DEVELOPMENT AND EVALUATION OF AN ACECLOFENAC-LOADED BIGEL SYSTEM FOR ENHANCED TOPICAL DELIVERY IN THE MANAGEMENT OF ARTHRITIC CONDITIONS

Alok Tiwari, Malti Arya

Chandra Shekhar Singh College of Pharmacy, Kaushambi

Abstract

The present study was aimed at the development and evaluation of an Aceclofenac-loaded bigel system for enhanced topical delivery in the management of arthritic conditions. Aceclofenac, a non-steroidal anti-inflammatory drug with limited aqueous solubility, was incorporated into a biphasic bigel system combining the advantages of both hydrogel and organogel networks to improve drug solubilization, stability, and topical performance. Preformulation studies including organoleptic evaluation, solubility analysis, melting point determination, partition coefficient determination, and FTIR compatibility studies were carried out to assess the suitability of the drug for formulation development. Various bigel formulations (B1–B10) were prepared using different hydrogel-to-organogel ratios and evaluated for physical appearance, homogeneity, pH, viscosity, spreadability, extrudability, drug content, in vitro drug release, and stability. The formulations exhibited acceptable physicochemical properties and good compatibility between the drug and excipients. Among the developed formulations, B5 demonstrated optimal characteristics with excellent physical stability, skin-compatible pH (6.10 ± 0.04), suitable viscosity (16050 ± 270 cP), satisfactory spreadability (18.1 ± 0.5 g·cm/sec), good extrudability (0.190 ± 0.006 g/sec), and high drug content (100.2 ± 0.6%). In vitro drug release studies showed sustained release behaviour, while stability studies conducted according to ICH guidelines confirmed the robustness and shelf-life stability of the optimized formulation. The results suggest that the Aceclofenac-loaded bigel system is a promising topical drug delivery platform for improving therapeutic efficacy and patient compliance in the treatment of arthritic conditions.

Keywords: *Aceclofenac, Bigel, Organogel, Hydrogel, Topical Drug Delivery, Arthritis, In Vitro Drug Release, Stability Studies.*

Corresponding Author

Alok Tiwari

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1. Introduction

Arthritis is a chronic inflammatory and degenerative joint disorder characterized by pain, swelling, stiffness, and progressive loss of joint function. It is a major cause of disability worldwide, significantly affecting mobility and quality of life. Osteoarthritis and rheumatoid arthritis are the most common forms of arthritis, and their prevalence continues to increase due to aging populations and lifestyle-related factors. The chronic nature of these conditions often requires long-term pharmacological management to control inflammation and alleviate pain (Hunter & Bierma-Zeinstra, 2019; Safiri et al., 2020).

Non-steroidal anti-inflammatory drugs (NSAIDs) are widely used in the treatment of arthritis because of their ability to inhibit cyclooxygenase enzymes and reduce prostaglandin-mediated inflammation. Aceclofenac, a phenylacetic acid derivative NSAID, possesses potent anti-inflammatory and analgesic activity with relatively improved gastrointestinal tolerability. However, its poor aqueous solubility and extensive first-pass metabolism may limit its therapeutic effectiveness following oral administration (Brogden & Wiseman, 1996; Hinz & Brune, 2002).

Topical drug delivery systems have emerged as an effective alternative to oral therapy by providing localized drug action, reducing systemic side effects, and improving patient compliance. However, successful topical delivery is often limited by the barrier properties of the stratum corneum, particularly for poorly water-soluble drugs such as Aceclofenac (Prausnitz & Langer, 2008; Benson, 2005).

Bigels are biphasic semisolid systems composed of hydrogel and organogel networks that combine the advantages of both aqueous and lipidic phases. They offer improved drug solubilization, enhanced stability, controlled drug release, favorable rheological properties, and better patient acceptability. Owing to these benefits, bigels have gained considerable attention as promising carriers for topical and transdermal drug delivery of lipophilic drugs (Singh et al., 2014; Bansal et al., 2021). Studies have also demonstrated their potential to enhance skin permeation and sustain drug release, making them suitable for the treatment of inflammatory conditions (Amin, Das, & Ali, 2022; Shakeel et al., 2019).

Therefore, the present study aimed to develop and evaluate an Aceclofenac-loaded bigel system for enhanced topical delivery in the management of arthritic conditions. The formulations were assessed for physicochemical properties, rheological behavior, drug

content, in vitro drug release, and stability to identify an optimized formulation with improved therapeutic performance.

2. Methodology

2.1 Collection and Authentication of Materials

Aceclofenac and all excipients required for the formulation of the bigel were procured from certified pharmaceutical suppliers and were of pharmaceutical grade. The materials were selected based on their suitability, safety, and compatibility for topical application and were stored under appropriate conditions to maintain their quality. Prior to formulation development, the identity of Aceclofenac was confirmed through melting point determination and FTIR spectroscopy by comparing the obtained results with standard reference values. Additionally, all excipients were evaluated for their physical appearance, purity, and compliance with pharmaceutical standards. Drug–excipient compatibility studies were performed using FTIR spectroscopy to ensure the absence of significant physicochemical interactions that could affect the stability, efficacy, or performance of the developed bigel formulation.

2.2 Preformulation Studies

2.2.1 Organoleptic Evaluation

The organoleptic evaluation of Aceclofenac was carried out to assess its physical characteristics and confirm its identity. The drug was examined for appearance, color, physical nature, and odor under normal laboratory conditions. The observed characteristics were compared with standard descriptions to verify the quality and suitability of the drug for further formulation studies.

2.2.2 Solubility Analysis

The solubility of Aceclofenac was evaluated in various aqueous and lipid media to support the development of the bigel formulation. Excess drug was added to different solvents, agitated until equilibrium was reached, and the dissolved drug content was determined after filtration. The study showed low solubility in aqueous media and higher solubility in lipid-based systems, providing guidance for the selection of suitable formulation components.

2.2.3 Melting Point Determination

The melting point of Aceclofenac was determined to confirm its identity and purity. A small quantity of the powdered drug was filled into a capillary tube and analyzed using a melting point apparatus. The temperature range at which the drug melted was recorded and

compared with the reported standard value. The results helped verify the purity and suitability of Aceclofenac for further formulation development.

2.2.4 Partition Coefficient Determination

The partition coefficient of Aceclofenac was determined using the shake flask method with an n-octanol–water system to evaluate its lipophilicity and potential for topical delivery. The drug was allowed to distribute between the two phases until equilibrium was achieved, and the concentration in each phase was analyzed using UV spectrophotometry. The partition coefficient was calculated as the ratio of drug concentration in the octanol phase to that in the aqueous phase, providing information useful for formulation design and skin permeation assessment.

