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# Design and Evaluation of Nanogel - Based Formulation Containing *Salvia officinalis L* Extract

**L.Gopi*[1], G.Haripriya[2], D.Harishkumar[2], R.Gunasekar[2], P.Gomathi[2], M.Hariharasudhan[2].**

[1] Assistant Professor Department Of Pharmaceutics [2] B.Pharm Students.
Aadhi Bhagawan College of Pharmacy, Rantham, Thiruvannamalai, Tamilnadu. India.

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**ABSTRACT:**

This study evaluates the formulation and performance of sage leaf-based nanogel (SNG 1 to SNG 4) for topical use. The results demonstrate that the nanogels are stable, safe, and exhibit favorable physical properties, including smooth texture, excellent spreadability, and homogeneity. In vitro release studies indicate sustained drug release, highlighting its potential for therapeutic and cosmetic applications. The presence of bioactive compounds such as flavonoids, tannins, and saponins further supports its anti-inflammatory and antioxidant properties, contributing to wound healing and skin protection. Stability studies confirm the gel's efficacy under varying storage conditions. The development of the sage leaf-based nanogel, utilizing xanthan gum as a polymer, shows promise as a therapeutic agent for skin care, particularly for conditions like erysipelas. The formulation offers good stability, bioavailability, and effective delivery of active phytoconstituents to the skin. The combination of nanotechnology and xanthan gum improves the gel's rheological properties, skin penetration, and bioactivity. Further in vivo studies are needed to validate clinical efficacy, and additional research on long-term stability and scalability is recommended to optimize the formulation for commercial use. This nanogel could serve as a promising alternative for skin health and wound care in the pharmaceutical and cosmetic industries.

**Keyword:** Nanogel, Novel Drug Delivery, *Salvia officinalis L*

## 1. INTRODUCTION:

A Novel Drug Delivery System (NDDS) refers to an advanced and innovative approach designed to deliver therapeutic agents to the body in a way that improves the drug's therapeutic effectiveness, reduces side effects, or enhances patient compliance. NDDS are distinct from traditional drug delivery systems by their ability to offer controlled, targeted, and sustained release of drugs, allowing for better treatment outcomes and more personalized therapy. These systems are often developed using new technologies and materials to overcome the limitations of conventional drug delivery, such as poor bioavailability, rapid metabolism, or inadequate targeting of the disease site.

International Journal of Pharmacy and Pharmaceutical Research (IJPPR)
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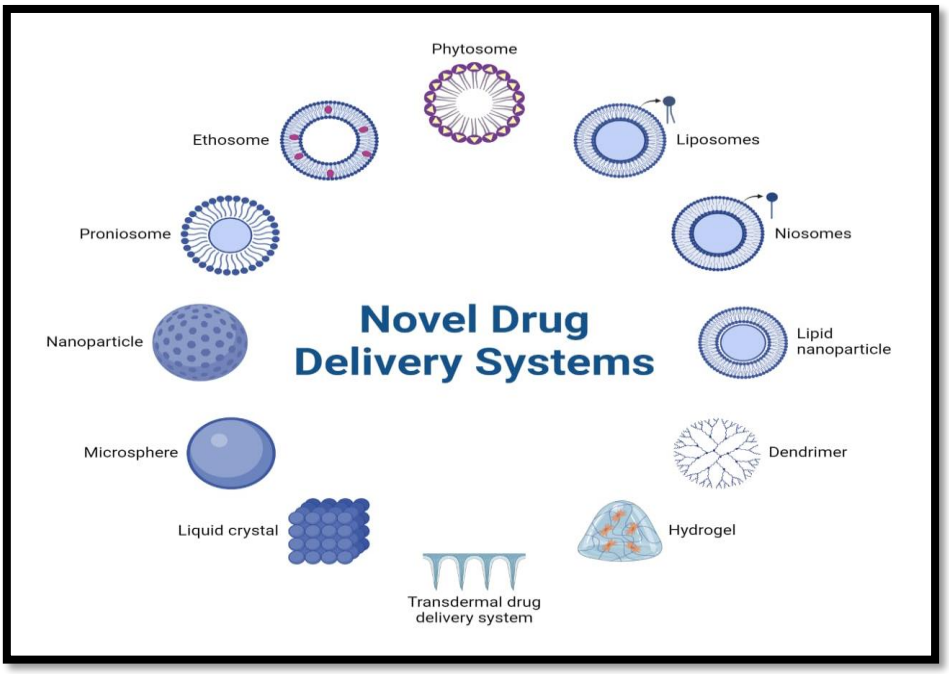


**Fig: 1 Novel Drug Delivery System**

**1.1 NANOGEL:**

Nanogels may be defined as highly cross-linked nano-sized hydrogel systems that are either co-polymerized or monomers which can be ionic or non-ionic. The size of nano-gels ranges from 20-200 nm. Nano-gels (NGs) are currently under extensive investigation due to their unique properties, such as small particle size, high encapsulation efficiency and protection of active agents from degradation, which make them ideal candidates as drug delivery systems (DDS). Stimuli-responsive NGs are cross-linked nanoparticles (NPs), composed of polymers, natural, synthetic, or a combination there of that can swell by absorption (uptake) of large amounts of solvent, but not dissolve due to the constituent structure of the polymeric network.

