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Research Article

Formulation And Evaluation Of Chewable Tablets Containing Dexibuprofen As An Antipyretic Drug

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ABSTRACT

Antipyretic medications are frequently required for fever, a natural physiological reaction to infection or inflammation, to reduce symptoms and enhance patient comfort. The active enantiomer of ibuprofen, dexibuprofen, offers a more appealing substitute because of its improved pharmacokinetic characteristics, which include a longer half-life and less gastrointestinal side effects. To overcome the drawbacks of traditional dose forms and enhance patient compliance, particularly in the case of juvenile and geriatric populations, this research study describes the development and assessment of a unique chewable tablet containing dexibuprofen as an antipyreticmedication. To maximize medication distribution and improve palatability, dexibuprofen was carefully blended with excipients and flavoring ingredients during the formulation process. The prepared chewable tablets were thoroughly examined for their physical attributes, homogeneity of drug content, disintegration time, dissolution profile, and palatability. According to the results, thechewable tablets met or exceeded pharmacopeial requirements for positive qualities such as consistent drug content, quick disintegration, complete dissolve, and acceptable palatability. The study's conclusions imply that the chewable tablet that was created offers a viable way to manage fevers, addressing issues with conventional dose forms while offering quick and efficient relief. Furthermore, the chewable formulation's appeal and convenience may help to boost treatment results and patient adherence, which would increase overall therapeutic efficacy in fever management circumstances.

Keywords: Dexibuprofen, Chewable tablets, Antipyretic drugs.

