

ORIGINAL ARTICLE

Formulation and Evaluation of Honey Gummy Containing Dandelion Extract for the Management of Osteoporosis

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ABSTRACT

Osteoporosis is a medical condition that primarily affects older adults, particularly women after menopause. It is characterized by a decrease in bone density and an increased risk of fractures, especially in areas such as the spine, hips, and wrists. Dandelion (Taraxaci herba) extract has been traditionally used for its potential health benefits, including its ability to support bone health. In this study, we aimed to develop and assess gummy containing dandelion extract as a potential management option for osteoporosis. Compared to other dosage forms, gummy food supplements are currently more widely accepted by customers and have less restrictions. The fascination in medications, nutritional substances, and vitamins and minerals based on natural components has grown significantly in the modern era. Our study's objective was to create a gummy composition using natural components and assess how each ingredient affected the many factors involved in the condition's therapy. Unlike previous gummy formulations, we did not utilize artificial sweeteners, which could pose a risk in the future. Instead, we used honey. Furthermore, honey functions as a preservative, preventing the need for additional preservative additions. With the coating of omega-3 oil it enhances the effect against bone calcium absorption. By formulating these in a convenient and enjoyable gummy form, we hope to provide individuals with a practical and effective way to support their bone health.

Keywords: Osteoporosis, Dandelion extract, honey, Gummies, bone health.

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INTRODUCTION

Osteoporosis is a condition where the bones become fragile and brittle due to a loss of tissue. This loss of tissue can occur when the body doesn't produce enough new bone or when too much old bone is reabsorbed by the body. As a result, the bones become weak and are more prone to fractures or breaks, even from minor falls or bumps. Bone tissue undergoes a constant cycle of resorption (the breakdown of old bone) and formation (the creation of new bone). If the rate of resorption exceeds the rate of formation, bone loss occurs. However, during menopause and as we age, there is an imbalance between the rates of bone resorption and formation. This leads to a higher risk of fractures. Additionally, certain factors can further increase the rate of resorption, resulting in the loss of bone density and changes in the microarchitecture of the bones [1]. The use of glucocorticoids, which are commonly prescribed medications for various conditions, can also have a negative impact on bone health and increase the likelihood of fractures. Furthermore, reduced bone quality, characterized by a decrease in bone density and strength, can make bones more susceptible to fractures [2].

Various approaches, such as imaging technologies and biochemical testing, are used to evaluate the physiological status of bone in living persons. Amongst them, bone mineral density (BMD) imaging has become the most frequently used. The measurement of BMD offers vital information regarding bone health, supporting the diagnosis and treatment for osteoporosis [3].

Osteoclasts are the multinucleated cells or also called as the primary resorbing cells. These are responsible for formation of pits so the release of calcium into the blood. Osteoclast growth and activity can also be regulated by inflammatory cytokines, involving as interleukin 1 (IL-1), IL-6, tumour necrosis

factor- α (TNF- α), and α V β 3 integrin [4,5]. In the process of remodeling bone, osteoblasts are responsible for creating new bone in the growing skeleton [6]. By the presence of more osteoclasts as compared to osteoblasts also leads to the porous bones. If osteoblasts are present in the lesser concentration it will lead to slow absorption of the calcium and slow ossification of bones leading to osteoporosis.

Herbal treatment for osteoporosis

Table 1: Medicinal Plant for the treatment of osteoporosis

Botanical names	ommon names	Uses
<i>Taraxacum officinale</i>	Dandelion	May support bone health and mineral absorption [10]
<i>Trifolium pratense</i>	Red Clover	May support bone health and density [11]
<i>Cissus quadrangularis</i>	Hadjod	Used traditionally for bone fractures and healing [12]
<i>Terminalia arjuna</i>	Arjuna	May have cardioprotective effects, indirectly benefiting bone health [13,14]
<i>Commiphora wightii</i>	Guggul	May support bone health and reduce inflammation [15]
<i>Withania somnifera</i>	Ashwagandha	May promote bone healing and density [16]
<i>Asparagus racemosus</i>	Shatavari	Traditional use for bone health and strength [17]
<i>Saraca asoca</i>	Ashoka	Traditional use for women's health, potential benefits for bone health [18]

