ISSN: 2320-2831

International Journal of Pharmacy and Analytical Research (IJPAR)

IJPAR | Vol.15 | Issue 1 | Jan - Mar -2026

www.ijpar.com

DOI: https://doi.org/10.61096/ijpar.v15.iss1.2026.309-320

Development of Clindamycin-Loaded Biodegradable Polymeric Films for Localized Wound Healing Applications

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Published by: 24.02.2026

Abstract: This work intended to create biodegradable polymeric films loaded with clindamycin for localized wound healing applications with natural polymer composites. Five formulations (F1–F5) were developed using the solvent casting method and comprehensively assessed for their physicochemical, mechanical, antibacterial, and in vitro drug release properties. All films displayed consistent thickness, negligible weight fluctuation, sufficient folding durability, and a surface pH suitable for skin, thereby affirming reproducible production and cutaneous safety. The moisture content, moisture absorption, and swelling index increased with elevated polymer concentrations, signifying enhanced hydration capacity crucial for wound healing. Mechanical assessment indicated a notable improvement in tensile strength and elongation, guaranteeing flexibility and durability appropriate for wound dressing applications. The drug content in all formulations was within acceptable limits, indicating consistent distribution of the medicine. In vitro release tests indicated regulated and prolonged diffusion of clindamycin, with formulation F5 exhibiting the most advantageous release profile. The antibacterial assessment demonstrated efficient suppression of Staphylococcus aureus, which aligned closely with the release characteristics. The release kinetics primarily adhered to the Higuchi model, signifying diffusion-controlled drug transport. Accelerated stability experiments validated the physical and functional stability of the optimized formulation. Clindamycin-loaded biodegradable polymeric films exhibited significant potential as effective localized antibacterial wound treatments.

Keywords: Clindamycin; Biodegradable polymeric films; Wound healing; Localized drug delivery; Antibacterial activity; Solvent casting.

INTRODUCTION

Since the early 1980s, the notion of mucoadhesion has garnered significant attention in pharmaceutical formulation research.[1] Mucoadhesive drug delivery systems are engineered to extend the retention duration of a dosage form at the site of administration or absorption. These systems improve drug absorption and therapeutic efficacy by fostering intimate and prolonged interaction with the mucosal surface. In recent years, many mucoadhesive delivery systems have been investigated for oral, buccal, nasal, rectal, and vaginal administration to facilitate both localized and systemic drug delivery.[2]

Muco-adhesive drug-delivery systems

(MDS) are formulations designed to stick to mucosal surfaces (oral, buccal, nasal, ophthalmic, vaginal, rectal, and gastrointestinal) to ensure extended residence time and targeted or systemic drug release. The fundamental justification for muco-adhesion is to enhance the contact duration between the drug-laden vehicle and the absorptive epithelium, thereby augmenting bioavailability, decreasing dosing frequency, mitigating systemic side effects, and facilitating more efficacious local therapy (e.g., for oral or vaginal candidiasis). Muco-adhesive strategies are especially appealing for pharmaceuticals that exhibit low oral bioavailability, considerable first-pass metabolism, or are designed for localized effects at mucosal locations.[3, 4]

Biodegradable polymers, including natural polysaccharides, modified polysaccharides, proteins, and certain aliphatic polyesters, undergo enzymatic or hydrolytic degradation at the application site, thereby obviating the necessity for removal and diminishing the danger of chronic irritation. Natural and bio-inspired polymers, including chitosan, alginate, pectin, gelatin, hyaluronic acid, carboxymethylcellulose, and guar gum, are widely utilized due to their inherent muco-adhesive characteristics, biodegradability, and advantageous biocompatibility profiles. Semi-synthetic cellulose derivatives, such as HPMC and CMC derivatives, are utilized in certain instances for their reliable film-forming and swelling properties.[5] The biodegradation rate, molecular weight, and cross-link density of the polymer matrix are design parameters that regulate residence duration and drug-release kinetics in muco-adhesive biodegradable systems.

Wound healing is a meticulously regulated biological process comprising sequential phases of haemostasis, inflammation, proliferation, and remodelling that collectively restore tissue integrity. Healing in chronic wounds is frequently compromised by microbial biofilm formation, which restricts antibiotic penetration, modifies the wound microenvironment, and perpetuates prolonged inflammation, consequently hindering granulation and re-epithelialization thus, effective biofilm management is essential for successful wound care.[6, 7]

