ORIGINAL ARTICLE

Standardization manufacturing procedure of *Darvyadi Yoni Varti* (vaginal suppository): An ayurvedic formulation

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Abstract

Context: *Darvyadi Yoni Varti* is an ayurvedic formulation indicated for the management of *Garbhasaya Grivamukhagata Vrana* (Cervical erosion). Cervical erosion adversely affects the physiological and psychological health of women and even interferes in their professional life. **Aims:** The present study was attempted to develop some new advances for quality control and standard operating procedure for *Darvyadi Yoni Varti* (vaginal suppository). **Materials and Methods:** 400 *Varti* of 3 g each were obtained from 1000 ml of *Darvyadi Kwatha*. No significant differences were found in all batches, so this method can be considered as standard procedure. **Results:** The samples were subjected to various preliminary analytical parameters and were almost similar in all bathes. The average values of water-soluble extract and methanol-soluble extract were found to be 22.71% w/w and 8.2% w/w, respectively. The average values of loss on drying and ash were observed 71.36% w/w and 5.06% w/w, respectively. **Conclusion:** The quality control parameters resulted after a scientific evaluation of *Darvyadi Yoni Varti* may be used as reference standard for quality control.

Key words: Analytical analysis, *Darvyadi Yoni Varti*, *Garbhasaya Grivamukhagata Vrana,* quality control, standardization

INTRODUCTION

In the global era, it is prime need to standardize ayurvedic preparations to establish their purity, safety, and efficacy. Herbal medicine is being manufactured on a large scale where manufacturers face many problems such as low-quality raw material, lack of authentication of raw material, non-availability of standards, lack of proper standardization methodologies of single drugs and formulations, and lack of quality control parameters. It is a timely necessity followed by a compulsion to go for quality control of the raw drugs as well as finished products. This better serves expectations on efficacy, safety, and organoleptic features. For the standardization of the finished products, it is essential to evaluate the prepared drugs or to fix some standards so that quality of the product can be established. Long historical use of many practitioners of traditional medicine, including experience passed on from generation to generation, has demonstrated the safety and efficacy of traditional medicine. However, scientific research is needed to provide additional evidence of its safety and efficacy.[1]

The drugs of Darvyadi Yoni Varti (vaginal suppository) are described by Sushruta in *Upadansha* Chikitsa.[2] Some of the drugs mentioned in this context were selected for *Yoni Varti* (vaginal suppository). Sushruta has described these drugs for local application but in cervical erosion, it is very difficult to apply these raw drugs on the cervix. Considering this, it had been planned to prepare a *Varti* (suppository) for easy application. Further, standardization of *Darvyadi Yoni Varti* (vaginal suppository) remains an unexplored issue. Thus, in the present work, attempt with following objectives has been done.

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- To develop standardized operating procedure (SOP) for the preparation of *Darvyadi Yoni Varti*
- To evaluate the physico-chemical profile of *Darvyadi Yoni Varti.*

MATERIALS AND METHODS

Drug Material

Darvi (*Barberies aristata* DC.), *Lodhra* (*Symplocos recemosa* Roxb.), *Haridra* (*Curcuma longa* Linn.), purified *Sphatika* (alum), and purified *Gairika* were collected from the pharmacy and authenticated by the Pharmacognosy Department. Gelatine, honey, and Propyl para ben sodium salt were purchased from a market. The drugs of *Kwatha* (decoction) and part used are given in Table 1. The ingredients of *Yoni Varti* are given in Table 2.

Preparation of *Darvyadi Kwatha*

The ingredients of *Kwatha* were taken 500 g in *Yavakuta* (Coarse power) form and to it 4 L clean water was added and allowed to soak 14 h overnight in normal room temperature. On the next day morning, the mixture was mildly heated until the volume reduced to 1/4th, i.e., up to 1 L. Throughout the procedure of boiling, the temperature was maintained in between 85°C and 95°C and approximately it took 5 h to prepare *Kwatha*. Total 3 batches of *Kwatha* were prepared; the average details are given in Table 3.