Osteoporosis can be treated in several ways, including parathyroid hormone, bisphosphonates, hormone replacement therapy, and denosumab. However, some people are concerned about the potential long-term negative effects of these medications. Since ancient times, natural herbs have been extensively utilized in clinical practice across numerous nations. Many plants and herbs include phytoestrogen, which interacts with estrogen receptors and has a structure identical to estrogen, indicating a potential mechanism for preserving bone mineral homeostasis and serving as a bioactive ingredient in quality control [7]. The involvement of estrogen-like actions is important, especially from soy phytoestrogenic substances and other herbal formulations. These substances decrease bone resorption biomarkers while increasing antioxidant and anti-inflammatory properties and improving markers of bone formation. As such, they can be used as a supplementary treatment for osteoporosis [8].

The plant, *Taraxaci Herba*:

(TH), also referred to as "dandelion," is a member of the Asteraceae (Compositae) family and is mostly found in Asia, Europe, and the United States. It grows best in warmer temperate climates [9]. The effects of TH on osteoclast activity and bone resorption are suppressive due to various flavonoids: Luteolin, Chlorogenic acid, caffeic acid. Studies have demonstrated that RANKL has a major impact on improving bone microstructure by reducing osteoclast differentiation, creation, fusion, and bone resorption. Moreover, it prevents the femur's reduced trabecular area. Also, research indicates that the pharmacological effects of TH in an animal model of osteoporosis were contrasted with those of osteoporosis drugs (17 β -estradiol (E2) and alendronate (ALN)). TH showed that the NFATc1/c-Fos pathway significantly inhibited the early osteoclast development. Consequently, osteoporotic rats showed a rise in femur bone density and regulation of osteoclast-related factor expression in serum and tissues. The results of this investigation offer objective proof in favor of TH's inhibitory effects on OVX-induced bone loss and osteoclastogenesis [10]. Subsequent studies have shown that preventive benefits with dandelion, vitamin C, and K administered in combination with rats treated with heparin were the most promising when compared to the administration of each drug separately [20].



Figure 1: *Taraxaci herba* (Dandelion)

Herbal formulation:

For patients under the age of eight, liquid formulations are the most suitable, according to EMA guidelines. The ability to dissolve of bioactives, limits the dosage that may be used in liquid solutions, and a multitude of additives, such as sweeteners, buffers, and preservatives, are needed to assure the products' physical, chemical, and microbiological stability as well as to enhance their flavour [19]. Currently, because of their nutritional and functional qualities, the responsible and effective use of food industry by-products in the medicine has gained the attention.

In this study, a novel approach to addressing osteoporosis is introduced through the development of *Taraxaci Herba* gummy supplements fortified with drug acting on osteoporosis cycle, essential vitamins crucial for bone health. The innovative use of honey as sweetener designed to minimize the potential health risks associated with traditional sweeteners. Through meticulous formulation and testing, the aim was to create a palatable gummy that not only supports bone strength but also manages the condition.

MATERIAL AND METHODS

Raw Material:

Taraxaci herba ethanolic extract (active ingredient), honey, gelatin, guar gum, ascorbic acid powder, polyethylene glycol 400, menthol crystals, water, omega-3 oil, rose oil.

Honey: Honey's special qualities lend support to its use as a natural food preservative. Honey's high sugar content dehydrates microorganisms, preventing their growth and prolonging the shelf life of the product. Its low pH also prevents bacteria from growing, creating an unfavourable environment for any possible spoiling agents [21].

