



Formulation And Characterization Of Pediatric Chocolate

MISS ALFIYA KHAN

B PHARM

Charak Institute Of Pharmacy Mandleswar teh.Maheswar,dist.Khargone Madhya Pradesh

MRS VINITA PATIDAR

M PHARM

Assistant Professor:-Charak Institute Of Pharmacy Mandleswar. teh.Maheswar,dist.Khargone
Madhya Pradesh

Abstract:

The aim of this study Is to develop a pediatric-friendly herbalchocolate by combining medicine with one of children's favorite foods, chocolate, to make treatment more appealing. Cough and viral infections are common among children, and Ocimum sanctum (Tulsi), a well-known herbal remedy, has significant medicinal properties, including antitussive (cough-relieving) effects. The goal is to create a chocolate formulation containing an aqueous extract of Tulsi that provides these therapeutic benefits. The formulated medicated chocolate will be evaluated for various factors, including appearance, size, hardness, bloom (fat stability), drug content, and physical stability. Chocolate, being a versatile food, allows for a variety of taste and texture combinations. Additionally, it serves as an anhydrous medium, preventing microbial growth and reducing the risk of hydrolysis of water-sensitive medicinal agents.

Chocolate is rich in beneficial compounds like saturated fats, polyphenols, sterols, and methylxanthines. It also contains phenyl ethylamine, a compound naturally present in the brain, known as the "love drug" for its ability to induce feelings of happiness and contentment. In chocolate, phenyl ethylamine can elevate blood pressure and Jaggery levels, promoting a sense of well-being.

Humans typically experience five basic taste sensations: sweet, sour, bitter, salty, and savory, with sweet being one of the most enjoyable. Sweetness, especially from high-calorie saccharides, plays a key role in making the formulation appealing, particularly for children.

Keywords: Viral infection, chocolate, pediatric, herbal, Tulsi

1.INTRODUCTION

Children love chocolate more than any other food, yet they despise medicine. In order to prevent disease, the goal of the current study was to create medicated chocolate, or chocolate that contains drugs. The most prevalent illness in children who cough is a viral infection. The herbal remedy tulsi, or *Ocimum sanctum*, has a number of therapeutic benefits, one of which is its antitussive action. It is therefore necessary to create a chocolate that contains an aqueous tulsi extract that has antitussive properties. The manufactured medicated chocolate is also assessed for overall look, dimensions, hardness, blooming test, medication content, physical stability, and other factors. Chocolate is a flexible food that can be used to combine flavors and textures to create entirely new experiences.

Chocolate is highly sophisticated a versatile food that is combined to create completely different taste and texture sensations. Chocolate is also an anhydrous medium that resist microbial growth and to hydrolysis of water-sensitive active agents. Chocolate abundantly contains compounds such as saturated fat, polyphenols, sterols, di and triterpenes, aliphatic alcohols, and methylxanthines.

Chocolate have been shown to help our body produce chemical known as “Serotonin”. It makes feel relaxed. Further chocolate is also having some advantages like quick onset of action, reduction in the drug dose of manufacture and scale, increases drug loading capacity. Some drugs are bitter in taste due to which oral administration of bitter drugs leads to patient incompliance especially in children.^[2]

Chocolate (in some regions also named bittersweet chocolate, semi-sweet chocolate, dark chocolate or “chocolate fondant”) shall contain, on a dry matter basis, not less than 35% total cocoa solids, of which not less than 18% shall be cocoa butter and not less than 14% fat-free cocoa solids.

Medicated chocolate is prepared by using chocolate base and the drug is incorporated into prepared chocolate base.

When consumed as a component of a reasonable and changed diet, chocolate can be both a wellspring of supplements too as joy, and can considered as be important for an invigorating, healthy eating regimen. Cured chocolate detailing is generally utilized for organization and it builds the patient's longing to consume the medicine. Sedated chocolate is ready by utilizing chocolate base and medication is integrated to arranged chocolate base. The sedated chocolate can be assessed for its appearance, dampness content, thickness, blossoming test. Cured chocolate is ready by utilizing chocolate base and the medication is integrated into arranged chocolate base. As the medication is consolidated inside the chocolate and the medication is let out of the chocolate, it is called as Chocolate medication drug delivery system.

It is a best drug delivery system specifically for those people who don't take any kind of drug. The aim of the present study was to prepare Herbal Chocolate. Furthermore, to evaluate the physiochemical parameters of the prepared formulations so that they can be further

standardized and used commercially.