2.2.5 Drug–Excipient Compatibility Studies

Drug–excipient compatibility studies were carried out using FTIR spectroscopy to evaluate potential interactions between Aceclofenac and the selected excipients. FTIR spectra of the pure drug, excipients, and their physical mixtures were recorded and compared for any significant changes in characteristic peaks. The absence of notable peak shifts or disappearance of functional group peaks indicated good compatibility between Aceclofenac and the formulation excipients, confirming their suitability for bigel development.

2.3 Selection of Formulation Components

2.3.1 Selection of Organogel Phase

The organogel phase was selected by screening different oils and organogelators based on their drug solubilizing capacity, biocompatibility, stability, and suitability for topical application. The selected components were evaluated for their ability to form a stable, homogeneous gel with desirable viscosity and texture. The optimized oil–organogelator combination was chosen for further development of the Aceclofenac-loaded bigel formulation.

2.3.2 Selection of Hydrogel Phase

The hydrogel phase was developed by evaluating hydrophilic polymers such as Carbopol and HPMC for their gel-forming ability, viscosity, stability, and compatibility with the formulation. The polymers were assessed for parameters including homogeneity, pH compatibility, spreadability, and rheological properties. Based on these evaluations, the most suitable polymer system was selected to obtain a stable hydrogel phase for incorporation into the Aceclofenac-loaded bigel formulation.

2.3.3 Selection of Surfactants and Co-surfactants

The selection of surfactants and co-surfactants was carried out to obtain a stable and homogeneous bigel system with improved drug solubilization and dispersion. Various non-ionic surfactants and co-surfactants were evaluated based on their emulsification efficiency, compatibility, stability, and suitability for topical application. The optimized combination was selected on the basis of its ability to form a stable system with minimal phase separation and favorable physicochemical properties, thereby supporting effective delivery of Aceclofenac.

2.4 Formulation Development of Bigel

2.4.1 Preparation of Organogel

The organogel was prepared by heating the selected oil phase and gradually adding the optimized concentration of organogelator under continuous stirring until a clear and homogeneous solution was obtained. The mixture was then allowed to cool to room temperature to form a stable gel network. Aceclofenac was incorporated into the organogel with continuous stirring to ensure uniform drug distribution. The prepared organogel was examined for homogeneity, consistency, and stability before its incorporation into the bigel formulation.

2.4.2 Preparation of Hydrogel

The hydrogel phase was prepared by gradually dispersing the selected polymer (Carbopol and/or HPMC) in distilled water under continuous stirring to ensure uniform hydration and prevent lump formation. The dispersion was allowed to swell completely, and in the case of Carbopol, neutralization was carried out using a suitable agent to facilitate gel formation and adjust the pH to a skin-compatible range. The resulting hydrogel was stirred until a smooth, homogeneous gel was obtained and was evaluated for clarity, consistency, and uniformity before incorporation into the bigel formulation.

2.4.3 Preparation of Aceclofenac-Loaded Bigel

The Aceclofenac-loaded bigel was prepared by blending the optimized organogel and hydrogel phases in different proportions under continuous stirring to obtain a homogeneous biphasic gel system. Aceclofenac was uniformly incorporated into the organogel phase prior to mixing. Various formulations (B1–B10) were developed by altering the hydrogel-to-organogel ratio and were mixed until a smooth, stable, and uniform bigel was formed. The prepared formulations were evaluated for homogeneity, consistency, and stability to identify the optimized formulation.

2.4.4 Optimization of Formulation

The Aceclofenac-loaded bigel formulations (B1–B10) were optimized by evaluating different hydrogel-to-organogel ratios for their physical appearance, homogeneity, phase stability, spreadability, viscosity, and overall consistency. Formulations showing phase separation or poor physical characteristics were excluded. Based on comparative assessment, the formulation exhibiting optimum stability, desirable rheological properties, and uniform drug distribution was selected as the optimized bigel for further evaluation studies.

Table 1: Composition of Aceclofenac-Loaded Bigel Formulations (B1–B10)

Formulation Code	Hydrogel Phase (%)	Organogel Phase (%)	Description
B1	90	10	High hydrogel content
B2	85	15	High hydrogel content
B3	80	20	Predominantly hydrogel
B4	75	25	Hydrogel rich system
B5	70	30	Balanced hydrogel dominant
B6	60	40	Intermediate ratio
B7	50	50	Equal biphasic system
B8	40	60	Organogel dominant
B9	30	70	High organogel content
B10	20	80	Highly organogel rich system

2.5 Evaluation of Bigel Formulations

2.5.1 Physical Evaluation

The prepared Aceclofenac-loaded bigel formulations (B1–B10) were evaluated for physical appearance, color, texture, consistency, homogeneity, and phase stability. The formulations were visually inspected for smoothness, uniformity, and the absence of grittiness, lumps, or particulate matter. Homogeneity was assessed by observing the uniform distribution of the gel matrix, while phase stability was evaluated by monitoring for any signs of syneresis, oil leakage, or phase separation during storage. Formulations exhibiting desirable physical characteristics were selected for further evaluation.

2.5.2 pH Determination

The pH of the Aceclofenac-loaded bigel formulations (B1–B10) was determined using a calibrated digital pH meter to ensure skin compatibility. A small quantity of each formulation was dispersed in distilled water, and the pH was measured after stabilization of the reading. All measurements were performed in triplicate, and the average values were

recorded. Formulations exhibiting pH within the acceptable skin-compatible range were considered suitable for topical application.

2.5.3 Viscosity Measurement

The viscosity of the Aceclofenac-loaded bigel formulations (B1–B10) was measured using a Brookfield viscometer at controlled temperature conditions. An appropriate spindle was immersed in each formulation, and viscosity readings were recorded at selected rotational speeds after stabilization. The measurements were performed in triplicate, and the average values were calculated. The viscosity data were used to assess the rheological behavior, consistency, and suitability of the formulations for topical application, and to identify the optimized bigel formulation.

2.5.4 Spreadability

The spreadability of the Aceclofenac-loaded bigel formulations (B1–B10) was evaluated using the slip and drag method to assess their ease of application. A fixed amount of formulation was placed between two glass slides, and the time required for the upper slide to move a specified distance under an applied weight was recorded. Spreadability was calculated using the formula:

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

where *S* is spreadability, *M* is the applied weight, *L* is the distance moved by the slide, and *T* is the time taken. The test was performed in triplicate, and the average values were recorded to identify formulations with suitable spreading characteristics for topical application.