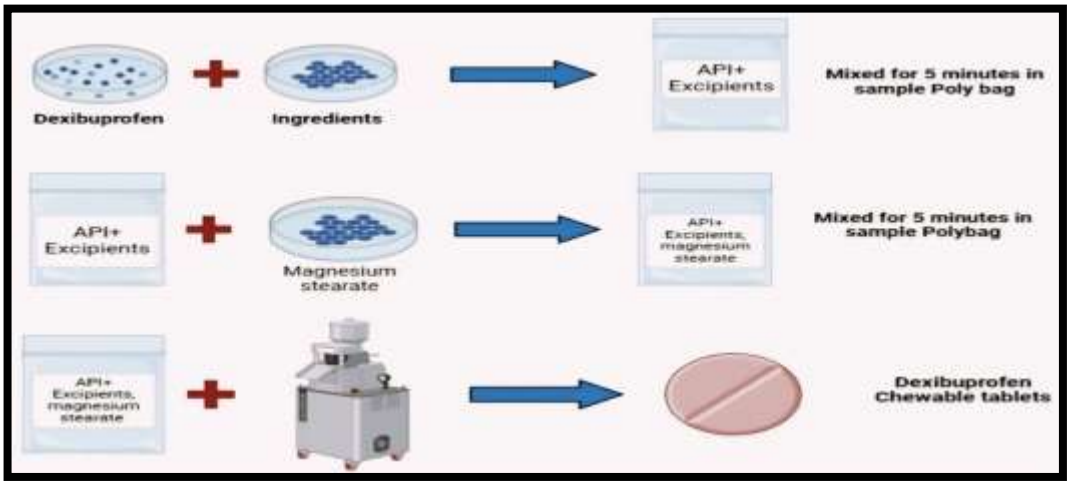

Figure 1. Structural Abstract

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INTRODUCTION

Fever is a common physiological reaction that can occur in a variety of conditions, from minor viral infections to serious systemic diseases. It is a cardinal indicator of infection and inflammation.Fever is an essential defense mechanism that fights microbiological invaders and boosts immune responses, but it also displays uncomfortable symptoms such as chills, lethargy, and discomfort. Therefore, it must be effectively managed to reduce patient suffering and avoid consequences. Ofall the antipyretic medications on the market, dexibuprofen stands out as a very effective treatment due to its strong analgesic, anti-inflammatory, and antipyretic qualities (Axelrod P et al 2000). The pharmacologically active enantiomer of ibuprofen, dexibuprofen, works by selectively blocking the cyclooxygenase (COX) enzymes, thereby preventing the production of prostaglandins that promote inflammation.Dexibuprofen reduces temperature, discomfort, and inflammation by reducing the synthesis of inflammatory mediators. This reduces inflammation and improves patient comfort by symptomatic relief. Though effective, some patient populations may find the traditional tablet formulations of dexibuprofen problematic, especially those who are young or elderly and may have trouble ingesting solid dosage forms. Given these difficulties, it is critical to find substitute dose forms with better patient acceptability, ease of administration, and increased compliance (Kaehler et al 2003). Chewable tablets are a desirable alternative because they offer a tasty and practical way to deliver drugs without having to swallow whole pills. Chewable tablets of dexibuprofen present a promising way to improve patient outcomes and optimize antipyretic therapy by utilizing the natural benefits of chewable formulations, like easy breakdown, agreeable flavor, and ease of administration. The desire to maximize the therapeutic efficacy and patient compliance of dexibuprofen therapy whileaddressing the unmet clinical needs of patients with swallowing issues is the driving force behind this research initiative. This research attempts to further the rapidly developing field of pharmaceutical technology by methodically clarifying the formulation and assessment of chewable tablets that contain dexibuprofen. These novel dosage forms will be able to better serve the variedneeds of patients with a range of age groups and medical conditions. This study aims to determine the viability and efficacy of chewable dexibuprofen tablets as a treatment option for fever management using careful formulation optimization, thorough assessment of tablet qualities, and extensive stability testing (Patil et al 2012, Patel Y et al 2011, Renu et al 2015)

Advantages of chewable tablets (Pharos et al 2011)

The use of chewable tablets in research offers several advantages, In the specialized realm of pharmaceutical formulation development and evaluation, meticulous attention is dedicated to crafting and scrutinizing formulations for their efficacy and safety profiles:

Magnify Patient Compliance: Chewable tablets are often preferred by patients, especially children and the elderly, who may have difficulty swallowing traditional tablets or capsules.

This improves patient compliance with medication regimens, leading to better treatment outcomes.

Convenient Dosage Form: Chewable tablets provide a convenient dosage form foradministering medications, particularly in situations where access to water is limited or inconvenient. This makes them suitable for use in various settings, including hospitals, clinics, and home healthcare.

Rapid Onset of Action: Chewable tablets typically disintegrate quickly in the mouth, leading to rapid drug absorption and onset of action. This is advantageous for medicationsrequiring fast relief of symptoms, such as analgesics and antipyretics.

Improved Palatability: Chewable tablets can be formulated with pleasant flavors and taste- masking agents to improve palatability and enhance patient acceptance. This is especially beneficial for medications with unpleasant taste or odor, increasing patient satisfaction and adherence to treatment.

Uniform Drug Delivery: Properly formulated chewable tablets ensure uniform distribution of the active pharmaceutical ingredient (API) throughout the tablet matrix, leading to consistent drug delivery and efficacy.

Ease of Administration: Chewable tablets eliminate the need for swallowing whole tablets or capsules, making them suitable for patients with dysphagia or those who have difficulty swallowing due to medical conditions or age-related factors.

Versatility in Formulation: Chewable tablets can accommodate a wide range of APIs, excipients, and flavoring agents, allowing for versatile formulation options to meet specific patient needs and therapeutic requirements.

Pediatric and Geriatric Applications: Chewable tablets are particularly useful in pediatric and geriatric populations, where swallowing solid dosage forms can be challenging. They offer a safer and more convenient alternative to traditional tablets or syrups, promoting better medication adherence and therapeutic outcomes.

Dexibuprofen

Dexibuprofen, the pharmacologically active enantiomer of rac-ibuprofen, has garnered significantattention in recent years due to its distinct pharmacological and metabolic characteristics. This paper provides a comprehensive overview of dexibuprofen, exploring its pharmacological properties, therapeutic applications, and clinical implications (Gliszczynska et al 2021). The advent of dexibuprofen represents a significant milestone in pharmaceutical research, offering a refined approach to harnessing the therapeutic benefits of ibuprofen while minimizing unwanted side effects. With itsenantiomeric purity and enhanced pharmacokinetic

