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Formulation Optimization and Invitro Skin Permeation Assessment of a Curcumin Loaded Emulgel

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Abstract: The present aim of the work was to formulate and evaluate curcumin topical Emulgel for transdermal drug delivery. To incorporate curcumin in Emulgel and to entrap the drug by carbopol polymer. Topical preparations are used for localized effect at the site of their application by virtue of drug penetration into the underlying the layers of the skin or mucus membrane. This avoids the first pass metabolism. Emulgels are the best for controlled drug release systems. Curcumin emulgel formulations were formulated and characterized for standardization, drug content, pH, viscosity, physical parameters, spreading coefficient, swelling index, in-vitro diffusion studies. The studies were resulted very good , drug content was found between 70-100%. The coefficient of spreading in the range of 7-10. pH was found between 7.01-7.6 . viscosity ranged between 200-1000 centipoise. percent drug release i.e 97.3 %. Release kinetics were fitted to kinetics model and the curcumin emulgel followed first order and peppas model where the emulgel can easily passes and penetrates through transdermal layers of skin. Finally the curcumin when loaded in emulgel and clove oil as oil phase and water as aqueous phase O/W emulsion, proved the better drug release profile when compared to all formulations. Also proved better controlled drug release

Keywords*: Curcumin, Entrap, Transdermal, Emulgel, Controlled Drug Release.*

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I. INTRODUCTION

For the treatment of numerous skin conditions, conventional topical formulations like ointments, creams, and lotions are frequently utilized. Nevertheless, these preparations may have a number of drawbacks, such as stickiness, greasiness, poor patient acceptance, insufficient spreadability, and the need to rub during administration. They could also show signs of instability while being stored. Transparent and non-greasy gel formulations are now more frequently used in pharmaceutical and cosmetic preparations as a result of these restrictions.[1,2]. An emulsion-based strategy can be used in conjunction with a gel system to address the drawbacks of traditional topical formulations and make it easier to incorporate and deliver therapeutic ingredients that are poorly soluble. At the time.

An emulgel is the dosage form that results from combining gels and emulsions. Emulgels are especially useful for the topical distribution of hydrophobic medications because they combine the benefits of emulsions and gels.[3,4] The application of a drug-containing formulation to the skin in order to achieve a localized therapeutic impact is known as topical medication delivery.[5] The creation of a concentration gradient, which serves as the catalyst for drug transport over the skin, is one of the key processes in percutaneous absorption. The main obstacle to percutaneous medication absorption is the stratum corneum. Preferred qualities of medications meant for topical delivery include a suitable

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partition coefficient, a comparatively small molecular mass, and sufficient solubility in both water and oil. Highly polar compounds and water-soluble ions typically exhibit restricted penetration through intact stratum corneum. In order to achieve localized therapeutic action while avoiding some of the drawbacks of systemic administration, such as gastrointestinal degradation, enzymatic effects, and variability in absorption, topical drug delivery is especially helpful8,9. Emulgel formulations have been created for several medications with topical or systemic activity 10. The dosage form known as emulgel11 is used when gels and emulsions are mixed. It is made by combining a gelling agent with an emulsion that is either water-in-oil or oil-in-water. Lipophilic medications are trapped in the direct (oil-in-water) system, while hydrophilic pharmaceuticals are encapsulated in the reverse (water-in-oil) system. Emulgel enables both emulsion and gel to be controlled in terms of their release from the formulation [12,13]. Emulgels acts as excellent medium for hydrophobic or water insoluble drugs.14 Moreover they also have less spreading coefficient and need to apply with rubbing.[15,16] Topical drug delivery is a localized drug delivery system anywhere in the body through ophthalmic, rectal, vaginal & skin as topical routes. [17] The surface of the stratum corneum presents more than 99% of the total skin surface available for percutaneous drug absorption. 18 Preferable characteristics of topical drugs include low molecular mass (600 Da), adequate solubility in oil and water, & a high partition coefficient.[19,20] Transparent gels has expanded both in cosmetics and in pharmaceutical preparations [21,22]. Gel Formulations generally provide faster drug release compared with ointments and creams .[23]

II. MATERIAL AND METHODS

➢ *Chemicals and Reagents:*

Curcumin, Poly ethylene glycol Carbopol procured from Loba chemie Pvt. Ltd Mentha oil, Clove oil obtained from Genuine chemical co.Pvt. Ltd, Paraffin liquid heavy from Merck specialities Pvt.Ltd, Span 20 Tween 20 from Pallav chemicals and solvents Pvt.Ltd, Ethanol from Changshu yangyuan chemicals Ethyl paraben from Sd fine chem Limited.

