WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
SJIF Impact Factor 8.453
Volume 14, Issue 15, 762-772. Research Article ISSN 2277–7105

FORMULATION & EVALUATION OF GUMMIES FROM MULBERRY LEAF EXTRACT

[1]Ishita Patel and [2]*Bijal Patel

[1]Department of Pharmaceutics, ROFEL Shri G.M. Bilakhia College of Pharmacy.

[2]Department of Pharmaceutical Quality Assurance, ROFEL Shri G. M. Bilakhia College of Pharmacy, Vapi – 396191, Gujarat, India.

Article Received on
05 June 2025,

Revised on 25 June 2025,
Accepted on 15 July 2025

DOI: 10.20959/wjpr202515-37520

***Corresponding Author**
Bijal Patel
Department of Pharmaceutical Quality Assurance, ROFEL Shri G. M. Bilakhia College of Pharmacy, Vapi – 396191, Gujarat, India.

ABSTRACT

The increasing demand for patient-friendly dosage forms has accelerated the development of functional gummies as an alternative to conventional tablets and capsules. In the present study, herbal gummies were formulated using mulberry (Morus alba) leaf extract, known for its rich phytoconstituent profile and potent antioxidant, antihyperglycemic, and lipid-lowering activities. Orange flavoring was incorporated to enhance palatability. Batch 6 was identified as the optimized formulation based on key physicochemical evaluations. The optimized gummies demonstrated acceptable weight variation (6.91 g), suitable hardness (11 units), uniform thickness (5 mm) and diameter (17 mm), minimal friability (0.2%), and acceptable moisture loss (5.6%). The pH value (3.04) was favorable for the stability of the herbal actives, and dissolution was achieved within 14 minutes, ensuring prompt release. The formulation maintained the integrity of bioactive compounds, offering a promising alternative delivery system for mulberry leaf phytoconstituents. This study highlights the potential of herbal gummies as an innovative, consumer-friendly dosage form for natural therapeutics, promoting better compliance and enhancing the appeal of herbal medications. Further studies focusing on stability, sensory evaluation, and clinical efficacy are recommended to establish large-scale production and commercialization.

KEYWORDS: Mulberry leaf extract, HM Pectin.

1. INTRODUCTION

Inflammation is a basic pathological process involved in defensive responses triggered by internal or external stimuli.[1] The main symptoms of inflammation are heat, redness, swelling, pain, and loss of function.[2] Moderate inflammatory responses have positive effects that are helpful and necessary for the body to resist harmful stimuli.[3] However, under certain conditions, such as excessive and chronic inflammation, they may be involved in a range of acute and chronic diseases, including inflammatory bowel disease (IBD), cardiovascular disease (CVD), type 2 diabetes mellitus (T2DM), rheumatoid arthritis (RA), and atherosclerosis (AS).[1,2] There is a close link between inflammation and oxidative stress, wherein the involvement of oxidative stress is a common underlying factor in the pathogenesis of most chronic inflammatory diseases.[4] Oxidative stress is the imbalance between cellular oxidants and antioxidants, which leads to the poor abolition of reactive oxygen and nitrogen species (ROS and RNS) formed in the cell.[5] Under normal physiological conditions, oxidants and antioxidants in the body maintain a redox balance. When the balance is disrupted, oxidative stress occurs and damages the proteins, lipids, and DNA in the cell. Genetic and environmental factors, such as diet, figure into inflammation and antioxidation.[6] Recently, a healthy diet that includes vegetables and fruits has attracted attention for its anti-inflammatory and antioxidant effects.[7] Scientific evidence has demonstrated that the health benefits of eating vegetables and fruit are a result of the combined action of numerous bioactive constituents, including carotenoids, minerals, polysaccharide, flavonoids, and vitamins.[8,9] Flavonoids, a class of plant-derived dietary compounds, are secondary metabolites abundantly found in fruits, vegetables, and herbal medicine, among other sources.[10,11] Previous studies have reported that flavonoids exhibit anti-inflammatory and antioxidative activities in other plants.[12,13]

