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**Research Article**

# Development And Topical Characterization Of Solid Lipid Nanoparticle (SLN) Gels Enriched With Orange Peel Ipomoea Batatas Extract And Essential Oils For Enhanced Vitiligo Therapy

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## ABSTRACT

The goal of the current study was to create a solid lipid nanoparticle (SLN) gel for topical application of sweet potato ethanolic extract in order to improve its penetration by employing tea tree oil as a permeation enhancer. The high-speed homogenisation method was used to create the suggested sweet potato ethanolic extract gel filled with solid lipid nanoparticles. Particle size, zeta potential, drug entrapment and release, drug excipient interactions, and thermal behaviour were all assessed in relation to varying lipid strengths. An in-vitro gelling test was used to test the final gel formulations, which were created by adding tea tree oil as a permeability enhancer and carbopol as a gelling agent. The prepared gel's viscosity, pH, and in-vitro permeation characteristics were assessed. The maximum drug release was 90.55% for over a period of 24 hours. Conclusion: In this study sweet potato extracts were successfully encapsulated within the SLNs and when applied topically the SLNs could reside on the surface of the skin for localized action as evident from the drug release study. The zeta potential obtained for the SLNs was approximately within the limit of –24mV that yields a formulation with fairly good physical stability.

## INTRODUCTION

- **Hypopigmentation**- The process when the skin completely loses its colour & goes white is known as depigmentation. Put otherwise, it decreases the production of melanin, which causes the skin to turn from dark to fair in tone.[3]. Hypopigmentation frequently manifests as parts of your skin that seem lighter or white. You may apply these patches to any part of your body. As with diseases like

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vitiligo and albinism, they might be little or dispersed across a greater region. Hypopigmentation involves a wide range of reasons.

- **Vitiligo**- Vitiligo is an autoimmune condition in which the body's immune system mistakenly attacks and destroys melanocytes—the cells responsible for producing melanin. Additionally, this results in symmetrical, well-defined white skin patches on both sides of the body. Though it is more frequent in younger people, vitiligo may occur at any age. Although it is not communicable or fatal, it affects around 1% of the world's population and can be emotionally upsetting owing to its look.[3] Fig 1 depicts a cross-section of vitiligo-affected skin, and the striking visual contrast highlights the condition's effects on the skin. Genetic predisposition, immunological reactions, oxidative stress, and environmental factors interact intricately in the multifactorial aetiology of vitiligo.[4] With an estimated 1% incidence globally, vitiligo is the most prevalent acquired pigmentary condition.[7] Due to the loss of functional melanocytes, the condition is characterised by the formation of depigmented patches and macules. [8,9] Segmental vitiligo lesions are often persistent, unilateral, and appear in a localised or dermatomal distribution. Non-segmental vitiligo is the more prevalent kind of vitiligo. Non-segmental vitiligo, which encompasses the generalised, acrofacial, and universal varieties, is traditionally defined by a waxing and waning course with depigmentation in a symmetric, bilateral pattern.

- **Solid Lipid Nano-Particle-** Physiological lipids are distributed in water or a surfactant solution to form solid lipid nanoparticles (SLN), a sub-micron colloidal delivery method with a size range of 50 to 1,000 nm. SLN exhibit phase interactions at the interface, significant drug loading, a tiny size, and a large surface area.[2] SLN is made up of circular-shaped solid lipids with nanoscale particles scattered in water or surfactant solutions. SLN is made up of circular-shaped solid lipids with nanometer-sized particles scattered throughout water or surfactant solutions.[1] Lipid-based systems are becoming more and more prevalent for a number of reasons.

- Lipids decrease plasma profile variability and improve oral absorption.
- More accurate lipoid excipient characterisation.
- A better capacity to deal with the major problems of manufacturing scaleup and technology transfer.

**Benefits of SLN**

- Control and/or target the release of drugs.
- Superior biocompatibility
- Enhance the stability of medications
- The drug content is high and boosted.