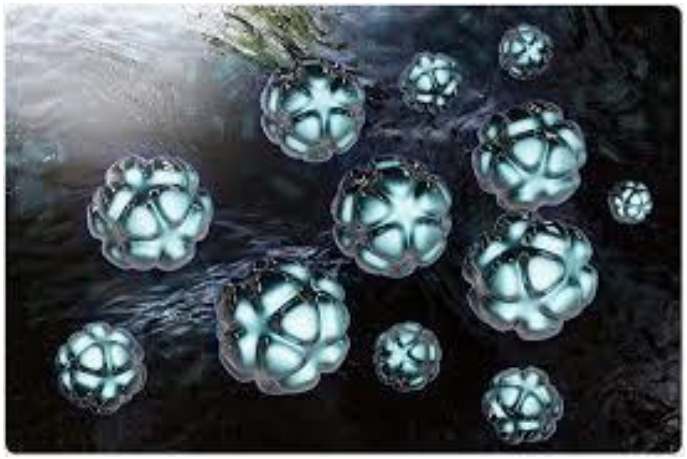

**Fig: 2 Nanogel**

International Journal of Pharmacy and Pharmaceutical Research (IJPPR)
Volume 31, Issue 5, May 2025 ijppr.humanjournals.com ISSN: 2349-7203

## 2. PLANT PROFILE:

### 2.1 SALVIA OFFICINALIS L:

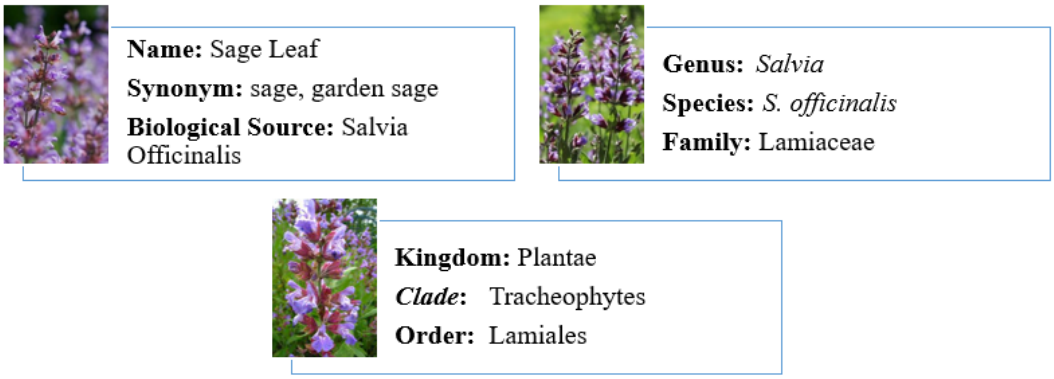


**Fig: 3 Plant Profile**


**Fig: 4 Plant Image Of Salvia Officinalis L**

### 2.2 CHEMICAL CONSTITUENTS:

Essential Oils, Flavonoids, Polyphenol, Carbohydrates, Alkaloids, Fatty Acids, Glycosidic Derivatives Terpenes / Terpenoids, Polyacetylene, Steroids, & Wax.

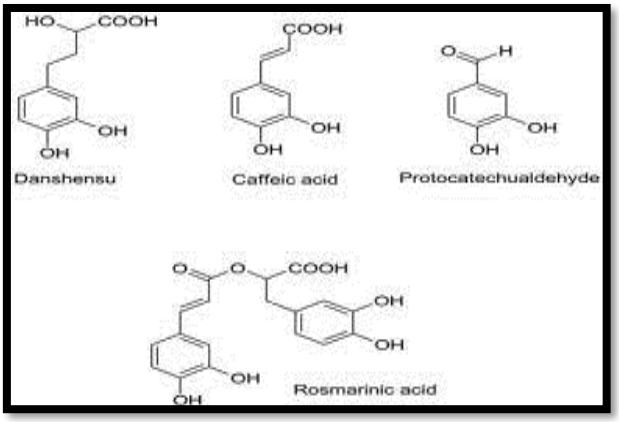


**Fig: 5 Chemical Constituents Of Salvia Officinalis L**

International Journal of Pharmacy and Pharmaceutical Research (IJPPR)
Volume 31, Issue 5, May 2025 ijppr.humanjournals.com ISSN: 2349-7203

**2.3 USES:**

- Antioxidant.
- Aiding brain function.
- Lowering blood sugar level and glucose level.
- Treat sore throat and throat and memory loss.

## 3. MATERIALS AND METHODS:

### 3.1 COLLECTION OF SEEDS:

Collect the sage leaf. Dry the leaf through shade dry method. separate the leaf from the other debris Spread the leaf on a clean, dry surface in a well-ventilated area. Allow them to air dry completely, turning them occasionally to ensure even drying. Grind the sage leaf into fine powders.