profile, dexibuprofen stands out as a promisingcandidate for a wide range of clinical applications. In this paper, we delve into the pharmacological intricacies of dexibuprofen, exploring its mechanism of action, pharmacokinetics, and comparativeeffectiveness with rac-ibuprofen. Additionally, we examine the evolving landscape of dexibuprofen research, highlighting recent advancements and potential avenues for future investigation (El-Houssieny et al 2014). Dexibuprofen exhibits unique pharmacological properties that distinguish it from rac-ibuprofen. Through targeted binding to specific molecular targets, dexibuprofen exerts potentanti-inflammatory, analgesic, and antipyretic effects, offering superior efficacy in pain management and inflammatory disorders. Moreover, its enantiomeric purity confers favorable pharmacokinetic properties, including enhanced bioavailability and reduced potential for adversedrug interactions (Hawel R et al 1997). The therapeutic versatility of dexibuprofen extends across a spectrum of medical conditions, encompassing acute and chronic pain management, rheumatic disorders, and fever reduction. Clinical studies have demonstrated its efficacy in alleviating pain associated with osteoarthritis, migraine, dysmenorrhea, and postoperative recovery, positioning dexibuprofen as avaluable therapeutic option in diverse clinical settings (Evans AM et al 1996).

Mechanism of action of chewable tablets

Taste perception begins with chemical interactions occurring on the surface of the tongue, which are then processed and interpreted by the brain. These interactions involve taste receptors locatedwithin specialized organs called taste buds. When molecules from food or beverages encounter these taste receptors, they initiate a series of biochemical signals that ultimately lead to the sensation of taste. These taste receptor organs, or taste buds, contain highly sensitive nerve endingsthat are responsive to the presence of specific taste molecules. As these molecules dissolve in saliva, they stimulate the taste buds, triggering the transmission of electrical impulses along nervesto the brain. These impulses are relayed to various regions of the brain, including the ninth, tenth,and seventh regions, where they are processed and interpreted as specific tastes, such as sweet, sour, salty, bitter, and umami (Tripathi et al 2011, Wagh et al 2009).

MATERIALS AND METHODS

Materials

Dexibuprofen raw material was a gift sample from Emcure Pharmaceuticals Limited New Delhi,India. Mannitol (powder) and Sucralose were kindly obtained from ChemCenter Hyderabad, Telangana, India. Calcium carbonate and Dicalcium Phosphate are obtained from PureChems group Bulandshahr, UP, India. Magnesium stearate, Sunset Yellow FCF, Orange flavor and Citric acid were purchased from the market.

Method

Preparation of the Chewable tablet

In this situation, the active pharmaceutical ingredient (API) is Dexibuprofen. Select any additional excipients that are required, such as disintegrants, binders, sweeteners, and flavorings.To enhance flow characteristics and compressibility, grind the ingredients if necessary. For consistent dispersion, thoroughly mix the excipients with API. Consolidate the blended powder into tablets using a tablet maker. If you want the desired hardness, adjust the compression force. The chewable pills' taste and palatability can be improved by adding flavorings and sweeteners. For assistance with tableting, think about adding a compression aid. Test the tablets' quality to make sure they adhere to requirements for consistency in content, dissolution, hardness, and weight variation.

Characterization of the prepared formulation

Fourier–transform infrared spectroscopy (FTIR): The infrared spectra of both the formulatedand raw Dexibuprofen were obtained utilizing an FTIR spectrophotometer manufactured by Bruker (Tensor 27 model, Ettlingen, Germany). Preceding the spectral analysis, the samples were combined with a spectroscopic grade of potassium bromide and compacted onto a disk. Thescanning process covered the range from 4000 to 400 $cm^{-1.}$

Particle size distribution: 30 g of the powder mixture was added to the sieve set's top. After that, it was cautiously closed and left in the sieve shaker for 10 minutes. The weight of the powder retained in each sieve was determined by calculating the difference between the weightsof the sieves before and after the agitation, considering the particle size. Plotting the particle sizedistribution graph was the last step.

The angle of repose: The stand has a funnel fastened in it. Weighing the powdered medication,we moved it into the funnel and used our thumbs to seal the opening. Next, the thumb was takenoff, allowing the powder to spill out. To determine the diameter, a circle was drawn at the edgesand a height (h) was measured. The angle was computed using the following equation:

tan-1 h/r = angle of repose (θ), where r is the radius.

