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Artículos originales

Formulation, Development and Evaluation of Herbal Pediatric Edible Jelly for Cough

Formulación, desarrollo y evaluación de jalea comestible pediátrica a base de hierbas para la tos

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Conflict of interests

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Resumen

Introducción: La resistencia de los niños a los regímenes de dosificación es uno de los retos de la terapia pediátrica. Los pacientes pediátricos presentan dos problemas importantes: la falta de habilidades para autoadministrarse los fármacos y el cumplimiento terapéutico por parte del paciente. Las características médicas de las hierbas son cada vez más importantes debido a su falta de efectos secundarios, bajo coste y biocompatibilidad.

Método: Las hierbas utilizadas son *Ocimum sanctum* (Tulsi), *Adhatoda vasika* (Adulsa), *Elettaria cardamomum* (Cardamomo), *Zingiber officinale* (Jengibre), *Mentha piperita* (Menta piperita), *Glycyrrhiza glabra* (Regaliz), *Eugenia caryophyllus* (Clavo), *Cinnamomum zeylanicum* (Canela) y Miel. La formulación se preparó por el método de decocción y se evaluó.

Resultados: Los extractos de estas hierbas muestran una buena actividad antimicrobiana contra *E. coli*. La gelatina formulada muestra buen aspecto, pH, desintegración y untabilidad. Realizamos un estudio de estabilidad de 6 meses de la gelatina formulada. Tiene buen aspecto y no cambia el pH. Por lo tanto, la gelatina formulada puede ser estable hasta 6 meses.

Conclusiones: Los datos revelaron que la formulación optimizada no había mostrado ningún cambio en su aspecto ni en su pH. Así pues, la jalea formulada puede ser estable hasta 6 meses. Las formulaciones mostraron una excelente actividad antimicrobiana, que es adecuada para administrar a los niños como una forma de dosificación sólida oral alternativa.

Palabras clave: Pediatría; Jaleas comestibles; *Ocimum sanctum*; *Glycyrrhiza glabra*; *Adhatoda vasika*; *Elettaria cardamomum*; *Zingiber officinale*; *Mentha piperita*; *Eugenia caryophyllus*; *Cinnamomum zeylanicum*; Miel.

Abstract

Introduction: The children's resistance to dosage regimens is one of the challenging issues in pediatric therapy. There are two significant issues with pediatric patients: a lack of self-drug administration skills and patient compliance. The medical characteristics of herbs have become increasingly important due to their lack of side effects, low cost, and biocompatibility.

Method: The herbs that will be used are *Ocimum sanctum* (Tulsi), *Adhatoda vasika* (Adulsa), *Elettariacardamomum* (Cardamom), *Zingiberofficinale* (Ginger), *Mentha piperita* (Peppermint), *Glycyrrhiza glabra* (Liquorice), *Eugenia caryophyllus* (Clove), *Cinnamomum zeylanicum* (Cinnamon), and Honey. The formulation were prepared by decoction method and evaluated.

Results: These herbs' extracts show good antimicrobial activity against *E. coli*. The formulated jelly shows good appearance, pH, disintegration, and spreadability. We conduct a 6-month stability study on the formulated jelly. It has a good appearance and does not change pH. So, the formulated jelly can be stable for up to 6 months.

Conclusions: The data revealed that the optimized formulation had not shown any change in their appearance or pH. So, the formulated jelly can be stable for up to 6 months. The formulations exhibited excellent antimicrobial activity, which is suitable to administer to children as an alternative oral solid dosage form.

Keywords: Pediatrics; Edible jellies; *Ocimum sanctum*; *Glycyrrhiza glabra*; *Adhatoda vasika*; *Elettaria cardamomum*; *Zingiber officinale*; *Mentha piperita*; *Eugenia caryophyllus*; *Cinnamomum zeylanicum*; Honey.