### 3.2 EXTRACTION METHOD:

**Alcoholic Extraction:** Use ethanol for extracting specific bioactive compounds. Stir the mixture and let it sit for 24-48 hours at room temperature or slightly warmer, shaking occasionally, after it filter the mixture and evaporate the solvent to obtain the extract. Store the extracted substance in a dark, airtight container at a cool temperature to prevent oxidation. Store concentrated extracts in a similar manner, or freeze-dry them for long-term storage.

### 3.3 PHYTOCHEMICAL EVALUATION:

- TEST FOR PHENOLIC COMPOUNDS: ( Litmus Test )
- Test For Flavonoids:
- Test For Tannins: ( Ferric Chloride Test )
- Test For Polysaccharides: ( Iodine Test )
- Test For Saponins: ( Foam Test )
- Test For Quaternary Ammonium Compound: ( Dragendorff's Reagent )

### 3.4 PREPARATION OF NANO-GEL:

**Table: 1 Composition Of Sage Leaf Extract Containing Nano-Gel**

| S.NO | INGREDIENTS | SNG 1 | SNG 2 | SNG 3 | SNG 4 |
|---|---|---|---|---|---|
| 1 | Sage Leaf Extract | 5 ml | 5 ml | 5 ml | 5 ml |
| 2 | Xanthan Gum | 0.50 gm | 0.75 gm | 0.50 gm | 0.75 gm |
| 3 | Tea Tree Oil | 1 ml | 1 ml | 1 ml | 1 ml |
| 4 | Formaldehyde | 1 ml | 1 ml | 1 ml | 1 ml |
| 5 | Vitamin E | 0.5 ml | 0.5 ml | 0.5 ml | 0.5 ml |
| 6 | Polyethylene Glycol | 0.85ml | 0.75ml | 0.85ml | 0.75ml |
| 7 | Polysorbate 80 | 2 ml | 2 ml | 1.5 ml | 1.5 ml |
| 8 | Purified water | 37 ml | 37 ml | 37 ml | 37 ml |

**Procedure:**

**Preparing the Aqueous Phase:** Start with the PEG (Polyethylene Glycol) and polysorbate (Polysorbate 80) in a beaker**.** These act as emulsifiers and stabilizers for the formulation. Add 5 mL of water (distilled or deionized) to the beaker if required, as a solvent

for dispersing the components. Heat the mixture to around 40°C–50°C (use a water bath) while stirring. This will help dissolve the PEG and polysorbate and improve their emulsification properties.

**Mixing Oil Phase:** In a separate beaker, combine the tea tree oil (1 mL) and sage leaf extract (5 mL). The tea tree oil is lipophilic (oil-based), while the sage leaf extract aqueous extract form, but it needs to be incorporated efficiently into the gel matrix. Add vitamin E (0.5 mL) to this oil phase. Vitamin E will help stabilize the formulation and provide antioxidant properties. Heat this oil phase to around 40°C (if necessary) while stirring to ensure all oil-based components mix together properly.

**Emulsification Step:** Slowly add the oil phase (tea tree oil + sage extract + vitamin E) to the aqueous phase (PEG + polysorbate + water). Use a magnetic stirrer or a high-speed mixer to emulsify the oil and water phases, forming a stable oil-in-water emulsion**.** Polysorbate will help emulsify the oil (tea tree oil) in the aqueous phase.

**Incorporating Formaldehyde (1 mL)**: Formaldehyde is usually used as a preservative in some formulations. It is important to add it after the emulsion has formed. Add 1 mL of formaldehyde slowly into the emulsion while stirring, making sure it's fully integrated into the formulation. It will help preserve the nano-gel for extended shelf life.

**Size Reduction (Nano-gel Formation)**: To achieve the nano-gel consistency, you can use an ultrasonicator or high-speed homogenizer for size reduction. This step is optional but recommended if you want to achieve the nano-scale particle size (typically 50-200 nm). Sonicate the mixture for around 10–15 minutes to break down the particle size and ensure uniform distribution of the components. This will ensure the consistency is uniform and the active ingredients are evenly distributed.

**Adjusting the pH and Viscosity**: Check the pH of the formulation using a pH meter**.** The pH should ideally be between 5 and 7 to ensure stability and compatibility with the skin or other intended uses. If the pH is too high or low, adjust it using citric acid or sodium hydroxide. If necessary, adjust the **viscosity** of the nano-gel by adding xanthan gum (a thickening agent), (if more viscosity is needed for gel-like consistency).

**Final Mixing**: Once the emulsion has been created and particle sizes reduced, you can allow the mixture to cool down to room temperature while stirring gently to avoid air bubbles. Check the viscosity and consistency again after cooling. If it's too thin, you can add a small amount of xanthan gum to thicken it. If it's too thick, you can add a small amount of water to achieve the desired consistency.

**Purification (Optional)**: If needed, purify the formulation by dialysis or centrifugation to remove excess solvents, unreacted particles, or larger aggregates.

**Packaging**: Once the nano-gel is prepared, store it in an airtight container to preserve its stability. Ensure it is kept in a cool, dry place, away from direct sunlight to prevent degradation.