**SLN's drawbacks**

- Particle expansion.
- The gelation propensity is unpredictable.
- Unexpected polymeric transition dynamics.[16]

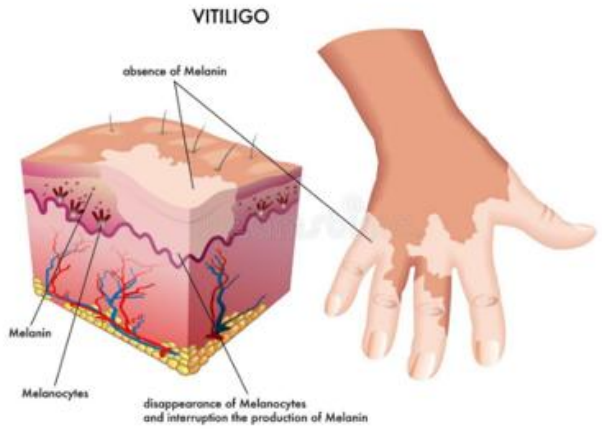


**Fig.1 Diagrammatic illustration of skin layers indicating how melanocytes vanish in vitiligo-affected regions, resulting in depigmentation**

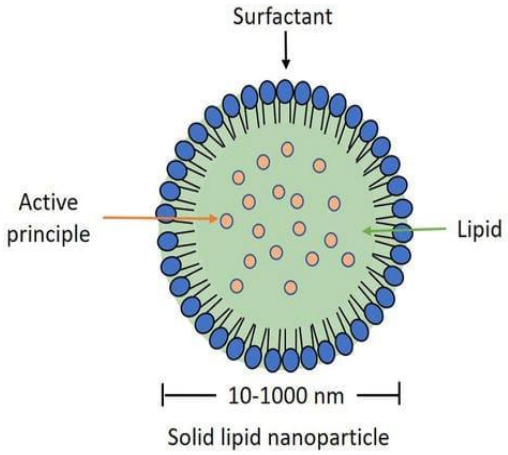


**Fig.2 General Diagram Of The Solid Lipid**

- **Drug & Excipient Profile-**

**a. Drug Profile-**

1. **Ipomoea batatas (L.) Lam, or sweet potato**, is one of the most nutrient-dense crops cultivated in tropical and subtropical areas.[5] Ipomoea batatas (L.) is frequently referred to as Due to their significant contribution to human nutrition, sweet potatoes are regarded as the second most important food crop in many industrialised and developing nations. Sweet potatoes' naturally occurring white, yellow, purple, and orange flesh is rich in nutrients.[5,6]

**Kingdom:** Plantae **Division:** Tracheophyta **Subdivision:** Spermatophyta **Class:** Magnoliopsida **Order**: Solanales **Family**: Convolvulaceae **Genus:** Ipomoea **Species**: batatas (L.) Lam[6]

**Fig.3 The Beta Carotene Rich Orange Fleshed Sweet Potato**

**Chemical Constituent-**

Sweet potatoes with orange flesh are primarily high in phenolic acid, carbohydrate, and dietary fibre. beta-carotene, phoshorus, and sponamins.[10]

**Beta-carotene**- With its strong antiradical activity and capacity to neutralise singlet oxygen, β-carotene is a powerful antioxidant. As a result, it can prevent sun damage and slow down the ageing process of the skin [11]. β-carotene, an orange pigment that is converted to vitamin A in living tissues and is frequently found in food supplements and cosmetics, is one of the active substances with demonstrated excellent antioxidative qualities[12]. It lowers the chance of getting skin cancer and shields the immune system from the harmful effects of UVA radiation [11].

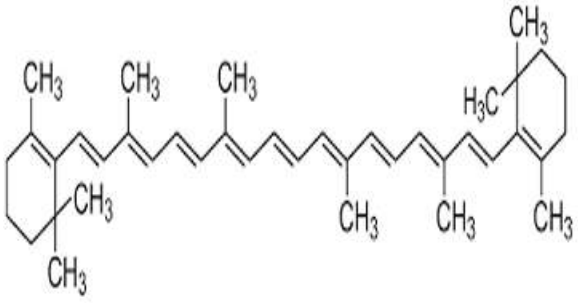


**Fig.4 β- Carotene**

2. **Orange Peel-** Orange peel is highly valued for its aromatic and medicinal properties. The sweet orange (Citrus sinensis) produces it as a byproduct. The presence of bioactive compounds like flavonoids, antioxidants, and essential oils is responsible for its health benefits[13].