Introduction

When it occurs suddenly and frequently, a cough aids in clearing the big breathing passages of fluids, irritants, foreign objects, and bacteria. Coughing is typically completely natural. Coughing may aid in the removal of mucus and other irritants from the throat. However, persistent coughing can also be a sign of a variety of diseases. The cough reflex typically involves three phases: an inhale, a forced exhalation against a closed glottis, and a sudden expulsion of air from the lungs once the glottis opens up. There are two types of coughing: forced and unforced⁽¹⁾. Coughing is one of the most common health issues. Additionally, respiratory tract infections like the common cold, acute bronchitis, pneumonia, pertussis, flu, and smoking, as well as medical conditions like asthma, TB, and lung cancer, can cause coughing. Chest pain, congestion, and an itchy throat are a few signs of a cough. Repeated coughing causes irritation and discomfort, both of which lead to additional coughing. In addition to suppressing the cough, cough suppressants also help to ease the discomfort brought on by frequent coughing. Back discomfort, headaches, fever, and malaise are examples of extra thoracic symptoms that may need symptomatic therapy. Expectorants and antitussive medicines are the mainstays of cough treatment^(2,3).

Jellies are semi-solid preparations that are clear or translucent, non-greasy, and intended for both internal and external use. With or without water, you can chew or swallow them^(3,4). Nowadays, jelly candies are particularly popular among kids because they like to chew them and because they offer an option to solid and liquid dose forms for delivering medications^(5,6). Medicated jelly can treat both systemic and local conditions, including those affecting the oral cavity. Medicated jellies can absorb medication into the pre-gastric, gastric, and post-gastric parts of the gastrointestinal tract, as well as local Oro mucosal tissues^(7,8).

Today, people frequently use herbal therapies to treat coughs. Additionally, herbal medications and herbal preparations are crucial in treating a variety of coughs. Today, we employ medications like cough suppressants as therapy. The antitussive medication only alleviates symptoms. Herbal jelly, a product of concentrated extracts of medicinal plants, uses agar, pectin, or gelatin as its substrate. Honey is added to the base of jelly before adding the extracts of various herbs, including *Ocimum sanctum* (Tulsi), *Adhatoda vasika* (Adulsa), *Elettaria cardamom* (Cardamom), *Zingiber officinale* (Ginger), *Mentha piperita* (Peppermint), *Glycyrrhiza glabra* (Liquorice), *Eugenia caryophyllus* (Clove), and *Cinnamomum zeylanicum* (Cinnamon) to the base of jelly with the addition of honey⁽⁹⁾.

Méthodes

Materials⁽¹⁰⁻¹⁵⁾

Table 1 describes the list of ingredients used in formulation of herbal pediatrics jelly.

Table 1. List of ingredients used in formulation of herbal pediatrics jelly.

Sr. No.	Ingredients	Botanical Name	Active constituents	Uses
1	Tulsi	<i>Ocimum sanctum</i>	Eugenol, Carvacrol	Antimicrobial, Antitussive, Antidepressant, Insecticidal, Spasmolytic, Immunomodulatory agent.
2	Liquorice	<i>Glycyrrhiza glabra</i>	Glycyrrhizin, Glycerrhethinicacid, Glycyrrhizic acid.	Demulcent, Expectorant, Anti-inflammatory, Laxative, Sweetening agent.
3	Adulsa	<i>Adhatoda vasika</i>	Vasicine, Vasicinone	Antitussive, Antimicrobial, Anti-inflammatory.

Sr. No.	Ingredients	Botanical Name	Active constituents	Uses
4	Ginger	<i>Zingiber officinale</i>	Zingiberin, gingerols, Cineole, sesquiterpene hydrocarbon	Anti-inflammatory, Antihistaminic, Antiemetic, Spasmodytic, Aromatic stimulant.
5	Peppermint	<i>Mentha piperita</i>	Menthone, Menthol, Cineole, limonene, Methyl acetate	Sinus infections, Common cold, Bronchitis, Aromatic stimulant.
6	Cardamom	<i>Elettaria Cardamomum</i>	Cineole, Eugenol, Limonene, Borneol	Antimicrobial, Antioxidant, Flavouring agent, Aromatic carminative.
7	Clove	<i>Eugenia caryophyllus</i>	Eugenol, Acetyl eugenol, Gallotannic acid	Antiseptic, Stimulant, Carminative, Flavouring agent, Expectorant.
8	Cinnamon	<i>Cinnamomum zeylanicum</i>	Cinnamaldehyde, Eugenol, Terpene hydrocarbon	Analgesic, Antiseptic, Expectorant, Antibacterial, Antifungal.
9	Honey	<i>Apis mellifera</i>	Eugenol, Ferulic acid, Caffeic acid, Gallic acid	Anti-inflammatory, Antioxidant, Antibacterial, Natural sweetener, Preservative.
10	Sucrose	-	-	Sweetening agent, Preservative.
11	Gelatin	-	-	Gelling agent
12	Agar	-	-	Gelling agent
13	Water	-	-	Vehicle



Figure 1: Herbal ingredients used for the formulation of jellies.

