

“Formulation and Evaluation of Nanosponges Gel Containing Mometasone Furoate”

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ABSTRACT

The present study was aimed at the formulation and evaluation of a nanosponge-based gel containing mometasone furoate to enhance its solubility, stability, and topical bioavailability. Mometasone furoate was characterized for organoleptic and physicochemical properties and was found to be an off-white, odorless solid powder with a pH of 4.3, melting point of 220 °C, and absorption maximum at 247 nm, complying with I.P. specifications. Solubility studies revealed that the drug was freely soluble in dimethyl sulfoxide and ethanol. Nanosponges were prepared by the emulsion solvent evaporation technique using ethyl cellulose and polyvinyl alcohol. Particle size analysis confirmed nanoscale dimensions ranging from 257.8 to 376.1 nm. Zeta potential values (–22.9 to –63.3 mV) indicated good colloidal stability, while drug entrapment efficiency ranged from 78.33% to 94.81%. SEM analysis demonstrated spherical nanosponges with a smooth, porous surface morphology. The optimized nanosponges were incorporated into a gel formulation, which exhibited acceptable physicochemical properties including viscosity (6830 cP), skin-compatible pH (6.15), and good spreadability (12.60 g-cm/s). In vitro drug diffusion studies and kinetic modeling showed that the optimized gel followed the Higuchi model ($R^2 = 0.979$), indicating diffusion-controlled drug release. The formulated nanosponge gel demonstrated potential for sustained topical delivery of mometasone furoate with improved bioavailability, reduced dosing frequency, and minimized side effects, making it suitable for the treatment of various skin disorders.

KEYWORDS: Mometasone furoate; Nanosponges; Emulsion solvent evaporation; Topical gel; Higuchi kinetic model; Sustained drug delivery; Skin targeting

I. INTRODUCTION

Topical drug delivery is the medication which can be defined as application of drug

containing formulation applied to the surface of the skin or mucous membrane, directly to treat the cutaneous disorder or cutaneous manifestation of general disease with the intent of confining pharmacological or other effect of drug to surface of skin or within the skin (Singh Malik et al., 2016). The combination of both the active ingredients and base provides the opportunity for a wide range of topical preparations such as gels, cream, foam, ointments, lotions etc appropriate for many types of drug delivery and therapy terms used to classify the bases of topical preparations in which therapeutically active ingredients are incorporated, based on their physical properties or on their intended use or on their composition (Garg et al., 2015). The outcome of topical dermatological drug treatment is significantly influenced by the choice of vehicle or delivery system. The most common dosage form example of topical dosage form includes solution, suspension, emulsion (e.g lotion), semisolids (ointment, cream, pastes, gels), solids such as powder and aerosol, spray (Maqbool et al., 2017).

Nanosponges are porous polymeric delivery systems that are small spherical particles with large porous surface. These are used for the passive targeting of cosmetic agents to skin, there by achieving major benefits such as reduction of total dose, retention of dosage form on the skin and avoidance of systemic absorption (Ghasemiyeh and Mohammadi-Samani 2020). These nanosponges can be effectively incorporated onto topical systems for prolonged release and skin retention thus reducing the variability in drug absorption, toxicity and improving patient compliance by prolonging dosing intervals. Nanosponges can significantly reduce the irritation of drugs without reducing their efficacy (Srilakshmi et al., 2020).

The nanosponges are solid in nature and can be formulated as Oral, Parenteral, Topical or Inhalation dosage forms. For the oral administration, the complexes may be dispersed in

a matrix of excipients, diluents, lubricants and anticaking agents suitable for the preparation of capsules or tablets. For topical administration they can be effectively incorporated into topical hydrogel(Surusheet al., 2023).

