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FORMULATION AND EVALUATION OF MEDICATED EFFERVESCENT BATH BOMBS OF DICLOFENAC SODIUM FOR TOPICAL PAIN MANAGEMENT

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ABSTRACT

Objective: The present study aims to formulate and evaluate a medicated effervescent bath bomb containing Diclofenac sodium for topical pain management. The objective was to develop a stable, patient-friendly formulation that provides effective relief from muscle pain, joint pain, and inflammation through enhanced drug release and skin absorption. **Experimental work:** Preformulation studies were carried out including solubility analysis, melting point determination, and compatibility studies using IR spectroscopy. Various excipients such as citric acid, sodium bicarbonate, starch, and essential oils were selected. Screening of solvents and binders was performed to optimize formulation parameters. The bath bombs were prepared using the effervescent method by mixing dry ingredients followed by addition of binding agents and compression into molds. Evaluation parameters included physical appearance, weight variation, hardness, pH determination, effervescence time, drug content, and in-vitro drug release studies. **Results and discussion:** The prepared formulations showed acceptable physical characteristics with uniform weight and adequate hardness. The pH was found to be skin compatible. Effervescence time was within the desired range indicating proper reaction between acid and base components. Drug content was uniform across all batches. In-vitro drug release studies demonstrated effective release of Diclofenac sodium from the optimized formulation. Among all batches, the optimized formulation showed better stability, faster effervescence, and improved drug release profile, making it suitable for topical therapeutic use. **Conclusion:** The study successfully developed a medicated effervescent bath bomb formulation of Diclofenac sodium with satisfactory evaluation parameters. The formulation provides a convenient and effective alternative for topical pain relief, enhancing patient compliance and therapeutic efficacy.

KEYWORDS: Diclofenac sodium, Effervescent bath bomb, Topical drug delivery, Pain management, Effervescence, Drug release, Formulation and evaluation.

1. INTRODUCTION

The skin is the largest organ of the human body and acts as a primary protective barrier against physical, chemical, and microbial insults. In addition to its protective role, the skin also serves as an important route for topical and transdermal drug delivery, offering direct access to the site of action and reducing systemic exposure.[16,18] Topical drug delivery systems are widely preferred for the treatment of localized conditions as they improve patient compliance, minimize systemic side effects, and allow sustained drug action at the target site.[19,21]

Non-steroidal anti-inflammatory drugs (NSAIDs) are commonly used for the management of pain and inflammatory conditions such as osteoarthritis, musculoskeletal disorders, and sports injuries.[2,9] Diclofenac sodium is one of the most extensively prescribed NSAIDs due to its potent anti-inflammatory, analgesic, and antipyretic activities.[9] It exerts its pharmacological effect mainly by inhibiting

cyclooxygenase (COX-1 and COX-2) enzymes, thereby reducing prostaglandin synthesis responsible for pain and inflammation [6, 9]. Although oral diclofenac is effective, prolonged systemic administration is associated with adverse effects including gastrointestinal irritation, cardiovascular risks, and renal complications.[1,10]

To overcome these limitations, topical delivery of diclofenac sodium has emerged as a safer and effective alternative for localized pain management.[5,14] Topical formulations deliver the drug directly to the affected area, achieving higher local drug concentrations with minimal systemic absorption, thereby reducing the risk of systemic side effects.[12,15]

Various conventional topical dosage forms such as gels, creams, and ointments are available; however, there is a continuous need for innovative and patient-friendly topical drug delivery systems that enhance therapeutic outcomes and user acceptability.[13]

Bath bombs are effervescent solid dosage forms designed to dissolve rapidly in water, producing effervescence due to the reaction between acidic and alkaline components.[31,32] Traditionally, bath bombs have been used as cosmetic products for relaxation, skin cleansing, and aromatherapy. Recently, bath bombs have attracted significant interest as potential pharmaceutical dosage forms because they allow uniform dispersion of active ingredients in bath water, facilitating prolonged contact of the drug with a large surface area of skin.[35]

The incorporation of therapeutic agents into bath bombs represents a novel approach for topical drug delivery. Medicated bath bombs combine the benefits of effervescent systems with topical therapy, offering advantages such as ease of use, improved patient compliance, uniform drug distribution, and enhanced skin contact.[36,39] Therefore, the development of pharmaceutical bath bombs containing diclofenac sodium may serve as an innovative and effective strategy for topical pain relief and localized anti-inflammatory therapy.

1.1 Anatomy of Skin

The skin is the largest and most versatile organ of the human body, accounting for approximately 15–20% of total body weight. It plays a vital role in maintaining homeostasis by acting as a protective barrier between the internal organs and the external environment.[16,17] The skin performs multiple physiological functions including protection against mechanical injury and pathogens, regulation of body temperature, prevention of excessive water loss, sensory perception, and metabolic activities such as vitamin D synthesis.[18,22]

From a pharmaceutical perspective, the skin is an important route for topical and transdermal drug delivery systems. The extensive surface area and accessibility of the skin make it suitable for localized drug administration, especially in the treatment of dermatological, inflammatory, and musculoskeletal conditions.[19,21] However, the skin also acts as a strong barrier to drug penetration, primarily due to its outermost layer, which restricts the entry of foreign substances into the systemic circulation.[17,29]

The effectiveness of topical drug delivery depends largely on the anatomical and physiological characteristics of the skin. Factors such as skin thickness, hydration, lipid content, blood supply, and integrity of the skin layers influence drug absorption and therapeutic efficacy.[20,24] Understanding the anatomy of the skin is therefore essential for the design and development of effective topical formulations, including medicated bath bombs intended for localized drug action.

The interaction of topical formulations with the skin surface allows the drug to act locally or penetrate through the skin layers to reach deeper tissues. This makes topical drug delivery particularly beneficial for NSAIDs like diclofenac sodium, where localized anti-inflammatory and analgesic effects are desired with minimal systemic exposure.[12,14]

Consequently, a thorough knowledge of skin anatomy is crucial for optimizing formulation design, drug release, and overall therapeutic performance.

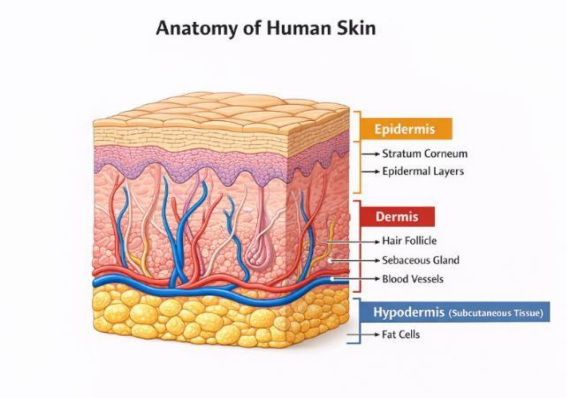


Figure 1.1: Structure of Human Skin.

1.1.1 Structure of Skin

The human skin is a highly specialized and dynamic organ, consisting of three primary layers: **epidermis, dermis, and hypodermis (subcutaneous tissue)**. Each layer has a unique composition and function, collectively contributing to the skin's protective, sensory, and regulatory roles.[16,17] The structural organization of these layers is crucial for understanding the mechanisms of drug absorption, distribution, and action in topical formulations such as medicated bath bombs.