Formulae for preparation of Herbal Jellies

Table 2. Formulae of herbal edible jellies

Sr. No	Ingredients	F1	F2	F3	F4	F5	F6	F7	F8	F9
1	Tulsi	2 g	2 g	2 g	2 g	2 g	2 g	2 g	2 g	2 g
2	Liquorice	2 g	2 g	2 g	2 g	2 g	2 g	2 g	2 g	2 g
3	Vasaka	2 g	2 g	2 g	2 g	2 g	2 g	2 g	2 g	2 g
4	Peppermint	0.5 g	0.5 g	0.5 g	0.5 g	0.5 g	0.5 g	0.5 g	0.5 g	0.5 g
5	Ginger	0.5 g	0.5 g	0.5 g	0.5 g	0.5 g	0.5 g	0.5 g	0.5 g	0.5 g
6	Cardamom	0.5 g	0.5 g	0.5 g	0.5 g	0.5 g	0.5 g	0.5 g	0.5 g	0.5 g
7	Clove	0.2 g	0.2 g	0.2 g	0.2 g	0.2 g	0.2 g	0.2 g	0.2 g	0.2 g
8	Cinnamon	0.2 g	0.2 g	0.2 g	0.2 g	0.2 g	0.2 g	0.2 g	0.2 g	0.2 g
9	Honey	5 ml	5 ml	5 ml	5 ml	5 ml	5 ml	5 ml	5 ml	5 ml
10	Agar	-	2.5 g	1.5 g	1.5 g	2 g	1g	2 g	1.5 g	1.7 g
11	Gelatin	3g	-	1 g	2 g	0.5 g	2.5 g	1 g	1.5 g	0.8 g
12	Sucrose	33.35 g	33.35 g	33.35 g	33.35 g	33.35 g	33.35 g	33.35 g	33.35 g	33.35 g
13	Colour	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.
14	Flavour	1ml	1ml	1ml	1ml	1ml	1ml	1ml	1ml	1ml
15	Water	200ml	200ml	200ml	200ml	200ml	200ml	200ml	200ml	200ml

Formulation and optimization of herbal jellies describe in Table 2 representing formulation F1 to F9 with various concentration of ingredients.

Preparation of Decoction of herbal ingredients

All herbal ingredients (*Ocimum sanctum*, *Glycyrrhiza glabra*, *Adhatoda vasika*, *Zingiber officinale*, *Mentha piperita*, *Elettaria cardamomum*, *Eugenia caryophyllus*, and *Cinnamomum zeylanicum*) were weighed accurately. Figure 1 shows Herbal ingredients used for the formulation of jellies. All herbs were transferred into 250 ml of RBF, and 200 ml of water was added to it. The mixture was refluxed at 60°C for 1 hour by using a heating mantle. The above mixture was filtered. The filtrate was boiled until the total volume became one fourth of the previous. Figure 2 shows the pictorial representation of preparation of decoction⁽¹⁶⁻¹⁸⁾.



Figure 2: Preparation of Decoction

Preparation of Herbal Jelly

All herbal ingredients (*Ocimum sanctum*, *Glycyrrhiza glabra*, *Adhatoda vasika*, *Zingiber officinale*, *Mentha piperita*, *Elettaria cardamomum*, *Eugenia caryophyllus*, and *Cinnamomum zeylanicum*) were weighed accurately. Figure 1 shows Herbal ingredients used for the formulation of jellies. All herbs were transferred into 250 ml of RBF, and 200 ml of water was added to it. The mixture was refluxed at 60°C for 1 hour by using a heating mantle. The above mixture was filtered. The filtrate was boiled until the total volume became one fourth of the previous. Figure 2 shows the pictorial representation of preparation of decoction^(19,20).