➢ *Formulation Methods*

- Step 1: Formulation of emulsion either O/W or W/O
- Step 2: Formulation of gel base
- Step 3: Incorporation of emulsion into gel base with continuous stirring

With a few minor adjustments, the procedure described by Mohammad et al. (2004) was used to create curcumin-loaded emulgel. In order to manufacture the gel bases, Carbopol 934 and Carbopol 940 were dispersed separately in purified water while being continuously stirred at a moderate speed until uniform dispersions were achieved. Triethanolamine (TEA) was used to raise the pH of each gel base to 6.0–6.5.

Tween 20 was dissolved in purified water to create the aqueous phase of the emulsion, whereas Span 20 was dissolved in light liquid paraffin to create the oil phase. Propylene glycol was used to dissolve methyl and propyl parabens.

The oil and water phases were individually heated to a temperature range of 70–80 °C. The heated oil phase was then slowly introduced into the aqueous phase with ongoing stirring to create the emulsion. The resulting emulsion was stirred continuously and permitted to cool to ambient temperature. Ultimately, the prepared emulsion was mixed into the Carbopol gel base in a 1:1 ratio while stirring continuously to create the curcumin-loaded emulgel. Glutaraldehyde was added during the mixing process of the gel and emulsion, as detailed in the formulation, to achieve the final emulgel. The resulting formulations were allowed to equilibrate before being subjected to evaluation..

➢ *Types of Emulgels [12]*

- Macro-emulsion gel
- Nano-emulgel
- Micro-emulsion

- *Macro-Emulsions Gel:*

Macroemulsions represent the most prevalent form of emulsion, characterized by droplet sizes typically exceeding 400 nm. These droplets are readily visible under a microscope, and macroemulsions tend to have an opaque appearance. Due to their thermodynamic instability, macroemulsions need stabilization through the use of surfactants to avoid coalescence and enhance their physical stability.

- *Nano-Emulgel:*

When nano-emulsion is merged into gel it is known as nano-emulgel. Nano-emulsions are hermodynamically stable transparent dispersions of water and oil stabilized by an interfacial film of surfactant and co-surfactant molecules having a droplet size of not more than 100 nm. Nano-emulsion formulations possess improved dermal and transdermal delivery properties in vitro as well as in vivo. Nano-emulsions have better transdermal permeation of many drugs over the conventional topical formulations.[24]

- *Micro-Emulsion:*

Micro-emulsions are transparent and thermodynamically stable. Their droplet size range from 10 to 100 nm and they do not merge. Micro-emulsions are composed of, surfactant, co-surfactant, oil and water in specific proportions. The ingredients of micro-emulsion could help the permeation rate of the drug by reducing the diffusion barrier of the stratum corneum. However, due to low viscosity of micro-emulsion their retention capacity is less in the skin restrains its application in the pharmaceutical industryAvoid combining SI and CGS units, such as current in amperes and magnetic field in oersteds. This often leads to confusion because equations do not balance dimensionally. If you must use mixed units, clearly state the units for each quantity that you use in an equation.

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➢ *Evaluations :*

- *Preformulation Studies*

✓ *FTIR- Spectroscopic Studies*

Drug excipients compatibility was analyzed by using ATR (Attenuated Total Reflectance) FTIR Spectrophotometer (Agilent cary 630 ATR.FTIR). the spectra of tizanidine, cholesterol, lecithin, mixture were recorded. A sample of material was placed on the diamond ATR Crystal and analyzed by using spectrum of sample average scans at a resolution of 4 cm-1 shown in fig 2,3,4.