Bulk density: The powder sample was carefully added to a 50 ml (about 1.69 oz) graduated cylinder after being weighed. The volume of the sample was recorded, and bulk density (BD)was calculated by dividing the sample weight by the recorded volume.

Tapped density: One hundred taps on the sample-containing cylinder served as the measurement method. By dividing the sample weight by its final volume, TD was computed.
Carr's index: The following formula was used to get the percentage compressibility: (Tappeddensity – Bulk density x 100)/Tapped density.
Hausner's ratio: The following formula was used to calculate it: HR = Tapped density/Bulkdensity.

Table 1:- Formulation of Dexibuprofen chewable tablets by direct compression method.

Ingredients	F1	F2	F3	F4	F5	F6	F7
Dexibuprofen	100mg	100mg	100mg	100mg	100mg	100mg	100mg
Mannitol	226mg	267mg	264mg	261mg	262mg	250mg	250mg
Sucralose	4mg	6mg	6mg	6mg	6mg	6mg	6mg
Calcium Carbonate	50mg	-	-	-	-	-	-
Dicalcium phosphate	100mg	100mg	100mg	110mg	110mg	118mg	123mg
Citric acid	10mg	15mg	17mg	10mg	15mg	15mg	10mg
Sunset Yellow FCF	2mg	2mg	3mg	3mg	2mg	3mg	3mg
Orange flavor	3mg	5mg	5mg	5mg	3mg	3mg	3mg
Magnesium stearate	5mg	5mg	5mg	5mg	5mg	5mg	5mg
Total weight of tablet	500mg	500mg	500mg	500mg	500mg	500mg	500mg

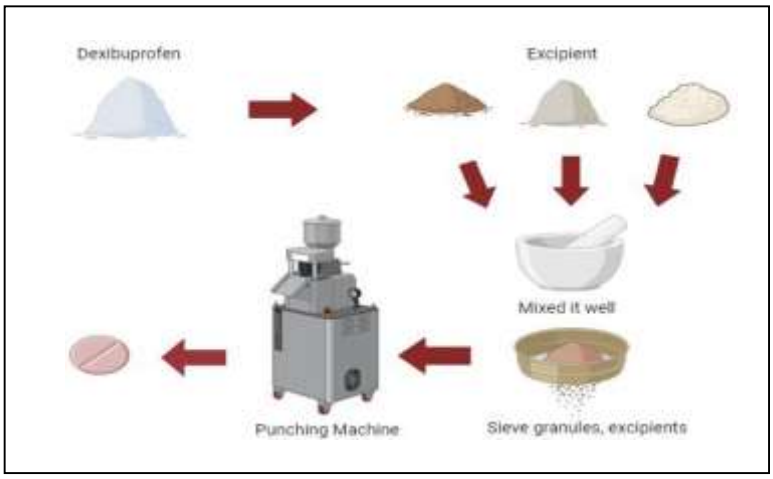


Figure 2. Schematic diagram of making chewable tablet.

Evaluation of Dexibuprofen chewable tablets

Friability

After weighing all twenty tablets, they were placed into the chamber of the friabilitytester, which rotates at 25 rpm. Following four minutes of rotation, the tablets were collectivelyweighed again. The percentage friability was determined using the equation:
Friability = (Initial weight - Final weight) / Initial weight.

Hardness

To assess the tablet's strength, it was placed inside the hardness tester, and the average force required to break twenty tablets was determined. The force was expressed in termsof kilograms per square centimeter.

Weight variation

A set of twenty pills was individually weighed, and the combined weight of all the tablets was used to compute the average weight. Each tablet's weight was compared to theaverage weight. The percent deviation was determined using the formula:
Percentage deviation = [(standard deviation / Average weight) × 100].

Calibration curve

After being weighed, 25 g of dexibuprofen was added to a volumetric flask.After adding Phosphate Buffer (pH 6.8), the capacity reached 100 milliliters (about 3.38 oz).
After that, this solution is diluted to provide a range of concentrations. Ultimately, the calibrationcurve was plotted after each solution's absorbance at 221 nm was measured.