Preparation of *Darvyadi Yoni Varti*

120 ml *Darvyadi Kwatha* were taken in stainless steel vessel from the 1 L due to the limitation of equipment. The purified *Gairika* (3 g) was added in decoction and mixed for around ½ min. Then, purified alum (3.5 g) was added and mixed for around ½ min and stirred with a spatula, and homogeneous mixture was prepared. Then, Gelatine (30 g) and Propyle para ben sodium salt was added to it and was heated on boiling water until melted into a homogeneous mixture it took 2 min and then honey (20 ml) was added and the whole mixture was poured into lubricated mold and allowed to set in refrigerator for 30 min [Figures 1-9]. The temperature of boiling water was maintained between 100°C and 120°C. The same parameters were followed in the remaining decoction. Total 3 batches were prepared; the average details are given in Table 4.

The average weight of *Varti* was approximate 3 g each. The shape of *Varti* was the oviform shape. Prepared *Varties* were kept in well-closed polythene bags and stored in the refrigerator to avoid disintegration and other contamination.

Table 1: Ingredients of *Kwatha*

Number	Drug name	Chemical/ Botanical name	Part used	Part
Kwatha drugs				
1	*Darvi*	*Barberies aristata* DC.	Root Bark	1
2	*Lodhra*	*Symplocos recemosa* Roxb.	Bark	1
3	*Haridra*	*Curcuma longa* Linn	Rhizome	1

Table 2: Ingredients of *Darvyadi Yoni Varti*

Ingredients	For 1 tab of 3 g
Kwatha (decoction)	2.4 ml
Madhu (Honey)	0.4 ml
Purified *Sphatika*	0.07 g
Purified *Gairika*	0.06 g
Gelatin powder	0.6 g
Propyl para ben sodium salt	0.016 g

Table 3: Details of *Kwatha* preparation

Parameters	Batch 1	Batch 2	Batch 3
Quantity of *Kwatha Churna* (g)	500	500	500
Size of *Kwatha Churna* (mesh no.)	08	08	08
Total quantity of water (L)	4	4	4
Total time for soaking (h)	14	14	14
Temperature during preparation of *Kwatha* (°C)	85-95	85-95	85-95
Total time taken for *Kwatha* (h)	4.45	5.00	4.50
Total quantity of *Kwatha* obtained (ml)	1000	980	990

Table 4: Details of *Varti* preparation

Parameters	Batch 1	Batch 2	Batch 3
Quantity of *Kwatha* (ml)	120	120	120
Quantity of purified *Gairika* (g)	3	3	3
Time of mixing of purified *Gairika* (s)	30	40	30
Quantity of purified *Sphatika* (g)	3.5	3.5	3.5
Time of mixing purified *Sphatika* (s)	40	30	40
Quantity of Gelatin (g)	30	30	30
Temperature of boiling water (°C)	100-120	100-120	100-120
Time of melting of Gelatin (min)	2.00	2.10	2.00

