	16.48	2.64
		B 2	4.25	7.85	0.79	0.14	16.60	2.40
		B 3	4.28	7.95	0.94	0.14	17.84	2.24
		Average	**4.25**	**7.85**	**0.85**	**0.13**	**16.97**	**2.42**

C) Analysis of finished product

1. Organoleptic character

Table 11: Organoleptic characters of VTV1

S. No.	Characteristic	Observations		
		B 1	B 2	B 3
1.	Color	Brown	Brown	Brown
2.	Odour	Characteristics	Characteristics	Characteristics
3.	Taste	Bitter	Bitter	Bitter
4.	Texture	Rough	Rough	Rough
5.	Appearance	Spherical	Spherical	Spherical

Table 12: Organoleptic characters of VTV2

S. No.	Characteristic	Observations		
		B 1	B 2	B 3
1.	Color	Black	Black	Black
2.	Odour	Characteristics	Characteristics	Characteristics
3.	Taste	Bitter, pungent	Bitter, pungent	Bitter, pungent
4.	Texture	Rough	Rough	Rough
5.	Appearance	Spherical	Spherical	Spherical

2. Physicochemical analysis:

Table 13: Physicochemical parameters of VTV1

No.	Parameters	Observations			
		B 1	B 2	B 3	Average
1.	pH	5.31	5.30	5.30	5.30
2.	Loss on Drying (%w/w)	6.20	6.63	6.62	6.48
3.	Total Ash (%w/w)	1.56	1.43	1.66	1.55
4.	Acid insoluble Ash (%w/w)	0.26	0.29	0.19	0.24
5.	Water soluble extractive (%w/w)	23.8	22.6	21.3	22.5
6.	Alcohol soluble extractive (%w/w)	6.56	7.52	6.8	6.96
7.	Uniformity of weight (mg)	124.5	123.5	125.1	124.3
8.	Friability (%)	0.17	0.16	0.17	0.16
9.	Hardness (kg/cm^2)	4.2	3.8	4.2	4.06
10.	Disintegration time (min.)	38	38	37	37.6

Table 14: Physicochemical parameters of VTV2

No.	Parameters	Observations			
		B 1	B 2	B 3	Average
1.	pH	5.09	5.02	5.05	5.05
2.	Loss on Drying (%w/w)	7.15	7.06	7.53	7.24
3.	Total Ash (%w/w)	2.27	2.22	2.7	2.39
4.	Acid insoluble Ash (%w/w)	0.29	0.26	0.23	0.26
5.	Water soluble extractive (%w/w)	23	24.2	24.1	23.7
6.	Alcohol soluble extractive (%w/w)	7.92	6.15	6	6.69
7.	Uniformity of weight (mg)	123.9	124.5	123.6	124

