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Research Paper

Formulation And Evaluation of Stevia Jelly

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ABSTRACT

Jellies are widely consumed semi-solid food products traditionally prepared using high amounts of sugar, which may contribute to various health issues such as diabetes, obesity, and cardiovascular diseases. The present study focuses on the formulation and evaluation of a sugar-free jelly using Stevia rebaudiana as a natural, non-caloric sweetener. Stevia contains steviol glycosides, which are significantly sweeter than sucrose and provide additional therapeutic benefits such as antioxidant and antihyperglycemic effects. The primary objective of this research was to develop a patient-friendly jelly formulation suitable for diabetic, paediatric, and geriatric populations, particularly those suffering from dysphagia. The jelly was formulated using stevia as a sweetener along with excipients such as HPMC Grade 15 and pectin as gelling agents, glycerine and propylene glycol as humectants, sodium metabisulfite as a preservative, and ascorbic acid as an antioxidant. Various formulations were prepared by varying the polymer concentration and evaluated for physicochemical parameters, including pH, viscosity, texture, stickiness, and weight uniformity. The pH of formulations ranged from 4.24 to 6.18, while viscosity increased with higher polymer concentration. Among all batches, formulation F5 exhibited optimal properties, with a near-neutral pH and higher viscosity, indicating better consistency and stability. Although the prepared jellies exhibited acceptable texture and performance, slight turbidity and stickiness were observed. The study concludes that stevia-based jelly is a promising sugar-free alternative with potential applications in nutraceutical and pharmaceutical fields, though further optimization is required to improve its aesthetic and sensory properties.

INTRODUCTION

Jellies are among the most popular sweetened products globally, typically made from fruit juice,

pectin, colours, and various sweeteners. Pectin, primarily derived from apples or sweet limes, serves as the primary gelling agent in jelly production. However, many commercially

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available jellies are excessively sweetened with artificial sugars, which can contribute to several adverse health issues. High sugar consumption is linked to obesity, diabetes, and cardiovascular diseases, prompting a growing demand for natural, non-caloric sweeteners as healthier alternatives. [2,3] One such natural sweetener is *Stevia rebaudiana Bertoni*, a small shrub belonging to the *Asteraceae* family. The leaves of this plant have been utilized for over 1,500 years due to their numerous health benefits. Stevia possesses antibacterial, anti-inflammatory, antihypertensive, diuretic, and immunomodulatory properties. The active compounds known as steviol glycosides are extracted from the leaves and are over 100 times sweeter than sucrose while containing zero calories. [1] These glycosides are a class of diterpene glycosides recognized for their intense sweetness. In this study, researchers aimed to develop jellies incorporating steviol glycosides as a natural sweetening agent. This approach offers a healthier alternative to traditional jellies that rely on high sugar content. The study involves comparing the physicochemical and sensory properties of commercially available jellies with those enhanced with stevia-derived sweeteners and various syrups. [31] The appeal of stevia-sweetened jellies lies in their taste profile, which closely resembles that of conventional products while providing significant health benefits. With a sweetness intensity ranging from 120 to 300 times that of sucrose, these jellies cater to diverse consumer groups across all age ranges and socio-economic classes, particularly individuals sensitive to diabetes. [7,8] As awareness of the health risks associated with high sugar intake increases, there is a notable demand for innovative products that can help mitigate these concerns. [22] This study aims to introduce new jelly formulations that not only satisfy consumer preferences but also promote healthier eating habits by reducing sugar consumption. By

demonstrating the advantages of stevia-sweetened jellies, this research contributes to the development of healthier food options in the market. [15]

Understanding Dysphagia

Dysphagia is not merely a swallowing problem; it encompasses a range of symptoms that can severely affect a person's quality of life. Patients may experience sensations such as food or drink feeling stuck in the throat or chest. [19] In some cases, they may also suffer from regurgitation, vomiting, or discomfort behind the sternum. Common signs include coughing during swallowing and the regurgitation of previously swallowed food. These symptoms often arise from various underlying issues, including neurological disorders, muscle coordination problems, inflammation, or neoplasia. [21] The management of dysphagia is critical for preventing complications such as aspiration pneumonia and ensuring adequate nutrition. Traditional oral medications may pose challenges for these patients due to their inability to swallow solid forms. Therefore, innovative delivery systems like medicated jellies have gained prominence as viable alternatives. [24]

The Need for Jelly Development

The development of oral medicated jellies addresses several key issues associated with traditional medication delivery methods:

1. **Patient Compliance:** Many patients struggle with conventional dosage forms due to difficulty swallowing pills or tablets. Medicated jellies offer an alternative that is easier to consume.
2. **Market Demand:** There is a growing need for innovative delivery systems that cater to specific patient populations, including paediatrics and geriatrics.