Drug content uniformity

Twenty tablets were crushed using a pestle in a mortar. Subsequently,grams of the resulting substance were transferred to a 100 ml (about 3.38 oz) volumetric flask. Phosphate buffer solution (pH 6.8) was added to the flask to make up the volume to 100 ml. For dilution, 100 ml of buffer solution was added to one milliliter of the

prepared solution. The absorbance at 221 nm relative to the blank, which consisted of phosphate-buffered saline (PBS) atpH 6.8, was measured using a UV-visible spectrophotometer.

Taste evaluation

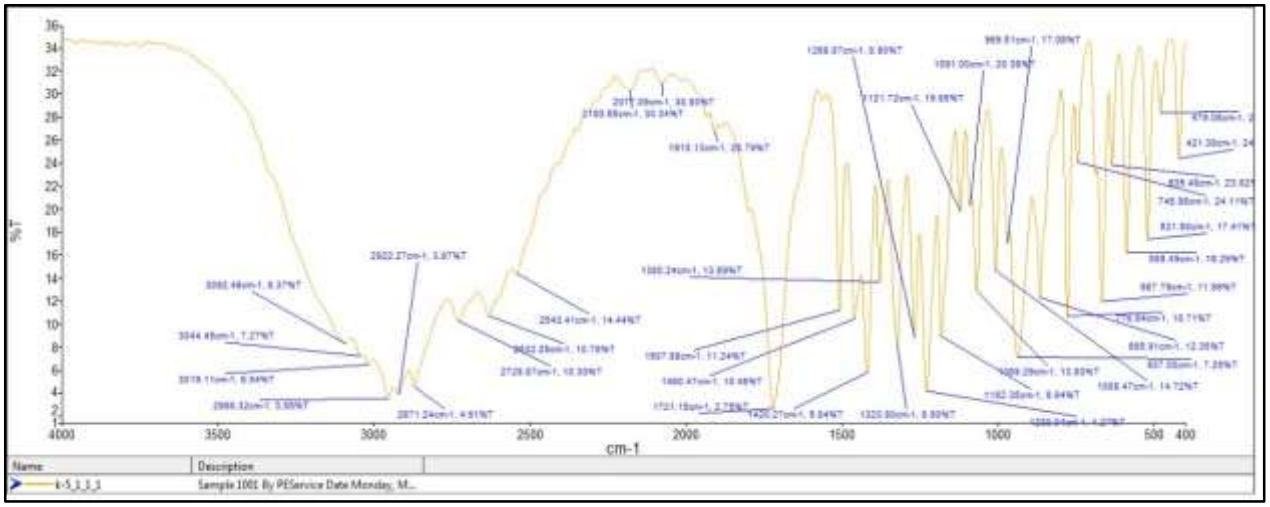
According to physiological principles, taste is the sensory perception resultingfrom the chemical stimulation of taste buds located on the tongue. The four primary taste sensations are salty, sour, sweet, and bitter. Six volunteers were selected randomly for the study. Pure medicine served as the control. Each volunteer was instructed to chew the prepared formulations, and the level of bitterness was assessed using a numerical scale with five distinct levels: level 0 representing no taste, level 1 indicating acceptable bitterness, level 2 denoting slightbitterness, level 3 representing moderate bitterness, and level 4 indicating strong bitterness.

