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Research Article

KARUTHAVATTU OINTMENT - AN APPROACH TO PHARMACEUTICAL MODIFICATION

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ABSTRACT

Repositioned or reformulated products are those products which are reconstituted into a new form investigating their impact on market demands. It has great relevance on drug research and development. As a result of such market needs, pharmaceutical companies are looking for cost-effective products and making it more patent friendly. Developing a new formulation or indication for already known drugs can be considered as an appealing strategy for drug developers. Aim of form change is to increase patient friendly usage of a product without compromising its quality and potency. *Lepa kalpana* is one among the *Bahirparimarjana Chikitsa* used in Ayurveda. *Karutha vatu* is a traditional *Gulika yoga* explained in *Sahasrayoga Gutika prakarana* for the treatment of headache. The formulation is intended to apply externally over forehead or bregma with suitable medium for the cure of various types of head ache. The formulation contains *Kundurushka* (Oleo gum resin of *Boswellia Serrata*), *Kanya rasa* (*Aloe vera*), *Kathini* (silicate of magnesia), *Karigoodha (Karndivenna)* and *Sahasravedhi* (limonite). Making *Lepa* out of pill is a tedious task for the patients in present scenario due to their busy life schedules. It also creates problem of non-uniform mixing. Hence a form change of this tablet into ointment is necessary for greater patient's acceptance. The formulation is tested for its analytical values and discussed in this article.

INTRODUCTION

Repositioned or reformulated products are those products which are reconstituted into a new form investigating their impact on market demands. It has great relevance on drug research and development. As a result of such market needs, pharmaceutical companies are looking for cost-effective products and making it more patent friendly. Developing a new formulation or indication for already known drugs can be considered as an appealing strategy for drug developers.

Lepa kalpana is one among the *Bahirparimarjana chikitsa* used in Ayurveda. *Lepakalpana* is detailed in *Ayurvedic* texts like *Sarangadhara Samhita, Ashtangasamgraha* and *Susruta Samhita. Acharya Susruta* had explained three types of *Lepa* viz., *Pralepa, Pradeha* and *Alepa*[1].

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While *Vagabhatacharya* had explained 10 types of *Lepa* based on action[2]. Three *Lepas* according to *Sarangadhara*[3] are *Doshaghna, Vishaghna* and *Varnya*. *Lepa* should have a thickness of buffalo skin as per *Susrutha*[4].

Karutha vatu is a traditional *Gulika yoga* explained in *Sahasrayoga Gutika Prakarana* for the treatment of headache. Apart from this it can also be used in muscle sprain, ligament tear and tennis elbow like condition. The formulation is intended to apply externally over forehead or bregma with suitable medium for the cure of various types head ache. The formulation contains *Kundurushka* (Oleo gum resin of *Boswellia Serrata*), *Kanya rasa* (*Aloe vera*), *Kathini* (silicate of magnesia), *Karigoodha (Karndivenna)* and *Sahasravedhi* (limonite). Making *Lepa* out of pill is a tedious task for the patients in present scenario due to their busy life schedules. It also creates problem of non-uniform mixing. Hence a form change of this tablet into ointment is necessary for greater patient's acceptance. The formulation is tested for its analytical values and discussed in this article.

MATERIALS AND METHODS

Collection of Raw material

Raw materials for the preparation of *Karuthavattu* ointment was procured from raw material store of pharmaceutical corporation, Thrissur.

Materials Required

Table 1: Formulation of *Karuthvattu* Ointment

S.No	Materials	Quantity
1	*Kundurushka*	80 gm
2	*Kanyarasam*	60 gm
3	*Kannaram*	30 gm
4	*Sahasravedhi*	10 gm
5	Aloe juice	200 ml
6	glycerine	5 ml
7	Petroleum jelly	30 gm
8	Stearyl Alcohol	25 gm
9	Sodium laurate sulphate (SLS)	1 gm
10	Methyl paraben	0.1 g
11	Propyl paraben	0.01 g
12	Menthol crystal	1 g

Procedure

- Initially ointment base was prepared by adding Petroleum jelly to stearyl alcohol and double boiling it.
- In another vessel distilled water is taken with SLS and glycerine and stir continuously.
- Mix 1 & 2 solution together and stir gently to aid uniform mixing.
- Dissolve *Kanya rasa* in aloe juice by gently heating and stirring it.
- After complete mixing of *Kanya rasa*, add rest of finely powdered medicine (item 3 & 4) and stir properly.
- Finally the base is added to the above medicine after gentle cooling and levigated to prepare a homogeneous ointment.
- Finally add preservatives and menthol crystals and ensure uniform mixing.
- Ointment prepared is transferred to suitable container.