**Kingdom** Plantae **Subkingdom** Tracheobionta **Family** Rutaceae **Genus** Citrus Species C. sinensis,

**Binomial name** Citrus sinensis.[13]

**Fig.5 Orange Peel And It's Powder**

**b. Excipient Profile-**

Glyceryl Monostearate, Tween 80 & Soy Lecithin, Carbapol, were used as Lipid, Surfactant, Co-surfactant, Gelling agent independently. All reagents and ingredient used Analytical grade**.**

**Table.1. - Excipient Profile**

| S.No. | Excipient | Properties |
|---|---|---|
| **1.** | Glyceryl Monostearate | Used as Lipid |
| **2.** | Tween 80 | Surfactant |
| **3.** | Soy Lecithin | Co- Surfactant |
| **4.** | Carbapol | Gelling Agent |
| **5.** | Glycerine | Humectant |
| **6.** | Water | Solvent / Vehicle |
| **7.** | Triethanolamine | Ph adjuster |
| **8.** | Tea Tree oil | Permeation Enhancer |

➢ **Material & Methods-**

A free sample of sweet potato extract powder was obtained from Panacea Phytoextracts in Gujarat, India. We bought carbopol 934 from BRM Chemical. We bought glycerol monostearate from BRM Chemical. Bennet Pharmaceutical in Baddi, India, provided a free sample of soy lecithin, while Loba Chemicals Pvt. Ltd. provided Tween 80. The remaining solvents and reagents were all of analytical reagent grade.

➢ **Preparation of SLNs (High-speed homogenization Method)**

1. **Phase preparation (lipid Phase):** It's involves melting the lipid (Glyceryl Monostearate), by heating it to 65°C. The melted lipid evenly dissolves the essential oil and sweet potato extract.

2. **Using a high-shear homogeniser**, Denatured water is used for dissolving Tween 80 standard and Poloxamer 188 and orange peel extract, which are then heated to the same temperature 65°C.

3. **Emulsion Formation:** Immediately place one-third of the heated aqueous phase in an ice-water bath. Dropwise add the remaining two-thirds of the aqueous phase with the sweet potato to the melted lipid phase.

4. **Nano-emulsion:** To reduce droplet size to the nanoscale, the heated emulsion is immediately exposed to probe ultrasonication for five to ten minutes.

5. **Solidification**: The lipid droplets recrystallise into solid lipid nanoparticles when the resultant nano-emulsion is cooled to room temperature or in an ice bath while being gently stirred.[15,16,17]

**The composition of different batches is shown in Table-2 and quantity is in mg .**

**Table-2 Composition Of Sln Formulation**

| Ingredient/ Excipient | FI | F2 | F3 | F4 |
|---|---|---|---|---|
| Drug | 15 | 15 | 15 | 15 |
| GMS | 100 | 100 | 200 | 400 |
| Tween 80 | 400 | 400 | 400 | 400 |
| Soy Lecithin | 50 | 100 | 200 | 400 |
| Ethanol | 2.5 ml | 2.5 ml | 2.5 ml | 2.5 ml |
| Distilled Water | 25 ml | 25 ml | 25 ml | 25 ml |

- **Characterization of Sweet Potato extract powder Loaded SLN**

1. **Particle Size Analysis:** The Malvern Zetasizer (Nano ZS) was used to measure the particle size of the prepared SLN. Before the sample was put through the device, the dispersion was suitably diluted 20 times with double-distilled water to make sure the light scattering signal, as measured by particle count per second, was within the equipment's sensitivity range. [19]

2. **Zeta Potential:** To determine the stability of SLN dispersion, zeta potential measurement is necessary. Zeta potential of prepared SLN dispersion was measured by Zetasize. [19]

3. **Drug entrapment efficiency-** The entrapment efficiency (EE), indicating the fraction of extract powder enclosed and attached to the nanoparticles, was evaluated by measuring the concentration of free Etoricoxib in the dispersion medium. A 2.0 ml aliquot of each drug-loaded sample underwent centrifugation at 5300 rpm for 70 minutes to separate the lipid and aqueous phases. Subsequently, the supernatant was diluted with methanol and analyzed at 233 nm using an Electronics India Model-1371 UV-VIS spectrophotometer. The formula below was applied to assess the trapping efficiency of the nanoparticle. [20]