8.	Friability (%)	0.15	0.15	0.14	0.14
9.	Hardness (kg/cm^2)	3.7	3.6	3.6	3.63
10.	Disintegration time (min.)	30	34	33	32

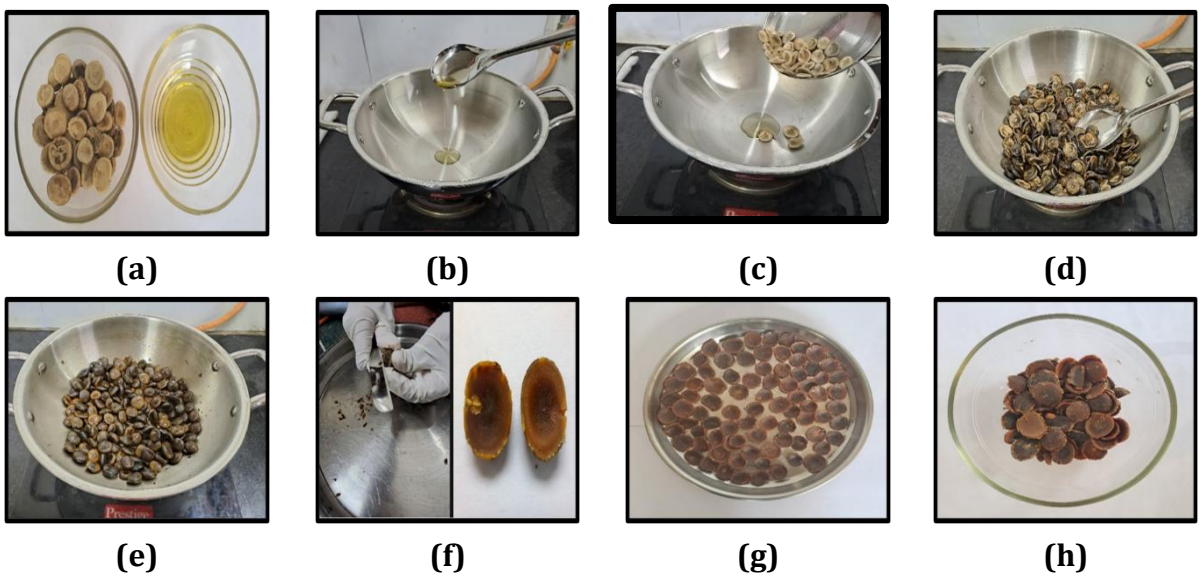

Figure.1: (a) Ingredients **(b)** Taking *Eranda Taila* in s.s.vessel **(c)** Adding *Ashuddha Kupilu* in *Eranda Taila* **(d)** *Bharjana* of *Kupilu* **(e)** Puffed *Kupilu* **(f)** Removing testa and embryo **(g)** *Kupilu* after removing of embryo **(h)** *Shuddha Kupilu*

Figure.2: (a)*Nagavalli Patra* **(b)**Griding in mixer grinder **(c)** *Kalka* of *Nagavalli Patra* **(d)** Straining through cloth and *Nagavalli Patra Svarasa*

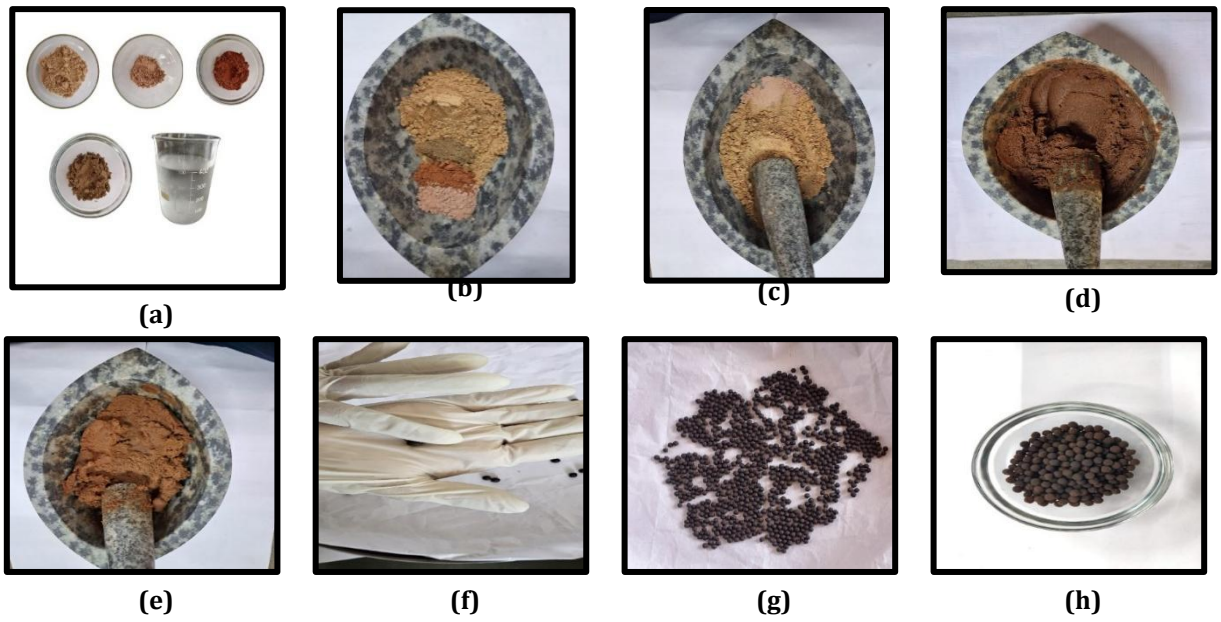

Figure.3: (a) Ingredients of *Vishatindukadi Vati* 1 **(b)** Taking ingredients in mortar **(c)**Homogenous mixture **(d)** After adding of Water in mixture **(e)** After levigation **(f)**Preparing *Vati* **(g)** Drying of pills **(h)** *Vishatindukadi Vati* 1