Chocolate (see Fig. 1) is one of the most popular foods among children, while medicine is often disliked. This study aims to create a “medicated chocolate,” combining chocolate with a medicinal ingredient to aid in disease prevention. Common ailments in children include coughs and viral infections. *Ocimum sanctum*, or Tulsi, is a herb known for its medicinal properties, including antitussive (cough-relieving) effects. This project focuses on formulating a chocolate Infused with Tulsi extract to provide antitussive benefits.

The medicated chocolate is evaluated for attributes such as appearance, dimensions, hardness, bloom stability (to test texture and color), drug content, and physical stability. Chocolate is a versatile food, able to pair with many ingredients to create unique tastes and textures. Being an anhydrous medium, it inhibits microbial growth and helps protect water-sensitive active ingredients. Additionally, chocolate contains compounds like saturated fats, polyphenols, sterols, di- and triterpenes, aliphatic alcohols, and methylxanthines. It also has phenylethylamine, often called “the love drug,” which naturally occurs in the brain and is linked to feelings of happiness. In chocolate, phenylethylamine can elevate blood pressure and blood sugar, contributing to a sense of well being.

Humans recognize five basic tastes: sweet, sour, bitter, salty, and savory. Sweetness is especially pleasurable, helping us identify high-calorie foods. In this study, the medicated chocolate is prepared by creating a chocolate base, into which the Tulsi extract is incorporated. This approach aims to make medicine more enjoyable for children by combining therapeutic benefits with the enjoyable taste of chocolate.

When chocolate is used as a vehicle to deliver medication, it enables the controlled release of drugs directly from the chocolate matrix, creating what is known as a “chocolate drug delivery system.” This method is especially effective for children,

combining a familiar and enjoyable food with medicinal benefits, making it a highly suitable drug delivery method for pediatric patients. The primary goal of this study is to develop a Pediatric Herbal Chocolate containing an extract of *Ocimum sanctum* (Tulsi), a herb known for its medicinal qualities, including its antitussive (cough-suppressing) properties. Given that coughs and viral infections are common ailments among children, the therapeutic profile of Tulsi makes it an ideal choice for formulating a medicated chocolate aimed at health prevention.

The prepared chocolate formulation undergoes evaluations based on multiple physical and chemical parameters, such as appearance, dimensions, hardness, bloom stability, drug concentration, and physical stability, to ensure its quality. The oral route is

typically favored for ease of patient use, though it does present challenges, particularly for drugs susceptible to first-pass metabolism. In such cases, alternative routes like the trans-mucosal method, which uses mucosal linings of areas such as the nasal, vaginal, rectal, and oral cavities, are employed to avoid early degradation in the digestive tract.

Chocolate's properties make it an ideal carrier for drug delivery: its anhydrous nature resists microbial growth and protects water-sensitive drugs from hydrolysis. Additionally, chocolate's sensory qualities, such as its smooth, creamy texture, are effective at masking unpleasant flavors and eliminating the gritty feel associated with certain active agents. Created by blending cocoa with cocoa butter and sugar, chocolate not only provides an enjoyable taste but also offers potential for bypassing first-pass metabolism. This study therefore focuses on formulating and evaluating Tulsi-infused medicated chocolate as a novel, child-friendly drug delivery system, emphasizing its therapeutic effects, stability, and suitability for commercial use.

Chocolate acts as an anhydrous medium, which helps prevent microbial growth and protects water-sensitive active ingredients from hydrolysis. These properties make chocolate an excellent vehicle for delivering medicinal compounds. Its versatility allows it to be customized to create various taste and texture profiles, making it a sophisticated option for food formulations. Additionally, chocolate's sensory qualities effectively mask unpleasant tastes of certain active ingredients, providing a smooth, creamy consistency that helps eliminate any gritty texture (Lang, 2007).

Among the many healthy substances found in chocolate include sterols, polyphenols, saturated fats, aliphatic alcohols, methylxanthines, di- and triterpenes, and polyphenols (Knight, 2000). Cocoa, the main component of chocolate, is particularly rich in polyphenols, especially flavan-3-ols like epicatechins, catechins, and procyanidins (Lamuela-Raventos et al., 2001; Hammerstone et al., 2000; Scalbert et al., 2000; Adamson et al., 1999; Lazarus et al., 1999). Research suggests that diets high in flavonoids, a type of polyphenol, may lower the risk of coronary heart disease, potentially due to their antioxidant effects (Geleijnse et al., 1999; Hertog et al., 1995; Fuhrman et al., 2001).