Alcohol Extract | Nano-Gel Preparation | Nano-Gel

**Fig: 6 Nano – Gel**

**3.5 EVALUATION PROTOCOL:**

Evaluating Nanogels involves assessing their properties, performance, and suitability for specific applications. This evaluation typically includes various physical, chemical, and mechanical tests. Below is an overview of the key aspects considered when evaluating Nanogels:

**3.5.1 Appearance:** The formulations physical appearance was analyzed visually. The Nanogels was Soft, flexible with a smooth surface. Moderately firm, as the borax concentration provides some cross-linking but not excessive stiffness. Elastic and slightly sticky, due to unreacted starch molecules retaining water.

**3.5.2 Color:** The color of the formulation was checked out against white & black backgrounds. The Nanogels was white or translucent in color.

**3.5.3 Odor:** The odor of the Nanogels was checked by taking smell of little amount of Nanogels. The Nanogels was mild or odorless.

**3.5.4 Determination of PH:** To determine the PH of the product, dilute the product in distilled water (1:10) then measure the PH of the dilution. The PH of the Hydro gel was 7.0-7.4. Citric acid is used to adjust the PH of the product.

**3.5.5 Rheology**: Viscosity of Nanogels is evaluated by using Cone plate type viscometer under constant temperature at 4ºC. This viscometer is highly specific for the evaluation of viscosity.

**3.5.6 Spreadibility study:** The apparatus was made of wooden block with scale and two glass slides having a pan mounted on a pulley. Excess formulation was placed between two glass slides and 100 gm weight was placed on upper glass slide for 5 minutes to compare the formulation to achieve uniform thickness. Weight can be added and the time to separate the two slides was taken as spreadibilty time.

$$S = (m \times l) / t$$

Where,

- S is spreadibilty,
- m is weight tied on upper slide,
- l is length of glass slide and
- t is time taken in seconds

**3.5.7 Viscoelastic Properties:** Rheological tests are conducted to measure the Nanogels viscoelastic behavior, which includes both its elastic (solid-like) and viscous (liquid-like) responses.

**3.5.8 Gel Fraction:** The gel fraction represents the proportion of the Nanogels that is cross-linked and does not dissolve in water. It is measured by extracting the soluble components from the Nanogels and weighing the remaining material.

$$GF\ (\%) = Wg / Wo \times 100$$

- Wg = weight of the dried gel after extraction (i.e., after removing soluble fractions)
- W0 = initial dry weight of the polymer before extraction.

**3.5.9 Scanning Electron Microscopy (SEM)**: SEM can be used to provide information about the sample's composition, surface topography, and other properties such as electrical conductivity.

**3.5.10 Homogeneity:** All developed Nanogels were tested for homogeneity by visual inspection after the gels have been set in the container. They were tested for their appearance and presence of any aggregates.

**3.5.11 Irritancy Test:** Mark an area (1sq.cm) on the left hand dorsal surface. The gel was applied to the specified area and time was noted. Irritancy, erythema, edema, was checked if any for regular intervals up to 24 hrs and reported.

**3.5.12 Antimicrobial Testing (Disk Diffusion Method):**

**Inoculate the agar plate**: Using a sterile swab, dip it into the bacterial suspension and evenly spread it over the surface of an agar plate (blood agar or nutrient agar). Make sure the entire surface is covered, ensuring uniform bacterial growth. Apply antimicrobial discs: If performing the disk diffusion method, place sterile antibiotic discs (or antimicrobial agents) onto the inoculated agar surface using sterile forceps. Ensure they are spaced sufficiently apart to avoid overlap of inhibition zones. Incubation**:** Place the inoculated plate in an incubator at 37°C **for** 18-24 hours**.** Interpretation**:** After incubation, check the plate for clear zones of inhibition around the antibiotic discs. The size of the inhibition zones helps to assess the susceptibility of Streptococcus pyogenes to the antimicrobial agents. Measure the diameter of these zones and compare them with standard susceptibility charts to determine the effectiveness.

**3.5.13 *In-Vitro* Diffusion Study:**

**Cellophane Membrane Treatment for Permeation study:** Cellophane membrane was boiled in the distilled water for 1 hour and washed with fresh distilled water for three times and kept in ethanol for 24 hours. It was treated with 0.3% sodium sulphite and soaked in distilled water for 2 min at $60^0$C followed by acidified with 0.2% sulphuric. Finally the membrane was dipped in boric acid buffer pH (9) till it is used for permeation study.

***In-vitro* diffusion study:** The *in- vitro* permeation rate of selected formulations of gel were evaluated by open ended tube through using pH 7.4 as diffusion medium upto 10 hours studies. The cellophane membrane was tied in one end of the tube and then immersed in the receptor compartment containing 200ml of 7.4 buffer solution which was stirred at 100±10 rpmand maintained at $37^0$C ±$2^0$C. A quantity of 5ml samples were withdrawn from the receptor fluid at the time intervals of 0, 1, 2, 4, 6, 7, 8, 10 hr. and 5ml of phosphate buffer of pH 7.4 was replaced immediately each time.

**3.5.14 Drug Release:**

To study kinetics, data obtained from in vitro release were plotted in various kinetic models.

