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Pharmaceutico analytical study of *Mukha Kanthikara Lepa* and development of its new dosage form into Cream and Gel

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ABSTRACT

The need for cosmetics is seen from very ancient days; peoples were using variety of cosmetic products both for curative purpose as well as enhancing beauty. *Mukhakantikara Lepa* is a polyherbal formulation mentioned in *Sharandhara Samhita* in the form of *Churna*, which is extensively used to enhance skin complexion. In present time, the difficulty of portability, application, removal and shelf life of the *Churna* is a great challenge to *Lepa* form though being effective. Here arises a need for newer dosage form. Creams and gels are semisolid preparations which may be defined as topical products intended for application on skin or accessible mucous membrane to provide localised and sometimes systemic effects at the site of application. This dosage forms are more stable, easy to handle, easy to apply and remove. Hence, modification of *Mukhakatikara Lepa* into Cream and Gel can be a better idea to overcome the shortcoming of *Lepa* form.

Key words: *Mukhakatikara Lepa, Mukhakatikara Lepa Cream, Mukhakatikara Lepa Gel.*

INTRODUCTION

In *Samhitha Kala, Kalka* was using in the form of *Lepa*, the same reference was noted in Vedic period also. In later period, *Madhuchishta, Sarjarasa* etc. were used in *Gritha* and *Taila Kalpanas* which give a semi solid consistency to the product and can be easily applied over the affected area. In *Adhunika Kala* creams and gel plays major role in external route of administration of drugs. *Mukhakanthikara Lepa* is one of the *Varnya Lepa* mentioned in *Sharangadhara Samhitha*[1] at around six *Varnya Lepa* are mentioned in *Sharangadhara Samhitha* and one of them is selected for present pharmaceutical standardization and its converted form as a cream and gel.[2]

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AIMS AND OBJECTIVES

To prepare and analyse *Mukhakanthikara Lepa* and *Mukhakanthikara Lepa* Cream and *Mukhakanthikara Lepa* Gel.

MATERIALS AND METHODS

Pharmaceutical Study

Preparation of *Mukhakanthikara Lepa*

Ingredients:

1. *Rakthachandana - 10gm*
2. *Kusta - 10gm*
3. *Lodra -10 gm*
4. *Priyangu -10 gm*
5. *Manjishta -10gm*
6. *Masura -10gm*

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7. *Vatankhura -10gm*

Procedure

- All the seven *Dravyas* of above mentioned quantity taken in *Khalvayantra*
- Trituration was done in order to obtained homogenous mixture of the *Churna*s.
- And it was stored in airtight container.

Mukhakanthikara Lepa cream

Ingredients

Composition of *Mukhakanthikara Lepa* cream (10gm)

1. *Mukhakanthikara Lepa* - 2g
2. Petroleum jelly - 4.4g
3. Hard paraffin - 2g
4. Cetyl alcohol - 0.5ml
5. Glyceryl monostearate - 0.5g
6. Methyl paraben - 0.4g
7. Propyl paraben - 0.3g
8. Fragrance - qs
9. Activated charcoal - 0.01gm

Preparation of *Mukhakanthikara Lepa* Cream

Measured quantity of propylene glycol was taken in a beaker. Carbopol 940 was added slowly in it (oil Phase) while heating. e.g. Part A. The emulsifier (glyceryl monostearate) and other oil soluble components (petroleum jelly, cetyl alcohol, hard paraffin) was dissolved in the oil phase (part A) and heated up to 80°C. In another beaker triethanol amine and di sodium EDTA was taken (Part B). *Mukhakanthikara Lepa* and water soluble components (methyl paraben, propyl paraben) was dissolved in part B and heated up to 80°C. After heating, the oil phase was added in portions to the aqueous phase with constant stirring. Then the whole mixture was allowed for gentle stirring until cream was formed. Then Perfume was added when the temperature was dropped to 45 to 50°C. Then the cream was packed in a tube/container and was allowed to store at room temperature.[3]