1.1 COMPOSITION OF CHOCOLATES

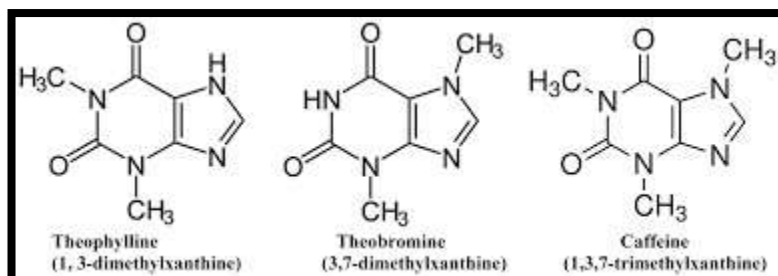
Depending on the desired taste and intended use, differing percentages of cocoa liquor, CB, and sugar are combined for dark chocolate. Milk chocolate, as the name implies, contains milk in addition to these other ingredients. The proportions of the major constituents in cacao beans, cocoa mass, and milk chocolate.

1. **Lipids:** -The oil in cacao, referred to as cocoa butter, is a mixture of monounsaturated and saturated fatty acids. The majority of the saturated fatty acids are palmitic acid and stearic acid. Although the lipid content of chocolate is relatively high, one-third of the lipids in cocoa butter is stearic acid.
2. **Fiber:** -Cocoa bean is high in fiber. The majority of fiber in cocoa is insoluble. Although soluble fiber is noted for reducing serum cholesterol, total dietary fiber is recognized as important for weight maintenance, and insoluble fiber has been associated with reduced risk of type 2 diabetes.
3. **Minerals:** -The cocoa bean contains several minerals necessary for vascular function. Dietary

magnesium, copper, potassium, and calcium all reduce risk of hypertension and atherosclerosis.

4. Polyphenols and antioxidant activity: -Cocoa powder contains up to 50 mg of polyphenols per gram. Cocoa contains a number of polyphenolic compounds, but it is particularly rich in flavonoids—specifically, flavanols, also called flavan-3-ols. Flavanols form complexes with salivary proteins and are responsible for the bitterness of cocoa. [7]

Figure No. - 1. Important Constituents of Chocolate



1.2. THERAPEUTIC BENEFITS OF PEDIATRIC CHOCOLATE

- 1. Easily Exceptable :** - Theo bromine acts a diuretic. This acts as effective therapy in cases of fluid accumulation in tissues (oedema) or removal of excess water and salts from the body through urination or in the reduction of high blood pressure due to increased water content of the fluid connective tissues.
- 2. Full fill some nutrition:** -Theo bromine helps in the increased dilation of blood vessels. This helps improve blood flow, and thereby contributes to the reduction of blood pressure.
- 3. preventing from recurrent cough and cold :** -Theobromine has been known for its properties for improving the functioning of the heart. It can be used for treating various cardiac problems such as arteriosclerosis, vascular disorders, angina, hypertension.
- 4. Harmless because of herbal extracts :** -Theo bromine possesses relaxant properties. It induces relaxation of the smooth muscles of the cardiac tissues.
- 5. Improving memory:** - Consumption of hot chocolate has a positive effect on the functioning of the brain and memory enhancement by improving neurovascular coupling (response of blood flow to brain activity) in the white matter of the brain as well as cognitive functioning. This positive effect of chocolate consumption on the

1.3 CHOCOLATE MANUFACTURING PROCESSES

Chocolate manufacturing processes generally share common features such as:

- (1) Mixing
- (2) Refining
- (3) Conching of chocolate paste
- (4) Tempering
- (5) Moulding of chocolate

1. **Mixing:** - Mixing of ingredients during chocolate manufacture is a fundamental operation employed using time–temperature combinations in a continuous or batch mixers to obtain constant formulation consistency. In batch mixing, chocolate containing cocoa liquor, sugar, cocoa butter, milk fat and milk powder (depending on product category) is thoroughly mixed normally for 12–15 minutes at 40–50°C. Continuous mixing is done by using well-known automated kneaders, producing somewhat tough texture and plastic consistency.