3. **Cost-Effectiveness:** The development of jellies can reduce healthcare costs associated with managing chronic conditions by improving medication adherence and minimizing complications related to dysphagia.
4. **Enhanced Safety:** By providing a non-invasive method of drug delivery that reduces the risk of choking and aspiration, jellies enhance patient safety during administration.

Ideal Characteristics of Jellies

For jellies to be effective as a drug delivery system, they must possess several ideal characteristics:

- **Mouth feel:** Jellies should provide a pleasant texture without leaving any residue in the oral cavity after consumption.
- **High Drug Loading Capacity:** They must be capable of incorporating significant amounts of active ingredients.
- **Taste Masking:** Jellies can effectively mask the bitter taste of certain medications.
- **Stability:** They should exhibit low sensitivity to environmental changes such as temperature and humidity.
- **Hygroscopic Nature:** Jellies should be able to retain moisture without compromising their structural integrity.
- **Adaptability:** They must be easy to process and package using conventional equipment.
- **Portability:** Jellies should be designed for easy transport without concerns about fragility.
- **Minimal Impact from Excipients:** The characteristics of both excipients and drugs should not adversely affect the jelly's disintegration in the mouth.

Advantages of Stevia Jellies ^[27,28,30]:

Stevia jellies offer numerous advantages over traditional oral dosage forms:

1. **Ease of Administration:** No water is required for consumption, making it convenient for use at any time or location.
2. **Rapid Onset of Action:** Medications delivered via jelly can dissolve quickly in saliva, facilitating faster absorption into the gastrointestinal tract.
3. **Improved Compliance:** They are particularly beneficial for patients who have difficulty swallowing pills, such as children or individuals with neurological disorders.
4. **Enhanced Perception:** The smooth mouthfeel alters how patients perceive medications, potentially improving their willingness to take them.
5. **Cost-Effectiveness:** Compared to other oral dosage forms, jellies are economical while allowing for high drug loading.
6. **Flexibility in Processing:** Jellies can be manufactured using existing processing and packaging technologies.
7. **Dual Effects:** They can provide both local effects (e.g., topical applications) and systemic effects when ingested.
8. **Prevention of Oral Health Issues:** Jellies can help mitigate problems like dental caries and candidiasis by delivering active ingredients directly to affected areas.
9. **Safety Improvements:** The risk of choking during administration is significantly reduced compared to solid dosage forms.

Types of Jellies in Medical Use

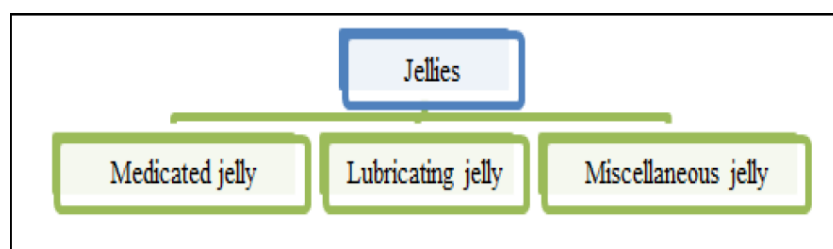


Figure 1: Different types of Jellies.

1. **Medicated Jellies:** These formulations are applied to mucosal layers or skin and may possess spermicidal, local anaesthetic, or antiseptic properties. For instance, domperidone oral medicated jellies are designed for rapid relief from nausea compared to traditional formulations.
2. **Lubricating Jellies:** Developed primarily for lubricating medical equipment such as surgical gloves and catheters, these jellies facilitate smoother procedures.
3. **Miscellaneous Jellies:**
 - Patch Testing: In this context, jellies act as vehicles for allergens applied to the skin's surface for sensitivity testing.
 - Electrocardiography (ECG): Electrode jelly is utilized to reduce electrical resistance between the patient's skin and ECG electrodes. Sodium chloride is often included to enhance conductivity while pumice powder may be used to remove dead skin layers that impede electrical flow. [6]

Need of Present Investigation

Jellies are vital in medicine for patients with dysphagia, a condition that complicates swallowing and can lead to malnutrition and aspiration pneumonia. This paper examines the importance of jelly formulations in addressing these challenges, focusing on their benefits and medical applications.

Aim & Objectives

To Formulate & Evaluate a sugar-free jelly using Stevia as a healthy alternative to sugar, catering to diabetic and health-conscious consumers. Test stability under different storage conditions.