✓ *Standard Curve of Curcumin in Phosphate Buffer pH 7.4:*

A precise amount of 100 mg of curcumin was measured, dissolved in phosphate-buffered saline (PBS) at pH 7.4, and the volume was adjusted to 100 mL with the same buffer to prepare the standard stock solution. Subsequently, further dilutions were created using phosphate buffer (pH 7.4) to achieve concentrations of 2, 4, 6, 8, and 10 µg/mL. The absorbance of each of these solutions was recorded at 419 nm using a UV–Visible spectrophotometer, with phosphate buffer (pH 7.4) serving as the blank. fig 5.

III. FORMULATION CHARACTERIZATIONS

➢ *Physical Parameters*

The physical parameters like colour, consistency, odour have been evaluated and the values were given in the table 2.

➢ *pH:*

The all finished formulations were taken and estimated for their pH with the help of digital pH meter (thermo scientific)and all the measurements were replicated three times shown the results in table 3.

- *Drug content Determination:*

The curcumin content in the emulgel was determined by dissolving a known quantity of the emulgel in ethanol, followed by sonication to ensure complete extraction of the drug. The resulting solution was filtered through Whatman No. 41 filter paper. The filtrate was suitably diluted with ethanol, and its absorbance was measured at 319 nm using a UV–Visible spectrophotometer (JASCO V-550, Japan). The curcumin content was calculated using the previously established calibration curve.The globule size and size distribution of the prepared emulgel formulations are presented in Table 3

➢ *Particle Size*

This study was performed for the optimized batches each from carbopol 934 based and xanthan gum based gels. Globule size and distribution was determined by Malvern zetasizer. A 1.0 gm sample was dissolved in purified water and agitated to get homogeneous dispersion. Sample was injected to photocell of zetasizer. Mean globule diameter and distribution was obtained presented the values in table no :

➢ *Swelling Index*

Emulgel of known weight (1 gram) was wrapped with Aluminium Foil (pricked with a pin to make holes) and placed in phosphate buffer pH 7.4 for 6 hours. [26] After 6 hours, the gels were scrapped and the wet weight of the swollen gel was determined by first blotting the gels with filter paper to remove absorbed water on surface and then it was immediately weighed on an electronic balance. The weight of the swollen gels was determined using an electronic balance

The swelling index of was calculated using the following formula,

$Sw = [(Wt – Wo) / Wo] \times 100$

Where,Sw = percentage of swelling of Emulgel

Wt = the weight (g) of the gels at time t

Wo = initial weight (g) of the Emulgel. Refer fig 6:

➢ *Determination of Viscosity:*

Viscosity of the formulated emulgel batches was measured using a Brookfield viscometer equipped with spindle No. 07. An adequate amount of each formulation was placed in a beaker and kept at the assay temperature for 30 minutes to reach equilibrium before analysis. The spindle was inserted vertically into the centre of the emulgel surface, ensuring that it remained clear of the beaker's base and walls. It was then operated at 12 rpm for 10 minutes. Viscosity was noted in cP (centipoise). The viscosity values of the formulated emulgel batches are presented in Table 3.

➢ *Spreadability:*

One of the criteria for an emulgel to meet the idealquantities is that it should possess good spreadability. It is the term expressed to denote the extent of area to which gel readily spreads on application to skin or affected part. The therapeutic efficacy of a formulation also depends upon its spreadability. The spreadability of both the formulated emulgel and the marketed gel was assessed by measuring the diameter of the circular area formed when each formulation was compressed between two uniformly weighted glass plates. A 50 mg quantity of the emulgel or marketed gel was placed on one glass plate, after which a second plate was gently lowered onto it from a height of 5 cm. The formulation was then allowed to spread between the plates, and the diameter of the formed circle was recorded. The spreadability coefficient was calculated using the following.

$S = m^* L/T$ Refer fig. 7.