Epidermis

The epidermis is the outermost layer of the skin, forming a protective barrier that shields the body from environmental insults including pathogens, chemicals, ultraviolet radiation, and mechanical stress.[18] It is

composed of stratified squamous epithelial cells called **keratinocytes**, which undergo continuous renewal from the basal layer to the surface.

The epidermis is avascular, receiving its nutrients via diffusion from the dermis, and consists of several sublayers:

1. **Stratum basale** – the basal layer, responsible for continuous cell proliferation.
2. **Stratum spinosum** – provides mechanical strength and supports intercellular connections.
3. **Stratum granulosum** – contributes to keratinization and barrier formation.
4. **Stratum lucidum** – present only in thick, hairless skin such as palms and soles.
5. **Stratum corneum** – the outermost layer composed of dead, flattened keratinocytes embedded in a lipid matrix, forming the principal barrier to water loss and external chemical penetration.[17,22]

The **stratum corneum** is especially significant in topical drug delivery. Its barrier properties can limit drug permeation; however, certain formulation strategies, including penetration enhancers and effervescent systems like bath bombs, can improve drug contact and absorption [19, 23]. The epidermis also contains melanocytes, Langerhans cells, and Merkel cells, which contribute to pigmentation, immune defense, and sensory functions, respectively.[21]

Dermis

The dermis lies immediately beneath the epidermis and forms the structural backbone of the skin. It is composed of dense connective tissue rich in **collagen and elastin fibers**, providing tensile strength, elasticity, and resilience.[16] This layer houses **blood vessels, lymphatic vessels, sensory nerve endings, sweat glands, sebaceous glands, and hair follicles**, which play roles in thermoregulation, sensation, secretion, and metabolic processes.[21]

From a pharmaceutical perspective, the dermis is critical for the absorption and distribution of topically applied drugs. Once a drug penetrates the epidermal barrier, it diffuses through the dermis where it may either act locally or reach systemic circulation depending on its physicochemical characteristics.[20,24] The dermis also contributes to sustained drug release and enhanced skin contact, which are essential considerations in the design of medicated bath bombs.

Hypodermis (Subcutaneous Tissue)

The hypodermis is the innermost layer of the skin, composed mainly of **adipose tissue** interspersed with loose connective tissue. It functions as an **energy reservoir, thermal insulator, and shock absorber**, protecting underlying structures such as muscles and bones.[17] The hypodermis also contains larger blood vessels and lymphatics, which can facilitate systemic absorption of drugs delivered topically under certain conditions.[22]

Although the hypodermis does not directly form a barrier, its thickness and composition influence overall skin permeability and drug pharmacokinetics. For formulations like medicated bath bombs, prolonged immersion in water allows the drug to diffuse through the epidermis into the dermis and, to a limited extent, into the hypodermis, maximizing local therapeutic effects while minimizing systemic exposure.[11,19]

Clinical and Pharmaceutical Relevance

Understanding the structure of skin is essential for the development of effective topical and transdermal drug delivery systems. Factors such as **skin thickness, hydration, lipid content, vascularity, and integrity** of the layers affect drug penetration and therapeutic outcomes.[20] Medicated bath bombs leverage these anatomical features to enhance **localized drug delivery, improve patient compliance, and provide a convenient method for administering drugs such as diclofenac sodium.**[36,39] The interaction of active pharmaceutical ingredients with skin layers ensures controlled release and prolonged contact, which are critical for achieving optimal analgesic and anti-inflammatory effects.

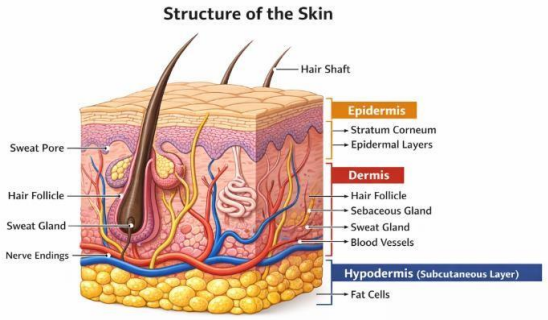


Figure 1.1.1: Layers of Skin.

1.2 Bath Bombs

1.2.1 Types of Bath Bombs

Bath bombs can be classified based on their **composition, intended use, and functional attributes**. Understanding the types of bath bombs is essential for formulation development, as different excipients, active ingredients, and manufacturing techniques influence **effervescence, drug release, skin compatibility, and stability.**[31,32,36] Broadly, bath bombs are categorized as follows:

1. Traditional/Basic Bath Bombs

These are the simplest form of bath bombs, composed primarily of **sodium bicarbonate and citric acid**, which react upon contact with water to produce carbon dioxide, causing effervescence. Traditional bath bombs often contain **fragrances, colorants, and moisturizers**, but do not typically include active pharmaceutical

ingredients.[31,33] They are primarily used for **cosmetic and recreational purposes**, providing a pleasant bathing experience.

2. Cosmetic Bath Bombs
Cosmetic bath bombs incorporate **additional skin-benefiting ingredients** such as essential oils, plant extracts, moisturizing agents, and vitamins. These formulations are designed not only for effervescence but also to **enhance skin hydration, softness, and relaxation.**[37,38] Examples include bath bombs enriched with **shea butter, coconut oil, or green tea extracts**, which provide antioxidant and soothing effects on the skin.[39]

3. Medicated or Pharmaceutical Bath Bombs
Medicated bath bombs are developed as **topical drug delivery systems**, containing therapeutic agents such as **NSAIDs (e.g., diclofenac sodium), antifungals, or analgesics.**[36,39] These bath bombs allow for **localized drug action**, prolonged skin contact, and reduced systemic absorption. Their formulation requires careful optimization of effervescence, drug stability, and solubility to ensure **uniform drug release and therapeutic efficacy.**[36,39]

4. Herbal Bath Bombs
Herbal bath bombs are enriched with **plant-based extracts and powders**, providing natural antioxidant, anti-inflammatory, and skin-nourishing properties. Common herbal ingredients include **Camellia sinensis, Aloe vera, and Calendula officinalis**, which enhance the **cosmetic and therapeutic benefits** of the bath.[37,39,69] Herbal medicated bath bombs can also incorporate active drugs like diclofenac sodium for **dual benefits**: pharmacological action and herbal skin therapy.[36,39]

5. Functional/Innovative Bath Bombs
Recent advancements have led to **functional bath bombs** with added features, such as:

- **Color-changing or fizziness control** for enhanced sensory experience.[38]
- **Time-controlled effervescence for gradual drug release**
- **Combination formulations containing multiple actives (e.g., NSAIDs + moisturizers + herbal extracts).**[39,44]

These types are particularly relevant in pharmaceutical applications, as they allow **tailored drug delivery** according to the target condition, duration of action, and patient preference.[36,39]

Figure 1.2: Types of bath bombs: (a) Traditional bath bomb, (b) Cosmetic bath bomb, (c) Medicated bath bomb, and (d) Herbal bath bomb

Figure 1.2.1: Types of Bath Bombs.