Mulberry (Morus alba L.), a fast-growing tree, is found in warm and humid climates and can withstand cold and drought. Mulberry is one of the herbs which is used in medicines from centuries ago due to its active chemical components and pharmacological functions. Mulberry belongs to the family Moraceae. The genus *Morus* contains a variety of species some of them includes *Morus alba*, *Morus nigra*, *Morus rubra*, *Morus indica*, *Morus australis*, *Morus cathayana, etc*. *Morus alba* Linn. which is also known as white mulberry. These plants show the beneficial effect in lowering serum glucose and blood cholesterol level; these properties are due to the presence of many active components such as flavonoids, alkaloids, polyphenols, terpenoids in the plant. The different parts of mulberry are

rich in flavonoids and exert anti-inflammatory and antioxidative activities, including the root bark, fruits, and leaves.[14,15] Mulberry leaves extracts are also rich in flavonoids that possess anti-inflammatory and antioxidative activities. Thus, it is necessary to further study its components and pharmacological properties. Black mulberry (*Morus nigra*) contains the highest total phenolic compounds compared to the species of another genus Morus and has antibacterial and antioxidant activity.8,9 2-arylbenzofuran (Moracin M) has known antibacterial activity against *Streptococcus faecalis* (MBC 500 µg/mL), and oxyresveratrol stilbenoid against *Staphylococcus aureus* (MBC 125 µg/mL).10 Mulberry fruits are a rich source of flavonoids and anthocyanin compounds as antioxidant.

Chewable gummy tablets (CGTs), also known as a gummy confection or confectionery gel, consist of sucrose or syrup combined with a gelling agent such as gelatin, gum, or pectin. Other excipients can be added to this formulation, including coloring agent, flavor, and acidulant. Nowadays, CGTs have been developed as nutraceuticals products since these are easier to swallow or chew compared to other dosage forms like tablets or capsules. Therefore, they are widely used in pediatric, geriatric, and patients with swallowing problems. CGTs are formulated using a gelling agent as the vehicle of this product. Several hydrocolloid substances serve as gelling agents, such as gelatin, pectin, sodium alginate, and gum. The selection of a gelling agent is a pivotal part of CGTs formulation because it significantly affects the physicochemical properties of these products.

Gelatin is a protein-based gelling agent extracted from animal collagen such as beef, pork, fish, and poultry. Gelatin is most widely used to manufacture CGTs because it easily forms a stable gel texture and can act as an emulsifier. The viscosity and texture of this preparation strongly depend on the concentration of gelatin used. A previous study showed that the texture profile of gelatin-based CGTs, expressed as hardness, cohesiveness, gumminess, and chewiness, improved with increasing gelation concentration. Other hydrocolloids extensively used in food products include pectin, sodium alginate, xanthan gum, and carrageenan. Pectin is the most promising substitute for gelatin as a gelling agent in CGTs. Pectin is classified as Hydroxy Methoxyl Pectin (HMP) with a degree of esterification (DE) > 50 and Low Methoxyl Pectin (LMP) with DE < 50. DE affects the environments and procedures that each type of pectin needs to form gels. When added with sucrose or glucose, HMP will form a gel in an acidic environment. Pectin is a cation that contains sugar and is sensitive to pH change. Pectin gel is thermoreversible, clear, transparent, dispersed in cold water, dissolvable in cold

and hot water, insoluble if the sugar content is more than 25%, acidic (pH 2.5–4), stable at 40-85°C, and synergistic; also, it has low viscosity and is generally used in the range of 0.15–6.3%. The suitable ratio of HMP and sucrose needs to be optimized. Taking this into account, the aim of this study is to develop healthy and palatable gummy jellies. This is a preliminary approach to the problem, and in this stage, we have also evaluated these gummy jellies in terms of color, texture, antioxidant activity, microbiologic safety, nutritional composition, and sensorial evaluation to demonstrate their health benefits while also preserving most of the desirable organoleptic properties of traditional gummies and jellies. Chewable gummy preparations of Mulberry leaves have many advantages over brewed preparations, which are easy to swallow, practical to use, have an acceptable taste and aroma, as well as quick onset of .

2. MATERIALS AND METHODS

Calcium chloride hydrate (Chemdyes Corporation), HM Pectin (Yanti D SM Andre Pectin Co. Ltd.), Citric acid monohydrate (Finar limited), Mango green color (Asian Chem Works), Green color (Asian Chem Works), Sodium benzoate Preservative, Toluene (Chemdyes Corporation), Chloroform (Molychem), Acetone (Rankem Laboratory agent), Ethyl Acetate (Molychem), Methanol (Finar), Sulfuric acid.

