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FORMULATION AND EVALUATION OF CHOCOLATES CONTAINING KALMEGH LEAF AND PAPAYA LEAF

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ABSTRACT

Chocolate is a versatile food with the potential to be used as a medium for drug delivery, offering an enjoyable and acceptable form of medication for pediatric patients. This study aimed to develop a palatable chocolate formulation containing kalmegh (Andrographis paniculata) leaf powder and papaya (Carica papaya) leaf powder for the treatment of dengue. The formulation was designed to enhance the acceptability of the medication, increasing the likelihood of patient compliance. A chocolate base was created using cocoa powder, cocoa butter, icing sugar, and pharmaceutical-grade sugar. The therapeutic agents were incorporated into this base to create a medicated chocolate. The prepared product was then evaluated for key properties, including appearance, moisture content, drug content, and its in vitro performance. Results showed that the medicated chocolate met the required standards for pharmaceutical use, maintaining a desirable texture and taste, while also delivering the necessary active compounds. This formulation provides a novel approach for pediatric drug administration, potentially improving patient adherence to dengue treatment regimens. Further studies are needed to assess the clinical efficacy and safety of the product in vivo.

KEYWORDS: Medicated Chocolate, Pediatrics, Chocolate formulation, Kalmegh, Papaya.

1. INTRODUCTION

The use of food-based drug delivery systems is an innovative approach to enhance patient compliance, particularly in pediatric and geriatric populations who may find it difficult to ingest traditional medicines. Among the wide variety of edible carriers, chocolate stands out as a promising medium for drug delivery due to its universal appeal, pleasant taste, and smooth texture. It is not only palatable but also a versatile substance that can be easily manipulated to deliver active pharmaceutical ingredients in an enjoyable format.

Chocolate, primarily composed of cocoa solids, cocoa butter, and sugar, has long been favored for its sensory properties and ability to mask the bitterness of various drugs. Its fat content allows for the controlled release of active compounds, offering potential benefits in the design of sustained-release formulations. Furthermore, chocolate's ability to encapsulate bioactive ingredients while preserving their therapeutic properties makes it an ideal candidate for delivering a range of medicinal compounds, from vitamins and minerals to herbal extracts and pharmaceutical drugs.

In recent years, there has been increasing interest in developing chocolate-based formulations for the treatment of various conditions, including infectious diseases like dengue, where patient adherence to medication is a significant concern. By combining therapeutic agents with chocolate, it is possible to improve the taste and texture of medicine, thereby increasing patient acceptance and potentially enhancing treatment efficacy.

This study explores the formulation of a chocolate-based drug delivery system incorporating kalmegh leaf and papaya leaf powders, aiming to create an effective and palatable pediatric formulation for dengue treatment.

1.1 Types of chocolate

There are several types of chocolate, each with distinct ingredients and characteristics. Here's an overview of the most common types:

1. **Dark chocolate**

- **Ingredients:** Cocoa mass, cocoa butter, sugar, and sometimes vanilla or lecithin.
- **Characteristics:** Dark chocolate contains a high percentage of cocoa solids (Usually between 50% and 85% or higher) and minimal added sugar. It has a rich, intense cocoa flavor, and is often less sweet than milk or white chocolate.

- **Health benefits:** Due to its higher cocoa content, dark chocolate is often considered healthier than other types, as it is rich in antioxidants and may provide cardiovascular benefits when consumed in moderation.

2. **Milk chocolate**

- **Ingredients:** Cocoa mass, cocoa butter, milk powder (or condensed milk), and sugar.
- **Characteristics:** Milk chocolate is sweeter and creamier than dark chocolate because of the addition of milk solids. The cocoa content is usually lower than that of dark chocolate (typically around 30%-50%).
- **Popular use:** This is the most widely consumed type of chocolate due to its smooth, sweet taste, and appealing texture.