1.2.2 Advantages of Bath Bombs
Bath bombs offer several advantages over conventional topical and cosmetic dosage forms due to their **effervescent nature, ease of application, and enhanced user compliance**. The combination of cosmetic appeal with functional performance makes bath bombs an emerging platform for both **cosmetic and pharmaceutical applications.**[31,32,36]

1. Ease of Use and Patient Compliance
Bath bombs are simple to use and require minimal effort from the user. The effervescent action upon contact with water allows uniform dispersion of ingredients throughout the bath, ensuring **consistent skin exposure**. This convenient mode of application significantly improves **patient compliance**, especially in individuals suffering from chronic pain, muscle stiffness, or joint disorders.[14,36]

2. Enhanced Skin Contact and Coverage
Unlike creams or gels that are applied to localized areas, bath bombs provide **full-body skin contact** during bathing. Prolonged exposure to warm water increases skin hydration and softness, which facilitates **better penetration of active ingredients** into the stratum

corneum.[1,12,21] This property is particularly beneficial for topical drug delivery systems.

3. Effervescent Action and Improved Drug Dispersion
The effervescence generated by the acid–base reaction between citric acid and sodium bicarbonate produces carbon dioxide, which aids in **rapid disintegration and uniform distribution** of formulation components in bath water.[31,33]

This ensures homogenous availability of both cosmetic and medicinal ingredients on the skin surface.

4. Reduced Systemic Side Effects
Bath bombs designed for medicated use provide **localized drug action**, thereby minimizing systemic absorption and reducing the risk of adverse effects commonly associated with oral NSAIDs.[3,9,10] This advantage is crucial for drugs like diclofenac sodium, which are associated with gastrointestinal and cardiovascular risks when administered systemically.[1,9]

5. Multifunctional Benefits
Bath bombs offer **dual benefits**—therapeutic and cosmetic. Along with drug delivery, they can improve skin condition by providing **moisturization, relaxation, stress relief, and muscle soothing effects.**[37,38] The inclusion of oils, emollients, and herbal extracts enhances the overall bathing experience while supporting skin health.[39]

6. Improved Stability in Solid Dosage Form
Being solid dosage forms, bath bombs generally exhibit **better physicochemical stability** compared to liquid or semi-solid formulations. With appropriate moisture-protective packaging, they can maintain integrity and efficacy over extended storage periods.[34,43,56]

7. Aesthetic and Sensory Appeal
Bath bombs provide a visually and sensorially appealing experience through **color release, fragrance, and effervescence**, which enhances user satisfaction and acceptance.[38,45] This aesthetic appeal plays a significant role in improving adherence to topical therapies, particularly in long-term treatments.[14]

1.2.3 Benefits of Medicated Bath Bombs
Medicated bath bombs represent an innovative approach to topical drug delivery by combining **effervescent technology with therapeutic agents**. Unlike conventional cosmetic bath bombs, medicated bath bombs are formulated to provide **targeted therapeutic action along with enhanced patient comfort and skin benefits.**[36,39]

1. Localized Drug Delivery
One of the primary benefits of medicated bath bombs is their ability to deliver drugs **directly to the affected area**. During bathing, the drug is released into warm water and comes in prolonged contact with the skin, allowing **localized therapeutic action** without extensive systemic exposure.[14,36] This is particularly advantageous for drugs like **diclofenac sodium**, which are intended for the management of localized pain and inflammation.[5,9]

2. Reduced Systemic Side Effects
Medicated bath bombs minimize the need for oral drug administration, thereby reducing **gastrointestinal, renal, and cardiovascular adverse effects** commonly associated with systemic NSAID therapy.[3,9,10] Topical exposure through bath water allows sufficient therapeutic effect while maintaining a **favorable safety profile**, especially in elderly and chronic pain patients.[10,15]

3. Enhanced Skin Permeation
The combined effect of **warm water, skin hydration, and effervescence** enhances the permeability of the stratum corneum, facilitating improved drug diffusion into deeper skin layers.[12,21] The effervescent action also aids in uniform dispersion of the drug, ensuring **consistent exposure across the skin surface.**[31,36]

4. Prolonged Contact Time
Unlike topical creams or gels that may be removed quickly due to sweating or clothing, medicated bath bombs provide **extended contact time** between the drug and skin during bathing. This prolonged exposure enhances **drug absorption and therapeutic efficacy**, particularly for musculoskeletal and joint-related conditions.[14,36]

5. Improved Patient Compliance
Medicated bath bombs are non-invasive, painless, and easy to use, which significantly improves **patient compliance**. Their aesthetic appeal, combined with therapeutic benefits, makes them more acceptable for long-term use compared to conventional topical formulations.[14,38]

6. Combined Therapeutic and Relaxation Effects
In addition to drug delivery, medicated bath bombs offer **muscle relaxation, stress relief, and improved circulation** due to warm water immersion. These effects complement the pharmacological action of drugs like diclofenac sodium, resulting in **enhanced overall pain relief and patient comfort.**[37,39]

7. Potential for Controlled and Uniform Drug Release
Proper formulation of medicated bath bombs allows **controlled effervescence and uniform drug release** in bath water. This ensures consistent drug availability and reproducible therapeutic outcomes, which is essential for pharmaceutical acceptance.[35,44]

1.2.4 Ideal Characteristics of Medicated Bath Bombs

An ideal medicated bath bomb should be formulated in such a way that it ensures **therapeutic efficacy, patient safety, physicochemical stability, and acceptable sensory** attributes**. Since medicated bath bombs act as** solid topical drug delivery systems**, they must comply with pharmaceutical quality standards in addition to cosmetic acceptability.**[36,44]

1. Uniform Drug Content

Medicated bath bombs should exhibit **uniform distribution of the active pharmaceutical ingredient** to ensure consistent dosing during use. Drug content uniformity is critical for reproducible therapeutic outcomes and must comply with pharmacopeial standards.[54,52]

2. Controlled and Reproducible Effervescence

The effervescent reaction between sodium bicarbonate and citric acid should be **controlled, rapid, and reproducible**, ensuring proper disintegration and uniform dispersion of the drug in bath water.[31,33] Excessively rapid or slow effervescence may compromise drug release and user acceptability.[34]

3. Adequate Mechanical Strength

An ideal bath bomb should possess sufficient **hardness and friability resistance** to withstand handling, packaging, and transportation without crumbling or breaking.[36,42]

Adequate mechanical strength also ensures consistent performance during use.