**Entrapment efficiency (%) = (Initial amount of drug – amount of free drug) / (Initial amount of drug) × 100. [19]**

4. **Transmission electron microscopy:** The morphological analysis of the extract powder-loaded SLNs was performed through transmission electron microscopy (TEM). The nanoparticles in the sample were treated with phosphotungstic acid (2% w/v). A small volume of nanoparticle suspension (approximately 5–10µL) was deposited on copper grids with films for analysis using TEM (Hitachi H-7500 Tokyo, Japan). Digital monographs and image viewing software were utilized to take the pictures. [21]

5. **Infrared spectroscopy (FTIR)-** FTIR spectroscopy was utilized for the physicochemical characterization. To achieve

this, an FTIR spectrometer (Shimadzu Corporation, Japan) was utilized to analyze the samples in the form of KBr pellets.[20]

6. **Drug Content Uniformity-** A quantity of SLN equivalent to 0.05% was dissolved in 100 mL of ethanol within a volumetric flask. For complete drug solubility, the SLN solution was stirred continuously for an entire day. Following filtration and proper dilution of the solutions, ethanol served as the reference solvent for spectrophotometric analysis at 239 nm. [19]

7. **Differential Scanning Calorimeter Analysis (DSC)-** A Shimadzu differential scanning calorimeter (TA Instruments, model SDT2960, USA) equipped with an intercooler and chilled air circulation system was used to measure the thermal properties of SLN using DSC. DSC with an intracooler was used to get thermograms of the drug and excipients separately, in combination as a physical mix, and as an improved freeze-dried product. Alpha alumina powder is used in a platinum crucible.as a benchmark to modify the DSC measurement of temperature and enthalpy. The powder samples were firmly sealed in the aluminium pan and heated at a constant rate of 10 °C per minute across a temperature range of 35 °C to 250 °C. Nitrogen was released at a flow rate of 150 mL/min to maintain the non-reactive environment.[19]

➢ **Formulation of SLN-Incorporated Gel (Nanogel)**

1. Carbopol 934, a water-soluble polymer, was combined with distilled water containing glycerine and stirred to prevent clumping to create a gel.
2. The Carbopol will fully hydrate and expand after enough time, giving it a smooth, thick consistency.
3. To ensure an even mixing of the medication in dispersion, SLN formulation F2 (amount equal to 0.10% w/w of extract) was added while stirring. 1.5% Tea Tree oil was added to the mixture while being constantly stirred.
4. To create a homogenous, viscous, and transparent gel or matrix, triethanolamine was added to the Carbopol dispersions until full neutralisation had place.
5. The hydrated Carbopol matrix is gently combined with the prepared SLN dispersion.[18]
6. **All composition in %w/w**

**Table.3 Composition Of Gel Formulation**

| Ingredient/ Excipient | FI | F2 | F3 | F4 |
|---|---|---|---|---|
| Carbapol | 1% | 1.5% | 2% | 3% |
| SLN | 0.10% | 0.10% | 0.10% | 0.10% |
| Tea Tree oil | 1.5% | 1.5% | 1.5% | 1.5% |
| Triethanolamine | q.s | q.s | q.s | q.s |
| Glycerin | 2 ml | 2 ml | 2 ml | 2 ml |
| Distilled Water | q.s | q.s | q.s | q.s |

**Evaluation Of Sln Gel-**

1. **Physical appearance & Homogeneity-** The gel's appearance and homogeneity were visually assessed. Clarity is among the most significant features. The formulations were visually inspected on a white and black backdrop to detect the presence of particle debris.[19]

2. **Spreadibility study of SLN gel-** The gel compositions' spreadibility was tested using a lab-modified device. The equipment consisted of two glass plates with a pan fixed on a pulley.A large amount of gel was spread between glass slides (10 x 10 cm2). To compress the formulation, a 1g weight was put on the upper glass plate for 2 minutes. A 100g weight tie was put to the pan. Spreadability was measured by the time necessary to separate slides (in seconds). The spreadibility was determined using the following formula.[20]

$$S = Mx\frac{L}{T}$$

Where S is spreadibility, M is weight tied on upper slide. L is the length of glass slide, t is time taken.