3. **White chocolate**

- **Ingredients:** Cocoa butter, milk solids, sugar, and often vanilla or lecithin.
- **Characteristics:** White chocolate does not contain cocoa solids (the powdery component of cocoa beans), which is why it lacks the dark color and bitter taste typical of dark and milk chocolates. Instead, it has a rich, sweet, and creamy flavor with a smooth texture.
- **Health considerations:** While it is often enjoyed for its sweetness, it lacks the antioxidants found in dark chocolate because it doesn't contain cocoa solids.

4. **Ruby chocolate**

- **Ingredients:** Cocoa solids, cocoa butter, milk powder, sugar, and the addition of a special processing technique that creates the pinkish-red color.
- **Characteristics:** Ruby chocolate is relatively new to the market, with its distinct pink hue and fruity, tangy flavor. It's made from specially processed cocoa beans and offers a balance between the sweetness of milk chocolate and the bitterness of dark chocolate.
- **Health aspects:** Like milk chocolate, ruby chocolate is sweet but may have a slight edge in antioxidant properties due to the unique processing of its cocoa beans.

5. **Blended or compound chocolate**

- **Ingredients:** Cocoa powder, vegetable oils (Instead of cocoa butter), milk powder, and sugar.
- **Characteristics:** Compound chocolate is made by replacing cocoa butter with cheaper vegetable oils, which makes it more affordable but results in a less creamy texture and taste. It's commonly used in baking, confectionery coatings, and snack foods.

- **Use in drug delivery:** Due to the lower cost and the ability to modify its texture, compound chocolate can be used for mass production of chocolate-based drug delivery systems.

6. Sugar-Free chocolate

- **Ingredients:** Sugar substitutes such as stevia, erythritol, or other low-calorie sweeteners, along with cocoa solids, cocoa butter, and milk solids.
- **Characteristics:** This chocolate is designed for individuals who need to reduce their sugar intake, such as those with diabetes or those following low-carb diets. It typically tastes less sweet than regular milk or dark chocolate and may have a slightly different texture.
- **Applications:** Sugar-free chocolate can also be used in pharmaceutical formulations where avoiding sugar is important for certain health conditions.

7. Vegan chocolate

- **Ingredients:** Cocoa mass, cocoa butter and plant-based milk alternatives (Such as almond, soy, or oat milk), without any animal-derived ingredients (such as dairy).
- **Characteristics:** Vegan chocolate is designed for those who follow a plant-based diet or have dairy allergies. It usually contains cocoa solids, cocoa butter, and a plant-based milk substitute, offering a similar creamy taste and texture to milk chocolate but without the use of animal products.

1.2 Chemistry of chocolate

The chemistry of chocolate is fascinating and involves the interplay of various compounds that contribute to its flavor, texture, and stability. The primary ingredients in chocolate are cocoa solids (Which include cocoa powder), cocoa butter, sugar, and sometimes milk. The specific interactions between these components, as well as the chemical reactions during processing, shape the final product's characteristics.

Here's a breakdown of the key chemical components involved in chocolate

1. Cocoa Beans and Cocoa solids

- **Cocoa mass:** The base ingredient in chocolate, cocoa mass (Also called cocoa liquor), is made by grinding roasted cocoa beans. It contains both cocoa solids (The non-fat portion) and cocoa butter (The fat portion).
- **Cocoa solids:** The solid components of cocoa mass include a variety of compounds:

- **Theobromine:** A stimulant similar to caffeine, theobromine is responsible for the mild stimulating effect of chocolate. It can also contribute to chocolate's slightly bitter taste.
- **Flavonoids:** These are antioxidants found in cocoa solids, which may contribute to health benefits such as cardiovascular support. Flavonoids, particularly flavanols (e.g., epicatechin), are thought to be responsible for the antioxidant properties of chocolate.
- **Polyphenols:** These compounds, also antioxidants, contribute to the astringent taste and bitterness of dark chocolate. They are more prevalent in higher concentrations of cocoa.
- **Acids (e.g., oxalic acid):** These contribute to chocolate's overall acidity and bitterness.