Figure 1: Preparation of *Kwatha*

Figure 2: Add *Gairika* in prepared *Kwatha*

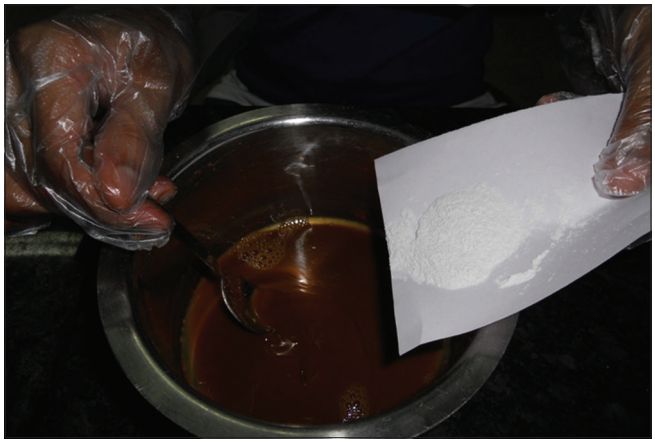

Figure 3: Add Sphatika

Figure 4: Add Gelatin

Figure 5: Add Propyle para ben sodium salt

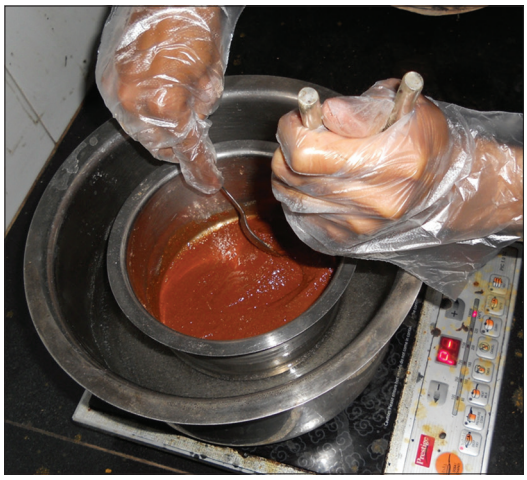

Figure 6: Made homogeneous mixture on boiling water

Analytical Study

This *Darvyadi Yoni Varti* was analyzed by various standard physico-chemical parameters at pharmaceutical chemistry laboratory. All physico-chemical parameters such as Loss on drying,[3] pH,[4] water-soluble extract, and methanol-soluble extract[3] as per ayurvedic pharmacopeia of India were considered for pharmaceutical evaluation.

For high performance thin layer chromatography (HPTLC): Methanol extract of *Darvyadi Yoni Varti* was

spotted on pre-coated silica gel GF 254 aluminum plate as 5 mm bands, 5 mm apart, and 1 cm from the edge of the plates. Toluene (8 ml) and ethyl acetate (2 ml) was used as the mobile phase. After development, densitometry scanning was performed with a Camag TLC scanner II (ver. 3.14) in reflectance absorbance mode at 254 nm and 266 nm under the control of win CATS software (ver. 3.17).[5]

Figure 7: Add honey in prepare mixture

Figure 8: Poured into lubricated mold

RESULTS

The color of *Kwatha* was observed light brown, which changed into dark brown after adding the *Gairika* and color of *Varti* was observed dark brown. Almost all the batches were prepared between 11 h to 11 h and 30 min.

The average values of water-soluble extract and methanol-soluble extract were found to be 22.71% w/w and 8.2% w/w,

Figure 9: Prepared *Varti*

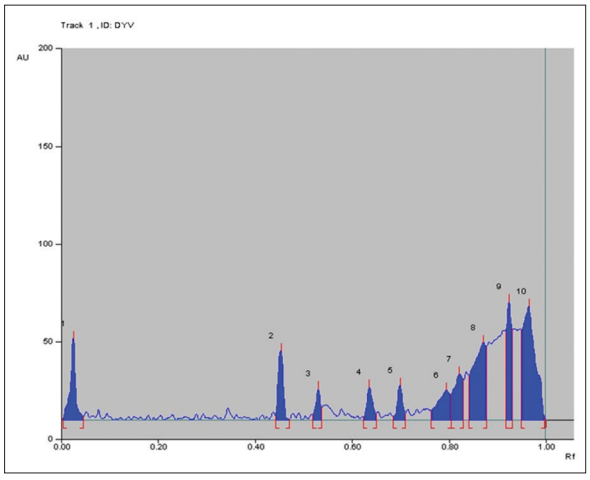

Figure 10: Densitometry of *Darvyadi Yoni Varti* at 254 nm

Table 5: Physico-chemical parameters of *Darvyadi Yoni Varti*

Test	Value			
	Batch 1	Batch 2	Batch 3	Average
Loss of drying (at 110°C)	71.73% w/w	72.35% w/w	70.0% w/w	71.36% w/w
Ash value	5.16% w/w	5.0% w/w	5.02% w/w	5.06% w/w
Water-soluble extraction	23.3% w/w	22.85% w/w	22.0% w/w	22.71% w/w
Methanol-soluble extraction	8.7% w/w	7.90% w/w	8.0% w/w	8.2% w/w
pH value by pH meter	5.0	5.0	4.5	4.8