Prior research has shown the efficacy of clindamycin administration using diverse topical and localised drug delivery methods, highlighting polymer-based methodologies for enhanced stability, release regulation, and therapeutic effectiveness. Đivić Ćorić et al.[8] developed clindamycin hydrochloride gels utilising Carbopol® polymers, demonstrating exceptional physical stability, suitable pH levels, and adequate drug content, so affirming its appropriateness for topical use. Alifah et al.[9] created a self-healing polyvinyl alcohol–borax hydrogel for the regulated release of clindamycin, demonstrating Fickian diffusion, improved wound healing, and stability when refrigerated. Film-based systems have been investigated; Chaiwarit et al.[10] formulated low-methyl pectin films infused with clindamycin HCl, attaining elevated drug-loading efficiency and enhanced mechanical properties, whereas Alternative carriers, including niosomes (Sharma et al.) and liposomes (Ghaffari et al.), have been examined to enhance skin penetration and facilitate regulated distribution. Recent analyses by Almadani et al.,[11] Jangra et al.,[12] and Borbolla-Jiménez et al.,[13] underscore the increasing significance of biodegradable polymers in wound management owing to their biocompatibility, moisture retention, and antibacterial properties. Nevertheless, few studies have concentrated on basic biodegradable polymeric films tailored for prolonged, localised clindamycin administration in wound healing, hence justifying the current research.

Clindamycin is a crystalline white to off-white powder. Readily soluble in water, marginally soluble in methanol and anhydrous ethanol, and virtually insoluble in solvents such as acetone, chloroform, and ether. It is a lincosamide antibiotic that obstructs bacterial protein synthesis. It particularly binds to the 50S ribosomal subunit, obstructing the translocation step and inhibiting peptide chain elongation. This produces bacteriostatic effects, yet it may have bactericidal properties at elevated concentrations against susceptible species. It exhibits notable efficacy against Gram-positive cocci and anaerobic bacteria.[14]

Traditional clindamycin formulations for wound care frequently exhibit poor retention, necessitate multiple doses, and provide variable localised drug delivery, underscoring the necessity for a biodegradable approach that offers prolonged antibacterial efficacy at the wound site. The objective of this study was to formulate and

assess clindamycin-embedded biodegradable polymeric films for efficient localised wound healing, featuring regulated drug release and enhanced patient adherence.

MATERIAL AND METHODS

Chemicals

Clindamycin phosphate was obtained as Gift sample from UniChem laboratories Ltd., Mumbai. Chitosan were purchased from HI media Lab Pvt Ltd., Mumbai. Gelatin, Glycerol and Methyl-paraben were purchased from S.D. Fine- Chemical Ltd, Mumbai. Acetic acid was purchased from Shilled Chemicals Pvt. Ltd., Delhi. All the used reagents and chemicals were of analytical grade.

Calibration of CLD

To a 100 millilitre volumetric flask, 100 milligrammes of carefully weighed CLD are introduced. The volume was raised to 100 ml using a stock solution of 1 mg/ml of 6.8 pH phosphate buffer. In order to create solutions with concentrations of 5-25 µg/ml, the stock solution was further diluted using 6.8 pH phosphate buffer. A UV-VIS spectrophotometer (EI 1372, Electronics India, Pune, India) with a blank of 6.8 pH phosphate buffer was used to draw a standard graph and quantify the absorbance of these solutions at wavelength 202 nm.

Fourier Transform Infrared (FT-IR) Spectroscopy

Using a FTIR spectrophotometer (Shimadzu FTIR-8400S, Japan), the drug's FT-IR spectra were recorded. When using the diffuse reflectance technique, the mid-IR 4000-400 cm-1 spectral region was covered. The sample is first dispersed in KBr (100 mg) using a motor, and the materials are subsequently triturated into a fine powder bed inside the container using a compression gauge. Five tons of pressure was applied for five minutes. Following the light route, the film was placed, the spectrum was recorded twice, and the characteristic peaks associated with the functional groups were determined.

Formulation Design[15]:

The formulation was created to produce biodegradable, mechanically stable, and bio adhesive polymeric sheets for localised and sustained administration of clindamycin at the wound site. Chitosan was chosen for its antibacterial, haemostatic, biodegradable, and film-forming characteristics, whilst gelatin was added to improve flexibility, moisture retention, and biocompatibility. The mechanical strength, swelling behaviour, bio adhesion, and drug release were optimised by adjusting the chitosan-to-gelatin ratio (F1–F5). Glycerol served as a plasticiser, while clindamycin phosphate was evenly distributed to provide uniform drug distribution and extended antibacterial efficacy.

Table 1: Formulation of Clindamycin (CLD)-Loaded Biodegradable polymeric films

Ingredient	F1	F2	F3	F4	F5
Clindamycin phosphate (mg)	100	100	100	100	100
Chitosan (mg)	400	350	300	250	200
Gelatin (mg)	0	50	100	150	200
Glycerol (mg)	100	100	100	100	100
Methyl-paraben (mg)*	10	10	10	10	10
1% v/v Acetic acid solution (mL)	q.s.	q.s.	q.s.	q.s.	q.s.
Purified water (mL)	q.s.	q.s.	q.s.	q.s.	q.s.