Mometasone Furoate is distinctive power of topical corticosteroid that reduces production, release, and action of endogenous mediators of irritation, containing prostaglandins, kinins, histamine and liposomal enzymes which changes body immune response. Mometasone furoate is a 17-ester of 16 α -methyl analogue of beclomethasone shows better potency with higher antiinflammatory effect to a longer duration of action(Spada et al., 2018). Mometasone furoate is a BCS class-II drug which has a low solubility so convert this drug into nanosponge will enhance solubility. This investigate work develops topical gel of mometasone furoate which are safer and it transfer active agent locally in an actual concentration for its action(Keriliset al., 2024). Dermatitis (eczema) is more common in people who have a family history of the condition. Red, dry and itchy rashes usually seen where skin are flexes. Different treatments like steroid creams, immunosuppressive drugs and Vit. D creams can be beneficial to control symptoms of dermatitis and psoriasis. But all among of that topical corticosteroid's formulation is most preferable for treatment of dermatitis and psoriasis. Nanosponge of mometasone furoate is improved efficacy & stability of drug. Mometasonefuroatenanosponic gel permeates a drug into stratum corneum and rise therapeutic concentration of drug into skin without going in systemic circulation so it avoids further systemic effect(Kumar et al., 2021).

The present work focuses on the development of a nanosponge-based gel formulation of mometasone furoate to enhance its topical delivery and therapeutic efficacy.

II. MATERIALS AND METHODS

2.1 Chemicals

Methyl paraben, Propylene glycol, Acetonitrile, and Ethanolwere obtained from Merck, a reputable supplier of analytical reagents. Lobachemie provided the Triethanolamine. FDC, Mumbai, Indiaprovided the Mometasone furoate. Methanolwere obtained fromRankem.Carbopol 934were obtained from Sulab.

2.2 Pre-formulation studies

2.2.1 Organoleptic Properties

The organoleptic studies of Mometasone furoate like general appearance like color, odor, state, etc. were performed.

2.2.2 Solubility study

Qualitative solubility of Mometasone furoate in different solvents was determined according to USP NF, 2007. Approximately 1 mg of Mometasone furoate was weighed and transferred into a 10 ml test tube and dissolved in the respective solvents (1 ml each of methanol, ethanol, acetonitrile, and water) (Jain and Verma 2020).

2.2.3 Melting Point

Melting point was analyzed by open Capillary method using Thiele's tube(Chowk, M. I. 2020).

2.2.4 Determination of Lambda max and calibration curve

• Lambda (λ) max

A stock standard solution containing 1 mg/mL of Mometasone furoate was prepared in methanol. Working standard solution equivalent to 100 μ g/mL of Mometasonefuroate was prepared by appropriate dilution of stock solution with the same solvent. The solution was scanned in the range of 200 – 400 nm UV spectrum using shimadzu 1700 double beam spectrophotometer (Kumbhar and Salunkhe 2013).

• Standard calibration curve

100 mg of Mometasone furoate was accurately weighted into 100 ml volumetric flask, dissolved in 80% Methanol and volume was made up with same solvent. Pipette 1ml of this solution into another 10 ml volumetric flask and the volume was made with Methanol and marked as Stock. The resultant solution is scanned in the range of (200-400 nm) by UV Spectrophotometer to get absorption maximum (λ max).

2.2.5 Preparation of calibration curve

The prepared stock solution was further diluted with solvent to get working standard solution of 5, 10, 15, 20, 25, 30 and 35 μ g/ml of Mometasone furoateto construct Beer's law plot for the pure drug, the absorbance was measured, against solvent as blank. The standard graph was plotted by taking concentration of drug on X-axis and absorbance on Y-axis in the concentration range of 5-35 μ g/ml (Behera et al., 2012).