Figure No. - 2 Mixing process

2. **Refining:** - Refining of chocolate is important to the production of smooth texture that is desirable in modern chocolate confectionery. Mixtures of sugar and cocoa liquor (and milk solids depending on the type of chocolate) at an overall fat content of 8–24% are refined to particle size of less than 30 μm normally using a combination of two- and five-roll refiners. Final particle size critically influences the rheological and sensory properties.



Figure No. - 3 Refining Process

3. **Conching:** - Conching is regarded as the endpoint or final operation in the manufacture of bulk chocolate, whether milk or dark. It is an essential process that contributes to development of viscosity, final texture and flavour. Conching is normally carried out by agitating chocolate at more than 50°C for few hours. In the early stages, moisture is reduced with removal of certain undesirable flavour-active volatiles such as acetic acid, and subsequently interactions between disperse and continuous phase are promoted. In addition to moisture and volatile acid removal, the conching processing promotes flavour development due to the prolonged mixing at elevated temperatures, giving a partly.



Figure No. - 4 Conching process

4. **Tempering:** - Cocoa butter used in chocolate manufacturing causes uncontrolled crystallization which causes rough surface. Tempering involves the selection of best crystal forming polymorphic form of cocoa butter to avoid crystallization. This is known as tempering.



Figure No. - 5 Tempering process

5. **Molding of chocolate:** - It involves proper selection of molds according to size and shape of the chocolate desired. Mould will be lubricated for easy removal of chocolate.



Figure No. - 6 Molding of chocolate

1.4. MECHANISM OF CHOCOLATES

Cocoa has been reported to be a source of natural antioxidants, the free radicals' scavengers that preserve cell membranes, protect DNA, prevent the oxidation of low-density lipoprotein (LDL) cholesterol that leads to atherosclerosis and prevent plaque formation in arterial walls. The antioxidant activity of cocoa has been attributed to the Procyanidins and their monomeric precursors, Epicatechin and Catechin, which inhibit oxidation of LDL. Dark chocolate and cocoa inhibit LDL oxidation and increase high-density lipoprotein (HDL)- cholesterol concentrations. Catechins are phytochemical compounds found in high concentrations in a variety of plant-based foods and beverages. The catechin content in dark chocolate is 12mg/100 gm. The Epicatechin content in dark chocolate is 41.5 mg/100 gm. The consumption of catechins has been associated with a variety of beneficial effects including increased plasma antioxidant activity, bronchial artery dilation, fat oxidation and resistance of LDL to

oxidation. Epicatechin seems to be a major bioactive constituent of cocoa and other flavonol-rich foods and beverages. It has been shown to improve endothelial function in animals and humans. In salt sensitive animal models of hypertension, epicatechin lowers blood pressure and the associated end-organ damage. Nitric oxide seems to play a key role in the protection of both hypertension and endothelial dysfunction.

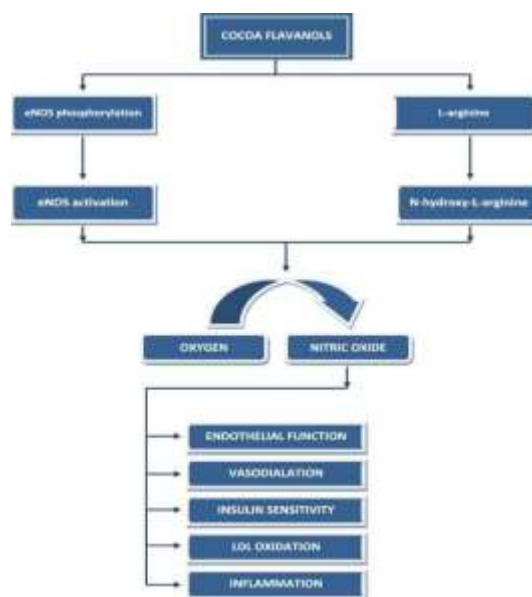


Figure No. - 7 Mechanism of Antioxidant Property of Chocolates

2. LITERATURE REVIEW

1. **Kolekar Yogesh, S et. al. (2021)** The chocolate is most loving food of children whereas the medicine is hating substance. So, objective of present study was to formulate the chocolate that contain drug i.e., medicated chocolate to prevent the disease. In children cough, viral infection is most common diseases. ocimum sanctum, tulsi is the herbal drug which having several medicinal properties, antitussive activity is one of them. Thus, we have to formulate the chocolate with aqueous extract of tulsi that gives antitussive activity. Further, prepared medicated chocolate is evaluated for general appearance, dimension, hardness, blooming test, drug content determination, physical stability etc.