2.5.5 Extrudability

The extrudability of the Aceclofenac-loaded bigel formulations (B1–B10) was evaluated to assess the ease of dispensing the formulation from collapsible tubes. A known quantity of each formulation was filled into aluminum tubes and subjected to a fixed load, and the amount of gel extruded within a specified time was recorded. The test was performed in triplicate, and the average values were calculated. Formulations showing smooth and uniform extrusion with minimal force were considered to possess good extrudability and suitable patient acceptability for topical application.

2.5.6 Drug Content Analysis

The drug content of the Aceclofenac-loaded bigel formulations (B1–B10) was determined to evaluate the uniformity of drug distribution within the formulation. An accurately weighed quantity of each formulation was dissolved in a suitable solvent, followed by stirring, sonication, and filtration to ensure complete drug extraction. The drug concentration was then measured using UV spectrophotometry at the predetermined wavelength of

Aceclofenac. The analysis was performed in triplicate, and the average drug content was calculated. Formulations containing drug content within the acceptable range were considered to possess uniform drug distribution and satisfactory dose consistency.

2.6 In Vitro Drug Release Study

The in vitro drug release of Aceclofenac-loaded bigel formulations (B1–B10) was evaluated using a Franz diffusion cell apparatus. A suitable hydrated membrane was mounted between the donor and receptor compartments, and phosphate buffer (pH 7.4) maintained at 37 ± 0.5°C was used as the diffusion medium. A known quantity of each formulation was placed in the donor compartment, and samples were withdrawn from the receptor compartment at predetermined intervals and analyzed using UV spectrophotometry. The cumulative percentage drug release was calculated and plotted against time to compare the release profiles of different formulations and identify the optimized bigel formulation with desirable release characteristics.

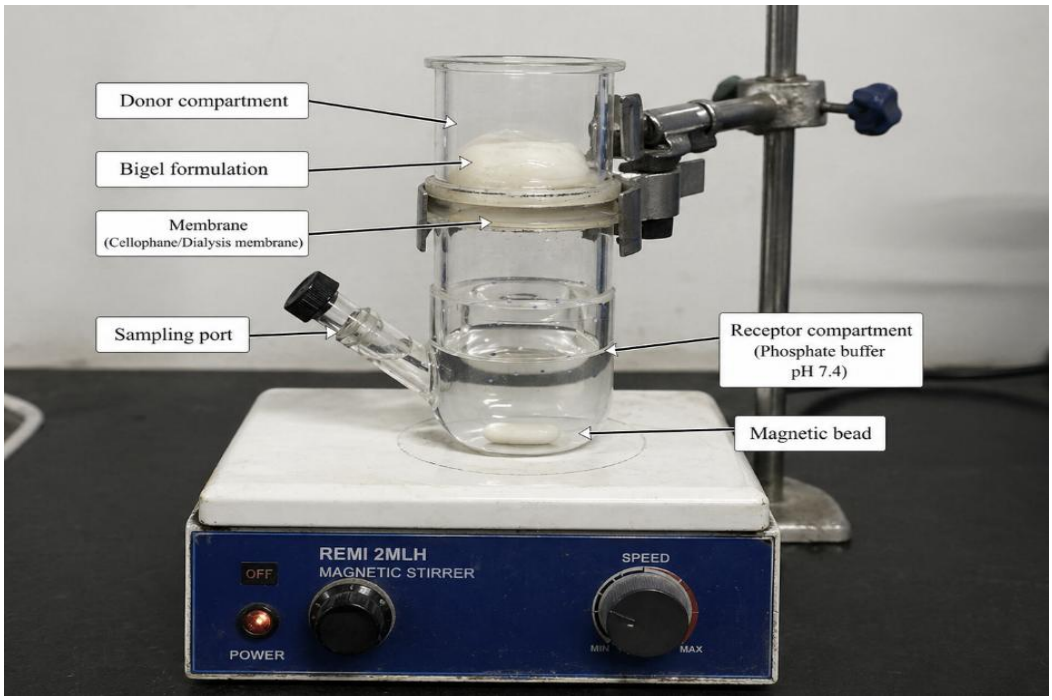

Fig 1: Schematic diagram of Franz diffusion cell used for in vitro drug release

2.7 Stability Studies as per ICH Guidelines

The stability of the optimized Aceclofenac-loaded bigel formulation was evaluated according to ICH guidelines under accelerated (40 ± 2°C/75 ± 5% RH) and long-term (25 ± 2°C/60 ± 5% RH) storage conditions. Samples were analyzed at predetermined intervals for physical appearance, homogeneity, phase separation, pH, viscosity, and drug content. The study was conducted to assess the formulation's stability and ensure that no significant changes occurred in its physicochemical properties or drug content during the storage

period.

3. Results

3.1 Preformulation Studies

3.1.1 Organoleptic Evaluation

The organoleptic evaluation of Aceclofenac revealed that the drug was a white to off-white crystalline powder with a uniform and free-flowing appearance. The sample was found to be odorless and showed no signs of contamination, discoloration, or other physical abnormalities. The observed characteristics were consistent with standard reported descriptions of Aceclofenac, confirming its identity, purity, and suitability for further formulation studies.

Table 2: Organoleptic Characteristics of Aceclofenac

S. No.	Parameter	Observation
1	Appearance	Crystalline powder
2	Color	White to off-white
3	Odor	Odorless
4	Physical nature	Free-flowing crystalline powder

3.1.2 Solubility Analysis

The solubility study revealed that Aceclofenac possesses poor aqueous solubility, exhibiting solubility values of 0.025 ± 0.004 mg/mL in distilled water, 0.041 ± 0.006 mg/mL in phosphate buffer (pH 5.5), and 0.056 ± 0.005 mg/mL in phosphate buffer (pH 7.4). In contrast, the drug showed significantly higher solubility in lipidic vehicles, with the highest solubility observed in isopropyl myristate (2.35 ± 0.15 mg/mL), followed by caprylic/capric triglyceride (2.01 ± 0.10 mg/mL) and olive oil (1.82 ± 0.12 mg/mL). These findings confirmed the lipophilic nature of Aceclofenac and supported the selection of a lipid-rich organogel phase for effective incorporation into the bigel formulation.