Gelatin and Guar gum: Gelatin and guar gum imparts certain qualities to the finished product. Gelatin gives gummy candies their distinctive chewiness. Guar gum, on the other hand, improves texture and acts as a stabilizer. It improves the mouthfeel by avoiding component separation and supports the gummy's general structural strength.

Ascorbic acid: Ascorbic acid as a source of vitamin c is a vital mineral for several multicellular organisms, especially in humans. Fruits and vegetables contain varying levels of ascorbic acid. The integrity of connective tissues, including bone, is compromised by vitamin C deficiency. As a result, ascorbic acid's detection and quantification in food samples, goods, and nutritional supplements has grown increasingly significant for researchers, health care and food industries.

- **Omega-3 Oil:** Since omega-3s have anti-inflammatory qualities, they may help to improve bone health by reducing inflammation around joints and bones. Furthermore, it's possible that omega-3 fatty acids improve the absorption of calcium, which is important for preserving bone strength and density.
- **Carnuba wax:** It helps to create a barrier between environment and the product resulting into preserving the product from the moisture loss and contamination due to exterior environment.
- **Polyethylene glycol:** It helps to keep the gummies moisturised and soft for the longer period of time. According to research it has also shown that it helps to reduce the acidity due to ethanolic extract of herbal extract.
- **TH preparation:** TH was supplied by Janani organics (Kundgol, Dharwad). TH (dried sample: 20g) was extracted in 80% Et-OH at 4 °C for 3 weeks, and the extract was concentrated using a vacuum concentrator. Thereafter, the dried powder (yield ratio: 9.5%) was obtained using a freeze-dryer and kept at -20 °C for use in the experiment [20].

FORMULATION OF GUMMY CANDIES:

The batch underwent trial and error in order to arrive at the ideal formulation. Taking into account every aspect, such as efficacy, taste masking, melting, stability, and nutrition. First the placebo batch was prepared i.e. without any active ingredient or drug. Only colouring agent, flavouring agent, gelatin, guar gum, PEG were added.

Design experiment:

Design Expert was used in the gummy study design process. The two distinct factors that were selected were guar gum and gelatin. Up to 30 g of water was added or subtracted based on the concentration of gelatin. Prior to the current investigation, the initial experiments were conducted to ascertain the ranges of guar gum (B) and gelatin (A). Hardness, strength, and firmness were selected alternatives. The multiple response (desirability) function was used to pick the optimized batch. By completing studies under the same experimental settings, the predicted response's compliance was confirmed.

Gummy composition:

Ingredients	F1	F2	F3	F4	F5	F6	F7
Gelatin	6.7g	6.5g	5.7g	5.7g	5.3g	5g	4.6g
Guar gum	1g	1g	2g	0.7g	0.5g	2g	1.5g
Honey	20g	20g	20g	20g	20g	20g	20g
Flaxseed oil	qs	qs	qs	qs	qs	qs	qs
Carnauba wax	qs	qs	qs	qs	qs	qs	qs
Menthol crystals	1-2	1-2	1-2	1-2	1-2	1-2	1-2
PEG-400	2 drops	1 drop	1 drop	1 drop	1 drop	1 drop	1 drop
Water	30g	30g	30g	30g	30g	30g	30g

Table 1: Composition of gummy**Formulation table:**

F7	Ingredients	Quantity taken (10N)	Role
1	Dandelion extract	3.5g	API
2	Gelatin	4.8 g – 6.8g	Gelling agent
3	Guar gum	1.5g	Thickener
4	Honey	20g	Sweetener, Preservative
5	Ascorbic acid	2g	Vit C, Reduce OC activity, preservative
6	Flaxseed oil	qs	For coating as vehicle
7	Carnauba wax	2-3 g	For coating
8	PEG 400	1 drop	Humectant, Reduces ethanolic effect
9	Water	30g	Vehicle

Table 2: Composition of Gummy**Formulation process:**

Each component was weighed individually. The water bath was turned on, and honey along with a small amount of water was placed in a beaker (1), followed by the addition of rose oil and menthol crystals. This mixture was held in the water bath, brought to a boil, and allowed to thicken. Gelatin was added to warm water in a second beaker (2) and stirred until a homogeneous mixture was achieved. In a third beaker (3), guar gum was combined with cold water, stirred constantly to prevent lumps and creating a paste. Beaker 2 and beaker 3 were then combined and reheated together to create a uniform mixture. One drop of PEG-400 was added to this mixture to enhance softness.