2. **Verma Poojashree et. al. (2020)** The objective of this study is to design and fabricate chocolate. It is also called as chocolate drug delivery. The essential target of this study was to formulate and evaluate natural nutritious chocolate and nutritional supplement containing women hormonal imbalance that will have the additional work in infertility, ovulation, menopause, and pcos. Present study was to make to get ready chocolate plan of Vitex agnus-castus, cinnamon and holy basil which enhance the ovulation, hormonal function and also used in stress and insulin management. Chocolate is a range of products derived from cocoa (cacao), mixed with fat and finely powdered coconut sugar to produce a solid confectionery The medicated chocolate formulation is widely used for hormonal imbalance and increases patient compliance. The prepared chocolate formulations were evaluated for general appearance, Ph and stability and blooming tests and also shows good drug release properties.

3. **Cheng .c et. al. (2019)** investigated the effects of palm olein (pol), cocoa butter (cb) and extra virgin olive oil (evoo) on the lipid profile and low-density lipoprotein subfractions in a young, healthy Chinese population. After screening, 72 subjects were randomly assigned to three groups, and an 18-week randomized crossover trial was conducted. The first phase was a 2-week run-in period, followed by three phases of the 4-week experimental periods with a 2-week washout period between experimental periods. Three groups of subjects alternately consumed a Chinese diet enriched with the different test oils. The various indices of subjects were collected before and after each experimental period. Sixty-seven subjects completed the study, and there were no significant differences in conventional indices amongst the three groups at the beginning of the three experimental periods ($p > .05$). Each test oil accounted for approximately 40% of total fat intake and approximately 11.3% of the total energy supply. After controlling for dietary interventions, only the serum triglyceride level of the pol-diet was significantly lower than that of the evoo-diet ($p = .034$), and most indices did not significantly differ amongst the three test oil diets ($p > .05$). Pol, cb and evoo have almost identical effects on serum lipids.

4. **Julia Kuhn. et.al. (2018)** Cocoa beans are susceptible to fungal contamination and often contain substantial amounts of ergosterol, the precursor to vitamin D₂. We hypothesized that sun-drying the fermented cocoa beans might lead to the conversion of ergosterol to vitamin D₂. We quantified vitamin D in cocoa and cocoa-based foods by liquid chromatography-tandem mass spectrometry. Here, we show that cocoa beans from different growing regions contain vitamin D₂. Particularly high vitamin D₂ content was found in cocoa powder and butter. Among the chocolates, dark chocolate had the highest vitamin D₂ content (ranging from 1.90 to 5.48 $\mu\text{g}/100\text{ g}$), white chocolate had the lowest vitamin D₂ content (ranging from 0.19 to 1.91 $\mu\text{g}/100\text{ g}$), and chocolate nut spreads had a comparatively low vitamin D₂ content, with an average of 0.15 $\mu\text{g}/100\text{ g}$. Thus, cocoa and chocolate are clearly a dietary source of vitamin D, therefore, it is necessary to update food composition databases.

5. **Farah shafi et. al. (2018)** reviewed on chocolate processing. It is a product processed from cocoa, rich in flavonoids and antioxidant compounds. It grows best in tropical rainforests. Chocolate processing consists of a multistep process which, starting from cocoa beans, involves fermentation, drying, roasting, nib grinding and refining, conching and tempering (owen, 2013). During cocoa processing, the naturally occurring antioxidants (flavonoids) are lost, while others such as maillard reaction products are formed. Primary chocolate categories are dark, milk and white chocolate, which differ in their contents of cocoa solid, milk fat and cocoa butter. Chocolate has become one of the most popular food types and flavours in the world. Chocolate is very sensitive to temperature and humidity (mattia and sager, 2014). Quality chocolate is characterized by glossy shine, snap, aroma, texture and taste. Chocolate processing is complex and requires several technological operations and processes to achieve the desired product quality. Chocolate is lower in caffeine than tea and coffee. Chocolate contains antioxidants which may help prevent cancer and heart disease (afoakwa, 2009).