Table 4: Solubility of Aceclofenac in Different Solvent Systems

S. No.	Solvent System	Solubility (mg/mL)	Observation
1	Distilled Water	0.025 ± 0.004 mg/mL	Very poor solubility

2	Phosphate buffer pH 5.5	0.041 ± 0.006 mg/mL	Slight increase vs water
3	Phosphate buffer pH 7.4	0.056 ± 0.005 mg/mL	Marginal improvement
4	Olive oil	1.82 ± 0.12 mg/mL	High solubility
5	Isopropyl myristate	2.35 ± 0.15 mg/mL	Very high solubility
6	Caprylic/capric triglyceride	2.01 ± 0.10 mg/mL	Good solubility

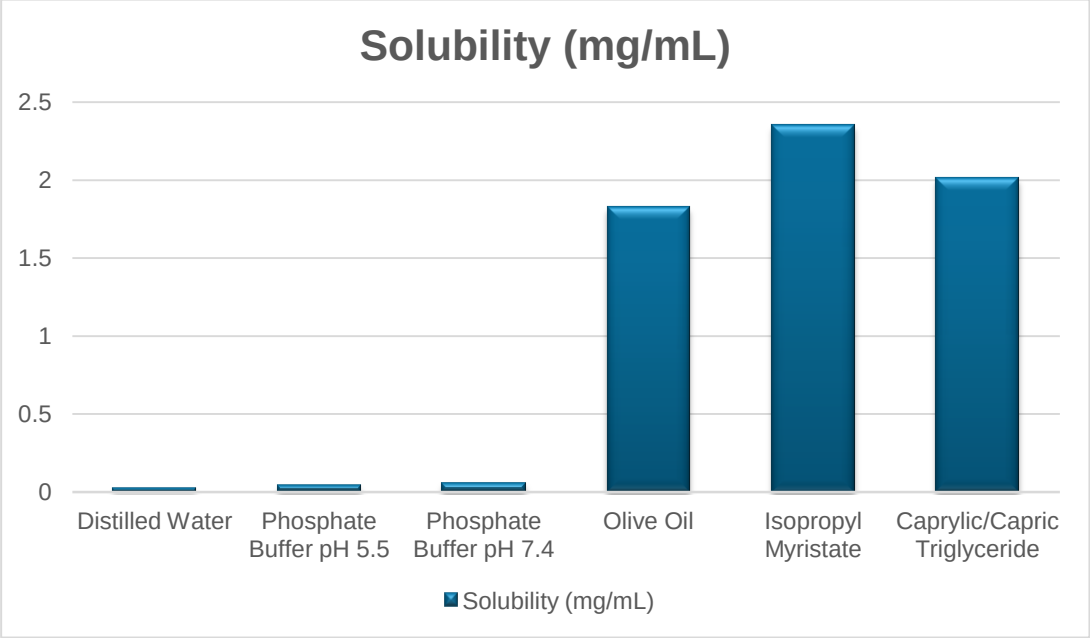

Fig 2: Solubility

3.1.3 Melting Point Determination

The melting point of Aceclofenac was determined using the capillary tube method and was found to be **150.2–151.8°C**. This value was in close agreement with the reported pharmacopoeial melting point range of **149–152°C**, confirming the identity and purity of the drug. The narrow melting range indicated the crystalline nature of Aceclofenac and suggested the absence of significant impurities, demonstrating its suitability for further formulation development.

Table 5: Melting Point of Aceclofenac

S. No.	Parameter	Observed Value (°C)

1	Melting point range	150.2 – 151.8 °C

3.1.4 Partition Coefficient Determination

The partition coefficient of Aceclofenac was determined using the n-octanol–water shake flask method. The drug concentration was found to be 3.42 ± 0.18 mg/mL in the n-octanol phase and 0.18 ± 0.02 mg/mL in the aqueous phase. The calculated partition coefficient (K) was 18.99 ± 1.12, corresponding to a log P value of 1.27 ± 0.05, indicating moderate lipophilicity of the drug. These results confirmed the affinity of Aceclofenac for lipid media and supported its incorporation into the organogel phase for enhanced topical delivery and skin permeation.

Table 6: Partition Coefficient of Aceclofenac (n-Octanol/Water System)

S. No.	Parameter	Observed Value
1	Concentration in n-octanol phase	3.42 ± 0.18 mg/mL
2	Concentration in aqueous phase	0.18 ± 0.02 mg/mL
3	Partition coefficient (K)	18.99 ± 1.12
4	log P value	1.27 ± 0.05

3.1.5 Drug–Excipient Compatibility Studies

Drug–excipient compatibility was evaluated using FTIR spectroscopy. The FTIR spectrum of pure Aceclofenac exhibited characteristic peaks at 3448 cm^{-1} (O–H stretching), 2932 cm^{-1} (C–H stretching), 1736 cm^{-1} (C=O stretching), 1582 cm^{-1} (aromatic C=C stretching), 1242 cm^{-1} (C–N stretching), and 1022 cm^{-1} (C–O stretching). The physical mixture of Aceclofenac with selected excipients retained all characteristic peaks with only minor, non-significant shifts and showed no appearance or disappearance of peaks. These findings indicate the absence of any significant drug–excipient interaction, confirming the compatibility of Aceclofenac with the selected formulation components for bigel development.

Table 7: FTIR Peak Analysis of Aceclofenac and Drug–Excipient Mixture

S. No.	Functional Group	Characteristic Peak (cm^{-1}) – Pure Drug	Peak in Physical Mixture (cm^{-1})	Observation
1	O–H stretching	3448 cm^{-1}	3446 cm^{-1}	No significant shift
2	C–H stretching (aromatic/aliphatic)	2932 cm^{-1}	2930 cm^{-1}	No change

3	C=O stretching	1736 cm^{-1}	1735 cm^{-1}	Retained intensity
4	C=C aromatic stretching	1582 cm^{-1}	1580 cm^{-1}	No shift observed
5	C–N stretching	1242 cm^{-1}	1240 cm^{-1}	No interaction
6	C–O stretching	1022 cm^{-1}	1020 cm^{-1}	Stable peak position