Evaluation of herbal jellies⁽²¹⁻²⁴⁾

Characterization of herbal jellies includes the following parameters:

Physical appearance:

Physical appearance of the herbal jellies' appearance, including colour, clarity, texture, transparency, consistency, and scent, is possible.

Determination of pH:

A digital pH meter can be used to determine the jelly's pH. The pH was measured after 0.5 g of the weighted formulation was dissolved in 50 ml of water.

Viscosity:

A Brookfield viscometer can be used to measure viscosity. Spindle number 4 can be used because the system is not Newtonian.

Content uniformity:

The jellies can be chosen and crushed in a mortar, and the final volume can be adjusted to the required amount by dissolving a mixture equal to that of the drug in 100 ml of volumetric flask containing 6.8 PH buffer. The solution can then be properly filtered, diluted, and subjected to spectrophotometric analysis using a UV spectrophotometer.

It becomes challenging to maintain polyherbal jellies' consistent content. A combination of various herbal elements is frequently included in the ingredients of polyherbal medical medicines.

In vitro dissolution study:

The dissolving media (900ml) and USP paddle device used in in-vitro dissolution studies can be maintained at 37°C +/- 0.5°C and 50 rpm. After 10, 20, 30, 40, 50, 60, 90, or 120 minutes, 5 ml of the sample can be removed, and the sink condition can be preserved by substituting fresh medium. Using a UV spectrophotometer, the sample's drug content can be determined. % drug release can then be computed.

Due to the extremely diverse ingredients, polyherbal medication dissolving testing becomes challenging. Dissolution technique development is significantly more difficult than it is for a defined single constituent since the contents of polyherbal medicinal goods sometimes include a mixture of several herbal constituents.

Disintegration test:

Disintegration tests can be utilised as an alternative to in vitro dissolving studies for polyherbal jellies. Six polyherbal jellies were chosen at random from various recipes to determine the disintegration time. The disintegration medium was 0.1N HCl, and the temperature was held constant at 37 0.5 °C. The duration of jellies' disintegration was recorded.



Figure 3: Disintegration test

Stability study:

According to ICH recommendations, a stability study of prepared herbal jellies was conducted by keeping the jellies at room temperature ($25^{\circ}\text{C}\pm 5^{\circ}\text{C}$ and RH $65\%\pm 5\%$). Every 30 days during the six-month stability trial, the formulations were examined for changes in their physical characteristics, such as appearance, pH, sugar crystallisation, and stiffness.

Syneresis:

The contraction and separation of water from jellies after storage is known as syneresis. Use of a lower concentration of the gelling agent is one of the main contributors to it.

Stickiness and Grittiness:

By lightly rubbing the herbal jellies between your fingertips, you may assess their stickiness and grittiness.

Antimicrobial assay:

Using the well diffusion method, an in vitro antibacterial research of the herbal extract against the pathogenic bacterial strain *E. coli* was conducted. *E. coli* initially multiplied in the agar plate while it was being grown. After striking the plate with inoculum, 5 mm diameter bores were made into the medium using a sterile cork borer. After that, produced extract was placed in the bores on the cultured plate, and the plate was incubated for 24 hours at 37°C . The plate was evaluated 24 hours after beginning the incubation process. Using a ruler and the zone of inhibition diameter, millimetres were recorded. A 4 mm zone of inhibition was discovered ^(25,26).

Spreadability:

Between two glass slides, 2.5g of jelly was placed and then crushed to the appropriate thickness by holding a weight of 1000g for five minutes. The amount of time, measured in seconds, required to separate two slides. A shorter time span to reach the 7.5 cm distance revealed higher spreadability ⁽²⁷⁾.

$$S = W L / T$$

Where,

S= Spreadability

W = Weight tide to upper slide

L = Lenght of glass slide

T = Time required to separate two slides

Results

The jellies were prepared by using herbal decoction with gelatin and agar as gelling agent. The prepared jellies were inspected visually and the results are shown in Table 3. The jellies were evaluated for their pH, Stickiness and Grittiness, and results are given in Table 4.