Observations

- Here all the process was done on 70° temperature.
- Before adding the colour of water phase was dark brown but when oil phase was added it became light brown.
- After mixing of all the ingredients, colour changed to light brown.
- It was mixed well to get proper cream like consistency
- Before adding fragrance to the cream, *Rakthachandana* smell was appreciated

Precautions

- Carbopol should be mixed with propylene glycol first. While mixing one thing should keep in mind that little amount of Carbopol will be added with continuous stirring.
- Due to the sudden change in the stirring direction, phase separation chances are there. Which is really not permissible through out the procedure.
- Avoid air contact and pack it in an air tight container

Mukhakanthikara Lepa gel

Ingredients

Composition of *Mukhakanthikara Lepa* gel (100ml)

1. *Mukhakanthikaralepa Lepa* - 2g
2. Carbopol 940 - 1.5g
3. Triethanol amine - 1.5g
4. Disodium EDTA - 5mg
5. Propylene glycol - 5g
6. Methyl Paraben - 0.4g
7. Demineralized water q.s to 100ml

Procedure[4]

A measured quantity of cabopol 940 was kept in a beaker. In that 40 ml of water was added and kept for soaking for 2 hours (Part A). In another beaker

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measured quantity of Propylene Glycol was taken and all the samples were added in the same beaker with this 10 ml of water was also added and all were mixed properly (Part B). If the samples were not mixed at room temperature then it was kept on water bath for heating at 75 to 80°C for getting a uniform mixture. On the other hand, in a beaker Triethanol amine and 10 ml water was mixed with disodium EDTA, methyl paraben (Part C). After proper mixing, the mixture Part B and Part C was transferred into the Part A mixture. It was allowed to stir until gel formed. Gel was stored in airtight glass container.

Observations

- Socked Carbopol was used because it was not mixing properly with all the ingredients.
- Then heating was not required so much while preparing. It was nicely mixing with all.
- Colour was changing from brown to light when water was added as it was water based gel. Mean while sometime heating was provided for few minutes for getting the proper consistency.
- Fragrance was added at last at room temperature. Then was mixed well.

Precautions

- Don't stir the soaked carbopol more or else it will not give the consistency like gel.
- After adding the other ingredients only stirring is allowed.
- If the other ingredients are not soluble then allow heating it for few minutes for getting uniform gel like formulation.
- Don't leave the formulation in open air or else it will form air bubble inside and that will be difficult to remove.
- As of the air bubbles, accurate results of different parameter you may not get.
- Pack it in an air tight container.

ANALYTICAL STUDY

Physico Chemical Analysis

Mukhakanthikara Lepa

pH value, acid insoluble ash, water soluble ash, loss on drying, alcohol soluble extractive value, total yeast and mould count were carried out out at Drug testing laboratory, Government Central Pharmacy, Jayanagar, Ashoka Pillar Bengaluru.

Mukhaknthikara Lepa Cream

pH value, viscosity value, Freeze-thaw cycle, Centrifugation test tube extrudability, Spreadability, Washability on day of preparation, 7th day, 15th day, 30th day and 60th day and average results were taken at PES College of Pharmacy, Hanumanth Nagar, Bengaluru.

Mukhaknthikara Lepa Gel

pH value, viscosity value, Freeze-thaw cycle, Centrifugation test tube extrudability, Spreadability, Washability on day of preparation, 7thday, 15th day, 30th day and 60th day and average results were taken at PES College of Pharmacy, Hanumanth Nagar, Bengaluru.

RESULTS

Pharmaceutical Results

Mukhakanthikara Lepa

- The total quantity of *Mukhakanthikara Lepa* obtained was 2729gm out of 3500gm
- Loss of weight : 751gms

Mukhakanthikara Lepa Cream

- Weight of Cream : 98.5
- Total time taken for the procedure : 1 hour

Mukhakanthikara Lepa Gel

- Weight of Cream : 100.5
- Total time taken for the procedure : 3 hours.