2.2.6 Fourier transmission Infra-Red Spectroscopy

FT-IR spectrum of Drug was recorded over the range of 4000 to 400 cm⁻¹ by KBr pellet method using a FT-IR spectrophotometer. The KBr disc was prepared using 1 mg of each Drug in 100 mg of spectroscopic grade KBr which has been dried using IR lamp. Both KBr and drug was mixed and subjected to hydraulic pressure to form disc. This disc was placed in FT-IR chamber. Infrared spectrum was recorded in the 4000 - 400 cm⁻¹ region (Chowk M. I. 2020)

2.3 Formulation of nanosponges

Mometasone furoate loaded NS (MNS) were prepared by the emulsion solvent evaporation technique (ESE-Tech) using the drug 100 mg and polyvinyl alcohol (PVA) 0.3%, w/v, compositions of formulations were tabulated in Table 4. Briefly, organic phase was prepared by dissolving ethyl

cellulose (EC) (100–350 mg) and Mometasone furoate in 20 mL dichloromethane (DCM). Separately, an aqueous phase was prepared composed of (0.3%, w/v) PVA in 100 mL of deionized water. Thereafter, the organic phase was emulsified dropwise into the aqueous phase by ultrasonication for 3 to 5 min (Ahmed et al., 2020). The formed NS was stabilized by PVA, which avoid particle agglomerations. Thereafter, the dispersion was kept on thermostatically controlled magnetic stirrer “(Remi)” with continuous stirring at under atmospheric pressure and room temperature for 3 to 4 h. After complete evaporation of the organic solvent, the Mometasone furoate nanosponges were washed three times with ultra-purified water to remove the adsorbed PVA, NSs were then collected by ultra-centrifugation and 4°C for 30 min and freeze dried (Ahmed et al., 2021).

Table 1: Composition of Nanosponges formulation

| Ingredients | F1 | F2 | F3 | F4 | F5 |
|------------------------------|-----|-----|-----|-----|-----|
| Mometasone furoate (mg) | 100 | 100 | 100 | 100 | 100 |
| Ethyl cellulose (EC) (mg) | 100 | 150 | 200 | 250 | 300 |
| Poly vinyl alcohol (PVA) (%) | 0.3 | 0.3 | 0.3 | 0.3 | 0.3 |
| Dichloromethane (DCM) (ml) | 20 | 20 | 20 | 20 | 20 |
| Distilled water (ml) | 100 | 100 | 100 | 100 | 100 |

2.4 Evaluation parameter of nanosponges

2.4.1 Particle size

The particle size analysis of Mometasone furoate loaded NS was performed by using “Malvern Zetasizer Nano ZS (Malvern Instruments (Ahmed et al., 2021).

2.4.2 Zeta potential

In the present work, the nanosponges was diluted 10 times with distilled water and analyzed by Zetasizer Malvern instruments (Kumar et al., 2018, Penjuriet al., 2016).

2.4.3 Entrapment efficiency

To calculate the entrapment efficiency accurately weighed the quantity of nanosponges (10 mg) with 5 ml of methanol in a volumetric flask was shaken for 1 min using vortex mixer. The volume was made up to 10 ml. Then the solution was filtered and diluted and the concentration of entrapped Mometasone furoate was determined spectrophotometrically (Solunkeet al., 2019).

%EE = Initial amount of drug added - Drug amount in supernatant / Initial amount of drug added * 100

2.4.4 Scanning Electron Microscopic (SEM)

The electron beam from a scanning electron microscope was used to attain the morphological features of the Mometasone furoate loaded nanosponges were coated with a thin layer (2–20 nm) of metal(s) such as gold, palladium, or platinum using a sputter coater under vacuum. The pretreated specimen was then bombarded with an electron beam and the interaction resulted in the formation of secondary electrons called auger electrons. From this interaction between the electron beam and the specimen’s atoms, only the electrons scattered at 90° were selected and further processed based on Rutherford and Kramer’s Law for acquiring the images of surface topography (Anweret al., 2019).