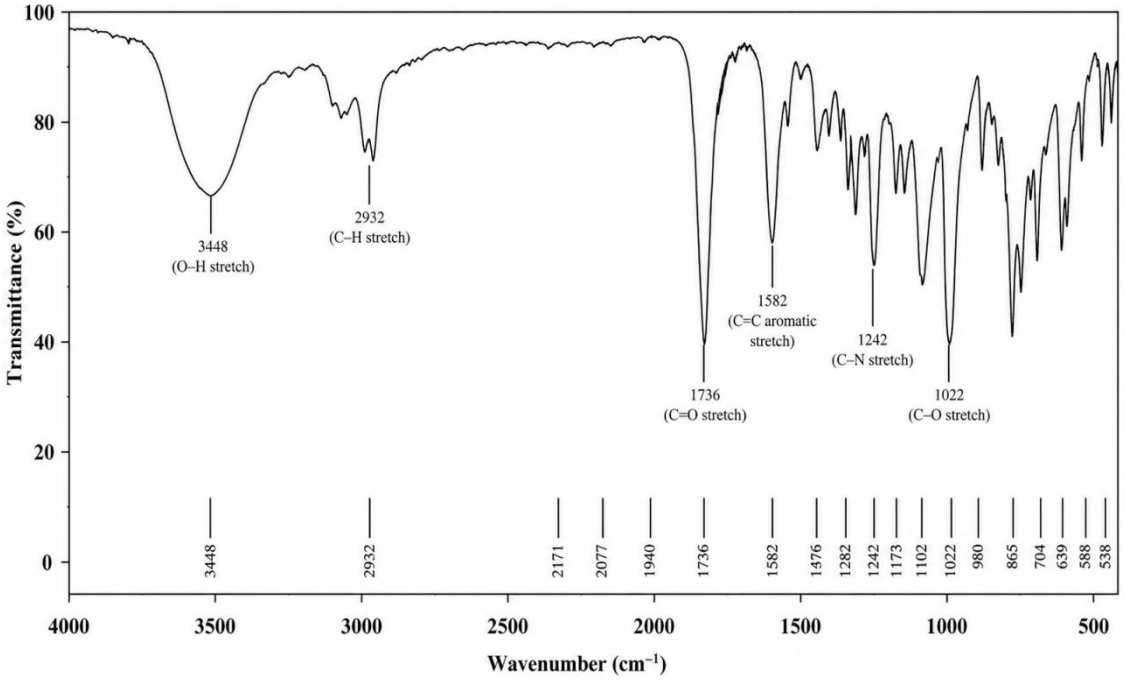

Fig 3: Ftir spectra of Aceclofenac

3.2 Evaluation of Bigel Formulations

3.2.1 Physical Evaluation

The physical evaluation of Aceclofenac-loaded bigel formulations (B1–B10) showed that all formulations possessed a white to slightly opaque appearance with semisolid consistency. Formulations B3, B4, B5, and B7 exhibited excellent homogeneity, smooth texture, and uniform drug distribution without any lumps or grittiness. No signs of syneresis, oil leakage, or phase separation were observed in formulations B1–B7, indicating good physical stability. In contrast, formulations B8–B10 showed varying degrees of instability, with B10 exhibiting noticeable phase separation. Based on appearance, homogeneity, and stability, B5 and B7 were identified as the most promising formulations for further evaluation.

Table 8: Physical Evaluation of Aceclofenac-Loaded Bigel Formulations (B1–B10)

S. No.	Formulation Code	Appearance	Texture	Homogeneity	Phase Separation	Overall Observation

1	B1	White, opaque	Soft	Good	Absent	Stable
2	B2	White, smooth	Semi-solid	Good	Absent	Stable
3	B3	White, uniform	Smooth	Very good	Absent	Stable
4	B4	White, glossy	Smooth	Very good	Absent	Stable
5	B5	White, creamy	Smooth	Excellent	Absent	Highly stable
6	B6	White, uniform	Moderate	Good	Slight syneresis	Moderately stable
7	B7	White, homogeneous	Smooth gel	Excellent	Absent	Highly stable
8	B8	Slightly opaque	Oily touch	Good	Minimal oil separation	Moderately stable
9	B9	Opaque	Greasy	Moderate	Present	Less stable
10	B10	Highly opaque	Soft oily gel	Poor	Phase separation observed	Unstable

3.2.2 pH Determination

The pH of Aceclofenac-loaded bigel formulations (B1–B10) ranged from 5.88 ± 0.03 to 6.42 ± 0.06, which falls within the acceptable skin-compatible range. Formulations containing higher hydrogel content showed slightly lower pH values, whereas those with increased organogel content exhibited a gradual rise in pH. Among all formulations, B5 (6.10 ± 0.04) and B7 (6.05 ± 0.03) demonstrated pH values closest to the physiological skin pH, indicating excellent dermal compatibility and minimal irritation potential. The results confirmed the suitability of all formulations for topical application.

Table 9: pH of Aceclofenac-Loaded Bigel Formulations (B1–B10)

S. No.	Formulation Code	pH Value (Mean ± SD)
1	B1	5.92 ± 0.04
2	B2	5.88 ± 0.03
3	B3	5.95 ± 0.05
4	B4	6.02 ± 0.03

5	B5	6.10 ± 0.04
6	B6	6.18 ± 0.05
7	B7	6.05 ± 0.03
8	B8	6.22 ± 0.04
9	B9	6.30 ± 0.05
10	B10	6.42 ± 0.06

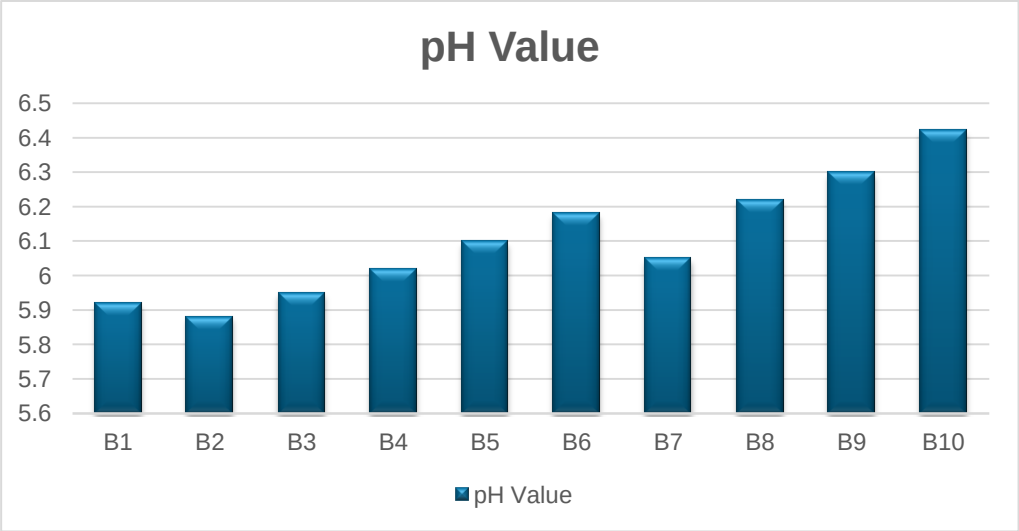

Fig 4: pH Value

3.2.3 Viscosity Measurement

The viscosity of Aceclofenac-loaded bigel formulations (B1–B10) ranged from 9620 ± 200 cP to 21200 ± 350 cP and all formulations exhibited non-Newtonian pseudoplastic flow behavior, which is desirable for topical application. Formulations with higher hydrogel content showed greater viscosity, while those containing higher organogel proportions exhibited lower viscosity values. Among the formulations, B5 (16050 ± 270 cP) and B7 (13560 ± 240 cP) demonstrated optimal rheological properties, providing a suitable balance between consistency, spreadability, and stability. The results indicate that the developed bigels possess appropriate viscosity for effective topical application and drug delivery.