- **Cocoa butter:** Cocoa butter is a fat that gives chocolate its smooth and creamy texture. It contains various triglycerides (Fat molecules), predominantly stearic acid, palmitic acid, and oleic acid. These fats are primarily responsible for chocolate's characteristic "melt-in-your-mouth" feel, as they melt at just below body temperature.

2. Sugar

- **Sucrose:** The primary sweetener in most chocolates, sucrose (table sugar) interacts with cocoa solids to balance their bitterness. Sugar crystallizes when cooled, influencing the texture and mouthfeel of chocolate.
- **Caramelization:** During chocolate manufacturing (especially roasting), sugar can undergo caramelization, which adds a complex, sweet, and slightly toasty flavor. However, this is more common in milk chocolate, where sugar content is higher than in dark chocolate.

3. Milk solids (In milk chocolate)

- **Lactose:** Milk chocolate contains lactose, the natural sugar found in milk. Lactose adds sweetness and contributes to the overall smooth texture of milk chocolate.
- **Proteins and Casein:** Milk proteins, especially casein, interact with cocoa solids and cocoa butter to form emulsions that help stabilize the fat-water mixture. These proteins can also help improve the texture and mouthfeel.
- **Whey:** A water-soluble protein that helps milk chocolate maintain a smooth consistency and prevents separation of the cocoa butter and cocoa solids.

4. Emulsifiers

- **Lecithin:** Lecithin is often added as an emulsifier, typically in the form of soy lecithin. It helps to blend the cocoa butter with cocoa solids and other ingredients, improving the

consistency and texture of the final product. Lecithin lowers the viscosity of chocolate, allowing it to flow more easily during processing.

5. **Flavor compounds**

- **Aroma volatiles:** The roasting of cocoa beans leads to the formation of volatile aromatic compounds, including aldehydes, ketones, and esters, which give chocolate its characteristic flavor profile. The balance between these compounds, along with the Maillard reaction (which occurs between amino acids and reducing sugars during roasting), contributes to the complex flavor of chocolate.
- **Pyrazines:** These are a group of compounds formed during roasting that contribute to the "roasty" and nutty aroma of chocolate.

6. **Crystallization of cocoa butter**

- **Polymorphism:** Cocoa butter exists in six different crystal forms, known as polymorphs, which affect the texture, gloss, and stability of chocolate. The most stable form is called **Form V**, which is what is typically desired in chocolate for its smooth texture and glossy appearance. The other forms, like **Form VI**, tend to be unstable and can cause the chocolate to bloom (i.e., develop a whitish, unattractive coating).
- **Tempering:** To achieve the desired stable crystal form (Form V), chocolate must be tempered. Tempering involves heating and cooling the chocolate to specific temperatures to ensure the cocoa butter forms a smooth and stable crystalline structure. This process ensures that chocolate has a nice snap when broken and a smooth, glossy finish.

7. **Maillard reaction**

- **Chemical reaction:** This non-enzymatic browning reaction occurs between amino acids (from milk proteins) and reducing sugars (like glucose and fructose). During roasting and processing, the Maillard reaction contributes to the complex flavor and brown color in chocolate.
- **Effect on flavor:** The Maillard reaction produces a variety of flavor compounds, such as toasted, roasted, nutty, and caramel-like flavors that enhance the overall taste of chocolate, particularly in milk and dark varieties.

8. **pH and Acidity**

- **pH Control:** The pH of chocolate influences its final texture, flavor, and appearance. Cocoa naturally has a slightly acidic pH, but the addition of alkali (in a process known as

"dutching") can reduce acidity, which helps mellow the flavor of dark chocolate and improve the color.

- **Alkalization:** Dutch processing of cocoa (adding an alkaline solution to cocoa beans) is common in commercial chocolate production, particularly for cocoa powder, as it reduces bitterness and improves solubility in liquids.

1.3 Pediatric dose of chocolate

The use of chocolate as a delivery system for pediatric medications is an innovative approach to improve patient compliance, especially in children who may have difficulty swallowing pills or who are averse to the taste of certain medications. However, when it comes to determining the pediatric dose of chocolate—whether for a therapeutic purpose (e.g., chocolate as a vehicle for delivering a drug) or for consumption—it's important to distinguish between dose of chocolate and dose of active pharmaceutical ingredient (API).

