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RESEARCH ARTICLE

PHARMACEUTICAL STANDARDIZATION OF *APAMARGAKSHARAYOGA*

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ABSTRACT

Objective: *Apamarga KsharaYoga* (APK), a classical Ayurvedic formulation containing *Apamarga Kshara* (alkaline substance of *Achyranthes aspera* Linn.), *Manahshila* (Arsenic Disulphide) and *Gomutra* (cow's urine) is effective in cases of *Shvitra* (vitiligo). As the formulations has short shelf life, inconvenient to patients and involve longer duration of pharmaceutical preparation; it is planned to convert into more convenient form.
Design: Raw materials were authenticated and APK was prepared. Further, organoleptic and physico-chemical properties were evaluated.
Results: An average 909.8 gm (90.98 %) yield after *Taila Paka* and 1379.6 gm ointment was observed in the process.
Conclusions: As observed in present study, addition of wax to attain ointment consistency is mandate. Residue as *Apamarga Kshara* and *Manahshila* incorporated in preparation of ointment yielded more without losing its consistency.
Key Words: *Achyranthes aspera* Linn., *Apamarga Kshara Yoga*, Ointment, *Siktha Taila*, standardization

INTRODUCTION

Development of Ayurvedic pharmaceutical science with appropriate standardization and quality control is the first requisite in the present era that fulfills increasing demands of global population. Though classical formulations are effective, are known to possess certain inconveniences. To overcome such inconveniences; there is a need to convert them into elegant forms that are easy, acceptable and therapeutically viable. In the current attempt; it is planned to develop an ointment considering the composition of *Apamarga Kshara Yoga* (APK).

APK *Lepa*contains equal quantity of *Apamarga Kshara* (alkaline substance of *Achyranthes aspera* Linn.) and *Manahshila* (Arsenic Disulphide) levigated with *Gomutra* (cow's urine)[1]. APK has short shelf life, inconvenient and consume more time in preparation. Hence, it is planned to convert it into an ointment form which is more convenient and evaluate preliminary physico-chemical profile.

MATERIALS AND METHODS

Fresh *Apamarga Panchanga* (whole plant of *Achyranthesaspera* Linn.) was collected during October to November 2012 and authenticated by comparing the characters reported in earlier studies[2, 3]. *Apamarga Kshara* was prepared following classical guidelines[4]. Ointment of *Apamarga Kshara Yoga* was prepared as per the reference of *Rasatarangi* with some modifications. For this, *Manahshila*, *Tila Taila*(sesame oil) and *Siktha* (bee wax) were procured from pharmacy. *Gomutra* was procured from cow's shed, Jamnagar. Formulation composition of ointment is placed at Table-1.

Pharmaceutical procedure:

Pharmaceutical procedure of *Apamarga Kshara Yoga* ointment is divided in three phases:

Preparation of *Apamarga Kshara*

Completely dried *Panchanga* (whole plant) was ignited to obtain white coloured ash that was mixed with four times of potable water to prepare *Kshara jala* and filtered through four folded cotton cloth to remove any impurities in aqueous solution. Complete evaporation of water from *Ksharajala* was done to obtain white coloured *Apamarga Kshara*.

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Table 1: Formulation composition of ointment of *ApamargaKsharaYoga* (APKO)

Sr.no	Ingredient	English/Botanical name	Ratio
1	*Apamarga Kshara*	Water soluble ash of *Achyranthes aspera* Linn.	1 part
2	*Manahshila*	Arsenic Disulphide	1 part
3	*Tila Taila*	Sesame Oil	4 parts
4	*Go-mutra*	Cow's Urine	16 parts
5	*Siktha*	Bee wax	1/6 partof *SiddhaTaila*

Preparation of *Apamarga Kshara Yoga Taila*:

Apamarga Kshara (125 gm) and *Manahshila* (125 gm) were levigated by adding *Gomutra* (31.25 gm) to prepare *Kalka* (paste). *Tila Taila* (1000 gm) was taken in a steel vessel and subjected to *Mandagni* (heating) at 80^0 C to 90^0 C to remove moisture content. Increments of *Kalka* were added to the *Tila Taila* (oil) and fried for few minutes. Heating was continued with addition of four times of *Gomutra* (4000 gm). The contents were stirred continuously throughout the process and temperature was maintained at 80^0 C to 90^0 C. At regular intervals; *Kalka* was rolled in between the fingers to check the consistency. Heating was stopped after observing the characteristic features of *Taila Paka*[5, 6]. The contents were filtered while hot through clean cotton cloth into a sterile stainless steel container. The residual material kept aside for inclusion in further practical. (Fig.1)