Table 3. Physical properties of oral edible jellies

Sr. No.	Formulation	Colour	Odour	Texture	Taste	Clarity
1	F1	Yellow	Pleasant	Smooth	Sweet	Transparent
2	F2	Green	Pleasant	Tough	Sweet	Transparent
3	F3	Red	Pleasant	Smooth	Sweet	Transparent
4	F4	Yellow	Pleasant	Smooth	Sweet	Transparent
5	F5	Red	Pleasant	Smooth	Sweet	Transparent
6	F6	Green	Pleasant	Smooth	Sweet	Transparent
7	F7	Red	Pleasant	Smooth	Sweet	Transparent
8	F8	Orange	Pleasant	Smooth	Sweet	Transparent
9	F9	Orange	Pleasant	Smooth	Sweet	Transparent

Above Table 3 describes the physical properties like colour, odour, texture, taste and clarity of formulated herbal jellies.

Table 4. pH, stickiness and grittiness of jellies

Sr. No.	Formulation	pH	Stickiness	Grittiness
1	F1	5.98	Sticky	Nongritty
2	F2	5.76	Non-sticky	Gritty
3	F3	5.38	Non-sticky	Nongritty
4	F4	5.67	Non-sticky	Nongritty
5	F5	5.65	Non-sticky	Nongritty
6	F6	5.31	Sticky	Nongritty
7	F7	5.47	Non-sticky	Nongritty
8	F8	5.24	Sticky	Nongritty
9	F9	5.51	Non-sticky	Nongritty

Table 4 representing the formulations F1 to F9 with pH, Stickiness and Grittiness.

Table 5. Disintegration, spreadability, and syneresis study of herbal edible jellies.

Sr. No.	Formulation	Disintegration Time (Min.)	Spreadability (gcm/s)	Syneresis
1	F4	23.34	9.67	No syneresis
2	F5	26.00	8.80	No syneresis
3	F7	25.12	9.31	No syneresis
4	F9	24.09	9.43	No syneresis

Disintegration, spreadability, and syneresis study of herbal edible jellies for cough has shown in table 5. It becomes challenging to maintain polyherbal jellies' consistent content. A combination of various herbal elements is frequently included in the ingredients of polyherbal medical medicines. Due to the extremely diverse ingredients, polyherbal medication dissolving testing becomes challenging. Dissolution technique development is significantly more difficult than it is for a defined single constituent since the contents of polyherbal medicinal goods sometimes include a mixture of several herbal constituents.

Table 6. Stability study of herbal edible jellies.

Formulations	Characteristics	After 1 month	After 2 months	After 3 months	After 4 months	After 5 months	After 6 months
F4	Appearance	Smooth	Smooth	Smooth	Smooth	Smooth	Smooth
	pH	5.64	5.66	5.61	5.59	5.64	5.62
F5	Appearance	Smooth	Smooth	Smooth	Smooth	Smooth	Smooth
	pH	5.63	5.67	5.65	5.70	5.67	5.66
F7	Appearance	Smooth	Smooth	Smooth	Smooth	Smooth	Smooth
	pH	5.49	5.44	5.48	5.51	5.47	5.50
F9	Appearance	Smooth	Smooth	Smooth	Smooth	Smooth	Smooth
	pH	5.53	5.49	5.50	5.54	5.48	5.52

Stability study of selected formulations F4, F5 and F7 from 1 to 6 month with their pH and appearance were studied and shown in table 6.

Antimicrobial Assay

The antimicrobial activity of the formulation was evaluated using the Disc diffusion method in relation to the standard streptomycin against *Escherichia coli*. The formulation exhibited exceptionally strong antibacterial activity against *Escherichia coli*, out performing the zone of inhibition seen with conventional streptomycin. This implies a greater effectiveness in preventing *Escherichia coli* from growing. Using a ruler and the zone of inhibition diameter, millimeters were recorded. A 4 mm zone of inhibition was discovered.