2.5 Formulation of Nanosponges loaded Gel

Initially carbopol-934 was immersed in 50 mL of warm water (A) for 2 hr and was homogeneously dispersed using magnetic stirrer at 600 rpm. In separate container carboxymethyl cellulose and methyl paraben was added into 50 ml warm water (B) and stirred continuously to make

stiff gel. Both the mixtures A and B were mixed with the continuous stirring. Then tri-ethanolamine (Drop wise) was added to neutralize the pH and nanosponges of optimized formulation were incorporated into the dispersion to obtained Gel. At

this stage, permeation enhancer (Propylene glycol) was added. The final dispersion was agitated until smooth gel was formed without lumps(Silpaet al., 2021).

Table 2: Composition of gel formulation

| Excipients | Quantity (gm) |
|-------------------------|---------------|
| Carbopol 934 | 1.00 gm |
| Carboxymethyl cellulose | 1.00 gm |
| Propylene glycol | 0.5 ml |
| Methyl paraben | 0.2 ml |
| Nanosponges | 1.0 gm |
| Tri-ethanolamine | q.s |

2.6 Characterization of nanosponges loaded Gel

2.6.1 Physical appearance

The prepared Gel formulation was evaluated for appearance, Color, Odor, and homogeneity by visual observation(Kumar and Eswaraiah 2020).

2.6.2 pH

pH of the formulation was determined by using Digital pH meter (EI)(McGlynn, W. 2003).

2.6.3 Viscosity

The viscosity of the gel formulations was determined using Brookfield viscometer with spindle no. 61 at 100 rpm at the temperature of 25°C(Monica and Gautami 2014).

2.6.4 Spreadability

An ideal topical gel should possess a sufficient spreading coefficient when applied or rubbed on the skin surface. This was evaluated by placing about 1g of formulation on a glass slide. Another glass slide of the same length was placed above that, and a mass of 50 mg was put on the glass slide so that the gel gets sandwiched between the two glass slides and spreads at a certain distance. The time taken for the gel to travel the distance from the place of its position was noted down. Spreadability was determined by the following formula

$$S = M \cdot L / T$$

Where, S-Spreadability, g.cm/s M-Weight put on the upper glass L-Length of glass slide T-Time for spreading gel in sec(Sandeep, D. S. 2020).

2.6.5 In-vitro drug release study

The in-vitro drug release study of Mometasone furoate loaded nanosponges

formulation was studied by dialysis bag diffusion method. Mometasone furoate loaded nanosponges were dispersed into dialysis bag and the dialysis bag was then kept in a beaker containing 100 ml of pH 7.4 phosphate buffer. The beaker was placed over a magnetic stirrer and the temperature of the assembly was maintained at 37 ± 2 °C throughout the experiment. During the experiment rpm was maintained at 100 rpm. Samples (2 ml) were withdrawn at a definite time intervals and replaced with equal amounts of fresh pH 7.4 phosphate buffers. After suitable dilutions the samples were analyzed using UV-Visible spectrophotometer. To analyze the in vitro drug release data various kinetic models were used to describe the release kinetics.

- **Zero Order Kinetics**

Zero-order drug release follows Eq. (2), where drug release is independent of concentration. A plot of cumulative % drug released vs. time gives a straight line.

The slope represents the zero-order release constant (K_0).

$$A_t = A_0 - K_0 t$$

----- Eq. (2)

- **First Order Kinetics**

First-order release follows Eq. (3), where release depends on drug concentration. A plot of log cumulative % drug remaining vs. time produces a straight line, indicating first-order kinetics.

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

- **Higuchi's Model**

Higuchi's model (Eq. 4) describes drug release from matrix systems by diffusion.

$Q = [DC / \tau (2A - CC_s) Cst]^{1/2}$eq (4)
 It relates drug release to the square root of time, assuming constant diffusion coefficient, solubility, and drug concentration.

- Korsmeyer–Peppas Model**
 The Korsmeyer–Peppas model (Eq. 5) explains drug release from polymeric systems:
 $Mt/M_\infty = Kt^n$
 Where n indicates the mechanism of drug release and k is the release rate constant, particularly useful for cylindrical matrices.