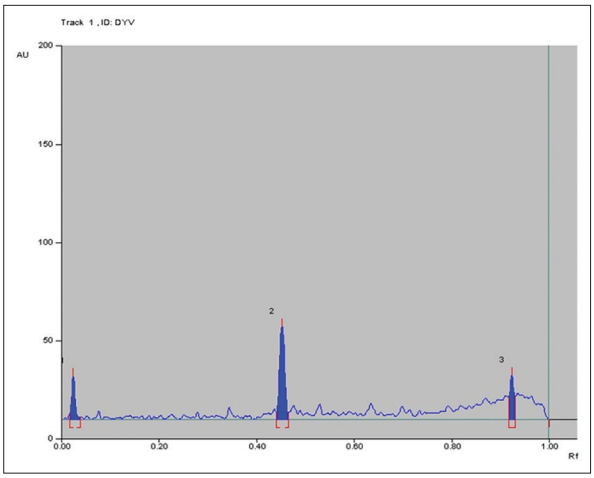

Figure 11: Densitometry *Darvyadi Yoni Varti* at 366 nm

respectively. The average values of Loss on drying and ash were observed 71.36%w/w and 5.06%w/w, respectively [Table 5].

HPTLC under 254 nm showed 10 spots at 0.02, 0.45, 0.53, 0.64, 0.70, 0.79, 0.82, 0.87, 0.92, and 0.96 R_f values and under 366 nm showed 3 spots at 0.02, 0.45, and 0.92 R_f values [Figures 10 and 11].

DISCUSSION

Quality assurance is an integral part of all system of medicine to ensure the quality medicament, various multi-disciplinary and bio-analytical approaches, such as the development of SOP, preliminary phytochemical and physico-chemical evaluation, chromatographic evaluation, and efficacy evaluation, have been employed and reported for the scientific evaluation of various traditional formulations.[6] In the present work, only suitable and available techniques were selected for standardization of *Darvyadi Yoni Varti*.

The preparation of *Darvyadi Yoni Varti* was divided into two parts; first *Kwatha* preparation and second *Varti* preparation. The whole procedure of preparation of *Kwatha* and parameter was followed in each batch [Table 3]. The particle size of *Kwatha Churna* was passed through mesh no. 08. Overnight soaking (15 h) was done before application of heat. Mild heating with peak temperature 85-95°C was done along with continuous stirring. Initially, some of the raw material was floating over the surface, which gradually settled down to the bottom. Continuous stirring was done for proper extraction and to lessen the possible chances of degradation of some active constituents which may be decomposed due to hydrolysis.[7] The color of *Kwatha* was found light brown due to the presence of *Haridra* and *Darvi* and typical smell of *Haridra* was observed during *Kwatha* preparation.

The preparation of *Varti* was quite tedious job. This job would be fruitful when well skilled and gently trend individual perform the duty. During preparation of *Varti* manifold attention should be required. *Prakshepa* ingredients should append in sequence. If any kind of variation would happen before putting the mixture in mold at the same time mixture might be thicken due to nature of ingredient. The prepared decoction was mixed with *Gairika*, *Sphatika,* and Gelatine and immediately heated on water bath until homogeneous mixture was prepared. Then, mixture was placed into mold and kept in the refrigerator for 10 min. The solidify *Varti* was packed in appropriate packing kit and again kept in the refrigerator for maintaining the quality of *Varti* or else it might liquefying after keeping it out more than 1.5-2 h. The time management is very essential for above mention procedure.

CONCLUSION

Standardization and development of reliable protocols for quality control of ayurvedic formulation using modern techniques of analysis are extremely needed. The method of preparation mentioned in the current study for *Darvyadi Yoni Varti* can be considered as standard. Approximately 1 L *Kwatha*, 25 g Purified *Gairika*, 30 g Purified *Sphatika*, 250 g Gelatin, and 180 ml honey were taken to prepare 400 *Varti* of 3 g, and an average 11 h time was taken for its preparation.

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