6. **Pravin shende et. al. (2018)** revealed on amalgamation of innovation and elegance in drug delivery. With the advent of new technology, there are many advances in the field of drug delivery for

sustained or controlled release of drug. The conventional drug delivery is undergoing reforms to develop new and innovative drug delivery systems (dds). The concept of elegant dds involves the administration of drug or combination of drugs in innovative and attractive way without individuals' acceptable route like administration of antifungal drugs for paronychia using medicated nail lacquer. Other systems involved are medicated lipsticks, medicated tattoos, medicated chewing gum, etc. Also, in the era of wearable technology and artificial intelligence, use of wearables to monitor and diagnose different disease conditions like anaphylaxis and cardiac disease is the area of interest for research. All these wearables and formulations are used to provide an elegant look as well as therapeutic effect. The present review highlights the present scenario of different elegant DDDS and also focuses on their method of preparation, excipients and also the evaluation parameters. The elegant drug delivery will be the modernized cosmeceuticals for management and treatment of complicated conditions in near future.

7. Reddy sunil et. al. (2017) designed and fabricated Chlorpheniramine maleate chocolate formulation by chocolate drug delivery system. Chlorpheniramine maleate binds to histamine h1 receptor. This blocks the action of endogenous histamine, which subsequently leads to temporary relief of negative symptoms brought on by histamine. Chocolate is a range of products derived from cocoa (cacao), mixed with fat (i.e., cocoa butter) and finely powdered sugar to produce a solid confectionery. The medicated chocolate formulation is widely used for pediatric administration and increases patient compliance. Chlorpheniramine maleate chocolate formulation is prepared to improve patient compliance. Chocolates were formulated (f1-f3) with a total fat of 25-35 % (w/w) from cocoa liquor and cocoa butter with more than 34% total cocoa, composition as specified for dark chocolate, lecithin, sweetening agents. The prepared chocolate formulations were evaluated for general appearance, drug content, in vitro drug release and DSC and FTIR, moisture content and blooming tests. F1 formulation releases complete drug within 60 mi. The results indicate that the formulation has no drug excipient interactions and there was no degradation in drug, it is stable during chocolate formulation preparation.

8. Magrone.t et. al. (2017) discussed that cocoa and dark chocolate possess polyphenols as major constituents whose dietary consumption has been associated to beneficial effects. In fact, cocoa and dark chocolate polyphenols exert antioxidant and anti-inflammatory activities switching on some important signaling pathways such as toll-like receptor 4/nuclear factor kb/signal transducer and activator of transcription. In particular, cocoa polyphenols induce release of nitric oxide (no) through activation of endothelial no synthase which, in turn, accounts for vasodilation and cardio protective effects. In the light of the above-described properties, a number of clinical trials based on the consumption of cocoa and dark chocolate have been conducted in healthy subjects as well as in different categories of patients, such as those affected by cardiovascular, neurological, intestinal, and metabolic pathologies. Quite interestingly, following cocoa and dark chocolate ingestion, cocoa polyphenols also modulate intestinal microbiota, thus leading to the growth of bacteria that trigger a tolerogenic anti-inflammatory pathway in the host. Finally, many evidences encourage the consumption of cocoa and dark chocolate by aged people for the recovery of the neurovascular unit.

9. Patel nidhi et. al. (2015) One of the most popular foods all over the world is chocolate and it has highly nutritious energy, fast metabolism and good digestibility. Nowadays, most important trend is healthy foods. Chocolate is derived from cocoa beans, central to the fruit of cocoa tree, theobroma cacao. Chocolate characters not only originate in flavor precursors present in cocoa beans, but are generated during post-harvest treatments and transformed into desirable odor notes in the manufacturing processes. In its many forms chocolate may be consumed as a beverage, as a syrup, as a flavoring, as a coating. And varied diet, chocolate can be both a source of nutrients as well as pleasure, and can be considered as being part of a healthful, wholesome diet. Medicated chocolate formulation is widely used for pediatric administration and it increases the patient's desire to consume the medication. Medicated chocolate is prepared by using chocolate base and drug is incorporated to prepared chocolate base. The medicated chocolate can be evaluated for its appearance, moisture content, viscosity, blooming test, drug content determination and in vitro drug release. This review paper focused on health importance and usage of medicated as well as conventional chocolates.

10. Franco Rafael. et. al. (2013) One may wonder why methylxanthines are so abundant in beverages used by humans for centuries, or in cola-drinks that have been heavily consumed since their appearance. It is likely that humans have stuck to any brew containing compounds with psychoactive properties, resulting in a better daily life, *i.e.*, more efficient thinking, exploring, hunting, *etc.*, however, without the serious side effects of drugs of abuse. The physiological effects of methylxanthines have been known for a long time and they are mainly mediated by the so-called adenosine receptors. Caffeine and theobromine are the most abundant methylxanthines in cacao and their physiological effects are notable. Their health-promoting benefits are so remarkable that chocolate is explored as a functional food. The consequences of adenosine receptor blockade by natural compounds present in cacao/chocolate are here reviewed. Palatability and health benefits of methylxanthines, in general, and theobromine, in particular, have further contributed to sustain one of the most innocuous and pleasant habits: chocolate consumption.