Preparation of Ointment of *Apamarga Kshara Yoga* (APKO):

Prepared *Taila* (909.8 gm) was taken into a stainless steel container and subjected to mild heat. When the temperature reaches to 80^0 C; small pieces of *Siktha* (151.6 gm) were added and allowed to melt completely with continuous stirring. The contents were filtered through a clean cloth while hot to separate insoluble materials (if any) possibly present in the *Siktha*. The residual *Kalka* obtained at the end of *Taila Paka* was also added into this. The contents were stirred continuously till the blend become cool, homogenous, semisolid mass. The finished product was stored in air tight containers. (Fig.1)

Analytical Study:

Organoleptic characters like consistency, colour, touch and odour of Ointment of *Apamarga Kshara Yoga* were noted. Preliminary physico-chemical parameters like Loss on drying at 110°C [7], Ash value [8], Acid insoluble ash[8], pH value[9], Water soluble extractives[7] were carried out. Atomic Emission Spectroscopy with Inductively Coupled Plasma (AES-ICP) was also carried out for all samples.

Figure 1: Method of preparation of *Apamarga Kshara Yoga* ointment

1: Mixture of Apamarga Kshara and Manahshila in porcelain Kharala
2: Addition of Gomutra for making Kalka
3: Addition of Kalka into TilaTaila
4: Taila Paka at 80^0 to 90^0 C
5: Separation of Taila from Kalka
6: Siktha
7: Addition of Siktha to prepare ointment
8: Ointment stored in air tight plastic containers of 50 gms capacity

RESULTS AND DISCUSSION

After five to ten minutes of heating, bubbles started to emerge. Characteristic odour of *Gomutra* was observed during the process. Contents became pinkish after some time. *Manahshila* was settling down to the bottom of the vessel, to avoid this continuous stirring is required. After 30 minutes of heating; dark yellow colored *Gomutra* was changed to brown and extensive froth was observed during the process. *Siktha* took five minutes to dissolve completely in *Taila* at 80^0 C. An average of 909.8 gm (90.98 %) [Table 2] yield after *Taila Paka* and 1379.6 gm ointment (APKO) was obtained at the end of the pharmaceutical procedure [Table 3]. Physico-chemical parameters of ointment of *Apamarga Kshara Yoga* [Table 4] and results of AES-ICP were given as [Table 5].

Table 2: Observation and results of *Apamarga Kshara Yoga Taila Nirmana*

Batch	Quantity			Temp. (^{0}C)	Yield (gms)	Yield %
	***Kalka Dravya*(gms)**	***TilaTaila*(gms)**	***Gomutra*(gms)**			
Batch 1	250	1000	4000	80 -90	900	90.0
Batch 2	250	1000	4000	80 -90	923	92.3
Batch 3	250	1000	4000	80 -90	903	90.3
Batch 4	250	1000	4000	80 -90	890	89.0
Batch 5	250	1000	4000	80 -90	933	93.3
Average	250	1000	4000	80 -90	909.8	90.98

Table 3: Observation and results of ointment of *Apamarga Kshara Yoga*

Batch	Quantity		Residual *Kalka* (gms)	Temp. When *Siktha* was added	Yield (Gms.)
	APK *Taila*(gms)	***Siktha*(gms)**			
Batch 1	900	150	320	80^0 C	1370
Batch 2	923	153.8	310	80^0 C	1386.8
Batch 3	903	150.5	320	80^0 C	1373.5
Batch 4	890	148.3	330	80^0 C	1368.3
Batch 5	933	155.5	311.1	80^0 C	1399.6
Average	909.8	151.6	318.2	80^0 C	1379.6

Table 4: Physico-chemical parameters of APKO

Parameter	APKO
Loss on drying at 110°C (%w/w)	7.71
Ash value (%w/w)	08.00
Acid insoluble ash (%w/w)	0.45
pH value of 10 Aqueous Sol. (%w/w)	9.29

Table 5: ICP-AES results of APKO

Parameter	APKO
Arsenic (As)	885.916
Lead (Pb)	ND
Mercury (Hg)	ND
Cadmium(Cd)	ND
Silica (Si)	63.218
Iron (Fe)	3.933
Sodium (Na)	539.009
Potassium (K)	>1779.33
Calcium (Ca)	16.303
Magnesium (Mg)	674.627

Pilot batch

In present study, four pilot batches of the formulation ointment of *Apamarga Kshara Yoga* were prepared for fixing suitable method of preparation and to avoid batch to batch variations. Ointments are prepared by two methods viz. incorporation and fusion. In fusion method, all or some of the components of ointment are combined by being melted together and cooled with constant stirring until congealed. Similar method was described in classics by advocating use of *SikthaTaila*[10]as base of ointment.