**1. Zero order equation:**

If the release rate follows Zero order then, the slope can be obtained by plotting % drug released Vs time in hours. It is an ideal release profile to achieve pharmacological prolonged action. The release rate was independent of concentration.

$$C=K_0t$$

Where,

- $K_0$ – Zero order constant in con/time
- t – Time in hours

**2. First order equation:**

The graph was plotted as log % cumulative drug remaining Vs Time in hours.

$$\text{Log } C = \log C_0 - Kt/2.303$$

Where,

- $C_0$ - Initial concentration of drug.
- K- First order constant and t- Time.

**3. Higuchi kinetics:**

The graph was plotted as % Cumulative drug released Vs square root of time

$$Q = Kt^{1/2}$$

Where,

- K – Constant reflecting design variable system.
- t -Time in hours

Hence drug release rate is proportional to the reciprocal of square root of time. If the plot yields a straight line, and the slope is one, then the particular dosage form is considered to follow Higuchi kinetics of drug release.

**4. Hixson and Crowell erosion equation:**

To evaluate the drug release with changes in the surface area and the diameter of particles, the data were plotted using the Hixson and Crowell rate equation. The graph was plotted by cube root of % drug remaining Vs time in hours.

$$Q_0^{1/3} - Q_t^{1/3} = K_{HC}t$$

Where,

- $Q_t$ – Amount of drug released in time t.
- $Q_0$ -Initial amount of drug.
- $K_{HC}$ – Rate constant for Hixson Crowell equation.

**5. Korsmeyer – Peppas equation:**

To evaluate the mechanism of drug release, it was further plotted in peppas equation as log cumulative % of drug released Vs time

$$M_t / M_\infty = Kt^n$$

Where,

- $M_t / M_\infty$ -fraction of drug released at time t
- t – Release time
- K – Kinetic constant
- n - Diffusional exponent indicative of the mechanism drug release.

**3.5.15 Stability Studies:**

Stability testing of drug products begins as a part of drug discovery and ends with the demise of the compound or commercial product. To assess the drug and formulation stability, stability studies were done according to ICH guidelines. The stability studies were carried out as per ICH guidelines. The gel filled in bottle and kept in humidity chamber maintained at 40 ± 2°C / 75 ± 5 % RH for TWO months. At the end of studies, samples were analyzed for the physical properties, pH and viscosity.

## 4. RESULTS AND DISCUSSION:

### 4.1 PRELIMINARY PHYTOCHEMICAL SCREENING:

Result of the preliminary phytochemical constituents present in Nano Gel:

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Volume 31, Issue 5, May 2025 ijppr.humanjournals.com ISSN: 2349-7203

**Table: 2 Preliminary Phytochemical Constituents**

| S.NO | CONSTITUENTS | GEL |
|---|---|---|
| 1. | Phenolic Compounds | Present |
| 2. | Essential Oils | Present |
| 3. | Tannins | Present |
| 4. | Flavonoids | Present |
| 5. | Polysaccharides | Present |
| 6. | Quaternary Ammonium Compounds | Present |
| 7. | Saponins | Present |


**Fig: 7 Chemical Test**

## 4.2 UV ANALYSIS:

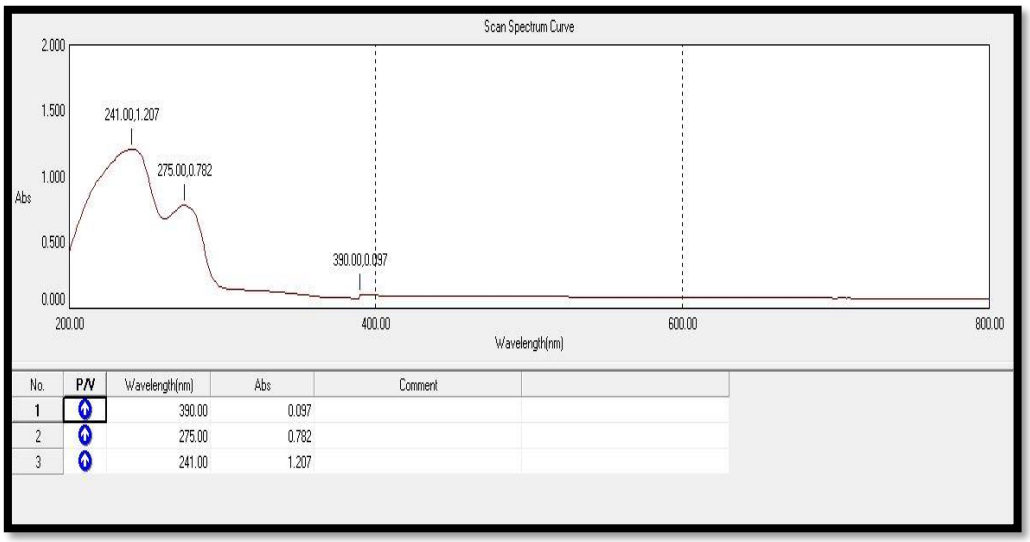


**Fig: 8 UV Analysis Of Nanogel**

International Journal of Pharmacy and Pharmaceutical Research (IJPPR)
Volume 31, Issue 5, May 2025 ijppr.humanjournals.com ISSN: 2349-7203