11. Gravina Stephen, A et. al. (2013) Taste or gustation is one of the 5 traditional senses including hearing, sight, touch, and smell. The sense of taste has classically been limited to the 5 basic taste qualities: sweet, salty, sour, bitter, and umami or savory. Advances from the Human Genome Project and others have allowed the identification and determination of many of the genes and molecular mechanisms involved in taste biology. The ubiquitous G protein-coupled receptors (GPCRs) make up the sweet, umami, and bitter receptors. Although less clear in humans, transient receptor potential ion channels are thought to mediate salty and sour taste; however, other targets have been identified. Furthermore, taste receptors have been located throughout the body and appear to be involved in many regulatory processes. An emerging interplay is revealed between chemical sensing in the periphery, cortical processing, performance, and physiology and likely the pathophysiology of diseases such as diabetes.

12. Sharma Mayank, Jain Dinesh Kumar, et. al. (2012) Chocolate is highly sophisticated and infinitely a versatile food that can be combined to create completely different taste and texture sensations. The objective of the present study is to develop a palatable chocolate formulation of Domperidone and Cetirizine for pediatric administration and to increase patient's desire to consume the medication. In present investigation chocolate base is prepared by use of cocoa powder, coco butter, lecithin, and pharmaceutical grade sugar. Thereafter drug is incorporated to prepared chocolate base. The medicated chocolate prepared is evaluated for appearance, moisture content determination using digital Karl Fischer titrator, blooming test, drug content determination & drug excipient interaction by differential scanning calorimetry.

13. David L Katz, et. al. (2011) Cocoa contains more phenolic antioxidants than most foods. Flavonoids, including catechin, epicatechin, and procyanidins predominate in antioxidant activity. The tricyclic structure of the flavonoids determines antioxidant effects that scavenge reactive oxygen species, chelate Fe²⁺ and Cu⁺, inhibit enzymes, and upregulate antioxidant defenses. The epicatechin content of cocoa is primarily responsible for its favorable impact on vascular endothelium via its effect on both acute and chronic upregulation of nitric oxide production. Other cardiovascular effects are mediated through anti-inflammatory effects of cocoa polyphenols, and modulated through the activity of NF-κB. Antioxidant effects of cocoa may directly influence insulin resistance and, in turn, reduce risk for diabetes. Further, cocoa consumption may stimulate changes in redox-sensitive signaling pathways involved in gene expression and the immune response. Cocoa can protect nerves from injury and inflammation, protect the skin from oxidative damage from UV radiation in topical preparations, and have beneficial effects on satiety, cognitive function, and mood. As cocoa is predominantly consumed as energy-dense chocolate, potential detrimental effects of overconsumption exist, including increased risk of weight gain. Overall, research to date suggests that the benefits of moderate cocoa or dark chocolate consumption likely outweigh the risks.

14. Gordon parker, et. al. (2006) reviewed on chocolate's properties and the principal hypotheses addressing its claimed mood-altering propensities. Food craving and emotional eating was distinguished, to consider their psycho-physiological underpinnings, and examine the likely 'positioning' of any effect of chocolate to each concept. Results: chocolate can provide its own hedonistic reward by satisfying cravings but, when consumed as a comfort eating or emotional eating strategy, is more likely to be associated with prolongation rather than cessation of a dysphoric mood. Limitations: this review focuses primarily on clarifying the possibility that, for some people, chocolate consumption may act as an antidepressant self-medication strategy and the processes by which this may occur. Conclusions: any mood benefits of chocolate consumption are ephemera.

Aim and objective

- **Aim-** Formulation and characterization of pediatric chocolate

□ **Objective-** There are many types of medicines in the market which are very useful but Their taste leads to swallowing problem. But herbal chocolate is one such way by which we can take any kind of medicine without any problem. And chocolate drug delivery system is the versatile technology which attracts people by improving the palatability of the bitter taste drugs, thereby increasing patient compliance.