Here are some general considerations and guidelines regarding pediatric dosing when using chocolate as a drug delivery medium

1. **Chocolate as a delivery vehicle (for Medications)**

If you are formulating chocolate to deliver specific drugs or therapeutic compounds (like kalmegh or papaya leaf powder for dengue treatment), the focus is on the dose of the drug, not just the chocolate itself. However, the amount of chocolate used should still be within safe limits for children, ensuring the final formulation is palatable and doesn't lead to excessive sugar or fat intake.

General guidelines for pediatric dosing

- **Recommended therapeutic dose of active ingredient:** The dose of the drug (e.g., kalmegh or papaya leaf powder) should be based on established pediatric guidelines or clinical recommendations.
  - **Example:** If the required pediatric dose of kalmegh leaf extract is 50 mg per dose, you would calculate how much chocolate to provide that dose while accounting for the drug's concentration in the formulation.

- **Chocolate as a matrix**
  - The chocolate base typically contains sugar, cocoa solids, and cocoa butter, which are safe to consume in moderate amounts. However, the amount of chocolate given should be balanced to avoid excessive intake of calories, sugar, or fat.

- For pediatric patients, especially those under the age of 5, the chocolate dose (based on weight) should be carefully considered to avoid excessive calorie or sugar intake, as pediatric obesity and dental health are ongoing concerns.

2. General guidelines for chocolate consumption in pediatrics

Chocolate, while often loved by children, should be consumed in moderation. The amount of chocolate a child can safely consume depends on age, body weight, and dietary needs. Here are some general guidelines for chocolate consumption:

Caloric and Sugar guidelines

- **Toddlers (1-3 years)**
  - **Caloric intake:** Around 1,000–1,400 kcal per day.
  - **Added sugar:** No more than 25 grams (about 6 teaspoons) of added sugar per day (per WHO recommendations).
  - A small serving of chocolate, typically 10-15 grams, would fit within these limits.

- **Preschoolers (4-5 years)**
  - **Caloric intake:** Around 1,400–1,600 kcal per day.
  - **Added sugar:** Again, a limit of 25 grams per day.
  - You could consider up to 20-30 grams of chocolate, depending on the sugar content, as part of their total daily sugar intake.

- **Children (6-12 years)**
  - **Caloric intake:** About 1,600–2,200 kcal per day.
  - **Added sugar:** The same 25–30 grams limit per day, though children often consume more sugar, so chocolate should be monitored.
  - Typically, one small chocolate bar (around 30-40 grams) would fit within daily sugar guidelines, but the focus should remain on the nutritional content and active ingredient dosage.

- **Adolescents (13-18 years)**
  - **Caloric intake:** 2,200–3,000 kcal per day.
  - **Added sugar:** Less than 30-40 grams of added sugar.
  - Adolescents can handle larger portions of chocolate, but the focus should be on their overall nutritional needs and ensuring that chocolate doesn't replace nutrient-dense foods.

3. Drug dosage formulation

When developing a chocolate-based delivery system for pediatric medication, it's important to account for:

- **Potency of active ingredient:** For example, if you're adding a plant extract like kalmegh or papaya leaf powder, you need to carefully calculate the concentration of the active ingredient per unit dose of chocolate. A pediatric dose of the active ingredient should not exceed safe therapeutic levels.

- **Chocolate as a matrix:** You would typically calculate how much chocolate to give based on the required dose of the active ingredient. For example:
  - If a child needs 50 mg of kalmegh leaf powder per dose, and the chocolate formulation contains 5% kalmegh leaf powder, then 1 gram of chocolate would contain 50 mg of kalmegh powder.
  - This means the child would receive 1 gram of chocolate to meet the therapeutic dose. You could give 1-2 grams of chocolate, depending on the specific formulation.