### 4.3 EVALUATION OF GEL:

**Table: 3 Evaluation Of Gel**

| S.NO | PARAMETERS | SNG 1 | SNG 2 | SNG 3 | SNG 4 |
|---|---|---|---|---|---|
| 1. | State | Semi Solid | Semi Solid | Semi Solid | Semi Solid |
| 2. | Color | Greenish | Greenish | Greenish | Greenish |
| 3. | Odor | Herbaceous Aroma | Herbaceous Aroma | Herbaceous Aroma | Herbaceous Aroma |
| 4. | pH | 7.22 | 8.31 | 8.35 | 8.23 |
| 5. | Grittiness | Smooth | Smooth | Smooth | Smooth |
| 6. | Viscosity | 8021 | 8719 | 7155 | 8635 |
| 7. | Sensitivity Test | No Irritation | No Irritation | No Irritation | No Irritation |
| 8. | Irritation Test | No Irritation | No Irritation | No Irritation | No Irritation |
| 9. | Spreadability | 8 cm | 7.5 cm | 8.9 cm | 8.2 cm |
| 10. | Homogeneity | Homogenous | Homogenous | Homogenous | Homogenous |
| 11. | Gel Fraction | 63% | 66% | 73% | 71% |
| 12. | Viscoelastic | Higher Elasticity Gel-Like Behavior | Higher Elasticity Gel-Like Behavior | More Gel-Like Behavior | Higher Elasticity Gel-Like Behavior |

### 4.4 ANTI-MICROBIAL ACTIVITY:

**Table: 4 Anti-Microbial Activity**

| S.No. | Microorganisms | Control | Sample 1 | Sample 2 | Sample 3 | Sample 4 | Ciprofloxacin |
|---|---|---|---|---|---|---|---|
| | | Zone of inhibition in mm | | | | | |
| 1. | *Streptococcus pyogens* | - | 8 | 12 | 15 | 18 | 40 |

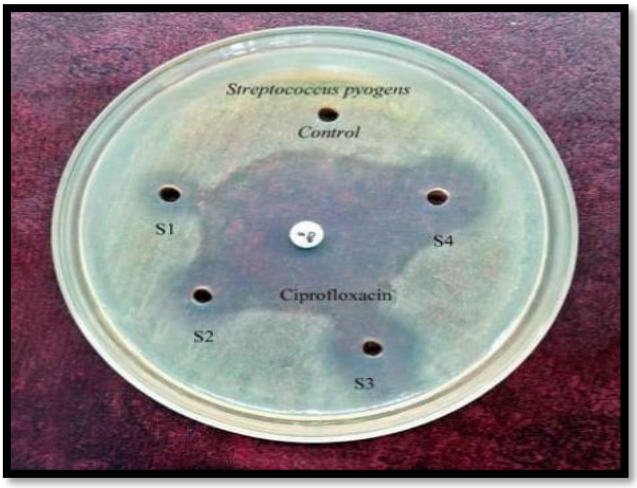


**Fig: 9 Anti-Microbial Activity**

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### 4.5 SEM ANALYSIS:

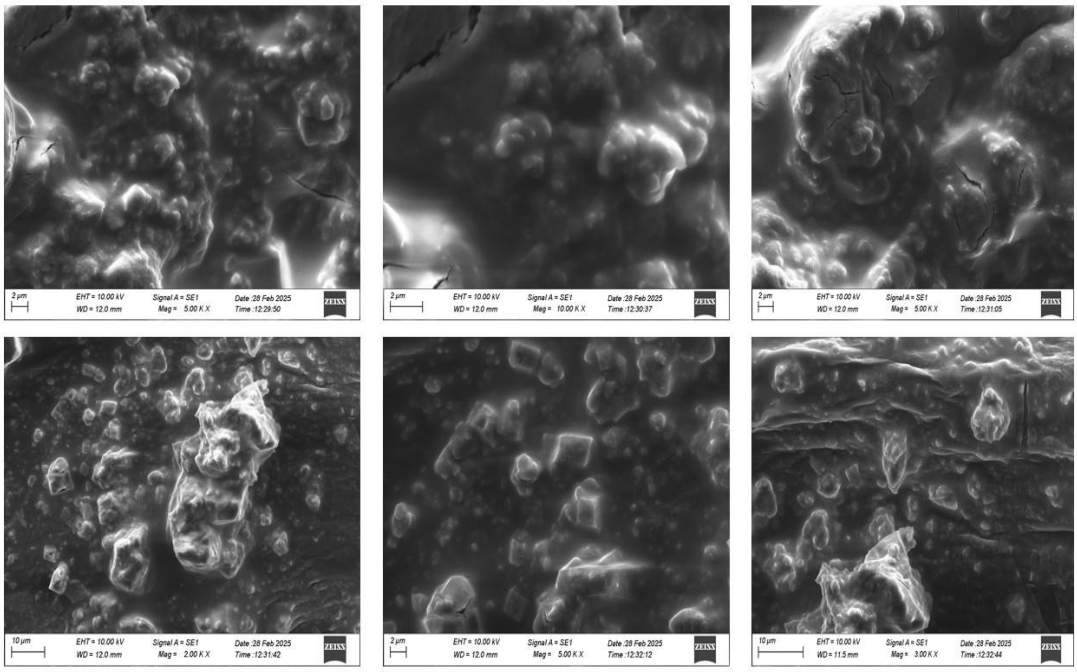

**Fig: 10 SEM Analysis**

### 4.6 *IN VITRO* RELEASE STUDIES:

**Table: 5 In Vitro Release Profile Of SNG 4 Formulation**

| S. NO. | TIME (IN HOURS) | % OF RELEASE OF SNG 4 FORMULATION |
|---|---|---|
| 1 | 0 | 0.000 |
| 2 | 1 | 5.531 ± 0.135 |
| 3 | 2 | 18.143 ± 0.255 |
| 4 | 4 | 35.083 ± 0.353 |
| 5 | 8 | 60.035 ± 0.311 |
| 6 | 10 | 96.335 ± 1.331 |

**Table: 6 Cumulative % Drug Release Of SNG 4 Formulation**

| Time (Hr) | Cumulative % Drug Released | % Drug Remaining | Square Root Time | Log Cumu % Drug Remaining | Log Time | Log Cumu % Drug Released | % Drug Released | Cube Root Of % Drug Remaining (Wt) | Wo-Wt |
|---|---|---|---|---|---|---|---|---|---|
| 0 | 0 | 100 | 0.000 | 2.000 | 0.000 | 0.000 | 100 | 4.642 | 0.000 |
| 2 | 5.531 | 94.469 | 1.414 | 1.975 | 0.301 | 0.743 | 5.531 | 4.554 | 0.088 |
| 4 | 18.143 | 81.857 | 2.000 | 1.913 | 0.602 | 1.259 | 12.612 | 4.342 | 0.300 |
| 6 | 35.083 | 64.917 | 2.449 | 1.812 | 0.778 | 1.545 | 16.94 | 4.019 | 0.623 |
| 8 | 60.035 | 39.965 | 2.828 | 1.602 | 0.903 | 1.778 | 24.952 | 3.419 | 1.223 |
| 10 | 96.335 | 3.665 | 3.162 | 0.564 | 1.000 | 1.984 | 36.3 | 1.542 | 3.100 |

International Journal of Pharmacy and Pharmaceutical Research (IJPPR)
Volume 31, Issue 5, May 2025 ijppr.humanjournals.com ISSN: 2349-7203