DISCUSSION

Karutha vatu is a traditional *Gulika yoga* explained in *Sahasrayoga gutika prakarana as Shirasthoda gulika.* Its ingredients are *Kundurushka* (Oleo gum resin of *Boswellia Serrata*), *Kanya rasa* (*Aloe vera*), *Kathini* (silicate of magnesia), *Kandivenna (Karigoodha)* and *Sahasravedhi* (limonite). The formulation is intended to apply externally over forehead or bregma with suitable medium for the cure of various types of head ache. In *Vatika shirashoola* it can be applied along with *Thaila*. In *Pittaja Shirashoola* with ghee and in *Kaphaja* type with coconut milk.

Making *Lepa* out of pill is a tedious task for the patients in present scenario due to their busy life schedules. It also create problem of non-uniform mixing. Hence it was modified into ointment so that it is easy for packing, increase shelf life and convenience of usage by patients.

Here ointment is prepared by using levigation and fusion method. By fusion method, all the components of the preparation melt due to the heat and combines together. Later it cools down with constant stirring.

Pharmaceutical Study

The ointment was prepared in trial batches for standardization.

Analytical Study

There are no standard parameters for the formulation previously, to compare with. The readings of the analytical study mentioned here are the average readings after 3 samples preparation. It was taken around 1 hour of continuous stirring to form in the proper ointment consistency

Since the loss on drying is only 0.078%, it indicates that the moisture content is minimal which is needed for the ointment to stick to the skin surface properly but it will help in maintaining the shelf life of the product.

The refractive index is measured to see the density of the solution before making it into ointment. The RI reading of 1.548 is indicative of fewer

impurities. The lesser the acid value of a formulation, the better is its shelf life. The lesser acid value of 3.917 indicates less chances of deterioration and better shelf life. The smell and the texture of the ointment will be better preserved.

The spreadability test can be performed by putting sample in between two slides and compressed to uniform thickness by placing a definite weight for definite time. The time taken was measured in gm-cm/sec. The spreadability value of 23.13gm-cm/sec is a good indicator of its thickness and indicates that it will hold to the skin surface during application and run off from the surface.

The formulation has desirable viscosity value of 75935 so that it is retained over the skin and absorbed quickly. The pH value of 5.8 indicates that the prepared sample is close to neutral in nature and will not harm the skin on application.

Stability study was carried out for 6 weeks at various temperature conditions like 2°C, 25°C, and 37°C. The ointment was found to be physically stable at different temperature within 6 weeks.

Fig 1: Ingredients of *Karuthavattu*

A: *Chenninayakam* B: *Kannaram* C: *Sahasravedhi* D: *Karigoodha* E: *kundurushka* F: *Kanya rasa*

Fig 2: Pharmaceutical preparation of karuthavattu ointment

A & B: Preparation of ointment base using petroleum jelly, Steryl alcohol, Sodium laurate sulphate
C: Dissolving *Chenninayaka* in *kanya* rasa D: Mixing rest of ingredients and triturate
E & F: *Karuthavattu* ointment

Table 2: Organoleptic properties

S.No	Properties	*Karuthavattulepa*
1	Colour	Dark brown
2	Odour	Smell of *Kundurushka*
3	Texture	Waxy
4	Consistency	Semisolid

Table 3: Physicochemical evaluation

S.No	Test	Values
1	Loss on drying	32 %
2	Refractive index	1.548
3	Acid value	3.917
4	Spreadability test	23.13gm-cm/sec
6	pH	5.8
8	Washability	Good
9	Non irritancy	Non irritant
10	Stability study (2°C, 25°C, 37°C)	Stable

CONCLUSION

Karutthavattu is a classical preparation mentioned in *Sahasrayoga.* In the present study, *Karuthavattu* was modified to a topical ointment form. The ointment was prepared using white petroleum jelly as the base substance and the method adopted was levigation and fusion method. The Pharmaceutical method of preparation was comparatively easy and involves levigation and fusion method. The ointment was found to be smooth in appearance with a dark brown colour with a characteristic smell of *Kundurushka.* Its modification to ointment form facilitates a longer shelf life. *Karuthavattu* ointment passed all test for identification like spreadabilty, washability and non irritancy etc. Its modification to ointment form assures a longer shelf life and high market acceptability.

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