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Formulation And Development Of Lip Cream Based On Microencapsulated Active.

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Abstract:

Lip hyperpigmentation is a common concern that many people face, often caused by factors like sun exposure, smoking, hormonal changes, dehydration, and environmental pollutants. To help improve the look of lips and reduce dark spots, depigmenting agents in topical treatments have become quite popular. One promising ingredient is (Undecylenoyl Phenylalanine), which works by blocking the hormone that triggers melanin production. However, simply adding such active ingredients directly into skincare products can sometimes cause them to break down, lose effectiveness, or become unstable over time.

This study focused on creating a lip cream with microencapsulated Sepiwhite MSH to improve the stability of the active ingredient and allow it to be released gradually. Using a special polymer-based technique, tiny capsules were made and tested for how well they held the active ingredient, how much they contained, and their structure. These capsules were then mixed into a lip cream, which was checked for its look, texture, pH balance, spreadability, thickness, ease of squeezing, and overall stability. The final product showed good physical and chemical qualities, remained stable, and had a pleasant feel. Overall, the results suggest that microencapsulation is a promising way to boost the effectiveness of cosmetic products aimed at reducing pigmentation.

Key words: Lip Cream, Undecylenoyl Phenylalanine, Microencapsulation, Cosmetic Formulation, Stability Study**.**

Introduction:

The lips are one of the most noticeable and important features of the face. They play a key role in expressing emotions, speaking clearly, eating, and sensing the world around us. Structurally, the lips mark the boundary between the inside of the mouth and the outside environment and are made up of three parts: the outer skin, the vermilion border, and the inner mucosal area. The vermilion is the pinkish-red part of the lips, with a thin skin layer and a rich network of blood vessels that give the lips their unique color. Unlike regular skin, lips have very few oil glands, sweat glands, and pigment cells, which is why they are more prone to dryness, dehydration, and damage from the environment**.** It act as a protective barrier that keeps them moisturized and flexible. However, because they don't produce enough natural oils and have a thinner outer layer compared to skin, they're especially sensitive to things like sun exposure, changing temperatures, wind, smoking, makeup, and pollution. These factors can weaken the lips' natural defenses, causing dryness, cracking, irritation, and uneven pigmentation.

Lip pigmentation is primarily determined by the concentration and distribution of melanin produced by melanocytes present in the basal layer of the epithelium. Although melanin serves a protective role against ultraviolet radiation, excessive melanin production can lead to hyperpigmentation and darkening of the lips. Several intrinsic and extrinsic factors, including prolonged sun exposure, smoking, hormonal imbalance, nutritional deficiencies, allergic reactions, certain medications, and environmental pollution, contribute to lip hyperpigmentation. Darkened lips often cause cosmetic dissatisfaction and may negatively affect an individual's self-confidence and overall appearance.Cosmetic products intended for lip care have evolved significantly over the past decade. Traditionally, lip care products were designed primarily to provide moisturization and protection against environmental damage. However, modern cosmetic formulations are increasingly being developed with multifunctional benefits, including hydration, nourishment, anti-aging effects, sun protection, and depigmentation. As a result, depigmenting agents are now commonly incorporated into cosmetic formulations to reduce excessive melanin production and restore the natural color of the lips. Undecylenoyl Phenylalanine is a synthetic amino acid derivative that has gained considerable attention as an effective depigmenting active ingredient. It acts as an antagonist of α-melanocyte-stimulating hormone (α-MSH), a key regulator of melanogenesis. By inhibiting the interaction between α-MSH and melanocortin receptors, Sepiwhite MSH suppresses melanin synthesis within melanocytes, thereby reducing pigmentation. Compared with conventional skin-lightening agents, Sepiwhite MSH offers improved safety, lower irritation potential, and better cosmetic acceptability, making it suitable for use in lip care formulations. Despite the effectiveness of Sepiwhite MSH, maintaining the stability of active ingredients in topical cosmetic formulations remains a major challenge. Factors such as temperature, humidity, oxidation, light exposure, and interactions with other formulation components may lead to degradation of the active ingredient, ultimately reducing its efficacy and shelf life. Therefore, innovative delivery approaches are required to protect sensitive cosmetic actives and ensure their sustained performance [1].