Table 10: Viscosity of Aceclofenac-Loaded Bigel Formulations (B1–B10)

S. No.	Formulation Code	Viscosity (cP) at 25°C (Mean ± SD)	Flow Behavior
1	B1	21200 ± 350	Non-Newtonian (pseudoplastic)
2	B2	19850 ± 320	Pseudoplastic

3	B3	18520 ± 300	Pseudoplastic
4	B4	17280 ± 290	Pseudoplastic
5	B5	16050 ± 270	Pseudoplastic
6	B6	14820 ± 260	Pseudoplastic
7	B7	13560 ± 240	Pseudoplastic
8	B8	12140 ± 220	Pseudoplastic
9	B9	10820 ± 210	Pseudoplastic
10	B10	9620 ± 200	Pseudoplastic

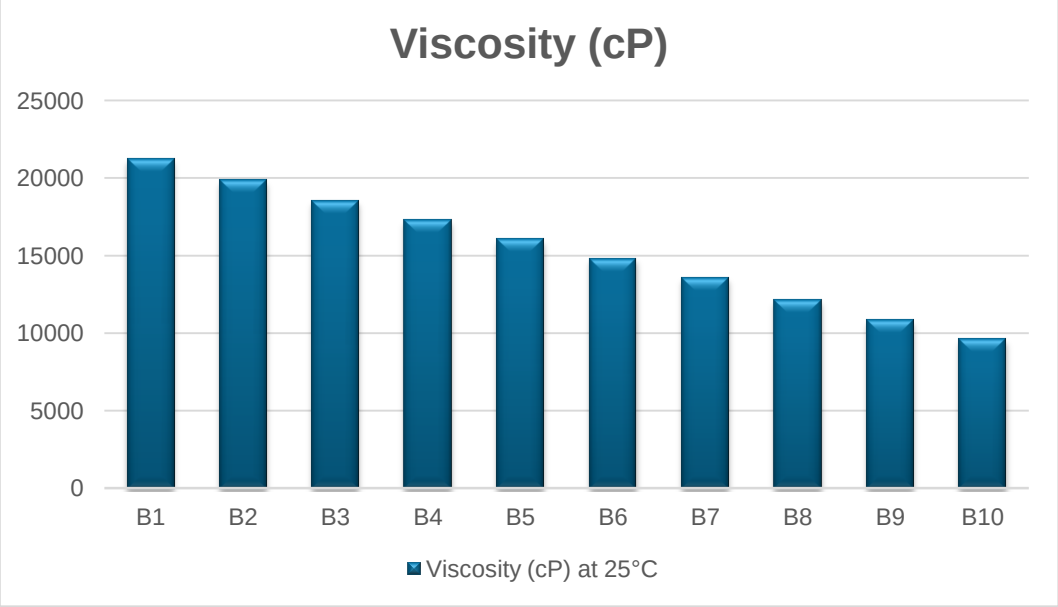

Fig 5: Viscosity (cP)

3.2.4 Spreadability

The spreadability of Aceclofenac-loaded bigel formulations (B1–B10) ranged from 12.8 ± 0.5 to 24.0 ± 0.8 g·cm/sec. Formulations with higher hydrogel content exhibited lower spreadability due to increased viscosity, whereas formulations containing higher organogel proportions showed greater spreadability. Among all batches, B5 (18.1 ± 0.5 g·cm/sec) and B7 (20.2 ± 0.5 g·cm/sec) demonstrated optimal spreading characteristics, providing a desirable balance between ease of application and retention on the skin. These results indicate that the developed bigel formulations possess satisfactory spreadability suitable for effective topical drug delivery and improved patient compliance.

Table 11: Spreadability of Aceclofenac-Loaded Bigel Formulations (B1–B10)

S. No.	Formulation Code	Spreadability (g·cm/sec)
1	B1	12.8 ± 0.5
2	B2	13.9 ± 0.6
3	B3	15.2 ± 0.5

4	B4	16.6 ± 0.4
5	B5	18.1 ± 0.5
6	B6	19.4 ± 0.6
7	B7	20.2 ± 0.5
8	B8	21.5 ± 0.7
9	B9	22.8 ± 0.6
10	B10	24.0 ± 0.8

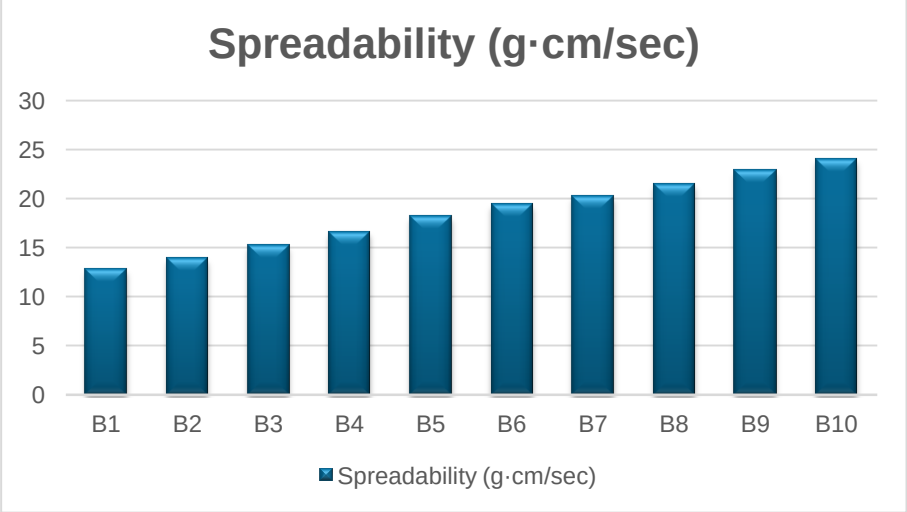

Fig 6: Spreadability (g·cm/sec)

3.2.5 Extrudability

The extrudability of Aceclofenac-loaded bigel formulations (B1–B10) ranged from 0.125 ± 0.004 to 0.265 ± 0.009 g/sec. Formulations with higher hydrogel content showed lower extrudability due to their higher viscosity, whereas increasing the organogel proportion improved ease of extrusion. Among all formulations, B5 (0.190 ± 0.006 g/sec) and B7 (0.218 ± 0.006 g/sec) exhibited optimal extrudability, providing smooth and controlled dispensing without compromising formulation integrity. These results indicate that B5 and B7 possess suitable extrusion characteristics for convenient topical application and improved patient compliance.