3. **Viscosity:** The drug's residence period on the skin is significantly influenced by the viscosity of the implanted formulation. Using a sample adapter with spindle number SC4-21 and a Brookfield viscometer (RVDV II+ Pro model), the rheological investigations of the formulations were conducted. The angular velocity was progressively raised from 0.5 to 100 rpm. The angular velocity hierarchy was then flipped from 100 to 10 rpm. The viscosity was determined by averaging two observations. A 0.5 N sodium hydroxide solution was added to the formulations to elevate their pH from 5.0 to 7.4. At the same time, the temperature was raised from 25 °C to 37 °C. Samples' viscosity was measured both before and after jelly formation.[19]

4. **pH**: One of the most crucial elements in the formulation process is pH. The effects of pH on stability and solubility are two crucial areas. The skin should not be irritated by the preparation. A digital pH meter was used to measure the pH of the manufactured SLN gel following the addition of all the ingredients.[19]

5. **Drug Content Uniformity:** A spectrophotometric approach was used to analyse the drug content of the produced gel in order to make sure that every formulation had the same quantity of active medication. One millilitre of the preparation was transferred to a 100 mL volumetric flask, and the volume was adjusted using phosphate buffer pH 7.4 after the vials holding the preparation were shaken for two to three minutes. The same phosphate buffer was used to further dilute an aliquot of the material to 10 mL. A UVVisible spectrophotometer was used to measure the extract (drug) concentration at 239 nm.

6. **Release Kinetics** - To determine the mechanism of drug release from the SLN, data from in vitro release tests were fitted to a variety of kinetic equations. The dissolved quantity of drug (M) is a function of the time (t), or M=f(t). The ata is fitted in a zero order, first order Higuchi model to examine the drug release process.

## RESULTS AND DISCUSSION:-

1. **Characterisation of SLN:**

**Size of Particles:** Particle Size: According to an analysis of the data, the range of particle sizes was

between 190 and 500 nm. The formulation containing 100 mg of fat (F2) produced the smallest particle size, 191.09 nm. Formulation F4 had the highest particle size, measuring 499.91 nm at 400 mg of fat. The particle size was found to be closely correlated with the amount of lipid used. The concentration of the surfactant was crucial in keeping the particle size within the nanoscale range. Particle size is dependent on surfactant concentration in addition to the amount of lipid utilised; at optimal concentrations, submicron particle size was attained with a low particle size dispersion. **In given table 4**.-

**Zeta Potential**: Zeta potential measurement provides information on particle charge and, consequently, the dispersion's stability. Zeta potential should generally be high; for a dispersion to be stable, it should have a value between -24.4 mV and +24 mV. Because of electrical repulsion, charged particles are less likely to aggregate inside this region. **Table 4** below provides the zeta potential for various formulations

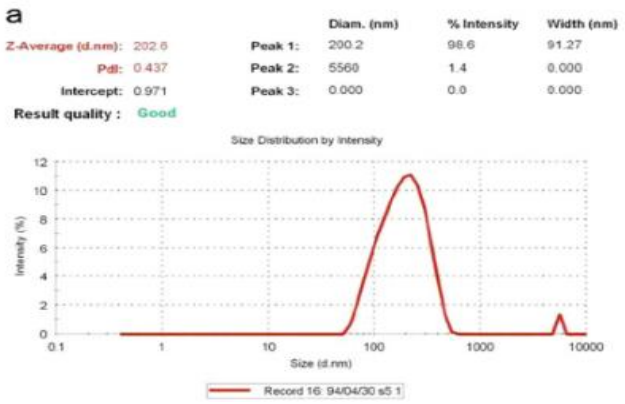


**FIG.5: Particle size distribution graph of SLN-F2.**

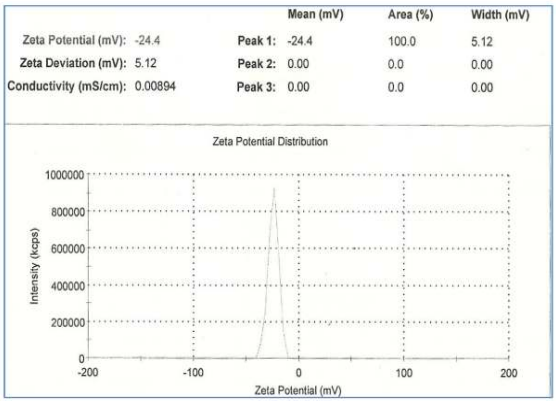


**FIG. 6: Zeta potential of SLN-F2 Dispersion**

**Transmission Electron Microscopy (TEM)-** The optimised formulation was examined morphologically using transmission electron microscopy (TEM). SLNs may be seen using TEM following freeze substitution and freeze fracturing. The size of SLNs was determined by TEM examinations to be 100 nm.