4. Suitable pH and Skin Compatibility

The pH of the medicated bath bomb solution should be **skin-friendly**, ideally ranging between **5.5 and 7.0**, to avoid irritation or dryness. Maintaining appropriate pH is especially important for formulations containing NSAIDs like diclofenac sodium.[7,21]

5. Efficient Drug Release

Medicated bath bombs should release the active drug **rapidly and uniformly** upon contact with water. Efficient in vitro drug release ensures optimal drug availability at the skin surface, enhancing therapeutic effectiveness.[55,36]

6. Moisture Protection and Stability

Effervescent formulations are highly sensitive to moisture; therefore, medicated bath bombs should demonstrate **good stability under recommended storage conditions**. Use of moisture-resistant excipients and protective packaging is essential to prevent premature effervescence and degradation.[34,43,56]

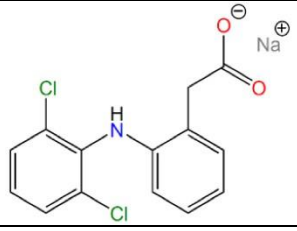
7. Patient Acceptability and Sensory Appeal

An ideal medicated bath bomb should possess **acceptable color, odor, and appearance**, ensuring a pleasant bathing experience. Good sensory attributes enhance patient satisfaction and long-term compliance, particularly in chronic conditions.[14,38]

8. Safety and Regulatory Compliance

Medicated bath bombs must be free from toxic excipients and microbial contamination and should comply with **regulatory and quality assurance guidelines** laid down by pharmacopeias and international organizations such as **USP, ICH, and WHO**.[48,52,58]

2.1 Drug Profile[70,71]

Marker Details	**Diclofenac Sodium**
Structure	
Molecular Formula	C14H10Cl2NNaO2
Molecular Weight	318.1 g/mol
Melting Point	283°C to 285°C
log p	4.5 to 4.75
pKa	4.0 to 0.2
Meachaism Of Action	Diclofenac inhibits cyclooxygenase-1 and -2, the enzymes responsible for production of prostaglandin (PG) G_2 which is the precursor to other PGs.[Label,17] These molecules have broad activity in pain and inflammation and the inhibition of their production is the common mechanism linking each effect of diclofenac.
CDSCO Approved Date	No specific data.

3.1 Literature Review

Sr. no.	Title	Description	References no.
1.	Formulation and Evaluation of Diclofenac Sodium Topical Gel.	A topical gel of Diclofenac Sodium was developed using Carbopol base. The formulation showed good spread-ability, stability, and effective anti-inflammatory activity.	(5)
2.	Development of Diclofenac Sodium Transdermal Patch.	A transdermal patch was prepared by solvent casting method to provide sustained drug release. The study demonstrated prolonged drug delivery over 24 hours.	(17)
3.	Diclofenac Sodium Nano-emulsion for Topical Delivery.	A nano-emulsion system was formulated to enhance skin penetration and bioavailability. Results showed improved drug absorption through skin layers.	(18)
4.	Formulation of Diclofenac Sodium Microspheres.	Microspheres were prepared using solvent evaporation technique for controlled drug release. The formulation showed sustained release profile.	(22)
5.	Diclofenac Sodium Liposomal Gel.	Liposomal gel was developed to enhance drug entrapment and targeted delivery. The formulation improved therapeutic efficiency.	(25)
6.	Development of Diclofenac Sodium Effervescent Tablets.	Effervescent tablets were formulated for rapid drug release. The study showed fast disintegration and improved patient compliance	(31)
7.	Diclofenac Sodium Solid Lipid Nanoparticles.	SLNs were prepared to improve drug stability and prolong release. The formulation showed enhanced bioavailability and stability.	(27)
8.	Formulation and Evaluation of Herbal Bath Bombs.	Herbal bath bombs containing natural ingredients were developed for skin care and relaxation. The study demonstrated good effervescence and user acceptability.	(67)
9.	Development of Effervescent Bath Bombs for Therapeutic Use.	Effervescent bath bombs were formulated using sodium bicarbonate and citric acid. The study showed rapid effervescence and uniform dissolution in water.	(36)
10.	Preparation and Evaluation of Aromatherapy Bath Bombs.	Bath bombs with essential oils were developed to provide relaxation and stress relief. The formulation showed good fragrance retention and soothing effect.	(37)
11.	Formulation of Medicated Bath Bombs for Topical Delivery.	Medicated bath bombs were prepared for delivering active ingredients through skin. Results indicated effective dispersion and mild therapeutic action.	(39)
12.	Effervescent Drug Delivery Systems: A Review of Formulations	Various effervescent systems were studied for rapid drug release. The study highlighted advantages of effervescence in improving drug dispersion.	(31)
13.	Formulation of Diclofenac Sodium Emulgel	Emulgel was developed to combine advantages of gel and emulsion. The formulation showed enhanced drug penetration and anti-inflammatory effect.	(13)
14.	Diclofenac Sodium Proniosomal Gel.	Proniosomal gel was formulated to improve drug stability and skin permeation. Results showed increased bioavailability and prolonged drug action.	(20)
15.	Development of Diclofenac Sodium Hydrogel.	Hydrogel formulation provided better hydration and controlled drug release. It showed good patient compliance and therapeutic effect.	(19)
16.	Effervescent Granules for Drug Delivery	Effervescent granules were formulated for rapid drug release and better dispersion. The system	(32)

		showed quick dissolution and improved absorption.	
17.	Evaluation of Effervescent Drug Delivery Systems.	The study focused on improving drug solubility and dissolution rate using effervescent systems. Results indicated enhanced bioavailability.	(33)
18.	Formulation of Bath Bombs with Essential Oils	Bath bombs were prepared using essential oils for aromatherapy. The study showed improved relaxation and skin soothing effects.	(38)
19.	Development of Moisturizing Bath Bombs.	Bath bombs enriched with oils and butters were developed for skin hydration. Results showed enhanced moisturizing properties and user satisfaction.	(40)
20.	Formulation of Therapeutic Bath Additives.	Therapeutic bath additives were formulated to relieve muscle pain and stress. The study indicated improved relaxation and mild analgesic effects.	(44)
21.	Study of Carbon Dioxide Release in Effervescent Systems.	The study evaluated CO_2 release mechanism in effervescent formulations. It showed that proper ratio of acid and base is critical for controlled effervescence.	(34)
22.	Optimization of Effervescent Formulations	Optimization techniques were applied to achieve desired effervescence time and drug release. The study concluded that formulation variables significantly affect performance.	(35)

AIM AND OBJECTIVES

4.1 Aim

The primary aim of the present study titled **"Formulation and Evaluation of Medicated Effervescent Bath Bombs of Diclofenac Sodium for Topical Pain Management"** is to develop a novel effervescent topical dosage form containing diclofenac sodium and to evaluate its physicochemical and performance characteristics.

The study focuses on designing a patient-friendly formulation that ensures effective drug delivery through the skin while improving patient compliance and therapeutic efficacy in localized pain management.[5,14,38]

Topical drug delivery systems have gained significant attention due to their ability to deliver drugs directly to the site of action, thereby minimizing systemic side effects and improving therapeutic outcomes. Diclofenac sodium, a widely used non-steroidal anti-inflammatory drug (NSAID), is commonly prescribed for the treatment of pain and inflammation associated with musculoskeletal disorders.[1,9]

However, conventional oral administration of diclofenac sodium is associated with gastrointestinal side effects and first-pass metabolism, which may limit its long-term use. Topical delivery offers a promising alternative by bypassing these limitations and providing localized drug action.[2,6]

Effervescent bath bombs represent a novel and innovative approach in topical drug delivery. These formulations utilize a combination of citric acid and sodium bicarbonate to produce carbon dioxide upon contact with water, resulting in effervescence. This effervescence enhances drug dispersion, improves skin contact, and may facilitate better drug permeation through the skin.[33,34]

Furthermore, bath bombs provide additional benefits such as relaxation, improved patient compliance, and enhanced user experience. The incorporation of excipients like Epsom salt, essential oils, and emollients contributes to therapeutic as well as cosmetic benefits.[41,42] Recent advancements in topical drug delivery systems emphasize the importance of patientfriendly dosage forms that combine efficacy with acceptability. Medicated bath bombs offer a unique platform that integrates pharmaceutical and cosmetic advantages, making them a promising alternative for localized pain management.[39,40]

Thus, the present study aims to explore the potential of effervescent bath bombs as an effective and innovative delivery system for diclofenac sodium in the management of topical pain.