4. Considerations in pediatric drug formulations

- **Taste masking:** Chocolate is an excellent vehicle for masking the bitter taste of certain medications. By incorporating the medication into a chocolate matrix, it improves the palatability and increases the likelihood that a child will take the medication.

- **Sugar content**: While chocolate can make a medicine more palatable, the sugar content should be carefully managed, particularly in children with conditions like diabetes or obesity. Using sugar-free chocolate or reducing the sugar content in the formulation is an option.

Fig. 1: Chocolate drug delivery.

2. Plant profile

2.1 Kalmegh *(Andrographis paniculata)*

- **Scientific name:** *Andrographis paniculata*
- **Common names:** Kalmegh, King of Bitters, Green Chiretta, Creat, Chiretta
- **Family:** Acanthaceae
- **Origin:** Kalmegh is native to the Indian subcontinent, particularly in tropical and subtropical regions of India, Sri Lanka, and Southeast Asia.

2.1.1 Botanical description

Kalmegh is an annual herbaceous plant, typically reaching a height of 30-90 cm. It is characterized by its bitter taste and is often referred to as the "King of Bitters" due to the intense bitterness of its leaves.

- **Stem:** The plant has a glabrous (Smooth) stem that is erect and branched, often with a reddish or greenish tinge.
- **Leaves:** The leaves are lanceolate (Long and Narrow) with a pointed tip, arranged in opposite pairs on the stem. They are bright green and have a strong, bitter flavor. The leaf surface is smooth, and the leaf margins are serrated.
- **Flowers:** Kalmegh produces small, purplish or white flowers that are arranged in a terminal panicle (A loose, branching cluster). These flowers are tubular in shape and have a characteristic, slightly sweet scent.
- **Fruit:** The fruit is a capsule that contains numerous small seeds. The capsule opens when mature to release the seeds.
- **Roots:** Kalmegh has a fibrous root system, but the therapeutic use is primarily in the leaves and stems.

2.1.2 Chemical constituents

Kalmegh is rich in several bioactive compounds, the most notable of which are:

- **Andrographolide:** The primary active compound responsible for the medicinal properties of Kalmegh. Andrographolide is a diterpene lactone with anti-inflammatory, antiviral, and immunomodulatory effects. It is also believed to have antioxidant, antimicrobial, and anticancer properties.
- **Andrographisides:** Glycosides found in the plant, contributing to its bitter taste and medicinal properties.
- **Flavonoids:** Including quercetin and rutin, which have antioxidant and anti-inflammatory effects.
- **Polyphenols:** These compounds contribute to the plant's antioxidant properties, helping to neutralize harmful free radicals in the body.
- **Triterpenes:** These have been linked to a variety of therapeutic actions, including anti-inflammatory and immune-boosting effects.

2.1.3 Medicinal uses

Kalmegh has been widely used in traditional medicine, particularly in Ayurvedic, Siddha, and traditional Chinese medicine (TCM). It has a long history of use for treating various ailments, primarily due to its powerful medicinal properties. Some of its common uses include:

- **Liver health:** Kalmegh is known for its hepatoprotective properties. It has been used to treat liver conditions like jaundice, hepatitis, and fatty liver disease.
- **Immune system support:** It is considered an immune booster and is used to enhance the body's resistance to infections, particularly viral and bacterial infections.
- **Anti-inflammatory:** Andrographolide in Kalmegh has been shown to reduce inflammation, making it useful in conditions like arthritis and other inflammatory diseases.
- **Antiviral and Antimicrobial:** Kalmegh is commonly used in the treatment of colds, flu, and other infections due to its antiviral and antimicrobial properties. It has shown efficacy against a variety of pathogens, including the dengue virus.
- **Digestive health:** It is used to treat indigestion, diarrhea, and other gastrointestinal issues. Its bitter compounds stimulate the digestive system, promoting bile production and improving digestion.