* (Quantities per casting batch for one 10 × 10 cm film). 1% v/v Acetic acid solution (mL) q.s. to dissolve chitosan (15 mL in all batches). Purified water (mL) q.s. to 25 mL total casting solution in all batches

Preparation of Clindamycin-Infused Polymeric Films (Solvent Casting Technique)

The films were fabricated utilizing the solvent-casting method. Chitosan was initially dissolved in 1% v/v acetic acid and permitted to swell for 4–6 hours to achieve a transparent solution. Gelatin was hydrated in warm purified water (45–50°C) and incrementally included into the chitosan solution while continuously stirring until a homogeneous polymer mixture was achieved. Clindamycin phosphate was separately dissolved in a small amount of warm water and thereafter integrated into the polymeric mixture with gentle agitation to prevent air trapping. Glycerol was included as a

plasticizer, and the resultant solution was agitated for 20 minutes with a magnetic stirrer. The deaerated solution was applied to a leveled glass casting plate measuring 10 x 10 cm, distributed uniformly, and allowed to dry at room temperature for 24 to 48 hours. The dried films were meticulously peeled, examined for imperfections, and sectioned into 4 × 4 cm squares, each possessing a consistent drug content. Films exhibiting bubbles, cracks, or irregular thickness were eliminated.

$$\text{Drug content} = \frac{\text{sample absorbance}}{\text{standard absorbance}} \times \frac{\text{standard dilution}}{\text{sample dilution}} \times \frac{\%\text{purity of drug} \times \text{Avg.wt}}{100}$$

$$\%\ \text{Drug content} = \frac{\text{Drug content} \times 100}{\text{Label claim}}$$

Evaluation of oral dissolving films formulations:

For polymeric film formulations, various quality control tests were carried out.

Different Performed in vitro examinations are:

Thickness measurement[16]:

A micrometer screw gauge was used to measure the thickness of the film five times, and an average of three readings was calculated. Maintaining uniformity in the film's thickness is essential because it has a direct impact on the dose's accuracy within the film. The thickness of the film should be less than 5%.

Weight variation[17]

A weight was determined by selecting ten prepared films at random and averaging them. Weighing each film, we compared its weight to the deviation's average. The average weight of the mouth-dissolving oral films was determined for each film using an analytical balance. It is preferable if the weight of films is almost consistent. Making sure a film has the right amount of API and excipients is helpful.

Folding endurance[18]

To test folding endurance, a film is sliced and quickly folded in the same spot until it breaks. The number of times the film could be folded in the same way without breaking is what determines the folding endurance value. The topical folding endurance of the film was 100–150. The total number of folds the film can withstand without breaking is used to calculate the folding endurance value.

Surface pH

After adding 0.5 mL of distilled water to the test film in a Petri dish, it was left to hydrate for 30 seconds. The pH electrode was carefully brought into touch with the film surface to measure the surface pH following another one-minute equilibration interval. Each formulation's pH value was measured three times, and the average result was reported.[19]

Swelling Index (SI)

Film samples (4 x 4 cm) were weighed (W_0) and immersed in PBS (pH 6.8) at 37°C. Films were extracted, blotted, and reweighed (W_t) at specified intervals of 5, 10, 20, 30, and 60 minutes.

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

Increased swelling signifies enhanced hydration capacity and improved medication diffusion.

Moisture Content

Films were measured (W_1) and preserved in a desiccator with silica gel for 24 hours. Subsequently, they were reweighed (W_2).

$$\text{Moisture Content}\ (\%) = \frac{W_1 - W_2}{W_1} \times 100$$

Reduced moisture content signifies diminished microbiological risk and enhanced stability

Moisture Uptake

Films were subjected to a humidity chamber at 75% relative humidity and 25°C for 24 hours, after which they were reweighed.

$$\text{Moisture Uptake}\ (\%) = \frac{W_t - W_0}{W_0} \times 100$$

Increased absorption signifies hygroscopicity, affecting storage stability.

Tensile Strength

The mechanical qualities were evaluated with a texture analyser (TA.XT Plus Stable Micro Systems, UK). Film strips of 4 × 1 cm were secured between clamps. Force was exerted until fracture occurred.

Tensile Strength (TS) was determined as follows:

$$TS = \frac{\text{Force at break (N)}}{\text{Cross-sectional area}}$$

Percentage Elongation

Percentage Elongation was determined as follows:

$$PE\ (\%) = \frac{\text{Increase in length}}{\text{Original length}} \times 100$$

Drug content uniformity

This will be determined by any standard pharmacopoeia that specifies a standard assay protocol for the particular API. Content consistency is determined by analysing the API content in each individual strip. The maximum content is 85–115%.

Antimicrobial Assay (Agar Diffusion Technique)

Antimicrobial efficacy was evaluated against Staphylococcus aureus and Staphylococcus epidermidis, prevalent bacteria associated with wounds. Nutrient agar plates inoculated with freshly created microbial cultures. Film discs with a diameter of 1 cm positioned on the agar surface. For a whole day, the plates were incubated at 37°C. The inhibitory zone (ZOI) was quantified in millimetres utilizing a Vernier caliper. Expanded inhibition zones signified enhanced antibacterial efficacy resulting from clindamycin release.