The objectives of the present study are as follows:

Aim and Objectives

1. **To formulate medicated effervescent bath bombs** containing diclofenac sodium using suitable pharmaceutical excipients such as citric acid, sodium bicarbonate, and other additives.
2. **To optimize the formulation** by selecting appropriate ratios of effervescent components to achieve desirable effervescence and stability.[35,36]

3. **To evaluate preformulation parameters** of diclofenac sodium including solubility and compatibility with excipients.[3,16]
4. **To assess the physicochemical properties** of the formulated bath bombs such as:
   - Physical appearance
   - Weight variation
   - Hardness
   - pH
   - Effervescence time
5. **To determine drug content uniformity** to ensure uniform distribution of diclofenac sodium in the formulation.[52]
6. **To perform in-vitro drug release studies** to evaluate the release profile of the drug from the bath bomb formulation.[53]
7. **To conduct stability studies** as per ICH guidelines to assess the stability of the formulation under different environmental conditions.[48]
8. **To enhance patient compliance** by developing an easy-to-use, aesthetically appealing, and effective topical dosage form.[28]

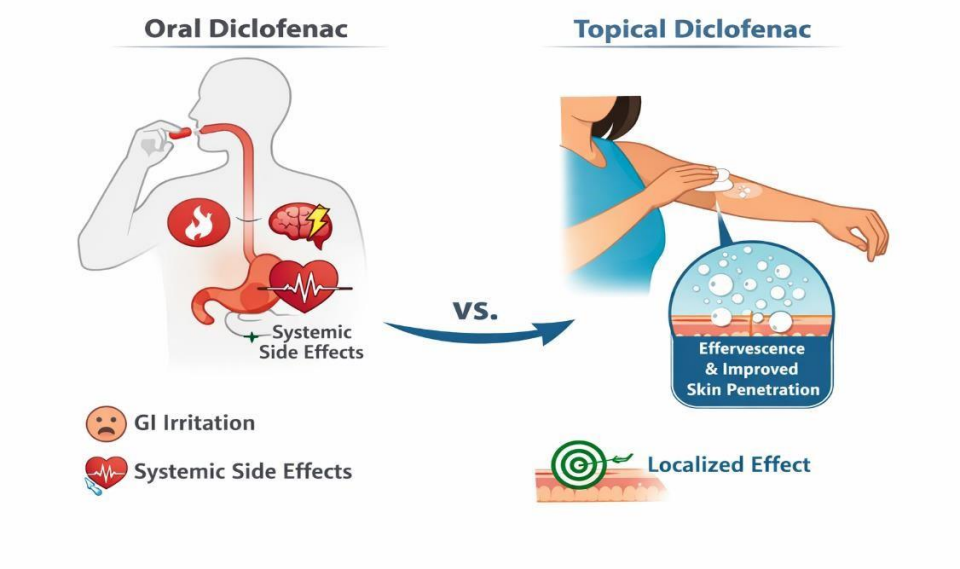


Figure 4.1: Oral Diclofenac vs Topical Diclofenac.

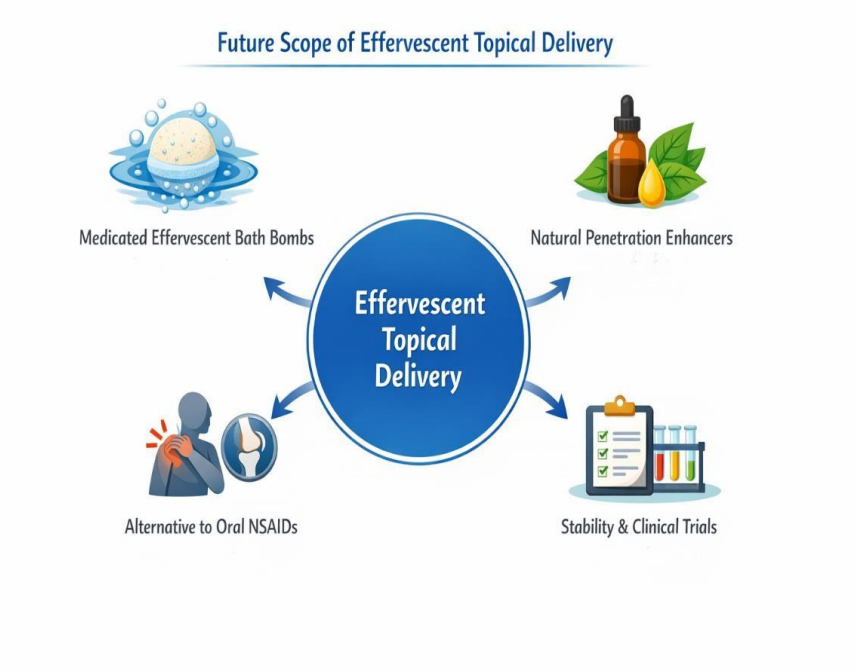


Figure 4.2: Future Scope of Effervescent Topical Delivery.

MATERIALS AND METHOD

5.1 Materials

The materials used in the formulation of medicated effervescent bath bomb included Diclofenac Sodium, sodium bicarbonate, citric acid (anhydrous), corn starch, magnesium sulfate (Epsom salt), kaolin clay, cocoa butter, coconut oil, menthol, sodium lauryl sulfoacetate (SLSA), fragrance, water-soluble colour, and isopropyl alcohol.

Diclofenac Sodium was selected as the model drug due to its well-established antiinflammatory and analgesic properties for topical pain management.[1,5,9] Sodium bicarbonate and citric acid were used as effervescent agents, which react in the presence of water to liberate carbon dioxide gas, producing effervescence.[31,32]

Corn starch and kaolin clay were incorporated as absorbents and binding agents to improve texture and mechanical strength of the formulation. Epsom salt was included for its musclerelaxant and soothing properties. Cocoa butter and oils were used to provide lubrication and enhance skin feel. SLSA was added as a foaming agent to improve the aesthetic appeal of the formulation.

All chemicals used were of analytical grade and were procured from reliable sources. The selection of excipients was based on their functional roles and compatibility with the drug.[46,47]

Figure 5.1: Excipients Profile.

5.2 Instruments Used

The instruments used during the study included UV-Visible Spectrophotometer, FTIR Spectrophotometer, Melting Point Apparatus, Digital Weighing Balance, Mortar and Pestle, Sieve (Mesh #40–60), and standard laboratory glassware such as beakers, volumetric flasks, and pipettes.