Table 1: Showing Organoleptic characters of *Mukhaknthikara Lepa*

Parameters	Observation
Varna	*Dark brown*

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Sparsha	*Mrudu*
Rasa	*Kashya, Tikta*
Gandha	Like *Rakthachandana*

Table 2: Showing results of standardization parameters of *Mukhaknthikara Lepa*[5]

SN	Parameters	Results
1.	Loss on ignition	93.52%
2.	pH (10.0% aqueous solution)	4.99
3.	Volatile oil, v/W	0.99%
4.	Total Ash , w/w	6.36%
5.	Acid - Insoluble Ash , w/w	1.45%
6.	Water - Insoluble Ash , w/w	2.22%
7.	Loss on Drying at 105 deg C , w/w	9.42%
8.	Total Yeast and Mould count	150CFU/gm/ml
9.	Determination of water soluble	30.24%
10.	Alcohol soluble extractive	20.154%

Table 3: Showing the observation of TLC of *Mukhakanthikara Lepa*

Band No	Rf value	Colour of the spot
1	0.03	Light yellow, non-fluorescent
2	0.05	Light yellow, non fluorescent
3	0.15	Grey , non fluorescent
4	0.25	Grey, non-fluorescent

Table 4: Showing classical parameters for analysis of *Mukhakanthikara Lepa* cream

Parameter	Observation
Colour	Light brown
Taste	Astringent and acrid
Odour	Characteristic odour
Appearance	Greasy
Texture	Smooth

Table 5: Showing results of standardization parameters of *Mukhakanthikara Lepa* cream[6]

SN	Physicochemical Parameters	Specification
1.	Appearance	Light homogenous, charcteristic odour, smooth textured cream
2.	pH	7.5
3.	Freeze thaw cycle	No separation
4.	Centrifugation	No separation
5.	Spreadability	Easily spreadable
6.	Tube Extrudability	2.12
7.	Sensitivity	Not observed
8.	Irritation test	Not observed
9.	Washability	Easily washable

Table 6: Evaluation of Viscosity (cps) at 21°C of *Mukhakanthikara Lepa* cream.

Viscosity (cps)	0.5rpm	1rpm	2rpm	2.5rpm	4.5rm	10rpm	20rm	50rm
	25840	17780	8916	6840	3694	1800	929	369

Table 7: Showing classical parameters for analysis of *Mukhakanthikara Lepa* gel.

Parameter	Observation
Colour	Dark brown
Taste	Astringent and acrid

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Odour	Characteristic odour
Appearance	Greasy
Texture	Smooth

Table 8: Showing results of standardization parameters of *Mukhakanthikara Lepa* Gel[7]

SN	Physicochemical Parameters	Specification
1.	Appearance	Dark Brown homogenous, charcteristic odour, smooth textured Gel
2.	pH	7.25
3.	Freeze thaw cycle	No separation
4.	Centrifugation	No separation
5.	Spreadability	Easily spreadable
6.	Tube Extrudability	4
7.	Sensitivity	Not observed
8.	Irritation test	Not observed
9.	Washability	Easily washable

Table 9: Evaluation of Viscosity (cps) at 21°C of *Mukhakanthikara Lepa* Gel.

Viscosity (cps)	0.5rpm	1rpm	2rpm	2.5rpm	4.5rpm	10rpm	20rpm	50rpm
Initial	10296	8940	5118	4755	3683	1835	923	360

DISCUSSION

The formulations that have been explained in the ancient classics have mostly proven to be authentic and practical. In the present era most of the pharmaceutical company tries to transform a classical formulation from its original classical forms to a desired form which is most required for the present society. E.g. application of a *Lepa* to a face for a desired effect may cause discomfort to the patients and its modified form into cream and gel may be comfortable but at the time of modification of the cream and gel the properties of the drugs and its action should not be hindered. Hence an effort was made to transform a *Lepa Choorna* into a cream and gel form by adopting a Standard Operative Procedure and analyze both the original form i.e., *Lepa Choorna* and the obtained cream and gel for various analytical procedures. In current study analysis was done for raw materials also because of quality of finished product greatly depend on quality of raw materials used. Here all the 7 raw materials that are common in *Lepa*, cream and gel are tested for their physicochemical values and preliminary Phytochemistry. API guidelines and published scientific articles were taken as standard references. In the context of *Mukhakanthikara Lepa,* Loss on drying, Ash value, Acid insoluble ash, Extractive values, pH, were conducted on the prepared samples in the context of physicochemical evaluation.