The spreadability values of the formulated emulgel batches and marketed gel are presented in Table 3**.**

- *In Vitro Drug Release Studies:*[30]

A modified vertical Franz diffusion cell with a diffusion area of 1.44 cm² and a receptor volume of 15.5 mL was used to assess in vitro drug release. A 0.45 µm nylon membrane, pre-soaked in phosphate buffer (pH 7.4) for 24 h, was positioned between the donor and receptor compartments. The receptor medium consisted of phosphate buffer pH 7.4 (80:20), maintained at 37 ± 0.2°C and continuously stirred at 50 rpm. At specified time intervals, 1 mL aliquots were collected, suitably diluted, and analyzed spectrophotometrically at 321 nm. The drug release profile is shown in Figure 8.

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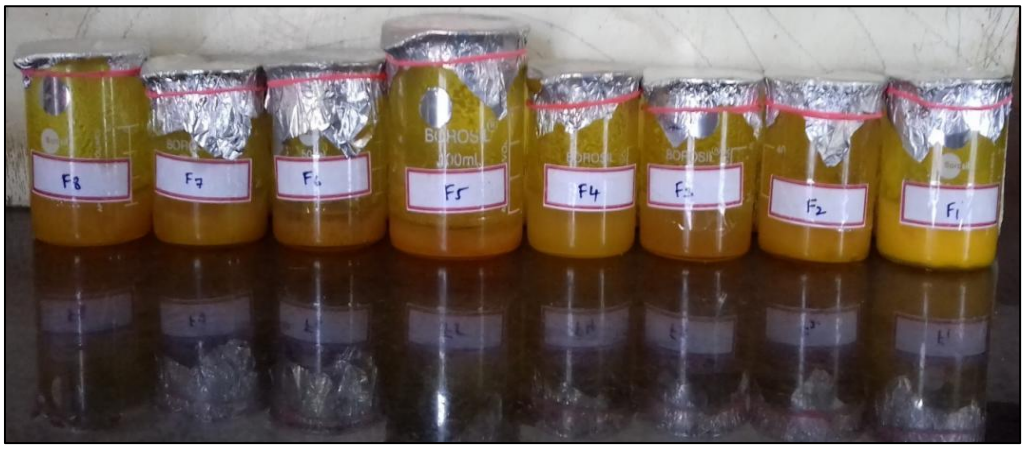