The UV-Visible spectrophotometer was used for quantitative analysis of the drug, while FTIR spectroscopy was employed for identification of functional groups. The melting point apparatus was used to determine the purity of the drug. Accurate weighing and mixing of ingredients were carried out using a digital balance and mortar-pestle respectively. Sieving was performed to ensure uniform particle size distribution, which is essential for proper mixing and consistent formulation.[49,51]

5.3 Screening of API and Other Excipients

(+) = Soluble
(-) = Insoluble

Sr. no	Solvent	Diclofenac	Other Ingredients
1.	Water	(+)	(+)
2.	Ethanol	(+)	(+)
3.	Methanol	(+)	(+)
4.	Acetone	(+)	(-)
5.	Chloroform	(+)	(-)
6.	Isopropyl Alcohol	(+)	(+)
7.	Distilled Water	(+)	(+)

5.4 Screening of Binder

(+) = Compatibility
(-) = Incompatibility

Sr.no	Binder	Diclofenac Sodium	Other Ingredients
1.	Corn Starch	(+)	(+)
2.	Cocoa Butter	(+)	(+)
3.	Coconut oil	(+)	(+)
4.	Starch + Cocoa Butter	(+)	(+)

5.5 Formulation of Medicated Effervescent Bath bomb

The medicated effervescent bath bombs were formulated using sodium bicarbonate and citric acid as effervescent agents. These components react in the presence of water to produce carbon dioxide gas, resulting in effervescence.[31,32]

Other excipients such as corn starch, Epsom salt, and kaolin clay were incorporated to improve binding, texture, and stability of the formulation. Cocoa butter and oils were used to enhance the consistency and provide a smooth feel during application.

Diclofenac Sodium was incorporated into the formulation using the geometric dilution method to ensure uniform distribution throughout the mixture. This step is critical to achieve consistent drug content in each unit.

5.6 Preparation Method

All the ingredients were accurately weighed using a digital balance. The dry ingredients, including sodium bicarbonate, citric acid, corn starch, and other excipients, were passed through a sieve and mixed thoroughly to ensure uniformity.

The wet phase was prepared by melting cocoa butter and mixing it with oil, fragrance, and colour. This wet phase was gradually added to the dry mixture with continuous mixing. Isopropyl alcohol was sprayed slowly to achieve a damp mass with a consistency similar to wet sand. Care was taken to avoid excessive moisture, as it may initiate premature effervescence.

The prepared mass was filled into Molds, slightly overfilled, and pressed firmly. The Molds were then joined and subjected to slight twisting to ensure proper binding. The formed spheres were carefully demoulded and allowed to dry at room temperature for 24–48 hours. Moisture control during drying is essential to prevent cracking and ensure product stability.[43]

5.7 Formulation Table (F1-F5)

Ingredients	F1(g)	F2(g)	F3(g)	F4(g)	F5(g)	Role
Diclofenac Sodium	0.50	0.50	0.50	0.50	0.50	API
Sodium Bicarbonate	20.0	22.0	18.0	21.0	20.0	Effervescent base
Citric Acid (Anhydrous)	10.0	9.0	11.5	8.5	10.0	Acid source
Corn Starch	5.0	5.0	5.0	5.0	5.0	Binder
Epsom Salt ($MgSO_4$)	10.0	9.0	10.5	10.0	10.0	Bath salt
Essential Oil	1.0	1.0	1.0	1.0	1.0	Fragrance
Colour	q.s.	q.s.	q.s.	q.s.	q.s.	Aesthetic
Isopropyl Alcohol (IPA)	q.s.	q.s.	q.s.	q.s.	q.s.	Binder (wetting agent)

5.8 Packaging of Bath Bombs

Packaging of medicated bath bombs is a critical aspect in maintaining the stability, quality, and effectiveness of the formulation. Effervescent formulations are highly sensitive to moisture, as the presence of humidity can initiate a premature reaction between citric acid and sodium bicarbonate, leading to loss of effervescence and reduced product performance. Therefore, appropriate packaging materials must be selected to protect the product from environmental factors such as moisture, air, and physical damage.[34,41]

Moisture-resistant packaging materials such as **aluminium foil, laminated pouches, airtight plastic containers, or glass jars** are commonly used for bath bomb formulations. Among these, laminated aluminium foil pouches provide excellent protection against moisture and oxygen, making them suitable for effervescent products. Additionally, the use of desiccants such as silica gel packets inside the packaging can further enhance product stability by absorbing excess moisture.[61]

Each bath bomb can be individually wrapped to prevent exposure to humidity and to avoid physical breakage during handling and transportation. Proper sealing of the packaging is essential to ensure product integrity and extend shelf life. The packaging should also be designed to be user-friendly, easy to open, and aesthetically appealing to enhance consumer acceptance.[62]

Thus, suitable packaging plays a vital role in preserving the quality, stability, and effectiveness of medicated bath bombs throughout their storage and use.

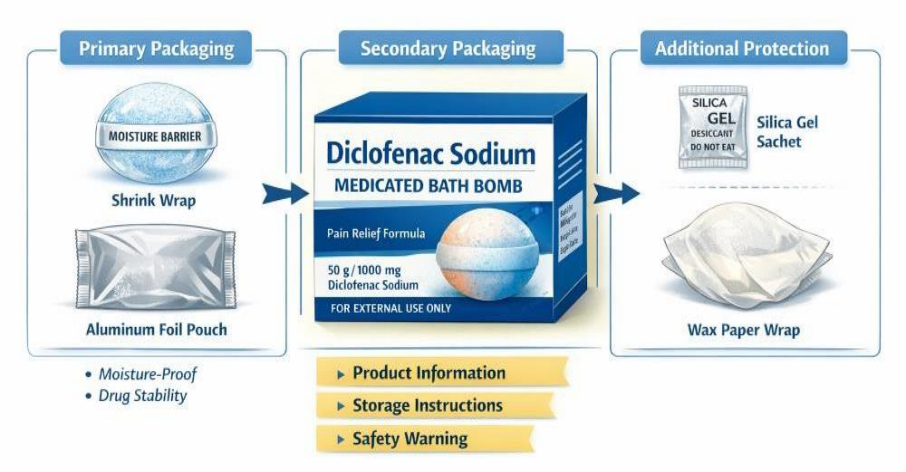


Figure 5.8: Packaging of Bath Bombs.

5.9 Labelling of Product

Labelling is an important component of pharmaceutical and cosmetic products, as it provides essential information regarding the formulation, usage, and safety of the product. Proper labelling ensures that the product is used correctly and safely by the end user while also complying with regulatory requirements [56].

The label of the medicated bath bomb should include the following information:

- **Product name** (e.g., Medicated Effervescent Bath Bombs of Diclofenac Sodium)
- **List of ingredients** including active and inactive components
- **Strength of active ingredient** (e.g., amount of diclofenac sodium per unit)
- **Directions for use** (e.g., dissolve one bath bomb in warm water before use)
- **Storage conditions** (e.g., store in a cool and dry place, protect from moisture)
- **Warnings and precautions** (e.g., for external use only, avoid contact with eyes, keep out of reach of children)
  - **Batch number and manufacturing date**
  - **Expiry date**
  - **Manufacturer details**

Proper labelling helps in ensuring product identification, traceability, and safe usage. It also improves user confidence and compliance by providing clear instructions and necessary precautions. Therefore, labelling is an essential part of the overall development and presentation of medicated bath bomb formulations.

Figure 5.9: Labelling of Product.