***In vitro* Dissolution test[20]:**

In-vitro dissolution studies of the clindamycin-loaded polymeric films were conducted utilising a dissolution test apparatus (EI-1916, Electronics India, Pune, India) equipped with a USP type II (paddle) configuration. The appropriately formulated films were immersed in vessels containing 500 mL of pH 6.8 phosphate buffer, maintained at 37 ± 0.5 °C and agitated at 50 rpm. At specified time intervals (5, 10, 15 to 120 minutes), 2 mL samples were extracted and promptly substituted with an equivalent volume of fresh dissolving medium to preserve sink conditions. The obtained samples were examined at 202 nm utilising a UV–Visible spectrophotometer (EI-1372, Electronics India, Pune, India), and the drug concentration was determined from the standard calibration curve and represented as cumulative percentage drug release. All dissolution studies were performed in six replicates, and average values were documented.

Release Kinetics[21]

The findings from the order and mechanism of the drug release kinetics of CLD films were examined using in-vitro diffusion analysis. The kinetic models that were shown included the zero order, first order, and Higuchi equations; the release was calculated using the Korsmeyer-Peppas equations.

Stability Studies

Drug stability denotes a formulation's capacity to maintain its physical, chemical, therapeutic, and toxicological characteristics within acceptable parameters throughout its shelf life. Stability evaluations were conducted in accordance with ICH Q1A criteria under accelerated conditions of 40 °C ± 2 °C and 75% ± 5% relative humidity for a duration of three months. The optimised formulations were strip-packed in aluminium foil, stored under specified conditions, and periodically assessed for appearance, drug content, and in vitro drug release.

RESULTS & DISCUSSION

Calibration of CLD

A calibration curve was established utilising diverse concentrations (5-25 µg/ml) and the appropriate dilution of the stock solution. The absorbance was measured at 202 nm. Figure 1 illustrates the CLD standard curve. The results were compiled in a table. The CLD was calibrated using a pH 6.8 phosphate buffer; linearity was found with 0.9989 R^2 value.

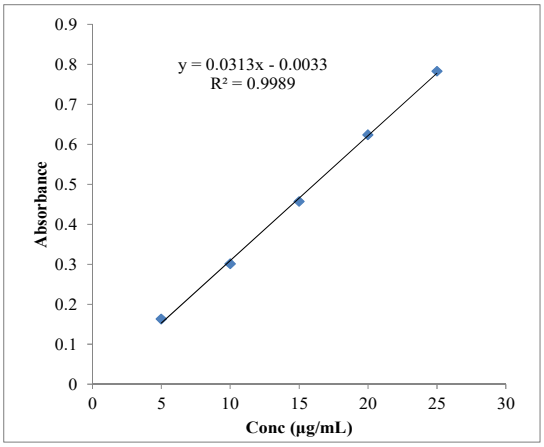

Fig 1: Standard Calibration Curve of CLD in 6.8 pH phosphate buffer

Drug – excipient Compatibility Studies

The compatibility of the drug and excipient was assessed utilising an FTIR spectrometer

(Shimadzu FTIR-8400S, Japan). Physical combinations of clindamycin (CLD) with chitosan and gelatin, as well as pure CLD and the optimised formulation, were examined to identify potential interactions. The absence of notable changes, the disappearance, or emergence of identifiable drug peaks validated the absence of chemical interaction and the compatibility of CLD with the chosen excipients.