III. RESULT AND DISCUSSION

3.1 Pre-formulation study of drug

3.1.1 Organoleptic properties

Table 1: Organoleptic properties of Mometasone furoate

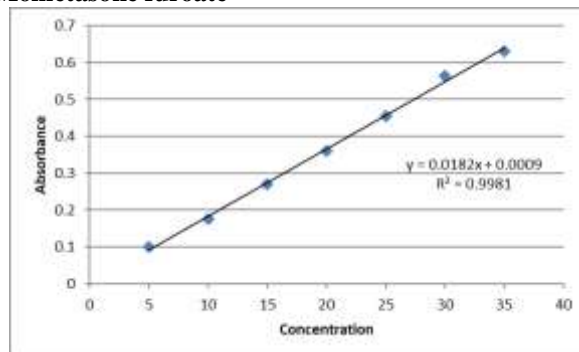
| Drug | Organoleptic properties | Observation |
|--------------------|-------------------------|--------------|
| Mometasone furoate | Color | Off- white |
| | Odor | Odorless |
| | Appearance | Powder |
| | State | Solid powder |

3.1.2 pH and melting point determination

Table 2: pH and melting point determination of Mometasone furoate

| Drugs | Observed (pH) | Observed (melting point) | Reference (melting point) |
|--------------------|---------------|--------------------------|---------------------------|
| Mometasone furoate | 4.3 | 220°C | 216°C-222°C |

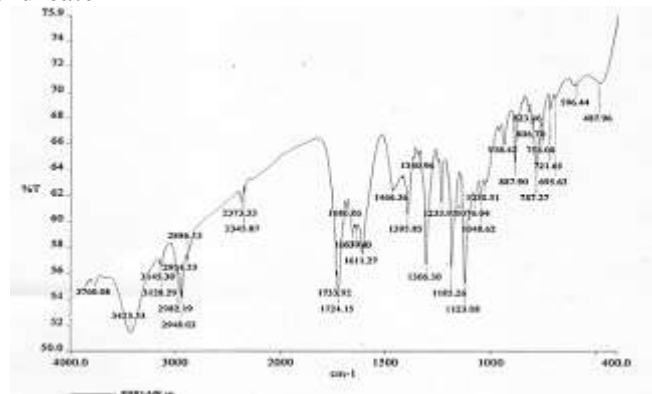
3.1.3 Calibration curve of Mometasone furoate



Graph 1: Calibration curve of Mometasone furoate

3.1.4 Functional group identified by Fourier transform infrared (FTIR) study

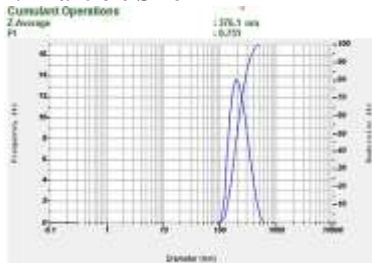
1. FTIR of Mometasone furoate



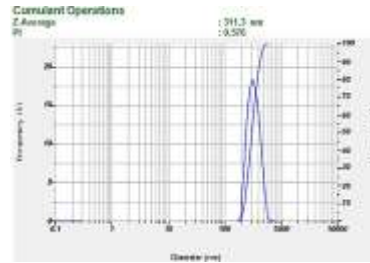
Graph 2: Mometasone furoate

3.2 Characterization of Nanosponges

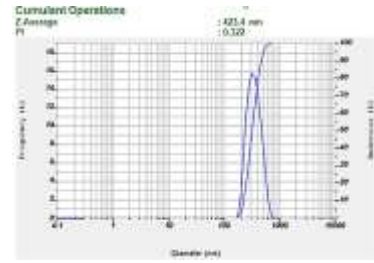
3.2.1 Particle Size



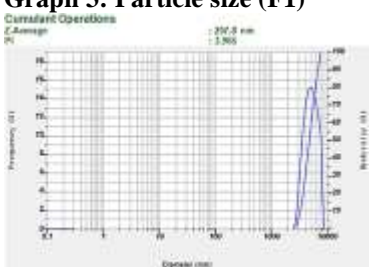
Graph 3: Particle size (F1)