In the context of cream and gel pH value, viscosity value, Freeze-thaw cycle, Centrifugation test tube extrudability, Spreadability, Washability were tested.

CONCLUSION

Mukhakantikara Lepa mentioned in *Sharangadhara Samhita, Uttara Khanda* 11th chapter can be developed as Cream and Gel. The prepared *Mukhakanthikara Lepa* cream was O/W type emulsion. The prepared *Mukhakanthikara Lepa* Gel was water base. Physical test shows *Mukhakanthikara Lepa* was dark brown in colour with characteristic odour, *Mukhakanthikara Lepa* Cream Light brown with characteristic odour and *Mukhakanthikara Lepa* Gel dark brown with no particular odour. *Mukhakanthikara Lepa Cream* and *Gel* showed, the consistency, colour and homogenicity of the Cream and Gel kept in room temperature were maintained and did not undergo any physical changes up to 5 months.

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Ingredients for *Mukhakanthikara Lepa*

Rakthachandana

Manjishta

Lodhra

Kushta

Vatankura

Masura

Priyangu

Mukhanthira Lepa Churna

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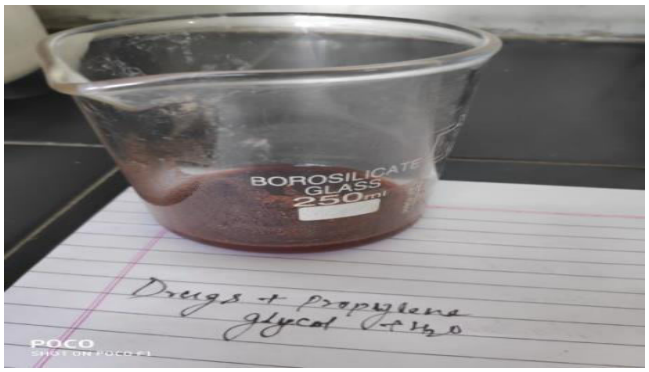
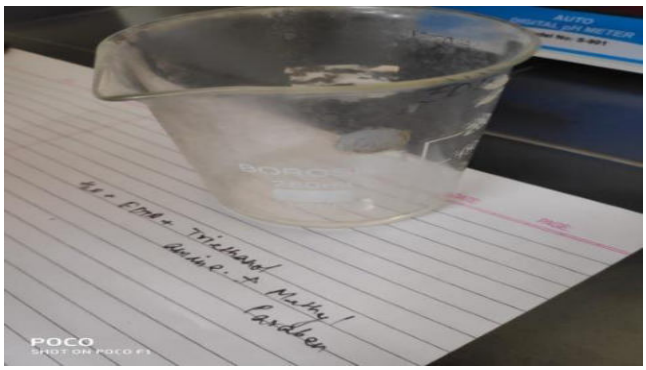
Preparation of *Mukhakanthikara Lepa* Cream