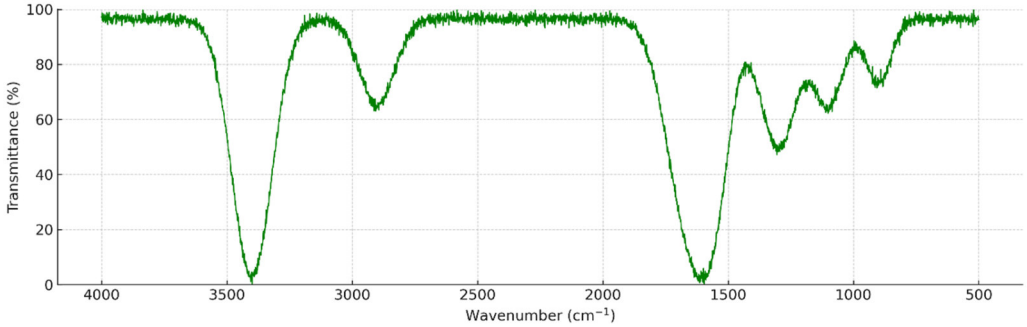

Fig 2: Pure CLD FTIR Spectral Analysis

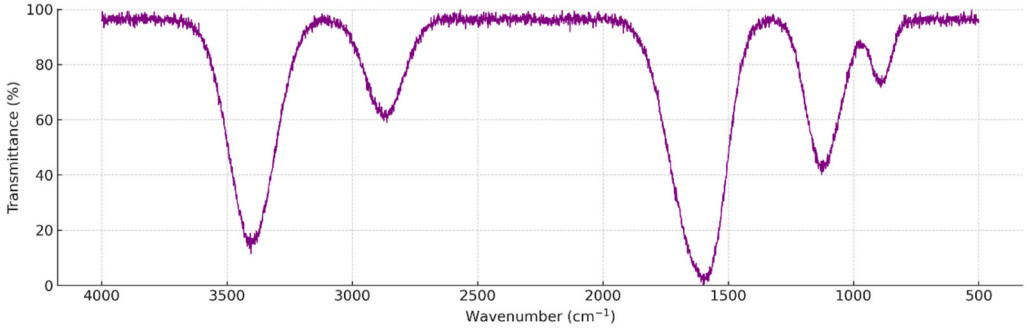

Fig 3: FTIR Spectral analysis of CLD+Chitosan.

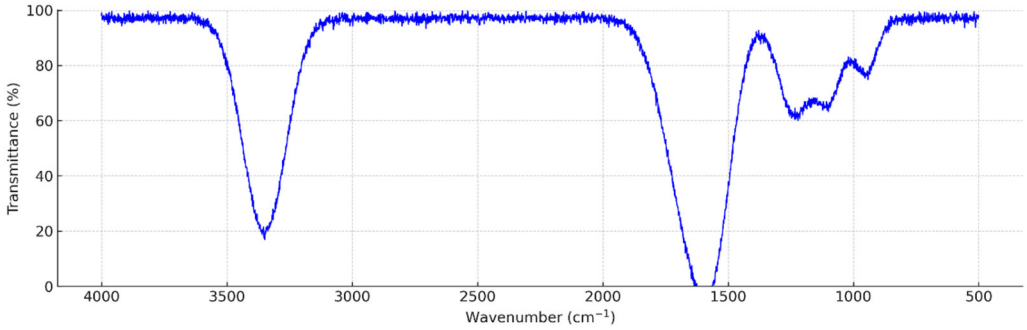

Fig 4: FTIR Spectral analysis of CLD+Gelatin.

The obtained FTIR spectra are superimposed in the Figure 2-4. The FTIR spectra of clindamycin, clindamycin–chitosan, and clindamycin–gelatin exhibit distinct changes that signify the successful integration of the antibiotic into both polymer matrices. Pure clindamycin exhibits characteristic absorption properties, including a large O–H/N–H stretching band about 3400 cm^{-1}, aliphatic C–H stretching in the range of 2920–2850 cm^{-1}, and significant amide peaks at approximately 1650 and 1550 cm^{-1}, alongside fingerprint vibrations between 1100 and 900 cm^{-1}. When combined with chitosan, the O–H/N–H region exhibits broadening and a slight shift, while additional chitosan-specific peaks particularly in the range of 1150–1080 cm^{-1} (C–O–C stretching) and around 890 cm^{-1} become apparent, indicating intermolecular hydrogen bonding and physical interactions without the establishment of new covalent bonds. The clindamycin–gelatin spectrum exhibits enhanced and slightly displaced amide I and amide II peaks, in addition to the emergence of an amide III band

about 1240 cm^{-1}, indicative of gelatin's peptide backbone. The alterations, coupled with slight peak displacements throughout the spectrum, indicate hydrogen bonding and electrostatic interactions between clindamycin and gelatin. The spectrum alterations in both polymer combinations indicate effective drug–polymer connection and strong compatibility, mostly driven by physical interactions.

Thickness

The thickness of clindamycin-loaded films escalated from 142 ± 4.2 μm (F1) to 188 ± 5.9 μm (F5), correlating with the augmented total polymer content (chitosan + gelatin) in the formulations. The regulated thickness is crucial for dose consistency and the mechanical manipulation of the films.

Evaluation of ODF:

Table 2: Determination of Thickness, weight variation, folding endurance, and surface pH of all formulations

F. code	Thickness (μm)	Weight (mg)	Folding Endurance	Surface pH
F1	142 ± 4.2	188 ± 5.8	162 ± 4	5.82 ± 0.12
F2	158 ± 4.8	196 ± 6.0	178 ± 5	5.76 ± 0.11
F3	165 ± 5.1	205 ± 6.5	191 ± 6	5.71 ± 0.10
F4	176 ± 5.4	214 ± 6.8	205 ± 7	5.67 ± 0.13
F5	188 ± 5.9	222 ± 7.0	218 ± 8	5.63 ± 0.14

Weight variation

The film weight exhibited a comparable upward trend, varying from 188±5.8 mg to 222±7.0 mg, indicating a greater solid content in formulations with increased polymer concentration. The standard deviation values (±5.8 to ±7.0 mg) fall within acceptable parameters, indicating commendable consistency of casting volume and solids distribution. This consistency in weight facilitates homogeneous medication loading per unit film.