**Drug Content:** Using UV spectroscopy at 239 nm, the drug content of the freeze-dried SLN formulations was ascertained. It was discovered that the optimised formulation of SLN had a drug content of 90.60%.

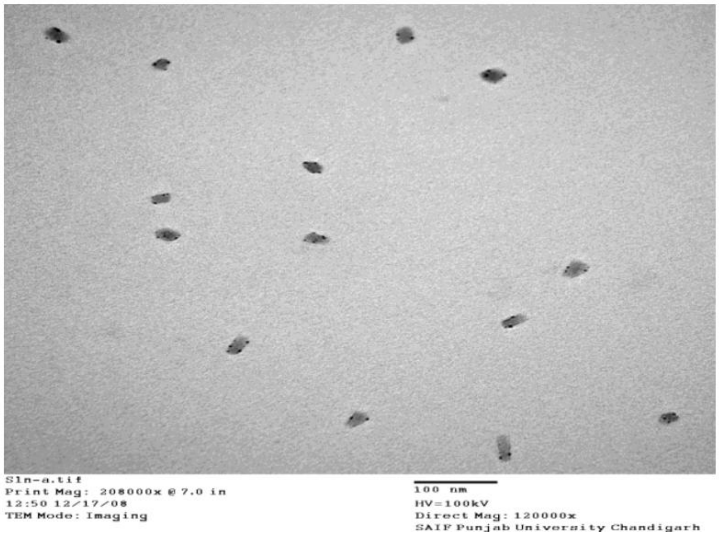


**FIG. 7: TEM image of SLN-F2 Dispersion**

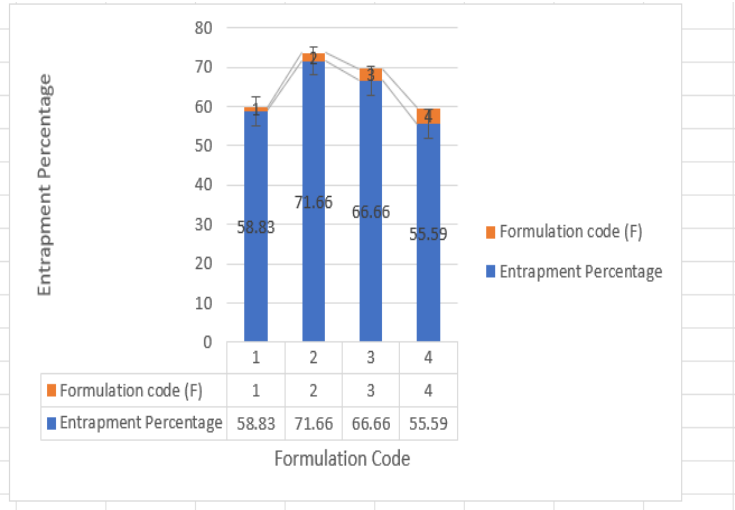


**FIG. 8: %DEE of SLN formulation**

**Drug Entrapment Efficiency:** According to the data shown in **Table 4**, formulation SLN-F2, which contains a high lipid content, has a greater entrapment than other formulations. SLN-F1 and SLN-F3 exhibit entrapment rates of 58.83% and 66.66%, respectively, compared to 71.66% for the SLN-F2 dispersion. Similar to what is observed in SLN-F4. In **Fig 8**

**FTIR Spectra-** The FTIR spectra of the SLN formulation and pure extract powder. The FTIR examination showed no clear physical or distinctive extract powder peaks in the SLN formulation, suggesting little interaction, while a few peaks were absent, which may indicate that the drug was well entrapped inside the lipid matrix. **Shown in fig 9.A & fig9.B**