Profile of Stevia [38]:

- Synonyms: Stevia rebaudiana, Steviol glycosides, Rebaudioside A, Stevioside, Natural sweetener.
- Chemical Formula: $C_{38}H_{60}O_{18}$ (for Stevioside) | $C_{44}H_{70}O_{23}$ (for Rebaudioside A) – the most common sweetening compounds in Stevia.
- Category: Natural non-nutritive sweetener, herbal extract.
- Pharmacological Action:
 - Non-caloric sweetener
 - Antioxidant
 - Potential antihyperglycemic and antihypertensive effects
 - Tooth-friendly sugar substitute (non-cariogenic)



Figure 2: stevia leaves

Excipient Profile [35,36]

HPMC Grade 15:

- **Synonyms:** Hydroxypropyl Methylcellulose, Hypromellose, Methocel.

- **Chemical** **Formula:** **Propylene Glycol:**
(C₆H₇O₂(OH)_x(OCH₃)_y(OC₃H₆OH)_z)_n
(polymer)
- **Category:** Pharmaceutical excipient and cellulose ether polymer.
- **Pharmacological Action:** Inert binder, controlled-release agent, film-former, and thickener

Ascorbic Acid:

- **Synonyms:** Vitamin C, L-ascorbic acid, Ascorbate.
- **Chemical Formula:** C₆H₈O₆.
- **Category:** Water-soluble vitamin and antioxidant.
- **Pharmacological Action:** Antioxidant, supports collagen synthesis, immune booster

Sodium Metabisulphite:

- **Synonyms:** Sodium metabisulfite, Sodium pyrosulfite, SMBS.
- **Chemical Formula:** Na₂S₂O₅.
- **Category:** Inorganic salt, preservative, and antioxidant.
- **Pharmacological Action:** Antioxidant, antimicrobial preservative, reducing agent.

- **Synonyms:** 1,2-Propanediol, PG, Propane-1,2-diol.
- **Chemical Formula:** C₃H₈O₂.
- **Category:** Solvent, humectant, and excipient.
- **Pharmacological Action:** Moisturizer, solvent, and stabilizer in formulations.

Glycerin:

- **Synonyms:** Glycerol, 1,2,3-Propanetriol.
- **Chemical Formula:** C₃H₈O₃.
- **Category:** Humectant, solvent, and pharmaceutical excipient.
- **Pharmacological Action:** Moisturizer, lubricant, and solvent.

Triethanolamine:

- **Synonyms:** TEA, Tris(2-hydroxyethyl) amine.
- **Chemical Formula:** C₆H₁₅NO₃.
- **Category:** Organic amine, emulsifier, and pH adjuster.
- **Pharmacological Action:** Emulsifying agent and pH buffer in formulations.

MATERIALS AND METHODS [12,13,14]:

Drugs and chemicals –

Table No. 1: Drugs and Excipients

Sr.No	Ingredients	Role of ingredient
1)	Stevia	Sweetener
2)	HPMC Grade 15	Thickening and gelling agent
3)	Pectin	Thickening agent
4)	Sodium metabisulphite	Preservative
5)	Ascorbic acid	Antioxidants
6)	Propylene glycol	Humectant
7)	Glycerine	Humectant
8)	Triethanolamine	PH adjuster

Instrumentation -

Apparatus: Beaker, measuring cylinder, stirrer, Glass rod, weighing machine and heating mantle.

Formulation: Different formulation were prepared which is based on the different Quantities of the Chemicals used in the preparation. For 100

grams of jelly formulation the following chemicals is weighed and used:

Step 1: All the ingredients were weighed and accurately measured.

Step 2: Propylene glycol, Glycerin and Triethanolamine which is oil based mixed in a beaker.

Step 3: Colour and essence is added to the solution

Step 4: Pectin is heated in different beaker for complete dissolution of the solution

Step 5: HPMC is dissolved in water; then the pectin and HPMC is added to the oil-based solution.

Step 6: Heat the solution for 2-3 mins

Step 7: Add sodium metabisulphite, Ascorbic acid in the solution.

Step 8: Add sweetener which is stevia

Step 9: Don't overheat the solution

Step 10: The solution at the room temperature and set in a moulds for jelly shapes

Step 11: Refrigerated the solution for 1-2 hours for setting the stevia jelly.

Characterization of jelly formulation [11,14, 17,18,19]:

The prepared Stevia jelly formulation were evaluated as per the standard procedure reported in the literature.

1. Physical appearance

The fabricated stevia jelly formulations were examined for their physical appearance in terms of clarity, texture and consistency, which are the prime characteristics of a nutraceutical's formulation.