The beaker with water and honey (beaker 1) was removed from the water bath and, at room temperature, ascorbic acid and the active pharmaceutical ingredient (API) were added and stirred together with the contents from the other beakers. Glycerine was applied to the mould and the mixture was chilled for two hours. After chilling, the gummies were unmoulded and stored at room temperature for minimum 2hr and maximum 24 hours. A coating of flaxseed oil and carnauba wax was then applied to the gummies to enhance their appearance and stability by creating a barrier between the product and the environment.

After the complete formation, the gummies were stored in the air tight container.

**Figure 2: Placebo Gummies**

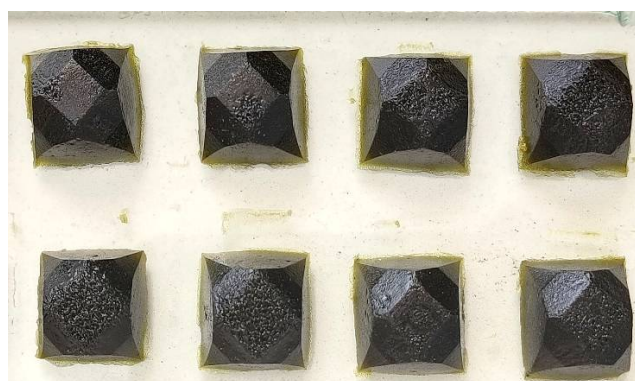


Figure 3: Drug incorporated Gummies

CHARACTERIZATION OF EXTRACT

Determination of (λ_{max}) of extract: The λ_{max} of the *Taraxaci herba* extract was independently calculated using a UV/visible spectrophotometer [22]. Methanol was used as a blank for scanning. 20 mg of *Taraxaci herba* extract were dissolved in 20ml of methanol, which was utilized as a solvent. Methanol is then added until the volume is full. The stock solution was gradually diluted up to five concentrations in a similar way. By scanning samples of various solutions in the UV range of 243 to 310 nm, the wavelength of maximal absorbance for the *Taraxaci herba* extract was found.

Table 4: Standard Calibration Data of Dandelion Extract at Different Wavelengths (243, 253 and 310 nm)

Sr No.	Conc.	WL 243 nm	WL 253 nm	WL 310 nm
1	2	0.168	0.113	0.286
2	4	0.428	0.287	0.418
3	6	0.642	0.431	0.648
4	8	1.058	0.732	0.872
5	10	1.318	0.906	1.082