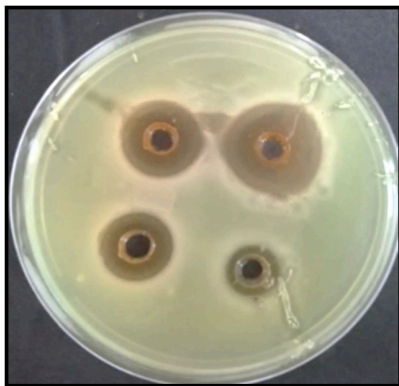


Figure 4: Zone of inhibition of herbal jellies in Antimicrobial assay

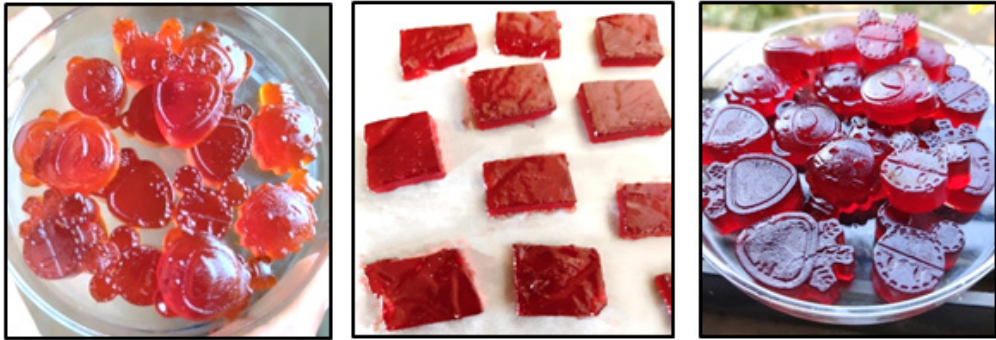


Figure 5: Images of formulated herbal edible jellies.

Discussion

The jellies were prepared by using herbal decoction with gelatin and agar as gelling agent. The prepared jellies were inspected visually and the results are shown in Table 3. The gelling agent jellies formulated with agar are non-sticky and gritty (F2). The jellies formulated using gelatin as a gelling agent is very smooth and sticky (F1). Combining agar and gelatin resulted in jellies that were non-sticky, non-gritty, transparent, and exhibited a good appearance (F4, F5, F7 and F9). We measured the pH of all formulations using a digital pH meter, and found that all formulations fell within the pH 5–6 range.

We further evaluated the formulations F4, F5, F7, and F9 for disintegration time, stability study, spreadability, and synthesis. Table 5 presents the results of disintegration, syneresis, and spreadability.

We found that the disintegration times for formulae F4, F5, F7, and F9 were 23.34, 26.00, 25.12, and 24.09 minutes, respectively, indicating good jelly disintegration. We found the spreadability of formulae F4, F5, F7, and F9 to be 9.67, 8.80, 9.31, and 9.43 g/s, respectively, indicating their good spreadability. These formulae do not exhibit syneresis upon storage.

We carried out the stability study of the formulated jellies by storing them at room temperature (25°C–5°C and RH 65%–5%) in accordance with ICH guidelines. We periodically checked the jellyfish every 30 days for 6 months for changes in their appearance, sugar crystallization, stiffness, and pH. Table 6 summarizes the information. The findings showed that the pH and appearance of the optimized formulation remained unchanged. The formulated jelly undergoes a 6-month stability study. So, the formulated jelly can be stable up to 6 months. Figure 4 shows the Zone of inhibition of herbal jellies in Antimicrobial assay, indicates the antimicrobial activity of formulated jellies. The formulation exhibited exceptionally strong antibacterial activity against *Escherichia coli*, outperforming the zone of inhibition seen with conventional streptomycin. Figure 5 pictorials of formulated herbal edible jellies for cough.

Conclusion

The present study successfully formulated edible jelly loaded with extracts from various herbs. Agar and gelatin were used as jelling agents. The optimized formulations F4, F5, F7, and F9 showed excellent appearance, texture, and no grittiness. The pH of the optimized formulations was between 5 and 6. We found that the optimized formulations had a disintegration time of 23 to 27 minutes and a spreadability of 8.5 to 10 gcm/s respectively. Optimized formulations did not show syneresis. The jellies showed excellent stability up to 6 months. The data revealed that the optimized formulation had not shown any change in their appearance or pH. So, the formulated jelly can be stable for up to 6 months. The formulations exhibited excellent antimicrobial activity, which is suitable to administer to children as an alternative oral solid dosage form.

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