Fig 1 Curcumin Emulgel Formulations f1-f8

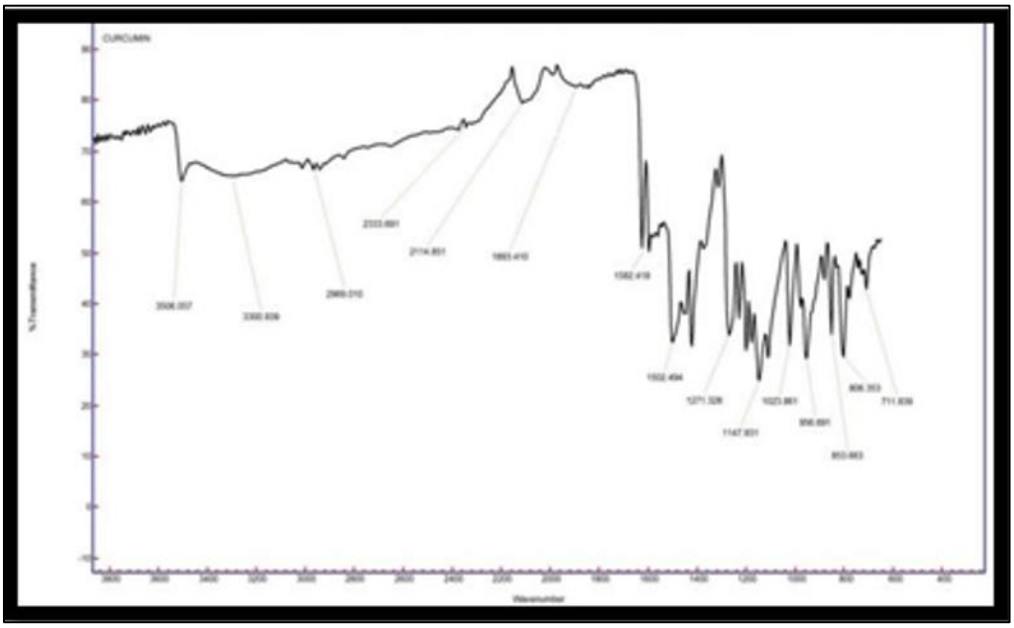


Fig2 FTIR-Spectroscopy of Curcumin

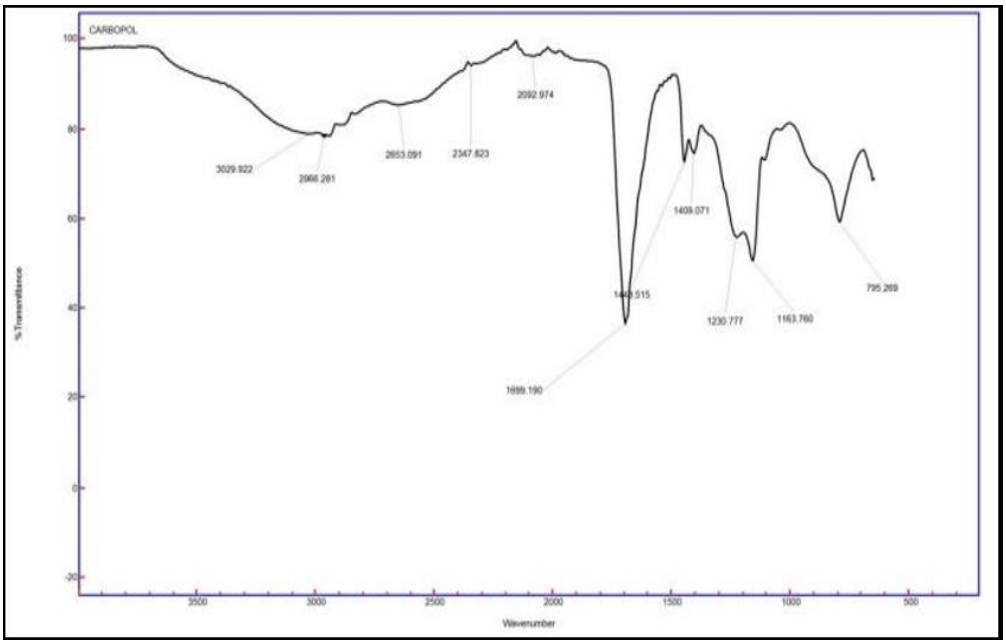


Fig 3 FTIR-Spectroscopy of Carbopol

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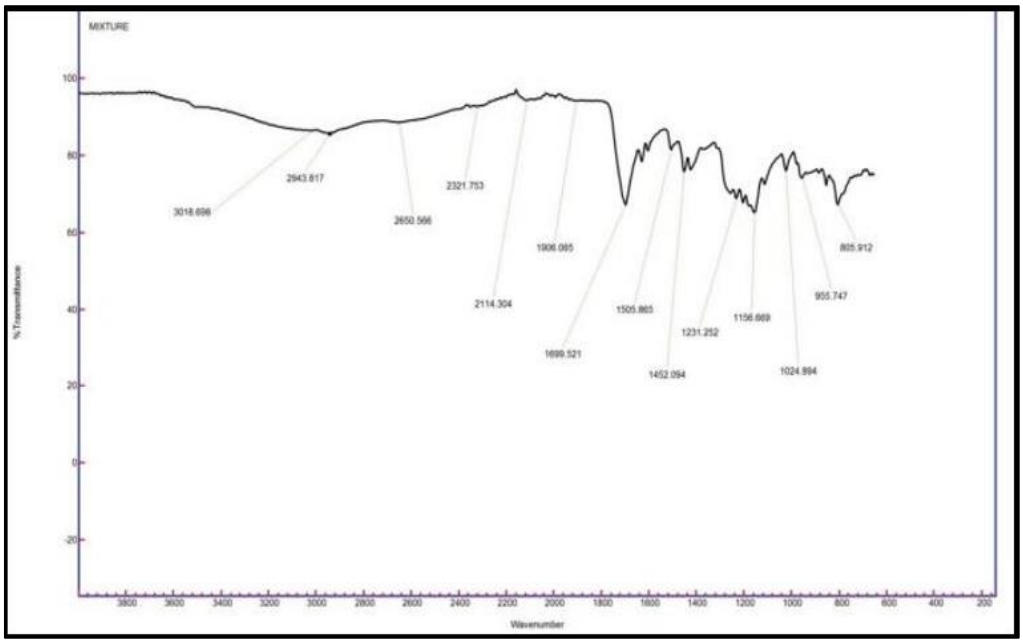