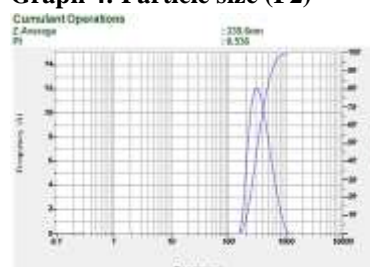
Graph 4: Particle size (F2)



Graph 5: Particle size (F3)

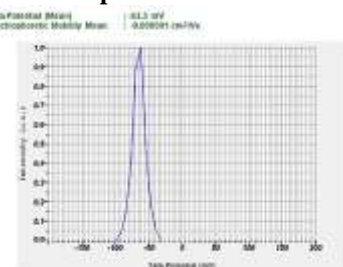


Graph 6: Particle size (F4)

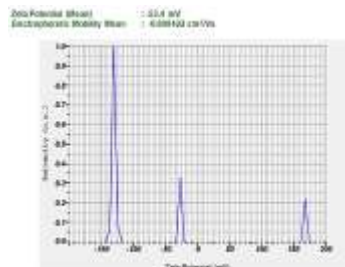


Graph 7: Particle size (F5)

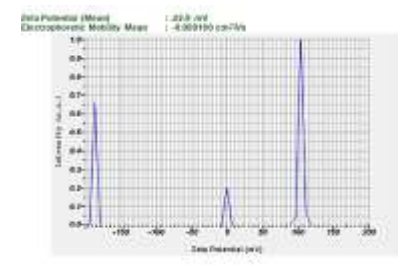
3.2.2 Zeta potential



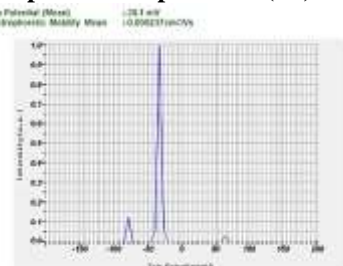
Graph 8: Zeta potential (F1)



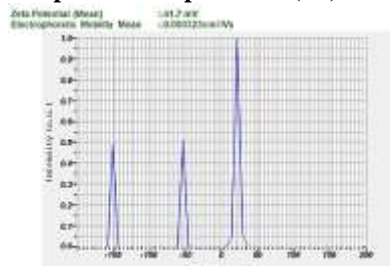
Graph 9: Zeta potential (F2)



Graph 10: Zeta potential (F3)



Graph 11: Zeta potential (F4)



Graph 12: Zeta potential (F5)

Table 3: Particle size and Zeta potential

| Formulation Code | Zeta potential | Particle size (nm) | Entrapment efficacy (%) |
|------------------|----------------|--------------------|-------------------------|
| F1 | -63.3 mV | 376.1 nm | 78.33 |
| F2 | -53.4 mV | 311.3 nm | 80.03 |
| F3 | -22.9 mV | 423.4 nm | 92.32 |
| F4 | -30.1 mV | 257.8 nm | 94.81 |
| F5 | -41.7 mV | 338.6 nm | 89.20 |

3.2.3 Scanning electron microscope (SEM) of F4 Formulation (Optimized)

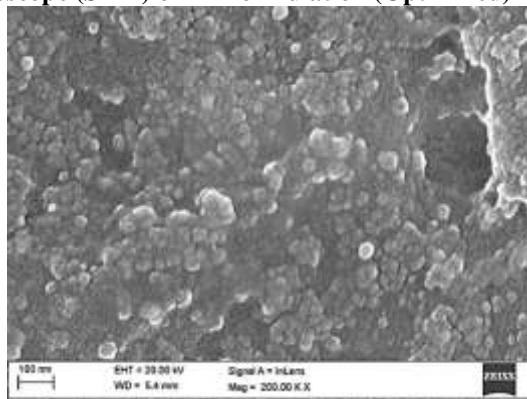


Figure 1: Scanning electron microscope

3.3 Characterization of nanosponges loaded gel

3.3.1 Physical appearance

Table 4: Physical appearance

| Parameter | Result |
|-------------|-------------|
| Colour | White |
| Odour | Odourless |
| Appearance | Transparent |
| Homogeneity | Homogeneous |