Dissolution test

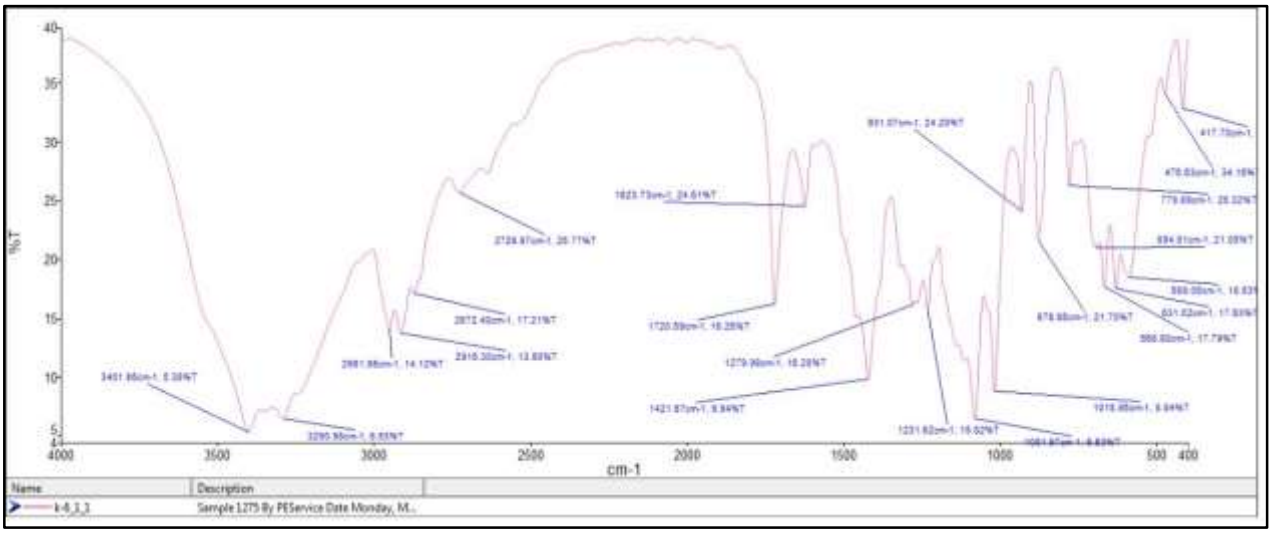
The study utilized linear regression analysis to examine the dissolution characteristics of chewable tablets containing dexibuprofen. A rotating basket operating at 100 rpm and containing 900 ml (about 30.43 oz) of pH 6.8 phosphate buffer solution at a temperatureof 37.0°C ± 0.5°C was employed for the dissolution testing. Chewable tablets were placed in the basket, and 1 ml (about 0.03 oz) samples were withdrawn after 45 minutes, with the dissolving medium refreshed every 10 minutes. The concentration of dexibuprofen in the samples was determined using spectrophotometry at a wavelength of 221 nm.

RESULT

Compatibility test – FTIR: After conducting thorough compatibility studies, it was determined that no discernible chemical changes or interactions occurred between the drug and the selected excipients. These findings, based on both physical and chemical compatibility assessments, affirmthe suitability of the chosen excipients for the formulation development of Dexibuprofen.



(Figure 3: FTIR spectra of unmixed Dexibuprofen drug)



(Figure 4: FTIR spectra of maximized formulation of Dexibuprofen chewable tablet)

Particle size distribution: By Malvern master seizer, dry method

Table 2: Dexibuprofen Particle size

Particle size	Results
10%	< 3 µ
40%	< 9 µ
90%	< 20 µ

Physico-mechanical characterization:

Table 3: Dexibuprofen Physio-mechanical properties

S.no.	Parameters	Results
1	Bulk Density	0.40gm/ml
2	Tapped Density	0.50gm/ml
3	Carr's index	22.45%
4	Hausner Ratio	1.15
5	Angle of Repose	38.25

Table 4: Dexibuprofen Physio-mechanical Properties of Formulation

Batch	Bulk Density(g/ml)	Tapped Density(g/ml)	The angle of Repose(θ)	Carr'sIndex	Hausner'sratio
F1	0.398	0.491	38°27'	22.561	1.110
F2	0.410	0.512	40°14'	23.621	1.218
F3	0.425	0.528	39°22'	19.355	1.309
F4	0.445	0.542	40°16'	19.233	1.244
F5	0.463	0.551	36°17'	18.546	1.695
F6	0.463	0.538	36°55'	17.294	1.547
F7	0.461	0.549	32°23'	16.496	1.366

Table 5: Post compression parameters of the formulation

Batch	Friability (%)	Hardness	Average weight (mg)
F1	0.43	2.0-3.0	499
F2	1.38	2.5-3.0	500
F3	0.24	2.0-3.5	498
F4	0.18	2.5-3.5	496
F5	0.16	2.0-3.0	500
F6	0.15	2.5-3.5	500
F7	1.55	2.5-3.0	502

Table 6: Weight variation of tablet as per the USP

Avg. Weight (mg)	Maximum % deviation
≤ 130	± 10
130-324	± 7.5
≥ 324	± 5

Table 7: Drug Content Uniformity Assessment for Dexibuprofen

Sample	Absorbance at 221nm
1	0.345
2	0.352
3	0.348
4	0.355
5	0.349
6	0.351
7	0.347