Fig 4 FTIR Spectroscopy of Mixture

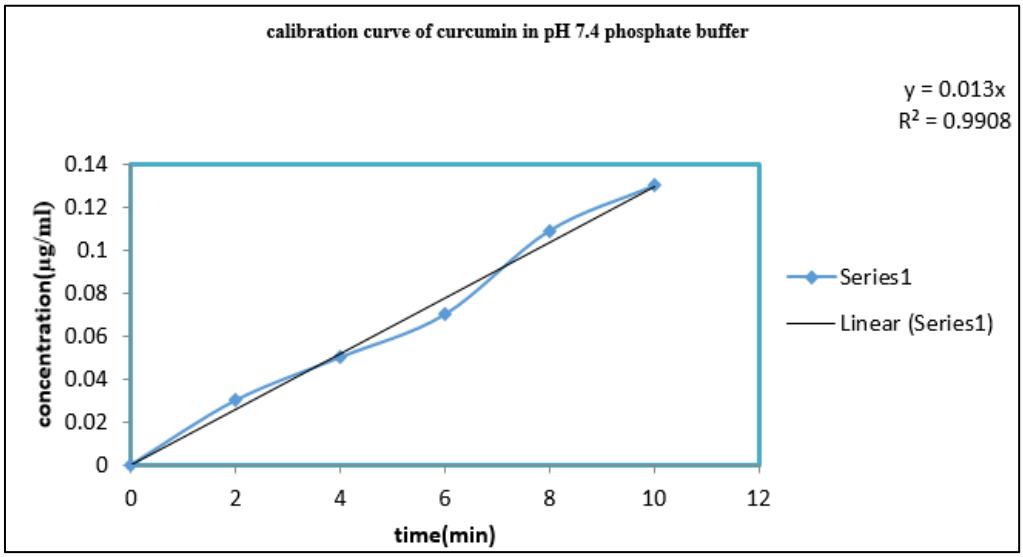


Fig 5 Calibration Curve of Curcumin in Phosphate Buffer pH 7.4

Table 2 Physical Parameters of Curmin Emulgel

Formulation	colour	homogeneity	Phase seperation
F1	Light Yellow	Excellent	No
F2	Yellow	Excellent	No
F3	Yellow	Excellent	No
F4	Yellow	Excellent	No
F5	Yellow	Excellent	No
F6	Yellow	Excellent	No
F7	Yellow	Excellent	No
F8	Yellow	Excellent	No

Table 3 Drug Content, pH and Viscosity of Curcumin Emulgel

S.NO	formulation	%Drugcontent±RSD	pH±RSD	Viscosity(cps) at 20 rpm±RSD
1	F1	78.860±0.45	7.01±0.25	930±0.35
2	F2	81.6±0.37	7.12±0.59	570±0.61
3	F3	88.9±0.56	7.17±0.36	540±0.29
4	F4	85.3±0.73	7.06±0.58	510±0.54

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5	F5	86.8±0.25	7.09±0.46	480±0.83
6	F6	89.6±0.28	7.47±0.81	330±0.47
7	F7	90.1±0.34	7.32±0.68	290±0.78
8	F8	92.7±0.55	7.52±0.37	210±0.56

