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### FORMULATION AND EVALUATION OF TOPICAL GEL CONTAINING MICROSPHERES OF KSHEERABALA OIL

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#### ABSTRACT

Herbal medicine, as a major part of traditional medicine, has been used in medical practice since antiquity and is a common element of ayurvedic, homeopathic, and naturopathic medicine. Ksheerabala oil with its nurturing, cooling and carming blend form an excellent nervine tonic, with anti-inflammatory, antirheumatic and analgesic properties. The present investigation involves the preparation and evaluation of gel formulations of microspheres Ksheerabala oil using different gelling agent. Six different formulae were prepared and characterized physically in term of color, syneresis, spreadability, and pH. The results showed that the F6 formula with Sodium Carboxy Methyl Cellulose as gelling agent shows comparatively good physical property.

#### KEYWORDS

Ayurvedic, Naturopathic, Analgesic properties and Formulations.

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#### INTRODUCTION

Herbal medicine, as a major part of traditional medicine, has been used in medical practice since antiquity and is a common element of ayurvedic, homeopathic, and naturopathic medicine. World health organization (WHO) notes that 74 % of the plant derived medicines are used in modern medicine, in a way that their modern application directly correlates with their traditional use as herbal medicines by native cultures.

Ksheerabala oil is traditional ayurvedic massage oil. It is used in the treatment of migraine and sciatica. It also helps cure insomnia and light headedness. Ksheerabala oil with its nurturing, cooling and carming blend form an excellent nervine tonic, with anti-inflammatory, antirheumatic and analgesic properties. It controls Vata imbalances arthritis, burning sensation, fibromyalgia, headaches, disorders involving CNS, paralysis, insomnia and for relaxation purposes. It has been proven effective in treating vertigo, gout, hemiplegia, paraplegia and in controlling hypertension to a certain extent. The major ingredients used in this oil are Bala (Sidacordifolia), Ksheera (cow's milk) and Thilathalia (Sesamum oil).

Microspheres are small spherical particles with diameter in the micrometer range (typically in  $\mu\text{m}$  to  $1000\mu\text{m}$  (1mm). Microspheres can be manufactured from various natural and synthetic materials. Poly ethylene, poly styrene and expandable microspheres are most common types. Polystyrene microspheres are typically used in biomedical application due to there ability to facilitate procedures such as cell sorting and immune precipitation Polyethylene microspheres are commonly used as a permanent or temporary filler.

The United States Pharmacopeia (USP) defines gels as semisolids, being either suspension of small inorganic particles or large organic molecules interpenetrated with liquid. This is a true two-phase system, as the inorganic particles are not soluble but merely dispersed throughout the continuous phase. . Gels find use as delivery systems for oral administration as gels proper or as capsule shells made from gelatin, for topical drugs applied directly to the skin, mucous membranes, or eye, and for long acting forms of drugs injected intramuscularly or implanted into the body. . Topical drug delivery is an attractive route for local and systemic treatment .1

The present investigation involves the preparation and evaluation of gel formulations of microspheres Ksheerabala oil using different gelling agent

## MATERIAL AND METHODS

Ksheerabala oil, albumin flakes, Hydroxyl Propyl Methyl Cellulose, Methyl Cellulose, Sodium CMC, glycerine.

## Preparation of microspheres of ksheerabala oil

Dissolved 5 gm of albumin flakes in distilled water. Heat 5ml Ksheerabala oil to about  $121^{\circ}\text{C}$ . To this preheated oil, added albumin solution drop wise to make emulsion. Stirred at 1500 RPM for 1 hour. After heat stabilization for 10 min the preparation was cooled to  $25^{\circ}\text{C}$ , which leads to the formation of microspheres.

## Formulation of Gel

The composition of microspheres of Ksheerabala oil containing topical gel formulae are shown in table 1. Microspheres of ksheerabala oil were dissolved in a mixture containing the gelling agents (Hydroxy Propyl Methyl Cellulose, Methyl Cellulose, and Sodium Carboxy Methyl Cellulose), glycerin, distilled water.

The gelling agents such as Hydroxy Propyl Methyl Cellulose, Methyl Cellulose, and Sodium Carboxy Methyl Cellulose were dissolved in distilled water with constant stirring using magnetic stirrer at a moderate speed. Then added the previous mixture containing the drug with continuous stirring until gel formed. The prepared gels were packed in wide mouth glass jar covered with screw capped plastic lid, covering the mouth with an aluminum foil and were kept in dark and cool place shown in Table No.1.

## Evaluation of Prepared Gel Formulations

### Visual examination

All developed gel formulae were inspected for their homogeneity; color and presence of lumps by visual inspection after the gels have been set in the container.

### Spreadability test

A sample of 0.5g of each formula was pressed between two slides (divided into squares of 5 mm sides) and left for about 5 minutes where no more spreading was expected. Diameters of spreaded circles were measured in cm and were taken as comparative values for spreadability.

### pH Determination

The pH of the gels was determined using digital pH meter. The readings were taken for average of 3times.

## RESULTS

### Particle Size Measurement

The particle size of prepared microspheres was measured by Optical microscopy. The average particle

size was expressed as the volume mean diameter in  $\mu\text{m}$ .