Microencapsulation technology has emerged as an effective strategy for enhancing the stability and functionality of active ingredients in cosmetic formulations. In this technique, the active substance is enclosed within a protective polymeric coating, forming micro-sized capsules that shield the active ingredient from environmental degradation. Microencapsulation offers several advantages, including improved chemical stability, protection against oxidation and moisture, controlled release of active ingredients, reduced irritation potential, enhanced shelf life, and improved product performance.

The incorporation of microencapsulated Sepiwhite MSH into a lip cream formulation may enhance the stability and efficacy of the active ingredient while providing prolonged release and improved consumer acceptability. Therefore, the present study was undertaken to formulate and evaluate a lip cream containing microencapsulated Sepiwhite MSH with the objective of developing a stable, effective, and aesthetically acceptable cosmetic product for the management of lip hyperpigmentation[2].

Materials and Methods:

All the ingredients which are used to formulate the lip cream was obtained from Yasham speciality ingredients Pvt. Ltd.,Andheri(India) for all experiments.

Preparation of microencapsulation:

Sr. No.	Variable	Sodium Alginate+Active		
	Batch No. -->	1	2	3
1	Sodium alginate (%)	0.5%	0.5%	0.5%
3	Calcium Chloride (%)	0.4%	0.4%	0.4%
4	Active	1%	1.5%	2%
	Observations (Depends on their rupturing ability)	Satisfactory rupturing power	Satisfactory rupturing power	Satisfactory rupturing power

Procedure:

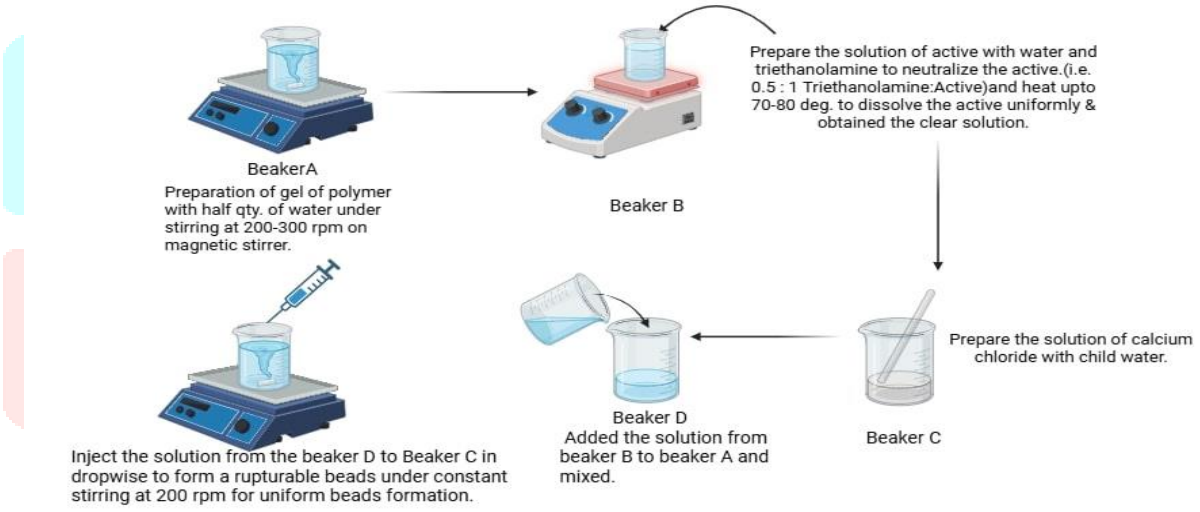

Fig. 1: Depicts the process of preparation of microencapsulated beads.