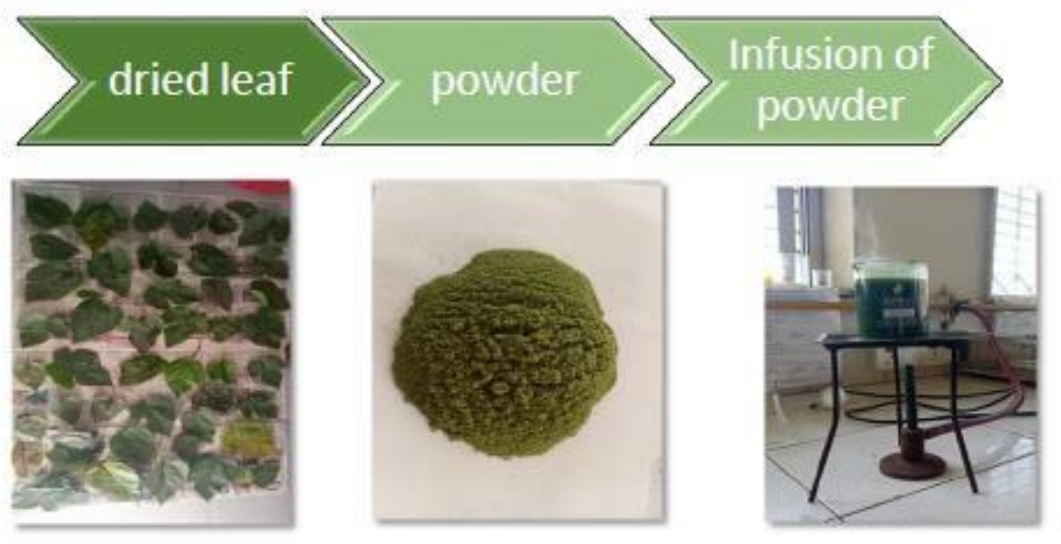
Procurement of Drug: Mulberry Leaves was obtained from Sanjan Market, Gujarat.

Role of Ingredients use in gummies formulation

Drugs	active ingredient use to treat the diseases
Pectin	Thickening agent
Calcium Chloride	Firming agent and moisture absorbent
Citric acid	preservative and flavoring agent
Ascorbic Acid	used to give texture and flavor to Gummies
Sugar powder	Sweetening agent and Coating agent in gummies. It also helps to enhance the texture and flavor of gummies. It also Forms a gel like structure along with pectin.
Mango Green Color	Flavoring agent
Green Color	Colouring Agent for appearance, product identification

Various Steps involved in Extraction process are

1. Collection of leaves.
2. Washing of leaves.
3. Drying of leaves.
4. Grinding of leaves.
5. Infusion of powder.
6. Filtration.
7. Collection of liquid extract.



Procedure for preliminary batches for gummies preparation

Preparation a pre-mixture of **[Pectin+ Sugar]:** This mixture is prepared to avoid the lump formation which tends to occur when pectin is directly added to the Formulation when placed on water bath. Place beaker 2 on water bath, add measured quantity of fruit juice in it. Once the fruit juice starts to boil, start to add pectin-sugar prepared mixture slowly with **continuous stirring.** Thereafter in a separate beaker, add accurately weighed quantity of Mulberry aqueous extract powder and dissolve in sufficient quantity of water. Add remaining amount sugar in the formulation with continuous stirring until the sugar gets completely dissolved in Beaker-2. Once the sugar is dissolved completely add gum and citric acid to Beaker-2 one after the other. After that allow the mixture to optimize on water bath **at controlled temperature of 110℃**. Once the required temperature is reached, Add prepared drug mixture slowly with continuous stirring in Beaker-2. Subsequently carefully release the beaker from the water bath and allow to stand for 5 to 10 minutes. Once the mixture arrives at room temperature, add calcium chloride, food colors and essence to it in the mentioned

sequence. Fill the molds completely and allow setting the formulation in refrigerator for approximately 2 to 3 hours.