- **Antioxidant:** The plant's antioxidant properties help protect the body from oxidative stress and may play a role in preventing chronic diseases, including cardiovascular diseases and cancer.
- **Anticancer:** Preliminary research suggests that Kalmegh may have anticancer properties, particularly in inhibiting the growth of certain cancer cells.
- **Fever:** It has been traditionally used to reduce fever, especially in tropical diseases like malaria and dengue.
- **Diabetes:** Some studies suggest that Kalmegh may help in regulating blood sugar levels, making it a potential aid in the management of diabetes.

2.2 Papaya (*Carica papaya)*

- **Scientific name:** *Carica papaya*
- **Common names:** Papaya, Pawpaw, Papaw, Tree Melon
- **Family:** Caricaceae
- **Origin:** Native to southern Mexico, Central America, and northern South America, papaya is now cultivated in tropical and subtropical regions worldwide.

2.2.1 Botanical description

Papaya is a fast-growing, herbaceous plant that behaves like a small tree with a single, unbranched trunk. It is cultivated mainly for its large, sweet fruit, which is popular worldwide.

- **Stem:** The stem is soft, hollow, and can reach 2-10 meters in height. It has large, lobed leaves at the top, and the trunk is marked with scars where leaves were once attached.
- **Leaves:** The large, deeply lobed leaves are bright green and have long petioles (stems) attached to the central trunk. The leaves are also rich in antioxidants and bioactive compounds.
- **Flowers:** Papaya plants are dioecious, meaning that individual plants are either male or female. The flowers are large, white or yellow, and usually fragrant. Male flowers are borne in clusters, while female flowers are solitary.
- **Fruit:** The fruit is large and oval or pear-shaped. It starts out green and ripens to a yellow or orange color, depending on the variety. The flesh inside is soft, sweet, and orange in color, with numerous black seeds in the center.
- **Seeds:** The seeds are small, round, and black, with a peppery taste. Though often discarded, papaya seeds have various medicinal applications.

2.2.2 Chemical constituents

Papaya is a rich source of several bioactive compounds, vitamins, and enzymes that contribute to its health benefits. The key constituents include:

- **Papain:** This is the main enzyme found in papaya and is used for its proteolytic (protein-digesting) properties. Papain helps break down proteins and aids in digestion, making it useful for gastrointestinal issues.
- **Carotenoids (e.g., Beta-carotene):** These compounds give papaya its characteristic orange color. Beta-carotene is a precursor to vitamin A and has potent antioxidant properties.

- **Vitamins**
  - **Vitamin C:** Papaya is a rich source of Vitamin C (ascorbic acid), which is vital for immune function, skin health, and collagen production.
  - **Vitamin A:** Derived from carotenoids, Vitamin A supports vision, skin health, and immune function.
  - **Vitamin E:** Papaya contains vitamin E, another potent antioxidant that helps protect the body from oxidative stress.

- **Flavonoids:** These are plant-based antioxidants that help protect the body from free radicals. They also contribute to the color and taste of the fruit.

- **Minerals**
  - **Potassium:** Papaya is a good source of potassium, which supports heart health, regulates blood pressure, and aids in muscle function.
  - **Magnesium:** Essential for muscle function and bone health.
  - **Calcium:** Important for bone health and maintaining normal muscle function.

- **Alkaloids:** Present in the seeds, these compounds can have antimicrobial and anti-inflammatory effects.

- **Folate:** This B-vitamin is vital for cell division and is particularly important during pregnancy.

2.2.3 Medicinal uses

Papaya, particularly its fruit, seeds, and leaves, has a long history of use in traditional medicine systems around the world. It is used for a variety of purposes, from digestive health to immune support. Below are some of the most common medicinal uses of papaya:

- **Digestive health**
  - **Papain:** Papain helps break down proteins, aiding digestion. It is often used as a meat tenderizer, but it's also available as a supplement for people with digestive issues like indigestion, bloating, or heartburn.
  - **Anthelmintic:** Papaya seeds have traditionally been used to treat intestinal worms in various cultures. The seeds contain compounds that may help expel parasites.

- **Anti-inflammatory**
  - Papaya has anti-inflammatory properties, particularly due to its enzymes (like papain) and antioxidants. It is used in treating conditions like arthritis and joint pain.