3.3.2 Viscosity, pH and Spreadability of Gel

Table 5: Viscosity, pH and Spreadability of Gel

| Formulation | Viscosity (cps) | pH | Spreadability (g.cm/s) |
|-------------|-----------------|------|------------------------|
| Gel | 6830±0.32 | 6.15 | 12.60 |

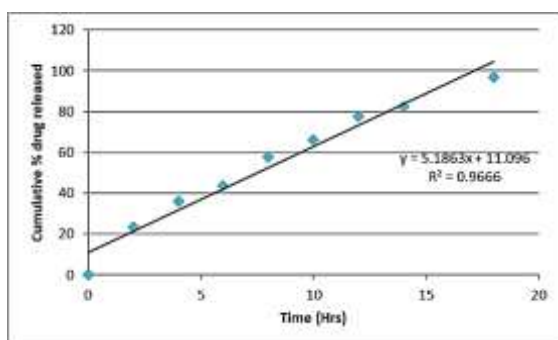
3.3.3 In-vitro drug release

Table 6: Release kinetics study of optimized (F4) formulation

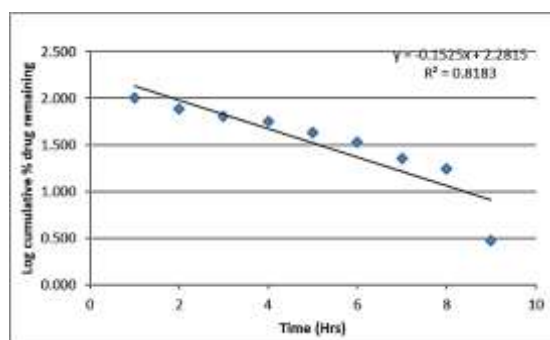
| Time (Hr) | cumulative % drug released | % drug remaining | Square root time | log Cumu % drug remaining | log time | log Cumu % drug released |
|-----------|----------------------------|------------------|------------------|---------------------------|----------|--------------------------|
| 0 | 0 | 100 | 0.000 | 2.000 | 0.000 | 0.000 |
| 2 | 23.18 | 76.82 | 1.414 | 1.885 | 0.301 | 1.365 |
| 4 | 36.09 | 63.91 | 2.000 | 1.806 | 0.602 | 1.557 |
| 6 | 43.63 | 56.37 | 2.449 | 1.751 | 0.778 | 1.640 |
| 8 | 57.6 | 42.4 | 2.828 | 1.627 | 0.903 | 1.760 |
| 10 | 66.13 | 33.87 | 3.162 | 1.530 | 1.000 | 1.820 |
| 12 | 77.56 | 22.44 | 3.464 | 1.351 | 1.079 | 1.890 |
| 14 | 82.45 | 17.55 | 3.742 | 1.244 | 1.146 | 1.916 |
| 18 | 97.01 | 2.99 | 4.243 | 0.476 | 1.255 | 1.987 |

Table 7: Correlation value (R² value)