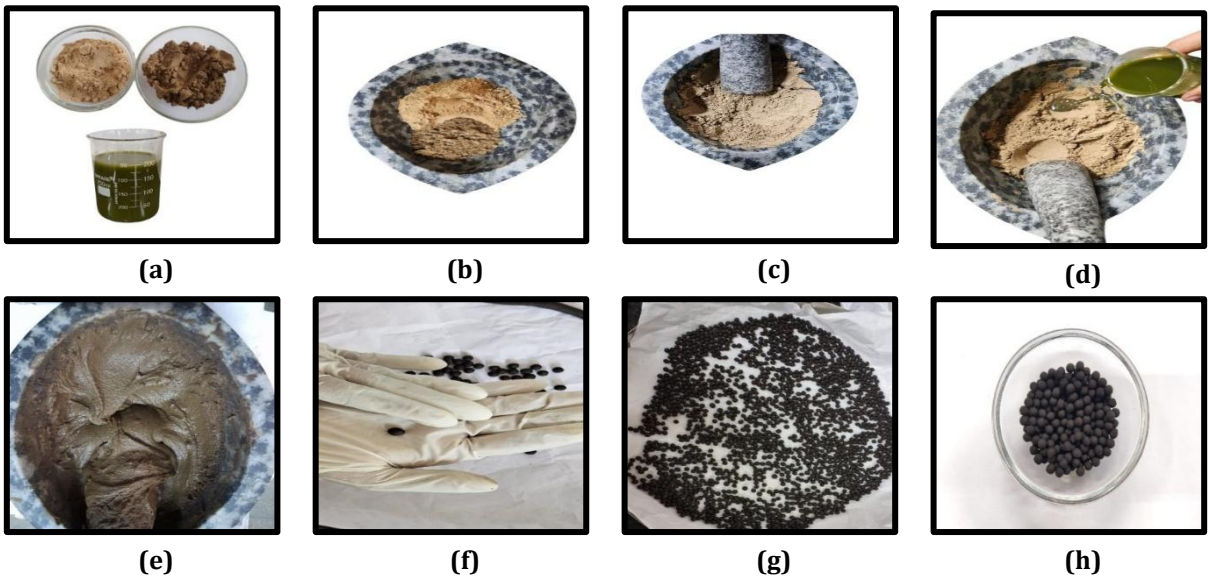

Figure.4: (a) Ingredients of *Vishatindukadi Vati* 2 **(b)** Taking ingredients in mortar **(c)** Homogenous mixture **(d)** After adding of *Svarasa* in mixture **(e)** After levigation **(f)** Preparing *Vati* **(g)** Drying of *Vati* **(h)***Vishatindukadi Vati* 2

DISCUSSION

The present study was to establish to pharmaceutical standardization though SMP of *Vishatindukadi Vati*. *Kupilu Shodhana* was carried out as per the reference of Rasatantrasaar and Siddhaprayog Sangraha part 1, *Dravya Shodhana Prakarana,*[18] *Bharajana* of *Kupilu* in *Eranda Taila.* Two pilot batches were conducted to determine the optimal quantity of *Eranda Taila*, assess temperature patterns, and evaluate changes during and after the process. In pilot batch 1, 1/16th of *Eranda Taila* was used for 50gm of *Kupilu,* and in batch 2, 1/32nd was used. The second batch required 1 more hour due to difficulties in removing the testa and embryo. The yield was 78% in the first batch and 76% in the second. After analyzing the results, three main batches were prepared using the methodology of pilot batch 1. The average yield after *Shodhana* was 83.53% from 1500gm of *Ashuddha Kupilu* and for that, 96gm of *Eranda Taila* was used. The *Kupilu* turned black during heating and became puffed and dark brown after 40 minutes of *Shodhana*.

For the preparation of *Vishatindukadi Vati*, *Churna* of *Shuddha Kupilu, Maricha, Chincha Beeeja* and *Puga Phala* were prepared and from which, an average yield of 84.59% was obtained for *Shuddha Kupilu* after sieving through a 60#, 95.16% for *Maricha*, 71% for *Puga Phala* and 62% for *Chincha Beeja* after sieving through a 120#. *Nagavalli Patra Svarasa* was prepared in 3 batches and for each batch, 1000gm *Nagavalli Patra* were taken. The average yield of *Svarasa* was 57.33% and average time required for *Svarasa* preparation was 2 hours.