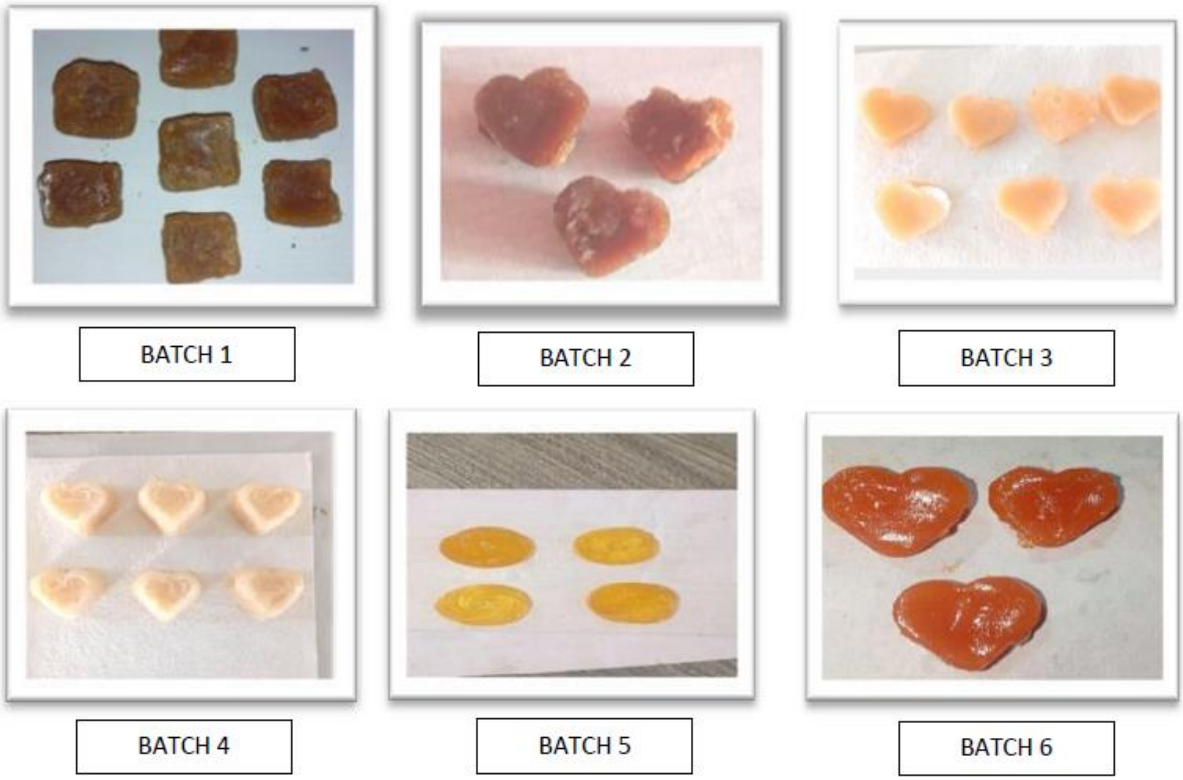
Trial Batches of Gummies Formulation with HM Pectin

SR NO.	INGREDIENTS	B1	B2	B3	B4	B5	B6
1	Sugar Powder	42gm	44gm	45gm	47gm	48gm	50 gm
2	Pectin	9.5 gm	10gm	10.5gm	11gm	11.5gm	12 gm
3	Citric acid	0.75gm	0.7gm	0.6gm	0.65gm	0.9gm	0.5 gm
4	Water	50ml	60ml	55 ml	70ml	65 ml	44 ml
5	Fruit juice	50ml	50ml	50 ml	50ml	50ml	50 ml
6	Ascorbic acid	1gm	1gm	1gm	1gm	1gm	1 gm
7	Calcium Chloride	0.5gm	0.5gm	0.5gm	0.5gm	0.5gm	0.5 gm
8	Food Color	q.s	q.s	q.s	q.s	q.s	q.s
9	Food Essence	q.s	q.s	q.s	q.s	q.s	q.s

Final Procedure for gummies preparation with HM pectin

Preparation a pre-mixture of [HM Pectin (12 gm) + Sugar (25 gm)]: This mixture is prepared to avoid the lump formation which tend to occur when pectin is directly added to the Formulation when placed on water bath. Place beaker 2 on water bath, add approx 50 ml of fruit juice in it, heat at temperature74^{0}C to 78^{0}C. Place beaker 3 on water bath, heat at tem 74^{0}C to 78^{0}C. After that add remaining amount sugar (25 gm) in the Beaker-3 until the sugar gets completely dissolved and make sugar syrup. Take new beaker, in to which add 1 gm. of sodium benzoate and dissolved in sufficient quantity of water. Once the required temperature is reached, Add prepared premixture [HM Pectin+ Sugar] slowly with continuous stirring in Beaker-2. After that add Beaker-3 content in to Beaker-2 with continuous stirring and add sodium benzoate solution and citric acid in required quantity. Subsequently carefully release the beaker from the water bath and, add calcium chloride, food colour and essence to it in the mentioned sequence. Fill the molds completely and allow to set the formulation in refrigerator for approximately 30 min at 20^{0}C.

Preliminary Batches of Gummies.