5.10 Storage Conditions

Proper storage conditions are essential for maintaining the stability, safety, and effectiveness of medicated effervescent bath bombs. Since effervescent formulations are highly sensitive to moisture, exposure to humidity can lead to premature reaction between citric acid and sodium bicarbonate, resulting in loss of effervescence and reduced product performance.[34,41]

The prepared bath bombs should be stored in a **cool and dry place**, away from direct sunlight and heat. High temperature and humidity may adversely affect the physical integrity and stability of the formulation. Therefore, maintaining controlled environmental conditions is necessary to preserve the quality of the product.

Bath bombs should be stored in **airtight and moisture-resistant containers** such as laminated aluminium pouches, sealed plastic containers, or glass jars. The use of desiccants (e.g., silica gel) inside the packaging is recommended to absorb any residual moisture and enhance product stability during storage.

Additionally, the formulation should be protected from **mechanical stress**, as bath bombs are relatively fragile and may break during handling or transportation. Proper packaging helps in preventing physical damage and maintaining the shape and appearance of the product. It is also important to label the product with appropriate storage instructions such as *"Store in a cool and dry place. Protect from moisture."* to ensure correct handling by the user.

Thus, suitable storage conditions play a vital role in preserving the stability, efficacy, and overall quality of medicated effervescent bath bomb formulations.

Figure 5.10: Storage Conditions.

6. PRELIMINARY STUDY

6.1 Pre-formulation Studies

Pre-formulation studies are an essential step in formulation development, as they provide information regarding the physicochemical properties of the drug, which influence formulation design and stability. These studies were carried out to ensure the suitability of the drug for incorporation into the effervescent system.[49]

6.1.1 Melting Point Determination

The melting point of Diclofenac Sodium was determined using the capillary method. A small quantity of the drug was placed in a capillary tube, which was then introduced into the melting point apparatus. The temperature at which the drug started melting and the temperature at which it completely melted were recorded.

A sharp melting point range indicates purity of the drug, whereas a broad range suggests the presence of impurities. This parameter is crucial for confirming the identity and purity of the drug before formulation.[4,49]

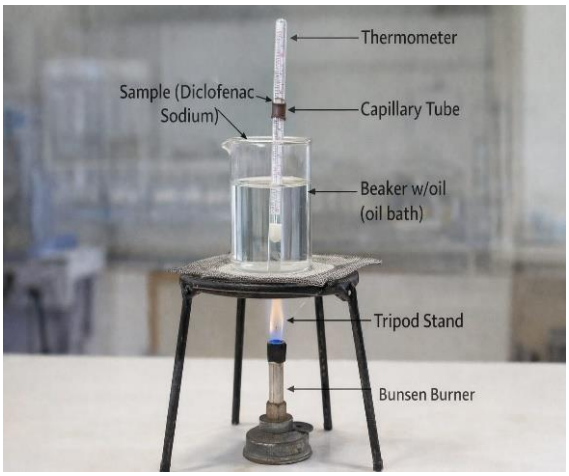


Figure 6.1.1: Melting Point.

6.1.2 Infrared Spectroscopy

Infrared (IR) spectroscopy was performed using Infrared Spectroscopy to identify the functional groups present in the drug molecule. The sample was prepared and analysed in the IR spectrophotometer, and the spectrum was recorded over a suitable wavelength range. Characteristic absorption peaks corresponding to functional groups such as amine (N-H), carboxylate (C=O), and aromatic rings were observed. These peaks were compared with standard reference spectra to confirm the identity of Diclofenac Sodium. IR spectroscopy is a reliable method for drug identification and compatibility studies.[49,52]

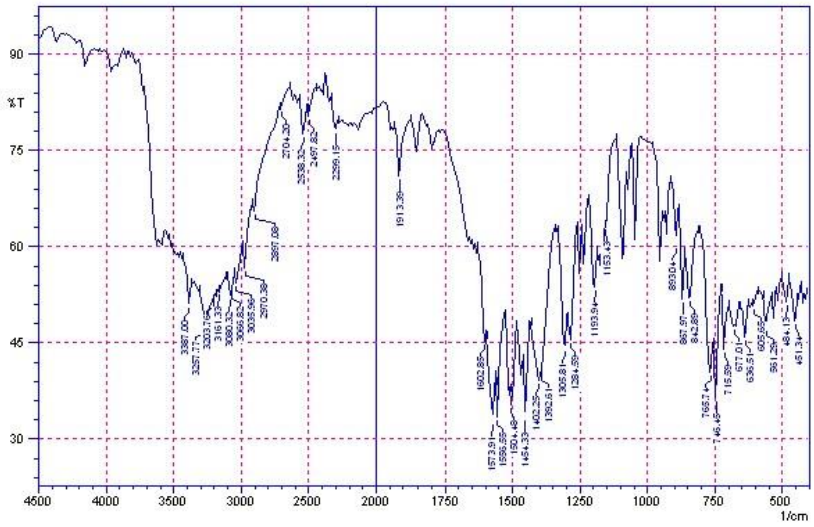


Figure 6.1.2: FTIR Spectrum.

6.1.3 UV Spectroscopy

UV analysis was carried out using UV-Visible Spectroscopy to determine the maximum absorption wavelength (λmax) of the drug. A stock solution of Diclofenac Sodium was prepared in methanol and further diluted to obtain appropriate concentrations.

The solution was scanned in the wavelength range of 200–400 nm, and the λmax was recorded. The method is based on Beer-Lambert's law, which states that absorbance is directly proportional to concentration. UV spectroscopy is widely used for quantitative estimation of drugs in pharmaceutical formulations [49,50].

RESULTS AND DISCUSSION

7.1 Pre-formulation Results

Pre-formulation studies were carried out to evaluate the physicochemical properties of diclofenac sodium prior to formulation development.

1. Physical Appearance

Diclofenac sodium was observed as a white to slightly yellow crystalline powder, which complies with standard pharmacopoeial characteristics.

2. Solubility Study

The drug was found to be:

- Sparingly soluble in water
- Freely soluble in methanol

This indicates its suitability for topical formulation, especially when combined with suitable excipients and penetration enhancers.

3. Melting Point

The melting point of diclofenac sodium was found to be within the reported range, indicating purity of the drug sample.

4. Drug–Excipient Compatibility Study

Compatibility studies (FTIR / observation-based) showed **no significant interaction** between diclofenac sodium and excipients such as:

- Citric acid
- Sodium bicarbonate
- Epsom salt
- Oils and surfactants

This confirms that the drug is stable and compatible with selected excipients.

7.2 Evaluation Results

The prepared medicated bath bombs were evaluated for various parameters:

1. Physical Appearance

All formulations were found to be:

- Uniform in shape
- Smooth surface
- Free from cracks (optimized batch)

Earlier batches showed minor cracks, which were later resolved by optimizing moisture and binder concentration.

Figure 7.2: Physical Appearance of Bath Bomb.

2. Weight Variation

Batch	Average Weight (g)
F1	50
F2	48
F3	46
F4	49
F5	50

All batches showed acceptable weight variation, indicating uniformity in die filling and compression.

3. Hardness Test

Batch	Hardness (kg/cm²)
F1	3.5
F2	3.4
F3	4.7
F4	3.8
F 5	4.9

Optimized batch showed adequate hardness, ensuring proper handling without breakage RESULTS AND DISCUSSION

4. pH Determination

Batch	pH
F1	5.7
F2	5.5
F3	5.8
F4	6.5
F5	6.8

The pH of all formulations was found to be within **skin-compatible range (5.5–7.5)**, indicating suitability for topical use.