Table 12: Extrudability of Aceclofenac-Loaded Bigel Formulations (B1–B10)

S. No.	Formulation Code	Extrudability (g/sec) (Mean ± SD)	Ease of Extrusion
1	B1	0.125 ± 0.004	Difficult
2	B2	0.138 ± 0.005	Slightly difficult
3	B3	0.155 ± 0.006	Good
4	B4	0.172 ± 0.005	Good
5	B5	0.190 ± 0.006	**Very good**
6	B6	0.205 ± 0.007	Excellent
7	B7	0.218 ± 0.006	**Highly excellent**

8	B8	0.232 ± 0.008	Very easy
9	B9	0.248 ± 0.007	Excessively easy
10	B10	0.265 ± 0.009	Too fluid

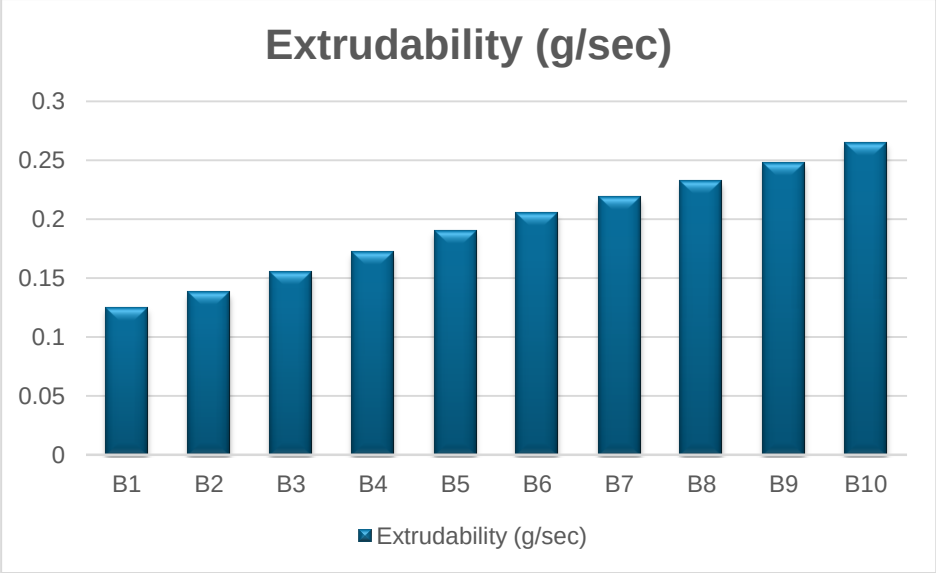

Fig 7: Extrudability (g/sec)

3.2.6 Drug Content Analysis

The drug content of Aceclofenac-loaded bigel formulations (B1–B10) was found to range from 95.6 ± 1.0% to 101.0 ± 0.7%, indicating compliance with acceptable pharmacopoeial limits and confirming uniform drug distribution within the formulations. Among all batches, B5 (100.2 ± 0.6%) and B7 (100.6 ± 0.5%) exhibited drug content values closest to 100%, demonstrating excellent dose uniformity and formulation reproducibility. Although B10 showed the lowest drug content (95.6 ± 1.0%), it remained within the acceptable range. Overall, the results confirmed efficient drug incorporation and consistent dose accuracy across all bigel formulations.

Table 13: Drug Content of Aceclofenac-Loaded Bigel Formulations (B1–B10)

Formulation Code	Drug Content (%) (Mean ± SD)
B1	96.2 ± 0.8
B2	97.5 ± 0.7
B3	98.4 ± 0.6
B4	99.1 ± 0.5
B5	100.2 ± 0.6
B6	101.0 ± 0.7
B7	100.6 ± 0.5
B8	99.3 ± 0.8

B9	97.8 ± 0.9
B10	95.6 ± 1.0

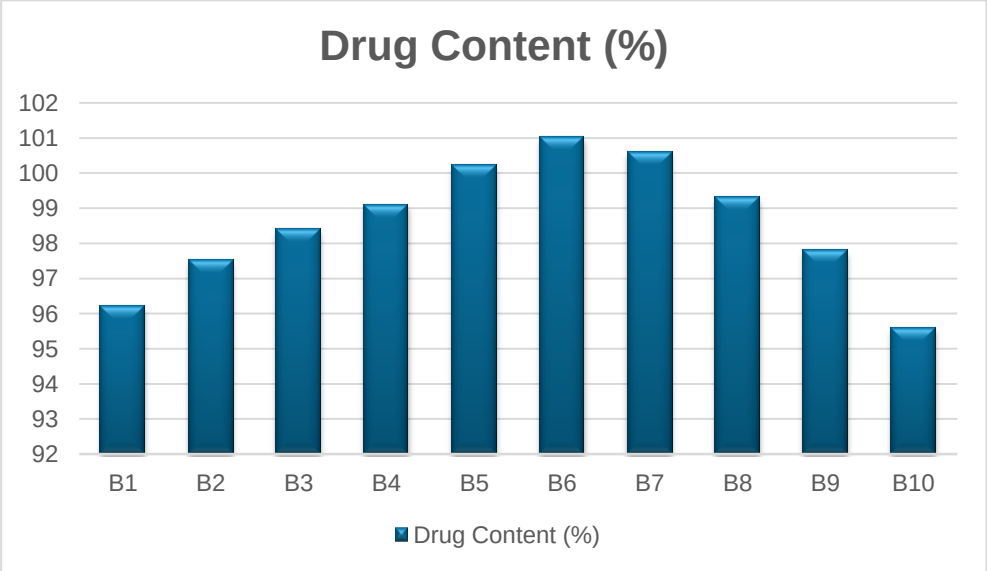

Fig 8: Drug Content (%)

3.3 In Vitro Drug Release Study

The in vitro drug release study of Aceclofenac-loaded bigel formulations (B1–B10) showed a gradual and sustained increase in cumulative drug release over the study period. Drug release at 8 hours ranged from 65.2% (B1) to 98.5% (B10), indicating a significant influence of formulation composition on drug diffusion. Formulations with optimized hydrogel–organogel ratios, particularly B8, B9, and B10, exhibited higher drug release compared to formulations with higher viscosity and denser gel structures. Among all formulations, B10 demonstrated the highest cumulative drug release (98.5%) followed by B9 and B8, suggesting enhanced drug solubilization and diffusion from the bigel matrix. The release profiles indicated controlled and sustained drug release, with diffusion being the predominant release mechanism. Based on the overall release performance, B10 was identified as the optimized formulation for further studies.