The formulation variables for microencapsulation were studied by varying the concentration of the active ingredient while keeping sodium alginate (0.5%) and calcium chloride (0.4%) constant across all batches. Three batches were prepared containing 1%, 1.5%, and 2% active ingredient, respectively, to evaluate the effect of active concentration on the rupturing ability of the microcapsules. The observations indicated that all batches exhibited good rupturing ability, suggesting that the beads ruptured easily upon application without requiring excessive force. This demonstrates that increasing the concentration of the active ingredient did not negatively affect the mechanical strength or functionality of the microcapsules within the studied range. Based on these the formulation containing 0.5% sodium alginate, 0.4% calcium chloride, and 2% Undecylenoyl Phenylalanin was selected as the optimized formulation, as it provided effective rupturing behaviour along with a higher concentration of the active ingredient for enhanced efficacy [3,5].

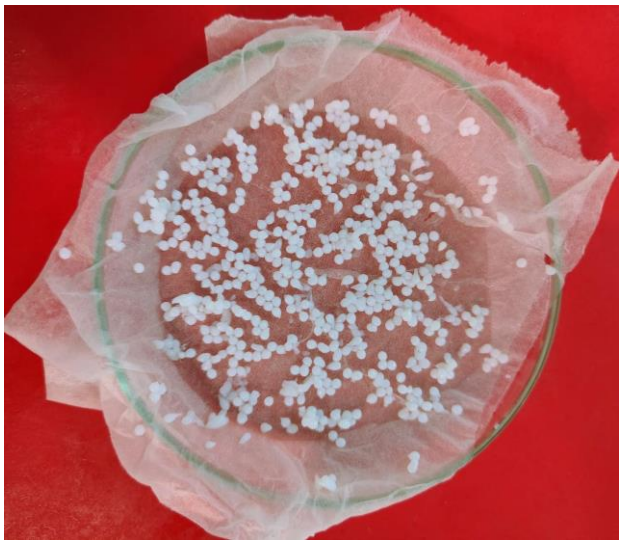

Fig.2: Microencapsulated beads

Preparation of lip cream:

Phases	Ingredients	Qty. For 100%
A	Aqua	Upto 100
	Sorbitol	3
	Sodium Hyaluronate	0.1
	Polyacrylate Crosspolymer-6	0.6
B	Caprylic/Capric Triglyceride	5
	C15-C19 Alkane	4
	PEG-100 Stearate (and) Glyceryl Stearate	2
	Cetearyl Alcohol (and) Cetearyl Glucoside.	2
	Dimethicone	1
	Dextrin Palmitate	0.1
	Shea Butter	5
C	Xylitylglucoside, Anhydroxylitol, and Xylitol.	1
	Tocopheryl Acetate	0.5
	Phenoxyethanol (and) Ethylhexylglycerin (and) Octenidine HCl	1
	Saccharin	0.1
	Flavour YNJU2405000188	0.1
D	Microencapsulated beads with active	0.15

Procedure:

1. To prepare the lip cream, Phase A components water, sorbitol, sodium hyaluronate (HA, 8000-15000 Da), and Sepimax ZEN were combined in a beaker. In a separate beaker, Phase B components caprylic/capric triglyceride (CCTG), C15-C19 alkane, PEG-100 stearate (and) glyceryl stearate, dimethicone, dextrin palmitate, shea butter, and vitamin E were mixed.

2. Both phases were heated to 75-80°C. Phase B was then added to Phase A with continuous stirring, and the mixture was homogenized for 10 minutes using an (IKA T25 Ultra Turrax high-speed homogenizer) to obtain a uniform and homogeneous emulsion.
3. After homogenization, Phase C ingredients were added one by one with continuous stirring to ensure proper mixing. The prepared lip cream was then transferred into a suitable, properly labeled container for storage and further evaluation.

Fig.3: Shows the formulation which we have prepared in our lab.

Evaluation of microencapsulated beads:

1. **Physical Evaluation:**

   The physical characteristics of the microencapsulated beads containing. The beads was take in a petry plate and distributed by visually identify the colour, shape and appearance. The colour of beads was white. The shape was Spherical and appearance was white coloured smooth beads. The beads showed good structural stability with a smooth, uniform surface. These results simply that the beads have the right physical properties to be used in topical preparations.