Table 8: Dissolution Characteristics of chewable tablets containing Dexibuprofen

Time (minutes)	Concentration of Dexibuprofen (mg/ml)
0	0
10	0.025
20	0.050
30	0.075
40	0.100
45	0.110

Table 9: Taste Evaluation of Prepared Formulation:

The level of bitterness was assessed using a numerical scale with distinct levels:

- **Level 0**: No taste
- **Level 1**: Acceptable bitterness
- **Level 2**: Slight bitterness
- **Level 3**: Moderate bitterness
- **Level 4:** Strong bitterness

Volunteer	Formulation	Taste Level
1	Formulation A	Level 0 (No taste)
2	Formulation B	Level 1 (Acceptable bitterness)
3	Formulation C	Level 3 (Moderate bitterness)
4	Formulation D	Level 2 (Slight bitterness)
5	Formulation E	Level 1 (Acceptable bitterness)
6	Formulation F	Level 4 (Strong bitterness)

Table 10: Calibration Curve for Dexibuprofen

Sr.no.	Concentration (µg/ml)	Absorbance at 221nm
1	0	0
2	3	0.158
3	6	0.314
4	9	0.465
5	12	0.593
6	15	0.739
7	18	0.901

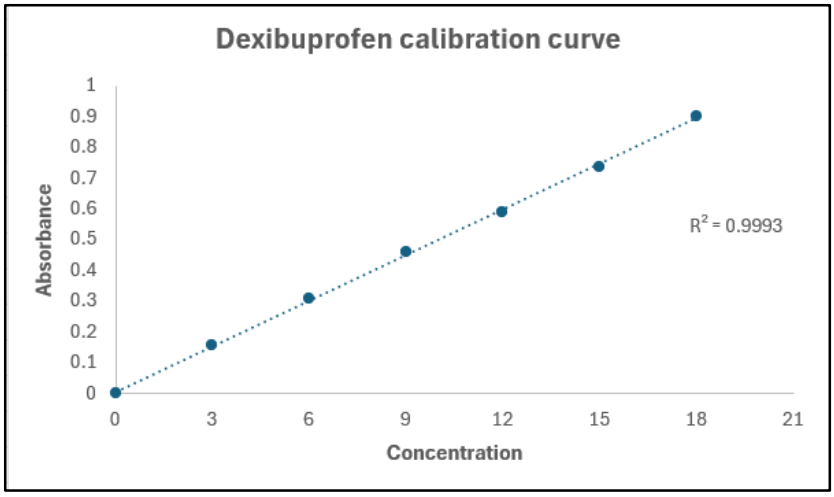


Figure 5: Calibration Curve for Dexibuprofen

A comprehensive series of evaluation tests were conducted on tablets of various formulations, encompassing assessments such as weight variation, friability, hardness, calibration curve establishment, drug content uniformity, dissolution studies, and taste evaluation through dissolving studies. These evaluations were executed meticulously in accordance with the protocolsoutlined in the Indian Pharmacopoeia (I.P.). Following the collation of test results, it was observedthat all outcomes fell within the predetermined Pharmacopeial limits. This study concluded that each formulation developed exhibited exemplary characteristics. Ultimately, Dexibuprofen chewable tablets were successfully formulated in a manner that ensures both safety and efficacy, following rigorous experimentation with multiple formulations. After careful consideration of pre-compression and post-compression parameters, formulation F5 was identified as the optimized choice.

DISCUSSION

The formulation and evaluation of chewable tablets containing dexibuprofen as an antipyretic drug is a complex process with several critical aspects to consider. Chewable tablets are particularly advantageous for certain patient populations, such as children and the elderly, due to their ease of administration and improved