Folding Endurance:

The folding endurance rose from 162 ± 4 (F1) to 218 ± 8 (F5), signifying that the films exhibited enhanced flexibility and resistance to mechanical stress with an increase in gelatin content. All formulations demonstrated values over 150 folds, which is often regarded as acceptable for film dressings. The standard deviation values (±4 to ±8) indicate consistent mechanical performance among duplicates, with F4 and F5 demonstrating superior flexibility and durability for application on wound surfaces.

Surface pH of Films:

The surface pH readings progressively diminished from 5.82 ± 0.12 (F1) to 5.63 ± 0.14 (F5), consistently remaining within the somewhat acidic spectrum of the normal skin pH (~5.5). This is advantageous to reduce the likelihood of irritation and to maintain the natural acidity barrier of the skin. The minimal standard deviation values (±0.10–0.14) signify consistent and reproducible surface properties. All formulations demonstrate a skin-compatible pH appropriate for localized wound application.

Table 3: Hydration and Moisture Parameters

F. code	Moisture Content (%)	Moisture Uptake (%)	Swelling Index (%)
F1	7.2 ± 0.3	18.5 ± 0.9	112 ± 4.5
F2	6.8 ± 0.2	20.1 ± 0.8	135 ± 5.2
F3	6.4 ± 0.2	22.4 ± 1.0	158 ± 6.1
F4	6.1 ± 0.3	24.9 ± 1.1	176 ± 6.8
F5	5.9 ± 0.2	27.3 ± 1.2	193 ± 7.4

Moisture Content (%)

The moisture content diminished progressively from 7.2 ± 0.3% (F1) to 5.9 ± 0.2% (F5), suggesting that elevated polymer contents, particularly gelatin and chitosan, improved film density and decreased free water retention. The minimal standard deviation values (±0.2–0.3%)

indicate a high degree of homogeneity among replicates. Reduced moisture content enhances stability and inhibits microbiological proliferation, a crucial characteristic for wound dressing films.

Moisture Absorption (%)

Moisture absorption progressively escalated from 18.5 ± 0.9% (F1) to 27.3 ± 1.2% (F5), indicating enhanced hygroscopic properties at elevated polymer concentrations. This is due to the hydrophilic characteristics of both chitosan and gelatin, which improve interaction with ambient moisture. The standard deviation values (±0.8–1.2%) indicate acceptable variability. Increased moisture absorption enhances film flexibility during storage, although it must be regulated to avoid tackiness; all measurements stayed below the permissible limits.

Swelling Index (%)

The swelling index demonstrated a significant rise from 112 ± 4.5% (F1) to 193 ± 7.4% (F5). The increased swelling capacity in films with higher polymer content results from improved hydration of hydrophilic chains and enhanced water infiltration into the polymer matrix. This activity is beneficial for wound healing, as swelling enhances medication diffusion and preserves a moist environment at the wound site. The standard deviation results (±4.5–7.4%) indicate consistent hydration habits.

Table 4: Findings of Mechanical Properties, Drug Content of Films and Antimicrobial Assay (ZOI)

F. code	Tensile Strength (MPa)	% Elongation	Drug Content (%)	ZOI (mm)
F1	12.8 ± 0.4	21.6 ± 1.0	96.2 ± 2.8	17.2 ± 0.7
F2	13.9 ± 0.5	24.3 ± 1.1	97.5 ± 2.5	19.3 ± 0.8
F3	14.6 ± 0.6	28.5 ± 1.3	98.4 ± 2.2	21.6 ± 0.9
F4	15.2 ± 0.6	32.1 ± 1.4	98.9 ± 2.0	24.1 ± 1.0
F5	15.8 ± 0.7	35.7 ± 1.6	99.3 ± 1.8	26.4 ± 1.2

Tensile Strength (MPa)

Tensile strength rose from 12.8 ± 0.4 MPa (F1) to 15.8 ± 0.7 MPa (F5), demonstrating that elevated concentrations of biodegradable polymers substantially improved the mechanical properties of the films. More robust films exhibit a reduced propensity to tear during manipulation and application. The standard deviation values (±0.4–0.7) indicate minimal variability and validate the consistency of mechanical performance.

Percentage Elongation

Elongation values rose from 21.6 ± 1.0% (F1) to 35.7 ± 1.6% (F5). This trend indicates enhanced flexibility and elasticity with rising polymer content, particularly gelatin/chitosan, which enhances stretch ability. Films F4 and F5 demonstrated optimal flexibility necessary for wound application, where adherence to uneven surfaces is crucial.

Drug Content

The drug content varied from 96.2 ± 2.8% to 99.3 ± 1.8%, indicating superior drug loading efficiency and consistent drug distribution throughout all formulations. Minor decreases in standard deviation readings with increased polymer content (2.8 → 1.8%) indicate enhanced homogeneity of clindamycin inside the polymer matrix. All films adhered to satisfactory requirements for dosage homogeneity.