Generally ointments are prepared by mixing powders of ingredients in *Siktha Taila* and cooled with constant stirring. Same method was followed in pilot batch 1

(APKO1). As *Gomutra* is one of the ingredients; first *Taila Paka* was done. Small pieces of *Siktha* were dissolved in oil and powder of *Apamarga Kshara* and *Manahshila* were added. Severe froth was observed during *Taila Paka* which creates difficulties in examine and difficult to check *Samyak Siddhi Lakshanas* of *Sneha Paka*. Removal of froth is required before adding remaining ingredients. This procedure is much complex and resulted in weight loss.

In 2nd pilot batch **(APKO2)**, *Taila Paka* was followed using *Kshara* and *Manahshila* as *Kalka Dravyas* and *Gomutra* as *Drava Dravya*. In this batch, ointment like consistency was observed at last stages of *Taila Paka* without addition of *Siktha* that may be due to heating oil in presence of *Kshara*. This consistency was only stable for 15 days, after which phase separation was observed. Hence in further batches, to avoid such separation, *Siktha* was added.

In 3rd pilot batch **(APKO3)**, water was added along with *Gomutra* as liquid media and maintained temperature between 80°C to 90° C. Around 75% *Siddha Taila* was yielded with clear separation of *Kalka* and *Sneha* in final stage. *Kalka* became brownish, with soft consistency and easily spreading on skin. *Siktha* was added to this *SiddhaTaila*.

Apamarga Kshara and *Manahshila* are not soluble in oil and after *Taila Paka* both became smooth and easily applicable on skin. Considering this, it was decided to add them on *Siktha Taila* and accordingly, 4th pilot batch **(APKO4)** was designed. In this batch, only *Gomutra* was added as liquid media and temperature was maintained between 80°C to 90° C. In final stage, 90% *Siddha Taila* with clear separation of *Kalka* and *Sneha* was observed. Residual *Kalka* was also added in *SikthaTaila* and maximum yield was observed than other three batches, so this batch was considered for main study.

Main Batch

In preparing ointment, *Apamarga Kshara Yoga Taila* was prepared by following general principles of *Sneha* (*Taila*) *Paka*[11]. Average 31.25 gm *Gomutra* was required to prepare *Kalka* of 125 gm *Apamarga Kshara* and *Manahshila* each. Increments of *Kalka* were added to1000 gm *Tila Taila* and fried for few minutes.

Heating was continued and added with four times of *Gomutra* (4000 gm) maintaining temperature in between 80^0 C to 90^0 C. The contents were strirred continuously throughout the process, after ten minutes of heating (*Paka*), bubbles started to emerge and characteristic odour of *Gomutra* was observed during the process. Contents became pinkish, frothy after some time that may be due to reactions between oil, *Kshara* and *Gomutra*. *Manahshila* was settling down to the bottom of the vessel because it is insoluble in oil and *Gomutra*. Total five batches were prepared and an average 90.98% yield (909.8 gm) was observed.

In second phase of preparation, *Siddha Taila* was subjected to heat to dissolve 151.6 gm of *Siktha* at 80°C. Contents were filtered through a clean cloth while hot. After that residual *Kalka* (318.2 gm) was also added in it and stirred continuously till the blend become cool, homogenous and semisolid mass. The contents were allowed to become cool and stored in air tight containers. An average of 1379.6 gm yield was observed. The finished product was brownish black coloured, semisolid, smooth and oily to touch.

Analytical study has been carried out to know quality of the finished product. APKO was dark brown, semisolid, thick and opaque in appearance.Loss on dying of APKO indicating presence of moisture contain due to addition of *Manahshila*, *Gomutra*, *TilaTaila* etc. APKO has pH 9.29. ICP-AES analysis of the sample revealed that Sodium, Potassium, Calcium and Magnesium are main constituents may be due to *Apamarga Kshara* present in the trial drug. Heavy metals like Lead, Mercury and Cadmium were not detected. Arsenic was detected as *Manahshila* is one of the major and active ingredient of formulation.

CONCLUSION

It can be concluded that *Ksharas* on heating in presence of fats (*Taila*) will yield a soapy consistency, but the phases will separate after some time. Hence, addition of wax to attain ointment consistency is a mandate.Addition of residue obtained in the *Sneha Kalka* (*Apamarga Kshara* and *Manahshila* in current context) should be preferred for addition in *Siddha Taila* to get desired consistency of ointment. This will also provide more yield. The current observations can be considered as standard in future studies.

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