- **Wound healing**
  - Both papaya fruit and papaya leaf extract have been used in wound healing. The enzyme papain helps remove dead tissue from wounds and accelerates healing. The leaf extract, particularly, has antimicrobial properties and can be applied to wounds to prevent infection.

- **Immune system support**
  - Due to its high vitamin C content, papaya is known to boost the immune system and protect the body from infections. Vitamin C also helps in the formation of collagen, which supports healthy skin and tissue.

- **Anticancer potential**
  - Some studies suggest that papaya leaf extract may have anticancer effects, particularly in its ability to boost the immune system and inhibit the growth of cancer cells. While more research is needed, preliminary findings suggest that papaya leaf might have potential in cancer prevention.

- **Antioxidant activity**
  - The carotenoids and flavonoids in papaya offer antioxidant properties, which help fight oxidative stress and protect the body from damage by free radicals. This may help reduce the risk of chronic diseases such as heart disease and diabetes.

- **Diabetes management**
  - Preliminary research suggests that papaya may help regulate blood sugar levels, making it beneficial for people with diabetes. The fruit is low in sugar and high in fiber, which helps regulate blood glucose levels.

- **Skin health**
  - Papaya is widely used in cosmetics and skincare products due to its exfoliating properties, thanks to papain. It is believed to help reduce acne, improve skin texture, and promote a healthy complexion. Papaya-based face masks and soaps are common in many cultures.

Fig. 2: Kalmegh & Papaya.

3. MATERIALS AND METHODS

3.1 Formulation of medicated chocolate

Table 1: Medicated chocolate.

S. No	Ingredients	F1	F2	F3	F4
1	Kalmegh leaf powder	1.0	1.0	1.0	1.0
2	Papaya leaf powder	0.5	0.5	0.5	0.5
3	Cocoa powder	0.8	0.8	0.8	0.8
4	Cocoa butter	1.0	1.25	-	-
5	Normal butter	-	-	1.0	1.25
6	Milk powder	1.2	1.2	1.2	1.2
7	Icing sugar	2.5	3	1.5	2.0
8	Sodium benzoate	0.04	0.04	0.04	0.04
9	Total	7.04	7.79	6.04	6.79

Procedure: Kalmegh leaf powder, papaya leaf powder, cocoa butter, cocoa powder, sodium benzoate, milk powder, and icing sugar were purchased from the local market. All other ingredients used in the study were of analytical grade. For the formulation of each chocolate, the following ingredients were used: cocoa butter, cocoa powder, milk powder, icing sugar, and sodium benzoate. All ingredients were weighed accurately before use.

The required amounts of cocoa butter and icing sugar were taken in a porcelain dish. A glass beaker, half-filled with water, was placed on a tripod stand, with a burner set below the stand to heat the water in the beaker. The porcelain dish containing cocoa butter and icing sugar was placed on top of the beaker. As the water in the beaker heated and evaporated, the steam caused the porcelain dish to heat up, melting its contents.

Once the cocoa butter and icing sugar were fully melted, cocoa powder and milk powder were added to the mixture and thoroughly mixed. Finally, the specified amount of the drug (Kalmegh and Papaya leaf powders) was added to the mixture and blended properly.

The melted mixture was then poured into pre-lubricated molds and stored in a freezer for 45 minutes to solidify. After the contents solidified, the chocolates were carefully removed from the molds and evaluated based on various parameters.

3.2 Evaluation parameters

3.2.1 Physical parameter

The general appearance of a chocolate including size, shape, colour, odour, taste having should be observed. It is must to have a good appearance for consumer acceptance. Physical changes may occur during storage, which can be determined P^H and melting point using P^H meter and melting point apparatus.

3.2.2 Weight variation

The formulated chocolate were tested for weight uniformity. 10 chocolate were collectively and individually. From the collective weight, average weight was calculated. Each chocolate weight was then compared with average weight to ascertain whether it is with in permissible limits or not.

3.2.3 Hardness

The chocolate crushing strength, which is the force required to break the chocolate by compression in the diametric direction was measured in triplicate using Pfizer tablet hardness tester.