Antimicrobial Efficacy (Zone of Inhibition, mm)

The antimicrobial efficacy significantly increased from 17.2 ± 0.7 mm (F1) to 26.4 ± 1.2 mm (F5) against Staphylococcus aureus. This indicates improved clindamycin diffusion from denser, more hydrated polymer matrices. The increased swelling and moisture absorption in F4 and F5 presumably enhanced the lateral diffusion of the medication into the agar media. Standard deviation results (±0.7–1.2 mm) demonstrate reliable antibacterial efficacy across repetitions.

In-vitro dissolution

For F1 through F5, the percentage cumulative drug release is shown in Figure 5. Utilizing a Type II USP paddle apparatus, the in vitro dissolution investigations were conducted in phosphate

buffer with a 6.8 pH. The in-vitro dissolution results indicated a progressive and regulated release of clindamycin from all polymeric films over 120 minutes. Formulation F1 exhibited a release of 18.9% at 15 minutes and attained 87.4% at 120 minutes, demonstrating the slowest release among all batches attributable to reduced polymer content and restricted swelling. Conversely, formulation F5 exhibited the most rapid and comprehensive release, commencing at 31.4% after 15 minutes and reaching 99.1% at 120 minutes. The improved release behaviour is due to the increased concentration of hydrophilic polymers, which enhances water absorption, film hydration, and drug diffusion inside the swelling matrix.

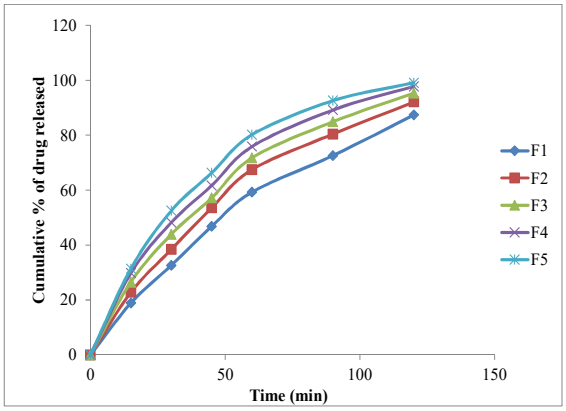

Fig 5: In vitro dissolution studies of Clindamycin formulations (F1-F5)

Release Rate Kinetics Application to Dissolution Data:

A variety of models were used to study drug release kinetics. A number of release models, including first-order, zero-order, Higuchi, and Korsmeyer-Peppas, were fitted to the acquired data in order to investigate the mechanism of the dosage form's drug release rate kinetics. The results were showed in figure 6-9.

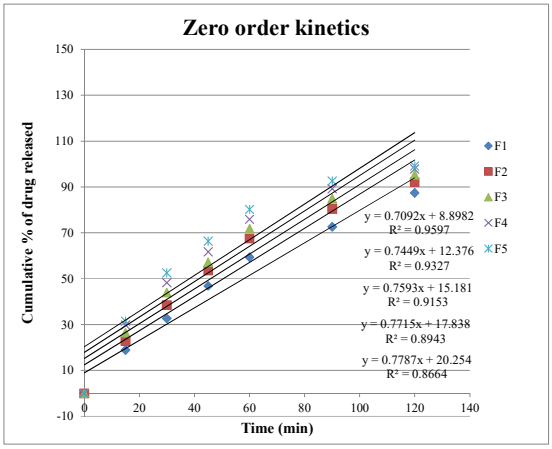

Fig 6: Zero order release kinetics graph of CLD formulations (F1-F5)

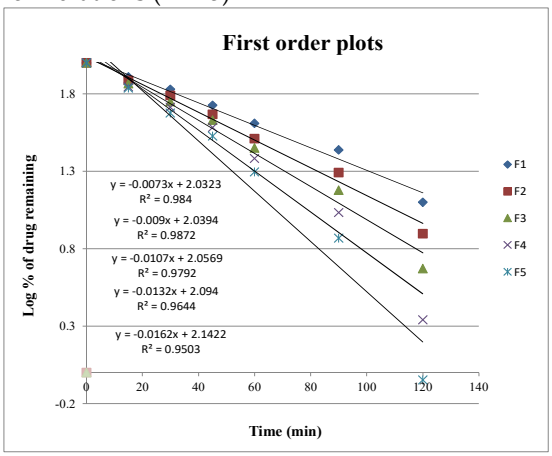

Fig 7: First order release kinetics graph of CLD formulations (F1-F5)