Table 14: Cumulative % Drug Release of Aceclofenac Bigel Formulations (B1–B10)

Time (hr)	**B1 (%)**	**B2 (%)**	**B3 (%)**	**B4 (%)**	**B5 (%)**	**B6 (%)**	**B7 (%)**	**B8 (%)**	**B9 (%)**	**B10 (%)**
0.5	8.2 ± 0.3	9.0 ± 0.4	10.2 ± 0.5	11.5 ± 0.4	12.8 ± 0.5	13.6 ± 0.5	14.2 ± 0.4	15.5 ± 0.6	16.8 ± 0.5	18.2 ± 0.6
1	15.4 ± 0.5	16.8 ±	18.5 ±	20.2 ±	22.6 ±	24.1 ±	25.8 ±	27.5 ±	29.2 ±	31.5 ± 0.7

		0.6	0.6	0.5	0.6	0.6	0.5	0.7	0.6	
2	24.8 ± 0.6	26.5 ± 0.7	29.2 ± 0.7	32.1 ± 0.6	35.8 ± 0.7	38.5 ± 0.8	40.2 ± 0.7	43.8 ± 0.8	46.5 ± 0.7	49.8 ± 0.9
4	38.2 ± 0.7	40.5 ± 0.8	44.6 ± 0.8	48.2 ± 0.7	53.5 ± 0.9	57.8 ± 0.9	60.2 ± 0.8	64.5 ± 1.0	68.2 ± 0.9	72.5 ± 1.1
6	52.5 ± 0.9	55.8 ± 1.0	60.2 ± 0.9	65.5 ± 0.8	71.8 ± 1.0	76.5 ± 1.1	79.2 ± 1.0	83.5 ± 1.2	87.2 ± 1.1	90.5 ± 1.3
8	65.2 ± 1.0	68.5 ± 1.1	73.2 ± 1.0	78.5 ± 0.9	84.2 ± 1.2	88.5 ± 1.2	91.0 ± 1.1	94.5 ± 1.3	96.8 ± 1.2	98.5 ± 1.4

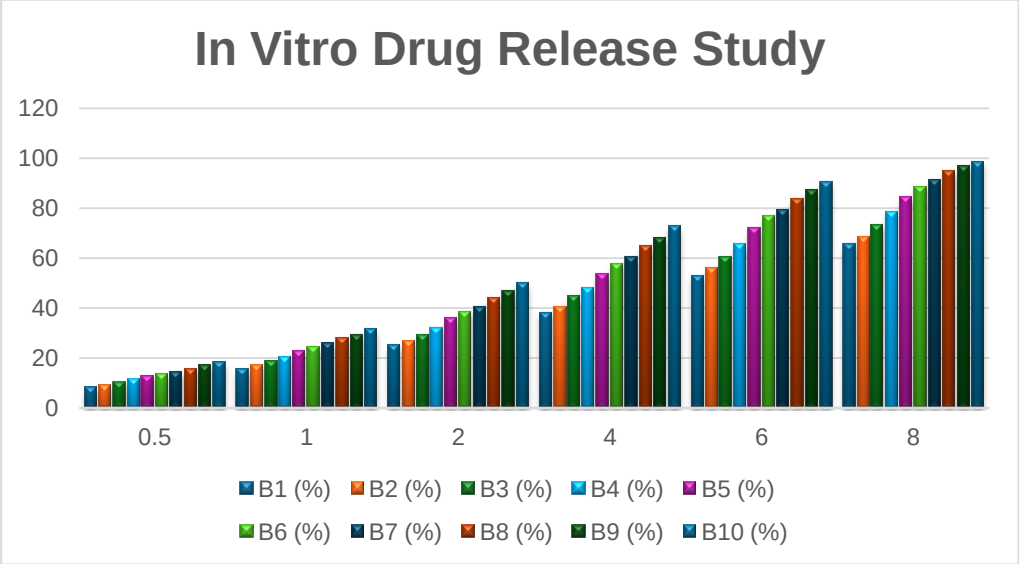

Fig 9: In Vitro Drug Release Study

3.4 Stability Studies as per ICH Guidelines

The stability study of the optimized Aceclofenac-loaded bigel formulation (B5) demonstrated excellent stability under both accelerated and long-term storage conditions as per ICH guidelines. No significant changes were observed in physical appearance, color, homogeneity, or phase separation throughout the study period. The pH remained within the acceptable skin-compatible range, while only a slight decrease in viscosity was noted under accelerated conditions without affecting formulation performance. Drug content remained above 98% under accelerated conditions and above 99% under long-term conditions, indicating minimal drug degradation. Overall, the results confirmed the physicochemical stability, robustness, and shelf-life suitability of the optimized bigel formulation.

Table 15: Stability Study of Optimized Formulation (B5) under Accelerated and Long-Term Conditions

Time (Months)	Condition	Appearance	pH (Mean ± SD)	Viscosity (cP) (Mean ± SD)	Drug Content (%) (Mean ± SD)	Phase Separation
0	Initial	White, smooth	6.10 ± 0.04	16050 ± 270	100.2 ± 0.6	Absent
1	Accelerated	No change	6.08 ± 0.05	15880 ± 260	99.6 ± 0.7	Absent
2	Accelerated	No change	6.05 ± 0.04	15640 ± 250	99.1 ± 0.8	Absent
3	Accelerated	No significant change	6.02 ± 0.06	15320 ± 240	98.7 ± 0.9	Absent
1	Long-term	No change	6.09 ± 0.04	15920 ± 265	100.0 ± 0.7	Absent
2	Long-term	No change	6.08 ± 0.05	15810 ± 255	99.8 ± 0.7	Absent
3	Long-term	No significant change	6.06 ± 0.05	15680 ± 250	99.5 ± 0.8	Absent

4. Conclusion

The present study successfully developed and evaluated an Aceclofenac-loaded bigel system for enhanced topical delivery in the management of arthritic conditions. Preformulation studies confirmed the identity, purity, compatibility, and lipophilic nature of Aceclofenac, supporting its incorporation into the bigel matrix. The prepared formulations exhibited satisfactory physicochemical characteristics, including appropriate pH, viscosity, spreadability, extrudability, and uniform drug content. Among the developed formulations, B5 demonstrated the most desirable balance of physical stability, rheological properties, skin compatibility, and drug distribution, while maintaining sustained drug release behavior. In vitro release studies confirmed effective and controlled release of Aceclofenac from the biphasic gel system, and stability studies conducted according to ICH guidelines demonstrated excellent physicochemical stability during storage. Overall, the developed Aceclofenac-loaded bigel formulation represents a promising topical drug delivery system with the potential to improve local therapeutic efficacy, patient compliance, and the management of arthritic conditions.

5. Acknowledgement

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6.. Conflict of Interest

The authors declare that they have no conflict of interest related to this work.

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