The pilot batch of VTV1 was prepared as per the reference of Rasatantrasaara and Siddhaprayog Sangraha, part 1, *Gutika Prakarana*[19] VTV2 was prepared as per the reference of Rasatantrasaara and Siddhaprayog Sangraha, part 2, *Vatavyadhi Prakrana.*[20] To generate the information regarding the requirement of liquid media, the weight of *Vati* after the drying procedure and total required time for the whole practical. After observing the findings of the pilot batch of VTV1, three batches were prepared to develop SMP. For each batch, 147gm of materials and 390 ml of water were used and levigated for 6 hours. It was observed that during levigation material became stickier and the characteristic smell of ingredients was felt. After drying, the color of *Vati* was brown and the weight of *Vati* in batch-1, batch-2 and batch-3 were 141gm, 141gm and 143gm respectively. The batch of VTV2 was prepared as per the reference of Rasatantrasaara and Siddhaprayog Sangraha, part 2, *Vatavyadhi Prakrana*.[21] After observing the findings of the pilot batch of VTV2, three batches were prepared to develop SMP. For each batch 240gm materials and 1720ml *Svarasa* were used and levigated for 12 hours. It was observed that during levigation material became stickier and the characteristic smell of ingredients was felt. After drying, the colour of *Vati* was black and the weight of *Vati* in batch-1, batch-2 and batch-3 were 230gm, 231gm and 231gm respectively. The average yield of VTV1 and VTV2 were 96.37% and 96.11% respectively.

This study was carried out to evaluate the analytical parameters of raw materials, in-process, and finished products, including *Kupilu*, *Maricha*, *Puga Phala*, *Chincha Beeja*, and *Nagavalli Patra*. Raw materials met API standards for organoleptic and physicochemical characteristics. After *Shodhana, Kupilu* turned into dark brown with the characteristic smell of *Eranda Taila*, bitter taste, and hard texture.

During *Shodhana*, toxic alkaloids like strychnine and brucine are reduced which are alkaline.[22] This may lead to decreases in the pH of *Kupilu* after *Shodhana*. *Shuddha Kupilu* seeds absorb some amount of *Eranda Taila*, which is a viscous, non-volatile substance.[23] This can increase the loss on drying. *Kupilu* seeds contain strychnine and brucine, which are partially water and alcohol-soluble.[24] During *Shodhana* with *Eranda Taila*, these alkaloids are decreased. This may reduce the water-soluble and alcohol-soluble extractive.

VTV1 was brown in colour, with a characteristic odour, bitter taste, rough texture and spherical appearance. VTV2 was black in colour, with a characteristic odour, bitter and pungent taste, rough texture, and spherical appearance.

pH, or 'potential of hydrogen', is a scale used to measure the acidity or basicity of an aqueous solution, with lower pH values indicating higher acidity.[25] Most raw materials tend to be acidic, which may explain the observed acidic pH values. The average pH values for VTV1 and VTV2 were 5.3 and 5.05, respectively. Loss on drying (LOD) measures the weight loss due to moisture and volatile matter, with values under 10% indicating better product stability, reduced microbial growth, and enhanced shelf life.[26] The average LOD values for VTV1 and VTV2 were 6.48% and 7.24%, respectively. Total ash is the residue remaining after incineration, reflecting the presence of various compounds like steroids, diterpenoids, and carbohydrates.[27] The acid-insoluble ash indicates the silica content in the sample.[28] The average total ash values for VTV1 and VTV2 were 1.55% and 2.39%, respectively, while the acid-insoluble ash values were 0.24% and 0.26%, respectively. The water and alcohol-soluble extractive values suggest solubility of active constituent in respective media i.e., water and alcohol. while average water-soluble extractive values of VTV1 and VTV2 were 6.96 and 6.69 respectively. Average alcohol soluble extractive values of VTV1 and VTV2 were 22.5 and 23.7 respectively.

Uniformity of weight is critical for tablet quality control, ensuring accurate dosing and product reliability. For tablets under 250mg, a permissible deviation of 7.5% is accepted.[29] The average weight uniformity of VTV1 and VTV2 was 124.3mg and 124mg, respectively.

Friability testing assesses a tablet's resistance to mechanical shock and attrition. Tablets that lose less than 0.5% to 1% of their weight are deemed acceptable.[30] The friability of VTV1 and VTV2 was 0.16% and 0.14%, respectively. Tablet hardness testing determines a tablet's breaking point and structural integrity under conditions of storage, transportation, packaging, and handling.[31] The hardness of VTV1 and VTV2 was 4.06kg/cm^2 and 3.63kg/cm^2, respectively. Disintegration time test is provided to determine disintegrate within the prescribed time when placed in a liquid media.[32] Average disintegration time of VTV1 and VTV2 were 37.6 min. and 32 min. respectively. In VTV1 disintegration time was more than VTV2.

CONCLUSION

The pharmaceutical standardization of *Vishatindukadi Vati* was carried out by preparing two formulations based on the references from Rasatantrasara and Siddhaprayog Sangraha. This study has established some preliminary pharmaceutical and analytical parameters of *Vishatindukadi Vati* prepared by two references. The present study may be beneficial for further research work and can be used as a reference standard for quality control researches. it needs further preclinical and clinical studies to prove its safety profile and therapeutic efficacy.

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