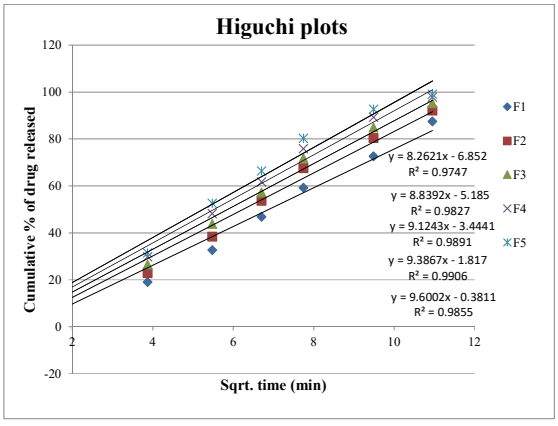

Fig 8: Higuchi release kinetics graph of CLD formulations (F1-F5)

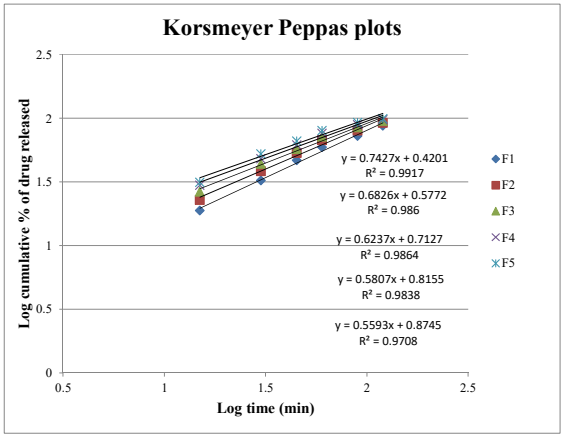

Fig 9: Korsmeyer-Peppas graph of CLD formulations (F1-F5)

Formulation F1 exhibited a release of 18.9% at 15 minutes and attained 87.4% at 120 minutes, signifying the slowest release across all batches due to reduced polymer concentration and constrained swelling. Conversely, formulation F5 exhibited the most rapid and comprehensive release, initiating at 31.4% after 15 minutes and reaching 99.1% at 120 minutes. The improved release behaviour is due to the increased concentration of hydrophilic polymers, which enhances water absorption, film hydration, and drug diffusion inside the expanded matrix. The release trend was consistent across all formulations throughout the investigation. F5 precedes F4, which precedes F3, followed by F2, and finally F1. This verifies that elevated polymer concentrations, particularly natural hydrophilic polymers such as gelatin or chitosan, facilitate accelerated erosion and swelling, thereby improving clindamycin diffusion. F5 demonstrated the most efficient release profile, consistent with its higher swelling index and mechanical properties noted in previous assessments.

Selection of best formulation:

Following a comprehensive assessment of mechanical strength, moisture behaviour, swelling capacity, drug content, antibacterial activity, and in-vitro release, formulation F5 was identified as the optimal batch. F5 exhibited the greatest tensile strength (15.8 ± 0.7 MPa), maximum elongation (35.7 ± 1.6%), and an exceptional swelling index (193 ± 7.4%), characteristics vital for creating a moist, hydrated wound environment that promotes healing. The results indicated exceptional drug loading (99.3 ± 1.8%) and the most extensive antibacterial zone (26.4 ± 1.2 mm) against Staphylococcus aureus, hence affirming robust therapeutic efficacy. Moreover, its disintegration profile was exemplary, with 99.1% cumulative release at 120 minutes. The amalgamation of these attributes substantiates F5 as the most efficacious and stable formulation for the regulated delivery of clindamycin in wound healing applications.

Stability Studies:

According to ICH recommendations, stability studies were carried out to assess the drug formulation's stability. The optimized F5 formulation was packaged in aluminum with a polyethylene laminate. The samples were kept at 40°C and 75% relative humidity for three months. The optimized film (F5) exhibited physical stability for 90 days, demonstrating no signs of cracking, discolouration, or brittleness. The drug content exhibited a slight decrease from 99.3% to 97.2%, although remained within acceptable pharmacopeia standards, signifying exceptional chemical stability. Tensile strength demonstrated a slight reduction (15.8 → 15.1 MPa), affirming maintained mechanical integrity under stress settings. The stability data demonstrate that the improved formulation preserves its structural and therapeutic efficacy throughout storage.

CONCLUSION

Clindamycin-embedded biodegradable polymeric films were effectively developed utilising natural polymer composites and demonstrated favourable physicochemical, mechanical, and therapeutic characteristics appropriate for wound healing applications. All formulations exhibited uniform film properties, satisfactory hydration performance, and a skin-compatible surface pH. Among the developed formulations, F5 emerged as the optimised batch, demonstrating greater flexibility, swelling capacity, sustained drug release, and higher antibacterial effectiveness against Staphylococcus aureus. The release of the drug adhered to diffusion-controlled kinetics, facilitating extended localised treatment. The stability investigations further validated the resilience of the optimised formulation under accelerated settings. These findings suggest the viability of biodegradable polymeric films as an efficient, patient-friendly alternative for localised clindamycin administration in wound treatment.

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