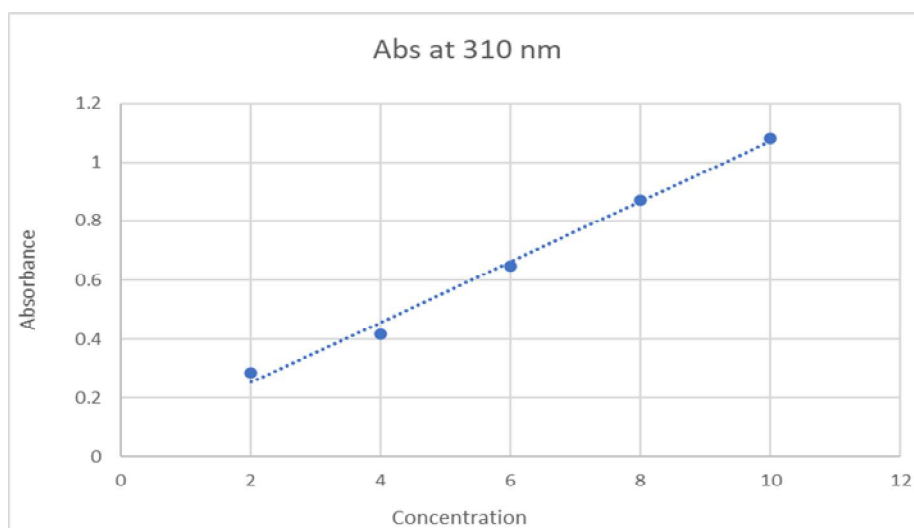


Figure 4: Calibration Curve

HPTLC of *Taraxaci Herba*:

Dandelions are rich in various phytochemicals that exhibit significant activity against osteoporosis. When High-Performance Thin-Layer Chromatography (HPTLC) was performed on the *Taraxaci herba* extract, it revealed the presence of luteolin. This specific compound is known for its role in mitigating osteoporotic activity, suggesting that luteolin is a key contributor to the extract's potential benefits for bone health.

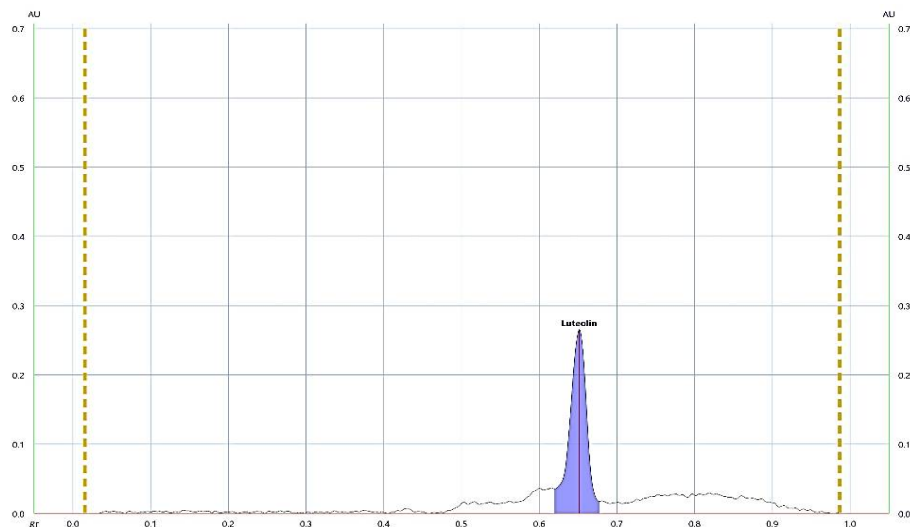


Figure 5: Densitogram of Luteolin

Phytochemicals in *Taraxaci Herba*:

Alkaloids	+
Flavonoids	+
Tannins	+
Saponins	+
Phenols	+
Terpenoids	+
Steroids	-
Glycosides	+
Carbohydrates	-
Proteins	-

Table 3: Phytochemicals in *Taraxaci herba*

EVALUATION OF GUMMIES

1. **Colour:** Golden yellow (without drug)/ Dark green
2. **Taste:** Sweet
3. **Appearance:** Smooth, lustrous
4. **Springiness:** 78%
5. **Deformation at Hardness:** 27 %
6. **Elasticity (Tensile Strength):** 42 %