Adding *Mukhakanthikara Lepa* and propylene glycol

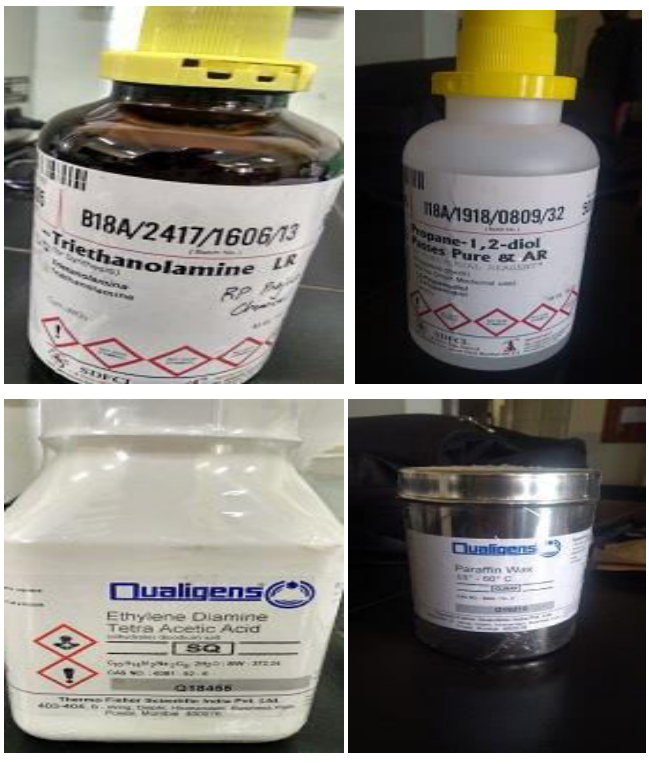
Adding carbopol while heating



Mixing methyl paraben

***Mukhakanthikara Lepa* cream**

Preparation of *Mukhakanthikara Lepa* Gel



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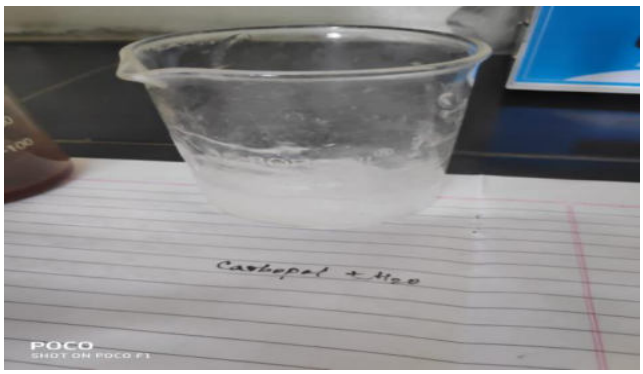
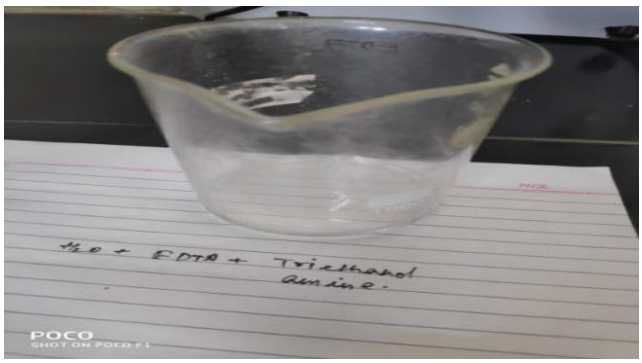
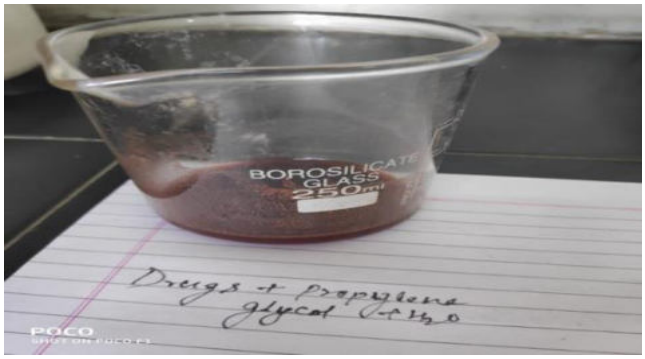


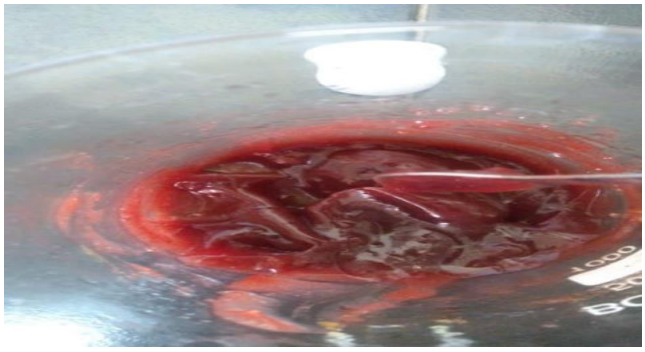
Adding carbopol and water



Then mixing EDTA and triethanol amine



Mukhakanthira Lepa **and propylene glycol**



Mixing all ingredients

Mukhakanthikara Lepa **Gel**

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