3.2.4 Friability

The Roche friability test apparatus was used to determine the friability of the chocolate. 5 pre-weighed chocolate were placed in the apparatus, which was subjected to 50 revolutions. Then the chocolate were reweighed.

3.2.5 *In-vitro* drug release

In vitro release studies were performed using USP Apparatus II (Paddle type). The dissolution test was performed using 900 ml of phosphate buffer (pH 7.4), 37 ± 0.5°C, 75 rpm. Samples (5 ml) were collected at predetermined time intervals and replaced with equal volume of fresh medium, and analyzed using UV-Visible spectrophotometer.

4. RESULTS AND DISCUSSION

4.1 Physical appearance

Table 2: Physical appearances.

S. No	Appearance	Colour	Taste	Dimensions (Diameter X height) CM
F1	Glossy, Even Shine, No Streaks	Dark Brown	Slightly Bitter	2.8X0.5±0.001
F2	Glossy, Even Shine, No Streaks	Dark Brown	Neither Bitter Nor Sweet	2.8X0.5±0.001
F3	Glossy, Even Shine, No Streaks	Dark Brown	Semi Sweet	2.8X0.5±0.001
F4	Glossy, Even Shine, No Streaks	Dark Brown	Sweet, Good After Taste	2.8X0.5±0.001

4.2 Physical evaluation

Table 3: Physical evaluation.

S. No	Hardness (KG/CM2)	Melting point	Weight variation	Friability
F1	2.1±0.01	34˚C	4.0±0.001	0.91
F2	2.4±0.01	36˚C	5.0±0.001	0.89
F3	2.3±0.02	34˚C	6.0±0.001	0.90
F4	3.1±0.03	35˚C	6.5±0.001	0.92

4.3 Dissolution study

Table 4: Dissolution study.

Time (Min)	F1	F2	F3	F4
5	12.82±0.08	12.15±0.34	11.92±0.24	10.12±0.13
10	29.02±0.12	27.54±0.51	25.87±0.21	24.52±0.34
20	43.47±0.45	38.56±0.53	43.24±0.14	38.02±0.42
30	60.75±0.26	66.6±0.42	63.9±0.24	68.85±0.21
40	73.8±0.17	79.2±0.12	72.45±0.42	76.05±0.12
50	86.4±0.14	88.2±0.13	87.3±0.21	86.85±0.34
60	98.45±0.26	99.9±0.21	98.12±0.13	98.56±0.16

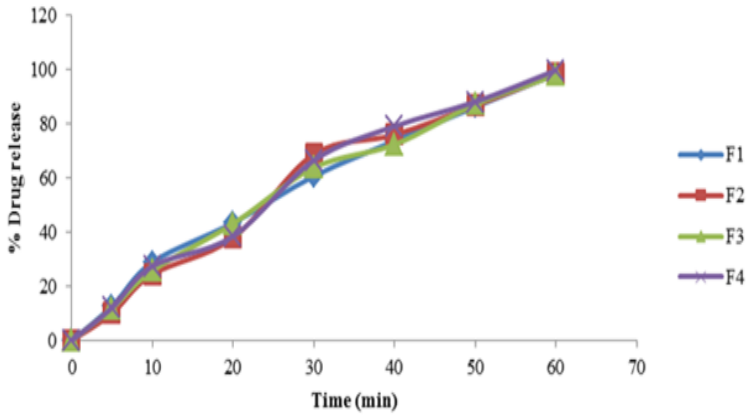

Fig. 3: *In-Vitro* drug release.

5. CONCLUSION

Kalmegh and papaya chocolates with satisfactory results were successfully prepared using cocoa butter and normal butter by heating method. Study indicated that both the butters used in the formulation had similar drug release. The F2 chocolate good drug release is obtained All the formulations were stable for a period of month and concentration of sugar played a role in the taste of chocolate and its acceptance. It was concluded that chocolates of various drugs with desirable drug release pattern can be prepared to increase patient compliance of different age groups.

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