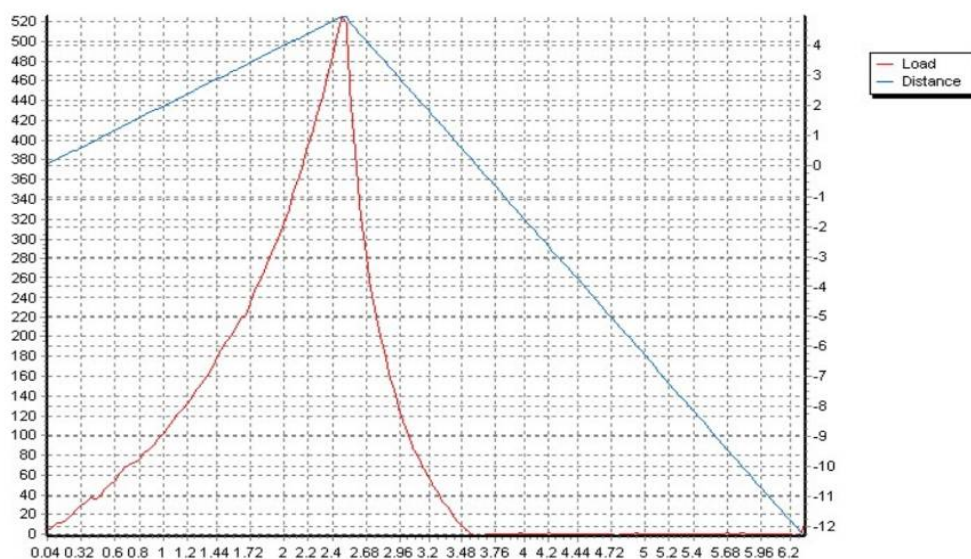


Figure 6: Tensile strength of Gummies

Factor Coding: Actual

Hardness (%)

Design Points:

● Above Surface

○ Below Surface

27 52

Hardness (%) = 27

Std # 1 Run # 7

X1 = A = 4.6

X2 = B = 1.5

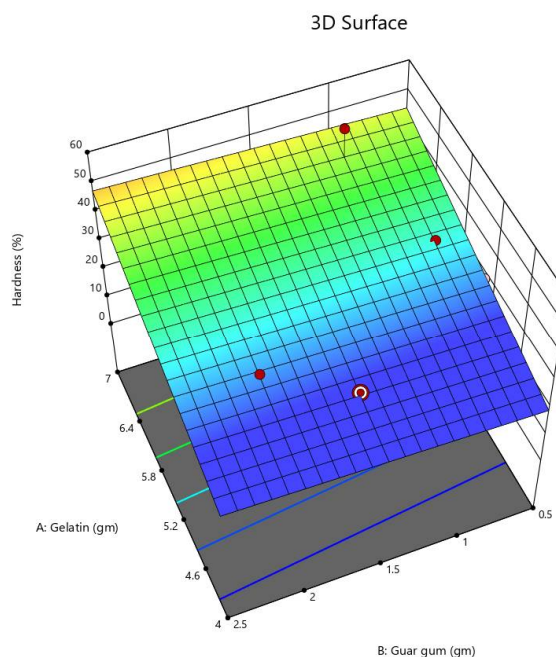


Figure 7: 3D surface response plot of Hardness

Figure 8: 3D response plot of Elasticity

Factor Coding: Actual

Elasticity (%)

Design Points:

● Above Surface

○ Below Surface

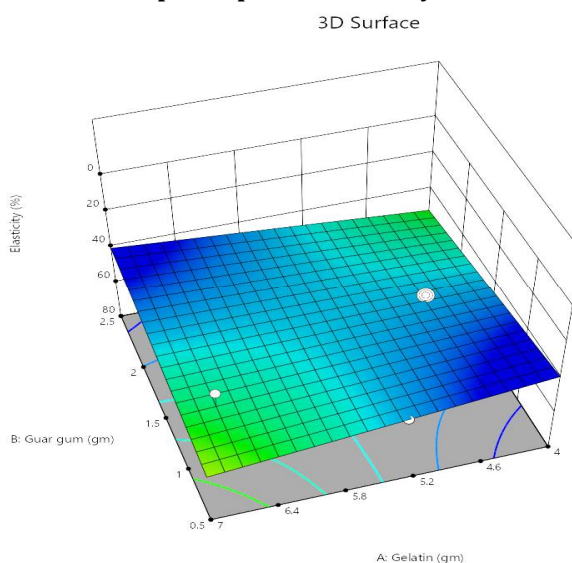
42 60

Elasticity (%) = 42

Std # 1 Run # 7

X1 = A = 4.6

X2 = B = 1.5



Dissolution:

In a dissolution apparatus, the dissolution test was conducted at 37 °C in stimulated gastric fluid with basket type of agitator (Only Gummies with firm shape must be consider for testing). Took a sample of at least 1ml from the container within the allotted time or at each interval. Like that dissolution test was carried out for all the samples.