compliance. Therefore, optimizing the formulation to ensure the desired therapeutic effect while maintaining acceptable taste and texture is paramount. Formulation development involves selecting suitable excipients to achieve the desired characteristics of the chewable tablets. Excipients such as sweeteners, flavors, disintegrants, and binders play crucial roles in masking the bitter taste of the active pharmaceutical ingredient (API), promoting rapid disintegration in the oral cavity, and ensuring adequate tablet integrity. The selection and concentration of these excipients must be carefully balanced to achieve the desired tablet properties. Evaluation of the formulations is essential to assess their quality, consistency, and performance. Various parameters, including weight variation, thickness, hardness, friability, and drug content uniformity, are commonly evaluated to ensure compliance with pharmacopeial standards. In addition, in vitro dissolution studies provide valuable insights into the release profile of the API from the tablets, which is critical for predicting its bioavailability and efficacy in vivo. Among the seven formulations tested in this study, formulation number 5 demonstrated the most promising characteristics, closely matching the standard requirements for chewable tablets containing dexibuprofen as an antipyretic drug. This suggests that the excipient composition and processing parameters employed in formulation number 5 were optimal in achieving the desired tablet properties, including taste masking, rapid disintegration, and uniform drug content. However, despite the success of formulation number 5, further studies are warranted to validate these findings and ensure the safety and efficacy of the optimized formulation. In vivo pharmacokinetic studies are necessary to evaluate the drug's absorption, distribution, metabolism, and elimination profiles following oral administration. Moreover, clinical trials are essential to assess the therapeutic efficacy and safety of the chewable tablets in target patient populations. Additionally, long-term stability studies are imperative to evaluate the shelf-life of the optimized formulation under various storage conditions, including temperature and humidity variations. Stability testing will provide valuable information regarding the formulation's physical and chemical stability over time, ensuring its quality and efficacy throughout its intended shelf-life. In conclusion, the successful formulation and evaluation of chewable tablets containing dexibuprofen represent a significant advancement in pharmaceutical technology, offering a convenient and effective dosage form for the management of fever and inflammation, particularly in pediatric and geriatric patients. However, further research and development efforts are necessary to fully characterize the optimized formulation and bring it to market for clinical use.

CONCLUSION

Given that dexibuprofen is classified as a BCS class II medication, the goal of this study was to develop chewable tablets of the medication that are stable, safe, and convenient to ensure prompt therapeutic effect. To provide a rapid beginning of effect, rapid tablet disintegration was prioritized. Seven formulations of chewable Dexibuprofen tablets were produced with success using a direct compression process. These formulations included mannitol, sucralose, calcium carbonate, dicalcium phosphate, citric acid, sunset yellow FCF, orange taste, and magnesium stearate. Using a production-friendly approach, the tablets' manufacturing was optimized for quality and consistency while eschewing expensive technology, equipment, and drawn-out processes. The tablets were evaluated based on many factors, including their thickness, hardness, and friability. Based on the results, formulation F5 was found to be the most optimal and outstanding of all the formulations created for chewable Dexibuprofen tablets. Moreover, evaluations of friability, hardness, and physical appearance revealed no appreciable alterations during storage conditions. In summary, the study's intended goals were met with the effective production of chewable Dexibuprofen pills.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

SUMMARY

The research article titled "Formulation and Evaluation of Chewable Tablets Containing Dexibuprofen as an Antipyretic Drug" presents a comprehensive investigation into the development and assessment of Dexibuprofen-based chewable tablets designed for antipyretic purposes. By meticulously adhering to the protocols outlined in the Indian Pharmacopoeia (I.P.), the study explores various formulation parameters and conducts a range of evaluation tests. Theseassessments encompass critical parameters such as weight variation, friability, hardness, calibration curve establishment, drug content uniformity, dissolution studies, and taste

evaluationvia dissolving studies. Through rigorous experimentation and analysis, the research ensures that all formulated tablets consistently meet the Pharmacopeial limits, indicating their suitability for pharmaceutical use. The culmination of these efforts results in the identification of an optimized formulation, denoted as formulation F5, which exhibits superior performance across pre- compression and post-compression parameters. This optimized formulation signifies a significant advancement in the development of Dexibuprofen chewable tablets, offering a safe, effective, andconvenient solution for fever management. In summary, this research not only demonstrates the successful formulation of Dexibuprofen chewable tablets as an antipyretic drug but also underscores their potential to address the evolving needs of pharmaceutical applications. The findings of this study hold promising implications for the field, paving the way for further advancements in fever management and pharmaceutical formulation technology.

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