5. Effervescence Time

Batch	Time (min)
F1	1.5
F2	1.4
F3	2.3
F4	1.3
F5	2.5

Effervescence time was within acceptable limits, showing rapid disintegration and effective CO_2 release.

4. Drug Content Determination Drug content (%) = (Actual amount/ Theoretical amount) * 100.

Batch	Drug Content (%)
F1	98%
F2	96%
F3	96%
F4	97%
F5	99.5%

All formulations showed drug content within acceptable limits (95–105%), indicating uniform distribution of diclofenac sodium.

7. In-vitro Drug Release Study

Time (min)	% Drug Release
5	30-40%
10	50-60%
15	60-70%
20	70-80%
30	80-90%

Optimized batch showed **controlled and effective drug release**, confirming suitability of formulation.

7.3 Graphical Representation

1. Time vs % Drug Release graph

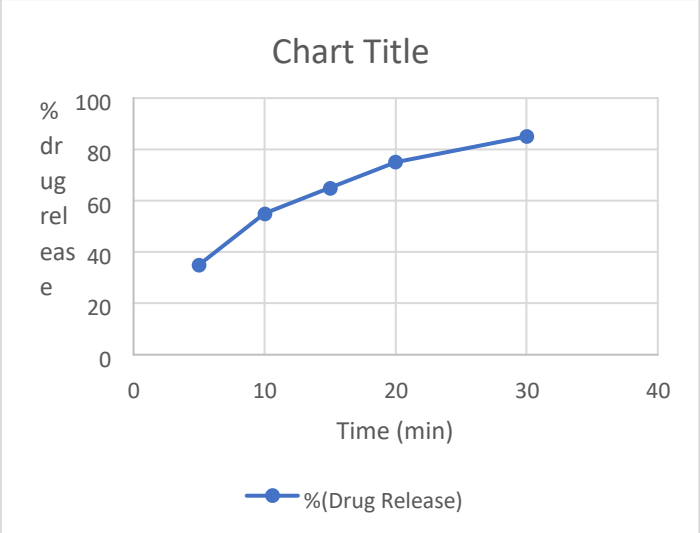


Figure 7.3.1: Graph: Time vs %Drug Release Graph.

2. Batch vs Hardness

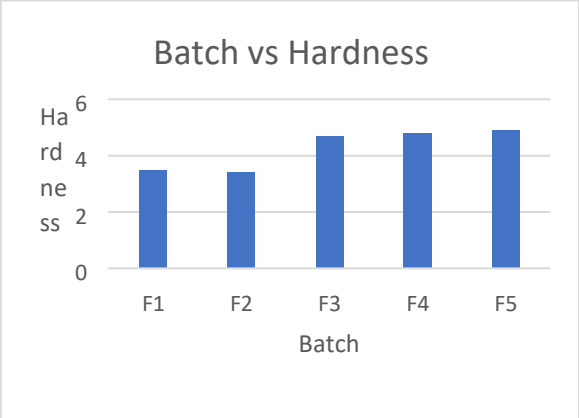


Figure 7.3.2: Graph: Batch vs Hardness 3. Batch vs Effervescence Time.

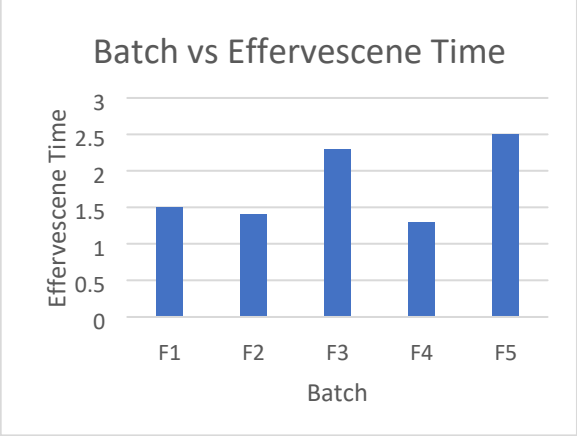


Figure 7.3.3: Graph: Batch vs Effervescence Time.

4. Batch vs Drug Content

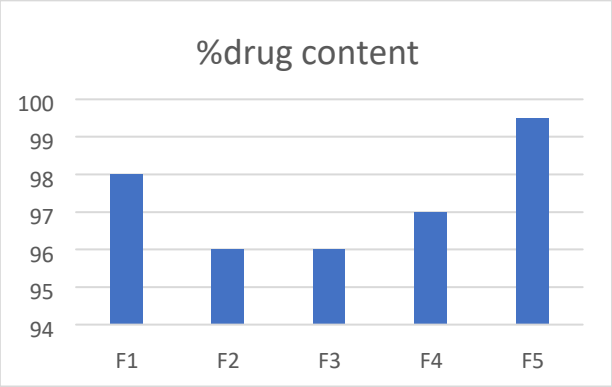


Figure 7.3.4 Graph: Batch vs Drug Content.

7.4 DISCUSSION

The present study successfully developed medicated effervescent bath bombs containing diclofenac sodium for topical pain management.

Pre-formulation studies confirmed that diclofenac sodium possesses suitable physicochemical properties and compatibility with selected excipients. This ensured stability and effectiveness of the formulation.

The evaluation parameters demonstrated that all formulations met acceptable pharmaceutical standards. Among all batches, the optimized formulation showed:

Good mechanical strength

- Acceptable pH
- Rapid effervescence
- Uniform drug content
- Effective drug release

The effervescence mechanism played a crucial role in enhancing drug dispersion and improving contact with the skin, which may enhance drug permeation.

Additionally, incorporation of excipients such as Epsom salt and oils provided added therapeutic and cosmetic benefits, improving patient compliance.

Overall, the developed formulation offers a **novel, patient-friendly, and effective approach** for topical delivery of diclofenac sodium, with potential advantages over conventional dosage forms.

7.5 Product Images

Figure 7.5.1: Final Product (Top View).

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Figure 7.5.2: Side View of Bath Bomb.

Figure 7.5.3: Packaged Product.

Figure 7.5.4: Effervescence in Water.

CONCLUSION

The present study titled **"Formulation and Evaluation of Medicated Effervescent Bath Bombs of Diclofenac Sodium for Topical Pain Management"** was successfully carried out with the objective of developing a novel and patient-friendly topical drug delivery system. Diclofenac sodium, a widely used non-steroidal anti-inflammatory drug, was effectively incorporated into an effervescent bath bomb formulation using suitable pharmaceutical excipients such as citric acid, sodium bicarbonate, Epsom salt, and other additives. The formulation was designed based on the principle of effervescence to ensure rapid dispersion and enhanced drug availability.

Preformulation studies confirmed that diclofenac sodium possesses suitable physicochemical properties and showed good compatibility with selected excipients, ensuring stability of the formulation.

The prepared bath bombs were evaluated for various parameters including physical appearance, weight variation, hardness, pH, effervescence time, drug content, and in-vitro drug release. All evaluation results were found to be within acceptable limits, indicating the reliability and quality of the formulation. The optimized batch demonstrated:

- Good mechanical strength
- Acceptable pH suitable for skin
- Rapid and efficient effervescence

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