Stability Studies:

Batch F7 was considered for the further stability studies.

Weight Variation:

	1 Day	15 Days	30 Days	45 Days
Closed container	3.5g	3.4g	3.4g	3.3g
Open environment	3.5g	3.2g	3.1g	3.1g

pH:

	1 Day	15 Days	30 Days	45 Days
Closed container	6.4	6.5	6.5	6.6
Open environment	6.4	6.5	6.6	6.6

Disintegration:

	1 Day	15 Days	30 Days	45 Days
Closed container	7:48	7:50	7:50	7:51
Open environment	7:48	8:12	8:54	9:32

Friability:

	1 Day	15 Days	30 Days	45 Days
Closed container	0.22	0.22	0.22	0.21
Open environment	0.22	0.21	0.20	0.20

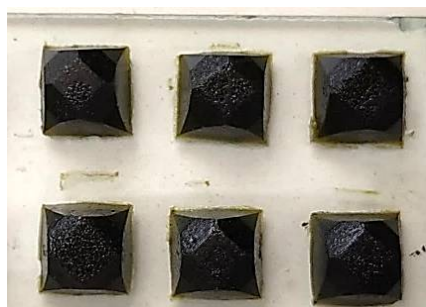


Figure 9: Gummy after 30 Days

RESULTS AND DISCUSSION

Gelatin and guar gum content has a big impact on compliance, chewability, and hardness or firmness. Because of the formulation's proper pH and moisture content, the product should be capable to withstand ambient temperatures. Honey was selected as a sugar alternative with significant applications for diabetes patients. In this study, it was found that using honey instead of sugar for making gummies improved the product's quality by preventing sugar crystals, reducing stress yield, and raising viscosity. Thus, Dandelion extract was successfully incorporated in honey gummies. Gummies were put through a variety of tests, and the results guarantee that they stay stable and don't undergo any physiochemical changes. Regarding friability, disintegration time, hardness, weight fluctuation, and solubility, all of the formulations provide findings that are satisfactory.

Weight variation: As per the USP requirements, every formulation exhibits sufficient percentage variances. Table (6) displays the weight variation of F1 to F7.

Hardness: Hardness is the major factor that determines the chewiness of gummy jelly. The hardness of the formulations is analytically obtained by the crushing strength (Fig 7).

Tensile strength: Tensile strength i.e. elasticity is the important factor or the quality needed for the gummy. The tensile strength is shown fig 6.

The gummy formulation exhibited a maximum tensile strength of approximately 520 units at 2.6 mm displacement. The gradual increase in force indicated good elasticity, while the sharp decline after the peak confirmed rupture of the gummy matrix. These results demonstrate satisfactory mechanical strength and flexibility for pharmaceutical or nutraceutical gummy applications.

Friability: Table (6) displays the friability of formulations F1-F7. F7 was found to be less than 1%, indicating satisfactory results [23].

pH determination: Chewable gummies were discovered to have a pH. The outcome of batches F1 to F7 were acceptable and their pH values fall within the advised range as given in table (6) [24].

In-vitro Disintegration: In accordance with their instructions and earlier research, it was discovered that every gummy would dissolve in 15 minutes [24]. The disintegration times of the F1 through F7 formulations ranged from 7:40 to 8:42 minutes, as shown in Table (6).