2. **Swelling Index Determination:**

   The swelling index of the prepared microencapsulated sodium alginate beads was determined to evaluate their swelling behavior in an aqueous medium.

   Accurately weighed dried beads (W_0) were placed in a beaker containing a known volume of swelling medium, such as phosphate buffer (pH 5.5), maintained at room temperature. The beads were allowed to swell freely without disturbance.

At predetermined time intervals, the beads were carefully removed from the medium and gently blotted using filter paper to remove excess surface moisture without applying pressure. The swollen beads were then immediately weighed (W_t) [70].

The swelling index was calculated using the following equation:

$$\text{Swelling Index (\%)} = \frac{W_t - W_0}{W_0} \times 100$$

Where:

3. W_0 = Initial weight of dried beads
4. W_t = Weight of swollen beads at time *t*

The swelling index was found to be 80%

3. Rupturing Ability:

The rupturing ability of the prepared microencapsulated beads was evaluated using a simple manual method. A small quantity of beads was placed on the palm and gently pressed to assess their mechanical strength and ease of rupture. The beads were observed for their ability to rupture without the application of excessive pressure.

The beads were applied onto the lips and gently rubbed to simulate practical application conditions. The ease of rupture on the skin surface was evaluated.

4. Percentage Yield:

The percentage yield of microencapsulated sodium alginate beads was evaluated after preparing the beads using the ionotropic gelation method. The dried beads were weighed to obtain the practical yield, while the theoretical yield was calculated based on the total amount of active and polymer (sodium alginate) used in formulation. The percentage yield was then calculated using the standard formula.

The results showed that formulation F1, containing 1000 mg of drug and 500 mg of polymer, had a theoretical yield of 1500 mg and a practical yield of 1060 mg, giving a percentage yield of 70%. Formulation F2, with 1500 mg of drug and 500 mg of polymer, showed a theoretical yield of 2000 mg and a practical yield of 1590 mg, resulting in a 79% yield. In the case of formulation F3, which contained 2000 mg of drug and 500 mg of polymer, the theoretical yield was 2500 mg and the practical yield was 2170 mg, giving the highest yield of 86%. Overall, the results suggest that the percentage yield improved as the drug concentration increased, indicating better efficiency of the encapsulation process.

Trails	F1	F2	F3
Active(mg)	1000	1500	2000
Polymer(mg)	500	500	500
Theoretical Yield(mg)	1500	2000	2500
Practical Yield(mg)	1060	1590	2170
Percentage Yield	70%	79%	86%

5. Encapsulation Efficiency (%):

The encapsulation efficiency (%EE) of Undecylenonyl Phenylalanine substances as the drug concentration increased, while the polymer concentration remained constant at 0.5%. The %EE was

70.25% for 1%, 86.40% for 1.5%, and 90.80% for 2%. This means that a higher drug concentration higher its drug entrapment.

The 2% formulation is the best batch for active because it strikes the best balance between high encapsulation efficiency and maximum drug loading.

Evaluation of Lip cream:

1. **Organoleptic Evaluation**:

The prepared lip cream was inspected visually to determine its colour, odour, Consistency and Texture. These parameters are observed in prepared lip cream formulation. The results are recorded [64].

Physical Characterstics	Results
Colour	White
Flavour	Sweet
Consistency	Semi-solid

2. **Determination of pH:**

Human skin typically has a pH between 4.5 and 7.00. Therefore, the lip skin was similar to the human skin. Therefore, a formulation must have the pH range in between the 4.5 to 6.5 to avoid any allargies or reaction to the skin. Before Took the pH the pH meter should be calibrated for avoid any errors in the results. The pH of lip cream was determined by preparing the 10% solution of lip cream by using the (Labman LMPH12 Digital pH Meter 5 Points) and inserted the electrode of a pH meter in the solution and recorded the readings [65,66].

The pH of lip cream was found to be 5.21.