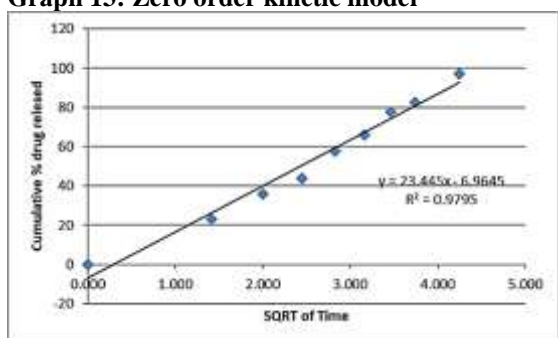
| Formulation | Model | Kinetic parameter values |
|-------------|-----------------|--------------------------|
| Gel | Zero Order | R ² = 0.966 |
| | First Order | R ² = 0.818 |
| | Higuchi | R ² = 0.979 |
| | Korsmeyerpeppas | R ² = 0.802 |



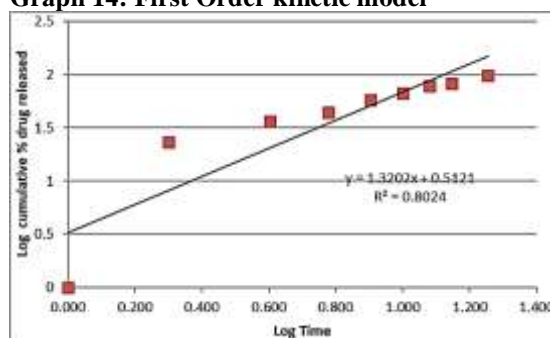
Graph 13: Zero order kinetic model



Graph 14: First Order kinetic model



Graph 15: Higuchi model



Graph 16: Korsmeyer peppas

Discussion

Mometasone furoate was evaluated for its physicochemical and organoleptic properties and was found to comply with I.P. specifications. The drug appeared as an off-white, odorless solid powder. It exhibited good solubility in dimethyl sulfoxide and ethanol, and moderate solubility in methanol and chloroform. The pH (4.3), melting point (220 °C), and λ_{max} (247 nm) were all within official limits, confirming drug purity and identity.

UV spectrophotometric analysis showed good linearity over the tested concentration range, with a regression equation of $y = 0.0182x + 0.0009$ and a high correlation coefficient ($R^2 = 0.998$), indicating suitability of the analytical method. Nanosponges loaded with mometasone furoate showed particle sizes ranging from 257.8 to 376.1 nm, confirming nanoscale formulation. Zeta potential values (-22.9 to -63.3 mV) indicated good colloidal stability. High drug entrapment efficiency (78.33–94.81%) was observed, with formulation F4 showing maximum entrapment (94.81%). SEM analysis revealed spherical, porous nanosponges with smooth surfaces, confirming successful nanosponge formation.

The formulated gel was white, odorless, transparent, homogeneous, and complied with I.P. requirements. The viscosity (6830 cP) was suitable for topical application, and the pH (6.15) was within the normal skin range, indicating good

compatibility. The gel showed adequate spreadability (12.60 g·cm/s), ensuring effective topical application. In vitro drug release and kinetic modeling revealed that the optimized gel followed the Higuchi model ($R^2 = 0.979$), indicating diffusion-controlled drug release. Zero-order, first-order, and Korsmeyer–Peppas models showed lower correlation coefficients. Thus, drug diffusion from the nanosponge-based gel matrix was identified as the predominant release mechanism.

IV. CONCLUSION

Mometasone furoate was confirmed to be an off-white, odorless solid with acceptable pH, melting point, and λ_{max} values. Nano sponges of mometasone furoate were successfully prepared using the emulsion solvent evaporation technique with ethyl cellulose and polyvinyl alcohol. SEM studies revealed spherical, porous nanosponges, while particle size analysis confirmed nanoscale dimensions and good stability. High drug entrapment efficiency was achieved. The nanosponge-loaded gel showed suitable viscosity, pH, and spreadability, indicating good skin compatibility and enhanced drug release. Overall, nanosponge-based formulation improved solubility and bioavailability of mometasone furoate and provided sustained drug delivery. The developed gel shows potential for effective treatment of skin

diseases with reduced dosing frequency and side effects.

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