Table 4: In-vitro evaluation of Gummy

Batch	Wt. variation	DT (min)	pH	Friability
F1	4.3g	8:58	6.7	0.23
F2	N/A	N/A	6.7	N/A
F3	N/A	N/A	6.7	N/A
F4	4.1g	8:32	6.6	0.25
F5	N/A	N/A	6.6	N/A
F6	3.6g	7:58	6.5	0.22
F7	3.5g	7:48	6.4	0.22

In-vitro Dissolution: Table 4 shows that the proportion of drugs release was tracked for thirty minutes. The drug release % vs time graph was utilized in the kinetic investigation to ascertain the release sequence for each formulation. In 25 minutes, 85% of the medication was discharged from batches that underwent dissolution tests. There is no drug release at time zero. The drug was released quite slowly at first. Within 15 minutes, 50% of the drug had been released from every batch but F7. After 30 minutes, the maximum amount of drug has been delivered by F1–F7. The formulation F7 is regarded as the best since it demonstrated the maximum drug release in less than 30 minutes.

Time	F1	F4	F6	F7
0 min	0	0	0	0
5 min	17.4	23.5	26.4	29.7
10 min	29.5	35.6	41.7	47.9
15 min	43.7	51.4	58.7	64.3
20 min	61.2	68.2	74.4	78.2
25 min	74.8	79.9	84.9	89.2
30 min	85.7	89.9	93.3	97.6

Table 5: In-vitro Dissolution

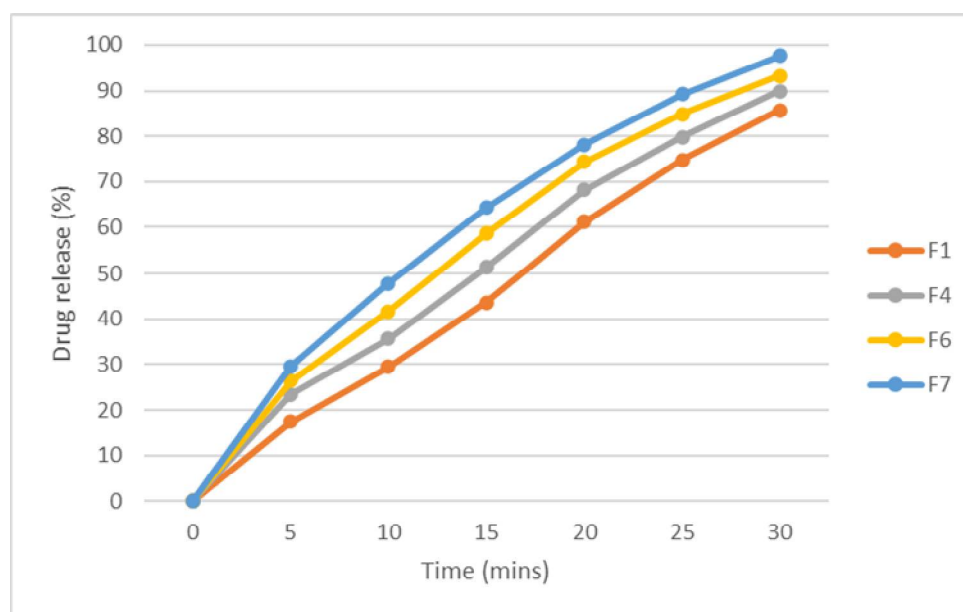


Figure 10: Drug release as per time

CONCLUSION

The study successfully developed dandelion-honey edible gummies using guar gum and gelatin, with F7 identified as the optimized formulation based on its desirable chewy and elastic properties. All formulations met USP requirements for weight variation, hardness, and friability, with disintegration below 10 minutes and approximately 85% extract release within 25 minutes. Flaxseed oil-carnauba wax coating provided protection while contributing omega-3 fatty acids, alongside vitamin C, to support bone health. Overall, the gummies represent a promising, palatable, and patient-friendly herbal dosage form for osteoporosis management, although further studies are needed to establish long-term efficacy, safety, and large-scale manufacturing feasibility.

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