3. EVALUATION OF GUMMIES

3.1. Mass uniformity

The aim is to keep the fill weight of gummies within a range. The ultimate objective of this test is to ensure correct dose administration. Mass uniformity was carried out to ensure that, each of tablets contains the proper amount of drug. Select 10 gummies and Weigh the 10 gummies individually using analytical balance. Calculate the average weight & standard deviation of gummies.

3.2. Weight variation

The weight of the Gummies being made was routinely determined to ensure that a Gummies contains the proper amount of drug. The USP weight variation test is done by weighing 20 Gummies individually, calculating the average weight and comparing the individual weights to the average. The Gummies met the USP specification that no more than 2 Gummies are outside the percentage limits and no Gummies differs by more than 2 times the percentage limitation.

3.3. Hardness

The hardness of each batch of Gummies was checked by using Monsanto hardness tester. The hardness was measured in terms of kg / cm-1. 2 3 lozenges were chosen randomly and tested

for hardness.

3.4. Thickness and Diameter

Thickness and diameter was measured using Vernier Caliper. It was determined by checking the thickness and diameter of 3 Gummies of each formulation. The extent to which the thickness of each Gummies deviated from 5% of the standard value was determined.

3.5. Friability test

The friability of the 4 Gummies from each batch was tested by a Friabilator at a speed of 25 rpm for 4 minutes. The Gummies were then dedusted. Reweighed and percentage weight loss was calculated by the equation.

3.6. Loss on drying

The sample was weighed. From this, one gram of the sample was weighed and placed in a Hot Air oven for 24 hours. After 24 hours the sample is weighed. The moisture content is determined by substracting the final weight from initial weight of Gummies.

3.7. pH Meter test

The sample was weighted 1 gm and dissolved in 10 ml of distilled water at 50 C and then its pH was determined using a pH meter.

3.8. In-Vitro Studies

The rate of the drug absorption was determined by the rate of drug dissolution from the Gummies. Thus, the rate of dissolution and bioavailability may be directly related to the efficacy of the Gummies. One sample gummy was weighed and dissolved in 100ml of distilled water at 37 C. The gummy was completely dissolved within 15minutes. It was then compared with dissolution test of Marketed Gummies.

RESULT

The optimized batch of gummies was evaluated for various physicochemical parameters. The weight variation was found to be 6.91 grams, indicating uniformity in the manufacturing process. The hardness test demonstrated a value of 11 units, reflecting an acceptable texture for consumer use. The measured thickness and diameter were 5 mm and 17 mm respectively, suggesting consistency in size and shape. Friability was minimal at 0.2%, showing excellent mechanical strength and resistance to physical stress. The percentage of loss on drying was recorded at 5.6%, suggesting suitable moisture content to ensure stability. The pH value was

measured at 3.04, indicating an acidic environment suitable for the intended formulation. Furthermore, the dissolution test revealed that the gummies disintegrated within 14 minutes, ensuring adequate release of active ingredients in the physiological environment.

Result of Gummies (Optimized Batch)

SR.NO.	PARAMETERS	FORMULATION
1	Weight Variation	6.91gm
2	Hardness Test	11
3	Thickness (mm)	5mm
4	Diameter (mm)	17mm
5	Friability Test (%)	0.2%
6	Loss on drying (%)	5.6%
7	pH Meter test	3.04
8	Dissolution Test (minutes)	14

CONCLUSION

The present study successfully formulated and optimized Batch 6, comprising herbal mulberry leaf extract incorporated into orange-flavored gummies. Consumers today increasingly prefer gummies over traditional capsules and tablets due to their improved palatability, ease of administration, and better compliance, especially among pediatric and geriatric populations. The phytoconstituents present in mulberry leaf extract, known for their antioxidant, antihyperglycemic, and lipid-lowering properties, were effectively incorporated into the gummies, preserving their therapeutic potential. The optimized batch demonstrated favorable physicochemical properties including minimal weight variation, appropriate hardness, uniform thickness and diameter, low friability, acceptable moisture content, suitable pH, and rapid dissolution. These attributes suggest that herbal gummies can serve as an effective and consumer-friendly delivery system for natural bioactives. Thus, the development of mulberry leaf herbal gummies not only offers a novel dosage form but also promotes the utilization of plant-based actives in preventive and therapeutic health care.

Future work focusing on large-scale production, stability testing, and clinical validation will be essential to ensure their commercial success and wider acceptance.