2. Stickiness and Grittiness

The texture of the stevia jelly in term of stickiness and Grittiness had been evaluated by Visual inspection of the product after mildly rubbing the jelly sample between two fingers. [11]

3. Determination of PH

The pH of the prepared jelly formulation was checked by using a calibrated digital PH meter at 25 \pm 1°C. For the purpose, 1 g of the weighed formulation was dispersed in 100 ml of distilled water and the PH was noted. [14]

4. Determination of Viscosity:

The viscosity of the jelly formulations were carried out by using Brookfield viscometer using a non-Newtonian spindle no.7 for the fixed time of 2 min at 50 rpm.

5. Weight uniformity test:

Table no. 2: Composition of Formulations

Ingredient	F1	F2	F3	F4	F5
Stevia	0.5gm	0.5gm	0.5gm	0.5gm	0.5gm
HPMC grade 15	5gm	3gm	4gm	2gm	6gm
Pectin	10gm	12gm	10gm	15gm	20gm
Ascorbic acid	5gm	5gm	5gm	5gm	4gm
Sodium metasulphite	2gm	2gm	2gm	2gm	2gm
Propylene Glycol	9ml/gm	10ml/mg	10ml/gm	9ml/gm	10ml/gm
Glycerin	7ml/gm	7ml/gm	8ml/gm	10ml/gm	10ml/gm
Triethalonamine	3gm	3gm	3gm	3gm	3gm
Food color	q.s	q.s	q.s	q.s	q.s
Essence	q.s	q.s	q.s	q.s	q.s
Distilled water	100ml	100ml	100ml	100ml	100ml

Weigh the jellies separately on analytical balance, then calculate average weight of jellies and calculate standard deviation (S.D)

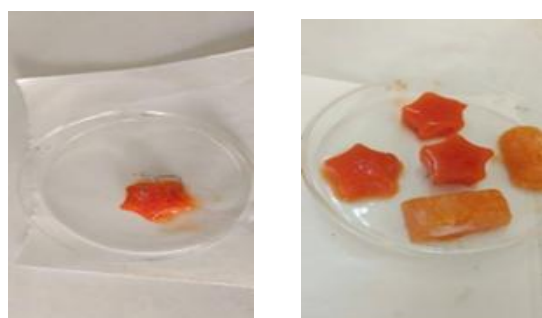
Table 3: Characterization Result of the Formulation

Batches	Clarity	Texture	Consistency	Stickiness	Grittiness	pH	Viscosity
F1	Turbid Form	Smooth	Fluid like	Sticky	More Gritty	4.24	3948
F3	Turbid Form	Smooth	Thin	Sticky	Gritty	5.09	4800
F3	Turbid Form	Smooth	Thin	Sticky	Slightly Gritty	5.85	5333
F4	Turbid Form	Smooth	Thick	Non-sticky	Less Gritty	5.98	8533
F5	Turbid Form	Smooth	Very Thick	Non-sticky	Less Gritty	6.18	9500

RESULT AND DISCUSSION

Characterization of jelly ^[4,5]

1. Organoleptic characters



All jellies have smooth texture and stickiness and have homogeneous mixture. The formulation appeared little turbid and impart its colour on the fingers. The stickiness caused because addition of HPMC gradient 15 and the jelly are not as desirable as marketed jellies.

2. PH.



The pH of formulation was measured to be in range of 4.24- 6.18 the f5 optimised formulation demonstrate pH 6.18 which is nearer to neutrality as essential criterion for formulation having lowest polymer concentration

3. Viscosity



Viscosity of jelly was measured to be in range of 3948-9500 due to concentration of hpmc k15 gradient it was 3% in f1 and 5% in f5 as compared f1 to f5, f5 exhibit twice viscosity which related to stiff consistent and drug loading properties of the formulation, the combination of glycerine, propylene glycol and citric acid which help in maintaining consistency of the formulation

4. Weight uniformity: The weight of jelly ranges from 4.01 to 4.68 gm



CONCLUSION

This research paper highlighted the production of edible jelly incorporated with stevia to give exact sweetness as marketed jelly it was a chance to produce patient friendly jelly that will help patients in managing hyperglycaemic activities. As we see in this research paper the concentration of polymer increase jelly become less sticky, gritty and turbid. The jelly is smooth, soft jiggly but it's not, but it failed to produce smooth, elegant, transparent and desirable product. This requires more work and polishing to look like commercial product. Jelly leaves colour stain and vanilla essence which added to impart desired fragrance to jelly become vanished due to high polymeric concentration

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