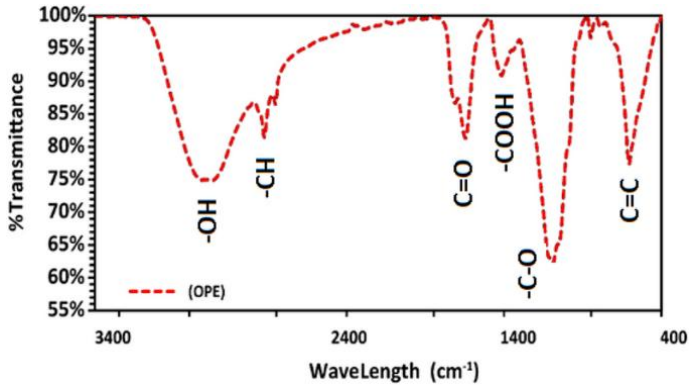


**Fig. 9.A- FTIR Spectra Of Pure Extract Powder Of Sweet Potato**

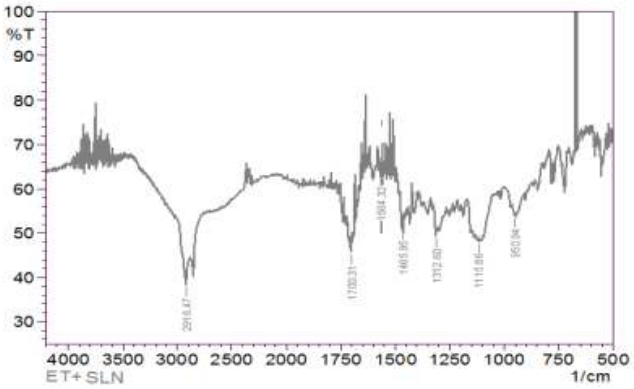


**Fig. 9.B- FTIR Spectra of Pure Extract Powder loaded SLN**

**Differential Scanning Calorimeter Analysis (DSC)-** SLN formulation and extract powder thermogram. With a melting temperature of 89.1 °C and a distinct endothermic peak beginning at 81.3 °C, the pure extract's thermogram demonstrates its crystalline form. Additionally, the SLN formulation maintained the endothermic peak of lipid between 50 and 60 °C. Figure 10 displays the thermogram for the SLN formulation, which begins at 150 °C and has a melting point of 165.60 °C. , 10.A and 10.B