#### Visual examination

The prepared gel formulae were inspected visually for their color and presence of lumps.

Sodium CMC gel formulae showed white color, good homogeneity with absence of lumps.

#### Spreadability

The spreadability is very much important as it shows the behaviour of gel comes out from the tube. The values of spreadability shown in table (2) indicate that all the polymers used gave gels spread by small

amount of shear. The diameters of the spreaded circles ranged from 8mm seen with the sodium CMC gel and 2.2 cm seen with HPMC gel. Data in Table No.2 revealed that increasing the concentration of any of the gelling agents was always associated with a decrease in the spreadability as expressed by the lower diameter of the spreaded circle.

#### pH Determination

The pH values of all developed formulae was in range 6-7 which is considered acceptable to avoid the risk of irritation upon application to the skin in Table No.2, 3 and Figure No.1.

**Table No.1: Materials used for formulation**

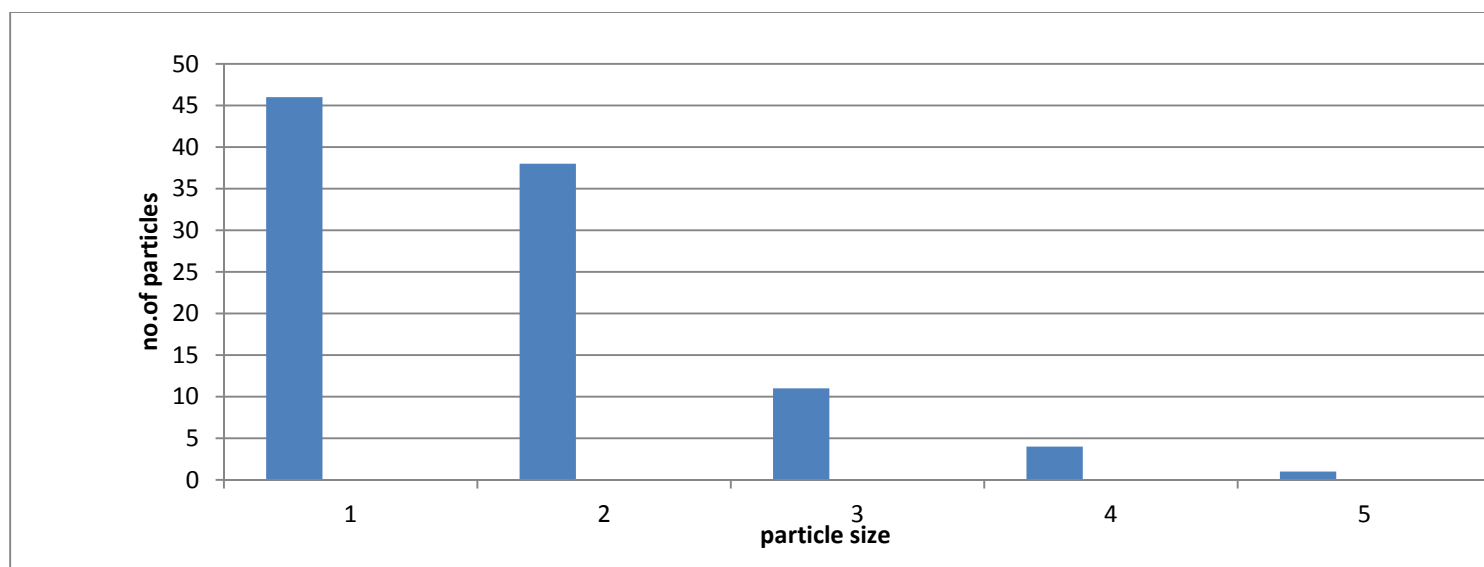
Materials	F1	F2	F3	F4	F5	F6
HPMC(% w/w)	1.5	2	-	-	-	-
Methyl cellulose(% w/w)	-	-	2	4	-	-
Sodium CMC(% w/w)	-	-	-	-	3	4
Microsphere(% w/w)	1	1	1	1	1	1
Glycerin	10	10	10	10	10	10
Distilled water	q.s	q.s	q.s	q.s	q.s	q.s

**Table No.2: Spreadability analysis of different formulations**

S.No	Gel formulation	Spreadability
1	F 1	1.8 cm
2	F 2	2.2 cm
3	F 3	1.9 cm
4	F 4	1.5 cm
5	F 5	9 mm
6	F 6	8 mm

**Table No.3: PH determination of different formulations**

S.No	Gel formulations	pH
1	F 1	6.89
2	F 2	6.90
3	F 3	6.70
4	F 4	6.85
5	F 5	6.93
6	F 6	7.12



**Figure No.1: Particle size analysis of microspheres**

## CONCLUSION

On the basis of the previous findings we can concluded that Ksheerabala oil was successfully incorporated into the different topical gel preparations. From among all the developed formulation the formula F6 shows white colour, good spreadability, and no skin irritation. Therefore, it was concluded that our formulae could be very promising topical preparation. However, further preclinical and clinical studies are required.

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## CONFLICT OF INTEREST

We declare that we have no conflict of interest.

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