REFERENCES

1. Medzhitov, R. Origin and Physiological Roles of Inflammation. Nature, **2008**; 454: 428–435.
2. Alessandri, A.L.; Sousa, L.P.; Lucas, C.D.; Rossi, A.G.; Pinho, V.; Teixeira, M.M. Resolution of Inflammation: Mechanisms and Opportunity for Drug Development.

Pharmacol. Ther., **2013**; 139: 189–212.

3. Qin, J.; Wang, W.; Zhang, R. Novel Natural Product Therapeutics Targeting Both Inflammation and Cancer. Chin. J. Nat. Med., **2017**; 15: 401–416.
4. Gasparrini, M.; Forbes-Hernandez, T.Y.; Giampieri, F.; Afrin, S.; Alvarez-Suarez, J.M.; Mazzoni, L.; Mezzetti, B.; Quiles, J.L.; Battino, M. Anti-Inflammatory Effect of Strawberry Extract against LPS-Induced Stress in RAW264.7 Macrophages. Food Chem Toxicol, **2017**; 102: 1–10.
5. Duracˇková, Z. Some Current Insights into Oxidative Stress. Physiol. Res., **2010;** 59: 459–469.
6. Maleki, S.J.; Crespo, J.F.; Cabanillas, B. Anti-Inflammatory Effects of Flavonoids. Food Chem., **2019**; 299: 125124.
7. Mozaffarian, D.; Wu, J.H.Y. Flavonoids, Dairy Foods, and Cardiovascular and Metabolic Health: A Review of Emerging Biologic Pathways. Circ. Res., **2018**; 122: 369–384.
8. Slavin, J.L.; Lloyd, B. Health Benefits of Fruits and Vegetables. Adv. Nutr., **2012**; 3: 506–516.
9. Liu, R.H. Health-Promoting Components of Fruits and Vegetables in the Diet. Adv. Nutr., **2013**; 4: 384S–392S.
10. Park, E.; Lee, S.-M.; Lee, J.e.; Kim, J.-H. Anti-Inflammatory Activity of Mulberry Leaf Extract through Inhibition of NF-_B. J. Funct. Foods, **2013**; 5: 178–186.
11. Warford, J.; Jones, Q.R.D.; Nichols, M.; Sullivan, V.; Rupasinghe, H.P.V.; Robertson, G.S. The Flavonoid-Enriched Fraction AF4 Suppresses Neuroinflammation and Promotes Restorative Gene Expression in a Mouse Model of Experimental Autoimmune Encephalomyelitis. J. Neuroimmunol, **2014**; 268: 71–83.
12. Qi, F.; Sun, J.; Yan, J.; Li, C.; Lv, X. Anti-Inflammatory Effects of Isorhamnetin on LPS-Stimulated Human Gingival Fibroblasts by Activating Nrf2 Signaling Pathway. Microb. Pathog, **2018**; 120: 37–41.
13. Wang, Y.; Gao, Y.; Ding, H.; Liu, S.; Han, X.; Gui, J.; Liu, D. Subcritical Ethanol Extraction of Flavonoids from Moringa Oleifera Leaf and Evaluation of Antioxidant Activity. Food Chem., **2017**; 218: 152–158.
14. Wen, P.; Hu, T.-G.; Linhardt, R.J.; Liao, S.-T.; Wu, H.; Zou, Y.-X. Mulberry: A Review of Bioactive Compounds and Advanced Processing Technology. Trends Food Sci. Technol., **2019**; 83: 138–158.
15. Cˇ ulenová, M.; Sychrová, A.; Hassan, S.T.S.; Berchová-Bímová, K.; Svobodová, P.; Helclová, A.; Michnová, H.; Hošek, J.; Vasilev, H.; Suchý, P.; et al. Multiple In Vitro

Biological Effects of Phenolic Compounds from Morus Alba Root Bark. J. Ethnopharmacol, **2020**; 248: 112296.

16. Ma, G.; Chai, X.; Hou, G.; Zhao, F.; Meng, Q. Phytochemistry, Bioactivities and Future Prospects of Mulberry Leaves: A Review. Food Chem., **2022**; 372: 131335.
17. Cizauskaite U, Jakuhaityte G, Zitkevicius V and Kasparaviciene G. "Natural ingredients-based gummy bear composition designed according to texture analysis and sensory evaluation in vivo". Molecules, 2019; 24(7): 1-16.
18. Feng W. Issaquah WA, Brenden W. Shoreline WA. "Pectin Gummy composition and methods of making and using thereof". United States PatentUS 2020/0138705 A1, 2020.