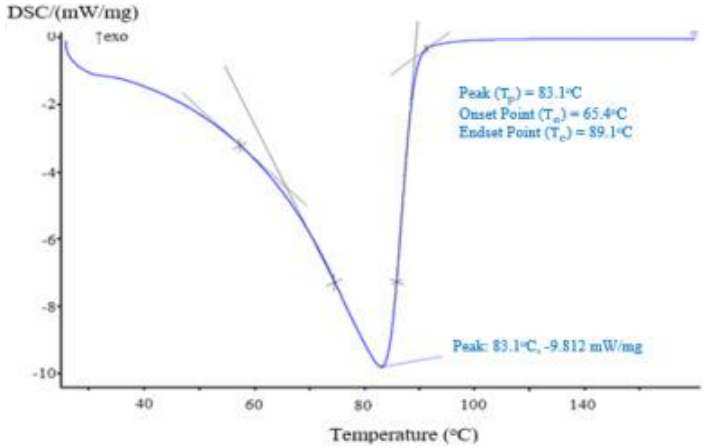


**FIG 10.A DSC Thermogram Of Extract**

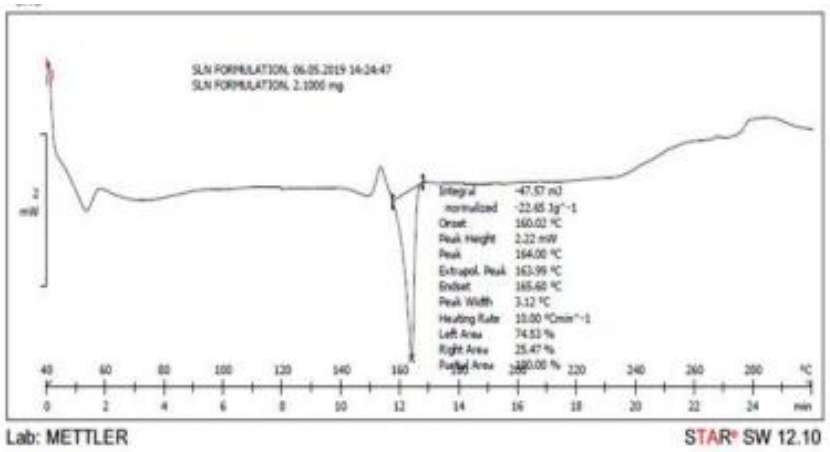


**Fig 10.B DSC Thermogram Of Sln**

**In- Vitro Drug Release**- The optimal topical formulation should exhibit a release or diffusion for a long enough duration to prevent repeated application and improve patient compliance, according to the in vitro investigation of tea tree oil-based loaded SLN gel. SLN-loaded gel demonstrated regulated drug release of up to 90% at 24 hours. The drug release experiments were conducted using the USP XXII paddle type dissolving test apparatus. The dissolution experiment was performed in 900 ml of dissolution medium (PBS pH 7.4) that was stirred at 100 rpm and maintained at 370.2°C. Samples were taken at different time intervals and replaced with the same volume of fresh dissolving medium. The collected samples were analyzed spectrophotometrically at 274nm using a UV visible spectrophotometer which show in table 4.

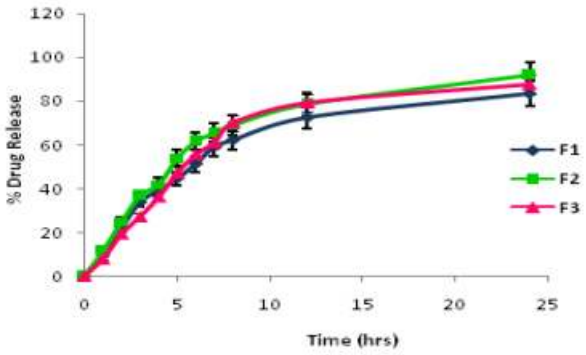


**Fig.11 In-Vitro Drug Release Study**

**Physical Characteristics of SLN gel**- The physical properties of tea tree oil influenced by powdered sweet potato extract. Loaded SLN Gel: Among various tea tree oil batches, drug uniformity results were found to be satisfactory, based on powdered sweet potato extract. SLN Gel that is infused which shown in table 5

**Table.4 Result for particle size, Zeta Potential, Drug content and entrapment efficiency & In-Vitro release drug loaded SLNs**

| Formulation Code | Particle size (nm) | Zeta Potential | Drug content (%) | % Entrapment efficiency | In-Vitro release drug |
|---|---|---|---|---|---|
| **F-1** | 195.33 | -19.29 | 87.89 | 58.33 | 79.58%±1.38 |
| **F-2** | 191.07 | -24.40 | 90.60 | 71.66 | 90.55%±0.25 |
| **F-3** | 299.45 | -32.49 | 80.45 | 66.66 | 74.38%±1.55 |
| **F-4** | 499.09 | -28.31 | 74.65 | 59.59 | 80.20%±0.36 |

**Table.5 Result For Characteristics Of Tea Tree Oil Orange Peel Ipomoea batatas Extract Loaded SLN Gel**

| Evaluation Parameter | F-1 | F-2 | F-3 | F-4 |
|---|---|---|---|---|
| **pH** | 5.9±0.2 | 6.0±0.4 | 5.8±0.6 | 5.4±0.8 |
| **Viscosity** | 4.8 cps | 5.5cps | 5.2cps | 4.9cps |
| **Spreadbility (g.cm/sec)** | 204.970 ± 10.520 | 208.155±15.01 | 203.250±28.66 | 199.180±10.12 |
| **Homogeneity** | ++ | +++ | ++ | + |
| **Drug Content** | 87.89 | 90.60 | 80.45 | 74.65 |

**+ = Smoothness**

**CONCLUSION-** Utilizing the high-speed homogenization technique, this study successfully produced sweet potato extract powder containing SLNs. Several characteristic evaluations were conducted on the created SLNs. The amount of lipid and surfactant significantly affects the particle size, drug content, entrapment efficiency, and in vitro release of the SLN formulation, based on evaluation criteria. SLN formulation F2 proved to be the most effective due to its optimal particle size, excellent entrapment efficiency, and improved release characteristics. Increased concentrations of GMS resulted in higher entrapment, whereas larger amounts of Tween 80 led to smaller particle sizes being observed. The in-vitro permeability study indicated uncovere Continuous release of Drug from the SLN gel and sustained drug levels over an extended duration.

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**Future Scope**

Further studies including long-term stability assessments can be conducted to establish its commercial feasibility and patient compliance.

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