### 4.7 PHARMACOKINETICS PARAMETERS:

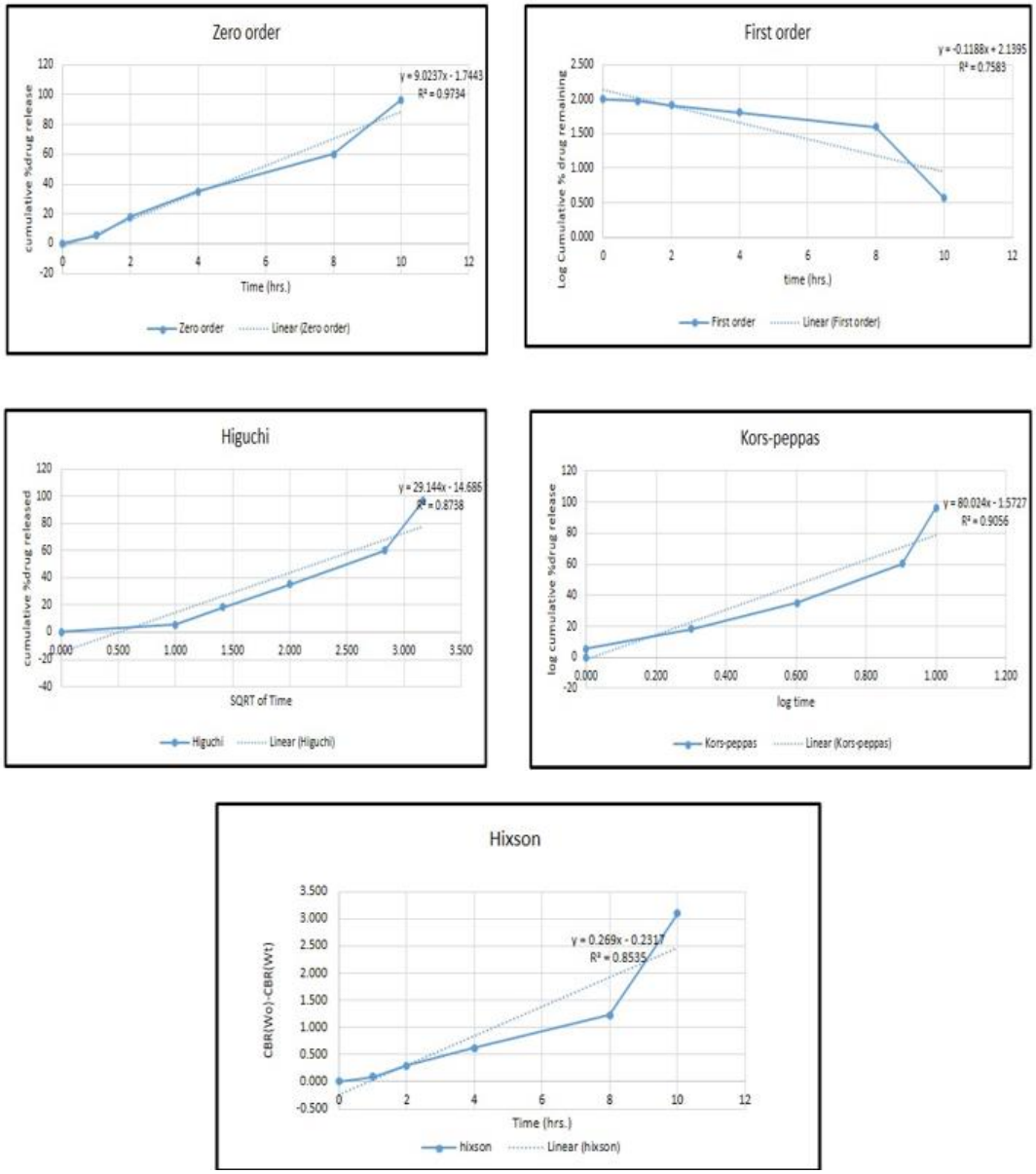


**Fig: 11 Pharmacokinetics Drug Release For SNG 4**

### 4.8 STUBILITY STUDIES:

**Table: 7 Stability Study Of SNG 4**

| S.No | Parameter | Observation | | | | |
|---|---|---|---|---|---|---|
| | | Initial | At the end of 1st month | | At the end of 2nd month | |
| | | | RT | 40 ± 2oC & RH 70 ± 5% | RT | 40 ± 2oC & RH 70 ± 5% |
| 1. | Appearance | Smooth | Smooth | Smooth | Smooth | Smooth |
| 2. | pH | 8.23 | 8.23 | 8.23 | 8.23 | 8.22 |
| 3. | Spreadability | 8.2 cm | 8.2 cm | 8.2 cm | 8.1 cm | 8.1 cm |
| 4. | Extrudability | Excellent | Excellent | Excellent | Excellent | Excellent |
| 5. | % drug content | 96.33 | 99.16 | 99.14 | 99.16 | 99.16 |

**DISCUSSION:**

The evaluation of the Nano gel formulations (SNG 1 to SNG 4) demonstrates promising results in terms of both physical and biological properties. All formulations exhibited semi-solid consistency, a greenish color, and a herbaceous aroma, which are characteristics that align with the expected nature of a sage leaf-based gel. The pH values of the formulations (ranging from 7.22 to 8.35) suggest that the gel is mildly alkaline, which is within an acceptable range for topical application. This indicates the gel should be safe for human skin use, as extremes in pH could lead to skin irritation. The viscosity of the formulations varies slightly, indicating different levels of thickness, but all formulations maintained smoothness and were homogeneous, confirming consistency in texture and appearance.

The sensitivity and irritation tests showed no signs of irritation or allergic reactions, suggesting that the gel is safe for topical application**,** especially on sensitive skin. Furthermore, the spreadability of the formulations (ranging from 7.5 cm to 8.9 cm) reflects good ease of application, which is crucial for user experience.

The gel fraction varied slightly (63% to 73%), indicating the gel's ability to retain its formulation characteristics and ensure adequate delivery of active ingredients. In the viscoelastic test, all formulations exhibited gel-like behavior with high elasticity, which suggests that the gel can hold its form while also being flexible enough for effective skin absorption.

In terms of phytochemical constituents**,** the presence of phenolic compounds, essential oils, tannins, flavonoids, polysaccharides, quaternary ammonium compounds, and saponins in the nano gel highlights its potential for anti-inflammatory, antioxidant, and antimicrobial activities. This aligns with the intended therapeutic application, as these compounds are known for their role in promoting wound healing and skin health.

The UV analysis**,** SEM analysis**,** and in vitro release studies provide additional insights into the formulation's stability and efficacy. The in vitro release data of the SNG 4 formulation shows an efficient release profile, with over 96% of the drug released within 10 hours, indicating a sustained release mechanism. This suggests that the nano gel formulation can maintain its therapeutic action over an extended period, reducing the need for frequent application. The pharmacokinetic study further validates this prolonged release.

Finally, stability studies over a two-month period demonstrate that the gel remains stable at room temperature (RT) and elevated conditions (40°C and 70% RH), with no significant changes in its appearance, pH, spreadability, or drug content. This ensures that the formulation retains its effectiveness and can be stored for an extended period without degradation.

## 5. CONCLUSION:

In conclusion, the development of the sage leaf-based nano gel using xanthan gum as a polymer shows strong potential as a therapeutic agent for skin care, particularly for treating conditions like erysipelas. The formulation demonstrated good stability, bioavailability, and the ability to deliver active phytoconstituents effectively to the skin. The combination of nano-formulation and xanthan gum enhances the gel's properties, including its rheological behavior**,** skin penetration**,** and bioactivity. Further in vivo studies are needed to confirm its clinical efficacy, and additional research focusing on long-term stability and scalability is recommended to optimize this formulation for commercial use. The nano gel formulation could provide a promising alternative in the pharmaceutical and cosmetic industries for skin health and wound care applications.

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