Fig.4: Digital pH meter

3. Determination of Rheological Property:

The viscosity of Lip cream was determined by Brookfield viscometer (Model No – D 220)

Fig.5: Digital Brookfield Viscometer

The rheological analysis of the formulated lip cream indicated that it exhibits non-Newtonian, shear-thinning (pseudoplastic) characteristics, signifying that its viscosity decrease with increasing shear. A viscometer was used to measure the lip cream viscosity, and it was found to be 27,800 cps.[7].

4. Determination of Spreadability:

The spreadability of lip cream was determine by slide to slip off method. The sample placed between to glass slide and upper slide is took 42 second to travel a 5 cm × 2 cm glass slide. Then calculating using the spreadability formula. The spreadability of lip cream was recorded as 7.81 g.cm/sec, indicating that the formulation is easily spreadable. Spreadability is an important physical property of topical preparations, as it reflects how easily a formulation can be applied and distributed over the skin surface. A spreadability value of 7.81g.cm/sec suggests that the lip cream has an optimal consistency neither too thick nor too runny which allows for effortless application and uniform coverage. This enhances consumer experience and ensures consistent application across the lip skin area. The good spreadability also indicates appropriate viscosity, contributing to effective skin contact and improved long efficacy of the lip cream [6].

$S=m*l/t$

here,

S = Spreadability, m= Weight tied to the upper slide, l =Length of glass slide, t=Time taken in seconds.

Fig.6.: Spreadability

3. Rupturing Ability:

Procedure:

- A small quantity of the prepared microencapsulated beads was taken and placed on a clean, dry surface.
- The beads were initially examined visually to assess their shape and surface integrity.
- A few beads were then placed on the palm and gently pressed using a finger to evaluate their rupturing ability under mild pressure.
- Also the beads were applied on the lips (or suitable skin surface) and gently rubbed to simulate actual application conditions. The ability of the beads to rupture during rubbing was observed.

- The evaluation focused on:
- Ease of rupture under slight pressure
- Release of encapsulated material upon rupture
- Smoothness of spreading after rupture
- Absence of coarse residue or grittiness after application

4. Percentage Yield:

Materials Required

- Prepared microencapsulated beads
- Weighing balance
- Filter paper
- Hot air oven/desiccator

Procedure

1. The microencapsulated beads were prepared using the ionotropic gelation method.
2. The formed beads were collected and washed thoroughly with distilled water to remove excess calcium chloride.
3. The beads were dried in a hot air oven or desiccator until a constant weight was obtained.
4. The dried beads were accurately weighed, and the weight obtained was recorded as the Practical Yield.
5. The Theoretical Yield was calculated by summing the total weights of the active ingredient and the polymer used in the formulation.

Formula

$$\text{Percentage Yield (\%)} = \frac{\text{Practical Yield}}{\text{Theoretical Yield}} \times 100$$

5. Encapsulation Efficiency (%):

Procedure

1. Weighing of Beads: A known quantity of dried microencapsulated beads (e.g., 100 mg) was accurately weighed.
2. Drug Extraction:

- The beads were crushed using a mortar and pestle.

- The crushed beads were transferred into a suitable solvent (e.g., phosphate buffer pH 5.5, depending on the solubility of Undecylenoyl Phenylalanine).
- The dispersion was stirred or sonicated to ensure complete release of the drug from the microcapsules.

3. Filtration: The resulting solution was filtered to remove polymeric debris and other insoluble materials.
4. Dilution: The filtrate was diluted appropriately with the selected solvent to obtain a suitable concentration for analysis.
5. Analysis: The absorbance of the diluted solution was measured using a UV-Visible spectrophotometer at the λmax of Undecylenoyl Phenylalanine.
6. Determination of Drug Content: The actual amount of drug present in the microencapsulated beads was calculated using the previously prepared calibration curve.

Formula,

$$\text{Encapsulation Efficiency (\%)} = \frac{\text{Actual Drug Entrapped}}{\text{Total Drug Added}} \times 100$$

The encapsulation efficiency was found to be 80%.

Evaluation Of Lip cream:

1. **Organoleptic Evaluation:**

Determined the colour, odour, texture by visual inspection.