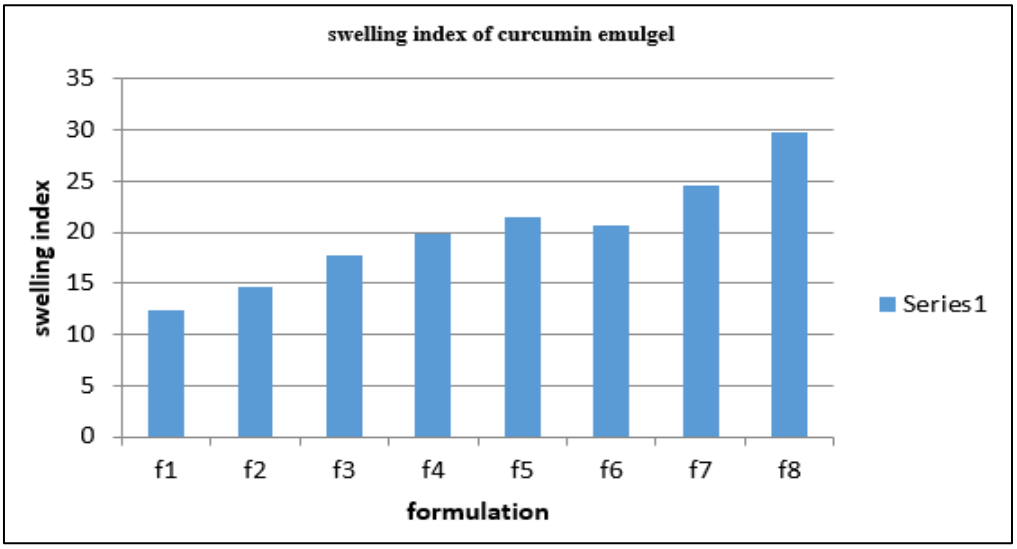


Fig 6 Swelling Index of Curcumin Emulgel from f1-f8

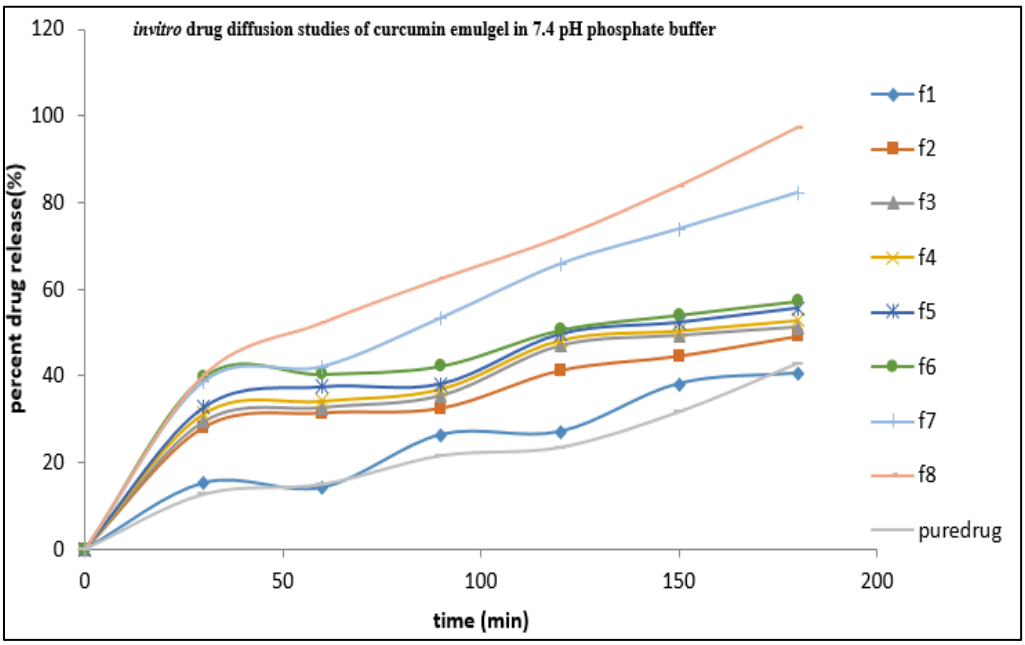


Fig 7 Invitro Drug Diffusion Studies of Curcumin Emulgel in 7.4 pH Phosphate Buffer

IV. DISCUSSIONS

Curcumin emulgel is prepared by using carbopol, methylparabenpropylparaben, span20, tween20, polyethyleneglycol, ethanol, curcumin, water, cloveoil, coconutoil. For each formulation gel was prepared and evaluated FTIR studies revelled that no interaction between the drug and excipients. Standardization of curcumin showed r2 = 0.990 which proved that no impurities were present. That they have no incompatibilities so they are well suited for doing the project.