2. **Determination of pH:**

The pH of the formulation was measured using a calibrated digital pH meter. The electrode was rinsed with distilled water, immersed in the sample, and the reading was allowed to stabilize. The pH value displayed on the meter was recorded, and the electrode was rinsed again with distilled water after measurement.

3. **Determination of viscosity:**

The rheological property of the lip cream was determined using a Brookfield viscometer. The formulation was transferred into a clean beaker, and a suitable spindle was immersed in the sample. After allowing the sample to attain temperature equilibrium, the viscometer was operated at the selected speed, and the viscosity reading was recorded once stabilized. The results were used to evaluate the flow behavior of the formulation.

4. Accelerated Stability Study:

Accelerated stability study was performed as per ICH Guidelines. The test was done for a time period of 3months, 6 months & 12 months at a temperature of 30°C ± 2 °C/65% RH [25, 26]. The parameters which are observed such as colour, odour and phase separation are evaluated by visually. The texture, pH, viscosity these are determined by instrumental analysis [6].

Table 01: Depicts Stability studies Data of formulation

Parameters	**1 Month**	**2 month**	**3 month**
Colour	No change	No change	No change
Odour	No change	No change	No change
Phase separation	No phase separation	No phase separation	No phase separation
Texture	No change	No change	No change
pH	No change	No change	No change
Viscosity	No change	No change	No change

Results and Discussion:

Table 02: Evaluation parameters of lip formulation

Sr. No.	**Parameters**	**Result**
1	Colour	White colour cream
2	Odour	Pleasant
3	Consistency	Semi-Solid
4	Texture	Smooth
5	pH	5.21
6	Viscosity	27800 cps
7	Spreadability	Easily spreadable
8	Homogeneity	Homogeous
9	Centrifugation	No phase separation
10	Stability Studies	Stable (no change)

Discussion:

The formulated lip cream based on microencapsulated active (Sepiwhite MSH) demonstrated satisfactory results across various evaluation parameters, indicating its potential as an effective and stable lip care formulation. The lip cream exhibited an attractive appearance with a smooth, uniform texture and pleasant feel, making it suitable for regular application. Its semi-solid consistency ensured easy application and good adherence to the lips. The pH of the formulation (5.21) was found to be

within the acceptable range for lip preparations, suggesting good compatibility with the delicate lip skin and minimizing the possibility of irritation.

The formulation showed appropriate viscosity, which contributed to good spreadability and uniform distribution on the lips without being excessively greasy or sticky. The incorporation of microencapsulated Sepiwhite MSH facilitated homogeneous dispersion of the active ingredient throughout the formulation, ensuring consistency and enhancing formulation stability. The lip cream remained smooth and free from grittiness, indicating successful incorporation of the encapsulated active. No phase separation or instability was observed during centrifugation studies, demonstrating good physical stability. Furthermore, accelerated stability studies conducted under different storage conditions showed no significant changes in appearance, pH, texture, or consistency, confirming the stability of the formulation over time. These findings suggest that the developed lip cream is stable, aesthetically acceptable, and suitable for delivering Sepiwhite MSH effectively, making it a promising formulation for lip care and lip brightening applications.

Conclusion:

In conclusion, the formulation and development of a lip cream based on microencapsulated active (Sepiwhite MSH) presents a promising approach for effective lip care and lip brightening. The incorporation of microencapsulated Sepiwhite MSH enhances the stability of the active ingredient and promotes its uniform distribution throughout the formulation. The developed lip cream exhibited desirable physicochemical characteristics, including appropriate pH, viscosity, spreadability, homogeneity, and aesthetic appeal, ensuring ease of application and user acceptability.

The evaluation studies confirmed that the formulation remained stable under various storage conditions, with no significant changes in appearance, texture, consistency, or pH. Furthermore, the absence of phase separation and the satisfactory performance in stability testing indicate the robustness of the formulation. Overall, the developed lip cream provides a stable, effective, and user-friendly delivery system for Sepiwhite MSH, making it a suitable formulation for lip moisturization, protection, and enhancement of lip appearance. The study demonstrates the potential of microencapsulation technology in improving the performance and stability of active ingredients in cosmetic formulations.

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