Drug content was found between 70-100. F7 and f8 showed more percent of drug content. Swelling index studies showed that emulgels proved better swelling and found in the range of 1000-1500. Of all formulatiuon f8 showed better swelling index.

Spreadability studies revealed that coefficient of spreading in the range of 7-10, f8 is the best spreading coefficient emulgel. pH and viscosity oparameters have been assessed and pH was found between 7.01-7.6 whic is favourable for permeation of emulgel thrugh the skin. Emulgel viscosity ranged between 200-1000 centipoise and of all f8 shwed less viscosity and exhibit better viscosity.

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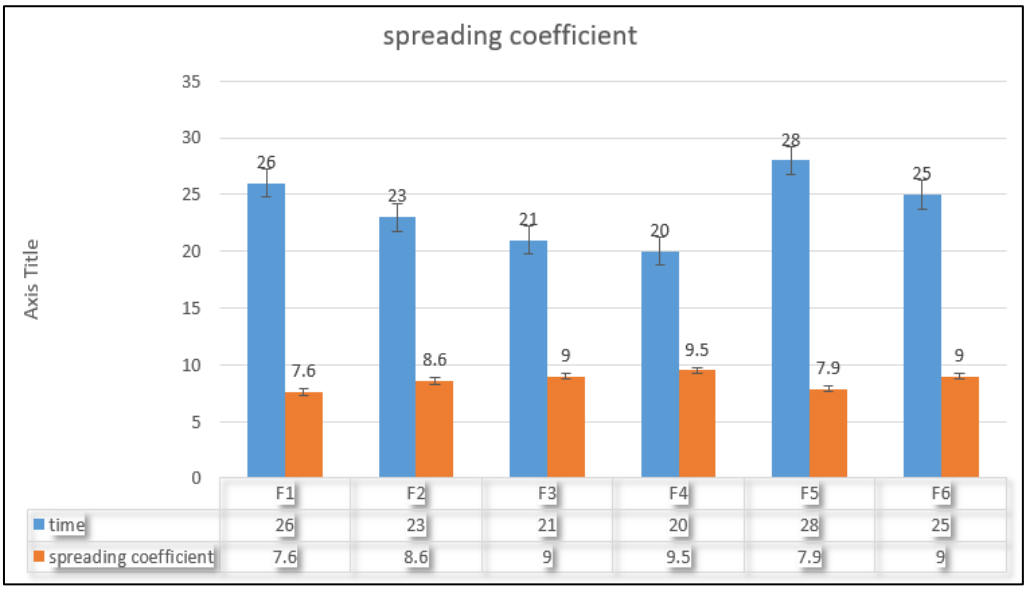


Fig 8 Spreading Coefficient of Curcumin Emulgel from f1-f8

Table 4 Particle Size

Formulation	Particle size (nm)
F1	182.4 ± 3.6
F2	196.7 ± 4.1
F3	214.3 ± 3.8
F4	228.6 ± 4.5
F5	165.8 ± 3.2
F6	178.9 ± 3.7
F7	192.5 ± 4.0
F8	207.3 ± 4.3

The formulated curcumin emulgels were assessed for colour, homogeneity, and phase separation. All formulations exhibited a uniform appearance without noticeable colour changes or phase separation. In vitro drug diffusion was evaluated in triplicate using a Franz diffusion cell fitted with a semipermeable membrane. Compared with pure curcumin, the emulgels showed enhanced drug release, with F8 achieving the highest release of 97.3%. The formulations followed first-order kinetics and the Korsmeyer–Peppas model. Overall, curcumin emulgels represent a promising controlled drug-delivery approach that may reduce first-pass metabolism and improve patient compliance.

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➢ *Conflict of Interest:*

The authors declare no conflict of Interest.

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