4. **PLAN OF WORK**

□ **PHASE I**

PREFORMULATION STUDIES

- Selection of raw materials
- Determination of melting point
- Methods Extraction

□ **PHASE II**

FORMULATION AND OPTIMIZATION OF CHOCOLATE BASE:

- Method of preparation of Chocolate base

□ **PHASE III**

CHARACTERIZATION OF CHOCOLATE BASE

- Determination of viscosity of chocolate base:

CHARACTERIZATION OF HERBAL CHOCOLATE

- Physical observation
- Weight variation test
- Thickness and diameter
- Determination of Drug content
- Determination of Moisture Content
- Determination of Blooming test

- Fat bloom

- Jaggery bloom

☐ **PHASE IV**

➤ In vitro drug release

➤ Release kinetics

☐ **PHASE V –**

➤ STABILITY STUDIES

5. MATERIALS AND METHODS

1. Materials - *chocolate ba, jagree, tulsi extract, piperment oil, cashew, almond*

2. Methods

❖ **PREFORMULATION STUDIES**

❖ **Selection of raw materials: -**

1. *Ocimum tenuiflorum* (Tulsi) - *Ocimum tenuiflorum* is a many branched, erect, stout and aromatic herb about 75 cms high. This small herb is found throughout India and is cultivated, worshiped in temples and houses of Hindus. This is commonly known as Vishnu-Priya, Tulsi in Sanskrit, Kala-Tulsi in Hindi and India's Holy Basil in English. The leaves, seeds and root of this plant have been used in indigenous Ayurvedic medicine.



Figure No. - 8 *Ocimum tenuiflorum*

☐ **Scientific Name:** *Ocimum tenuiflorum*

☐ **Common Name:** Tulsi, Holy Basil

☐ **Family:** Lamiaceae

☐ **Parts Used:** Leaves and the flowering tops

☐ **Active Principles:** Bioactive compounds include oleanolic acid, rosmarinic acid, ursolic acid eugenol, linalool, carvacrol, β elemene, β caryophyllene, germacrene.

☐ **Health Benefits:**

☐ Great for Healing skin problems

☐ Boosts the immunity

☐ Good dental health

☐ Digestive health

- Good source of Vitamin K
- Promotes respiratory health
- Promotes eye health
- Helps cure fever naturally
- Fights Allergies
- Improves Skin
- Curing Common Cold
- Improves Oral Health
- Gives Relief from Pain
- Improves Bowel Movement
- Gives relief from Indigestion

2. Jaggery : - If you are trying to live a healthier life, it is very obvious that every other person would suggest you cut down on your sugar intake. But when the sugar cravings are at their peak, you might fail miserably and end up eating all things sweet. And then, to deal with that, people would suggest you avoid refined sugar and switch to jaggery . Have you ever thought about why every other nutritionist or dietician says the same thing? And how far jaggery good for health? Let us weigh in .



Figure No. -9 Jaggery

- Scientific Name:** *Gur*
- Common Name:** Jaggery
- Parts Used:** Cooking
- Family:** Apidae

Use of Jaggery :

1. Baking : Jaggery can be used in cakes, cookies, muffins, and brownies as a substitute for refined sugar.

2. **Drinks :** Jaggery can be added to hot beverages like tea, coffee, or milk to sweeten them.
3. **Savory dishes :** A small amount of jaggery can balance the spice in curries, stews, and savory sauces.
4. **Desserts :** Jaggery is a staple ingredient in many Indian sweets like laddus, payasam, and barfi.
5. **Traditional snacks :** Jaggery is used in traditional snacks like chikki (peanut bars) and naru (small balls made with coconut gratings).
6. **Fermented beverages :** Jaggery can be used to make fermented beverages by sterilizing earthen pots with a layer of jaggery inside.

2. **Almond :** The almond is an important nut native to Central Asia, but today is produced worldwide in hot–arid Mediterranean climate regions. Nowadays, the USA is the largest almond producer, followed by Spain and Australia. Cultivated almond varieties display a different chemical profile due to genetic and ecological factors, as well as processing conditions. Regular consumption of nuts has been related to healthy effects, especially against cardiometabolic diseases. Epidemiological studies and clinical trials have reported positive effects of nuts consumption against a significant number of pathologies such as obesity, hypertension, diabetes mellitus and metabolic syndrome. In addition, individuals who consume nuts regularly present lower waist circumference and improved metabolic profiles. The almond kernel, which constitutes the edible part, is a seed formed by two large cotyledons covered by a brown skin and protected by an external hull with an intermediate shell. Once maturity is reached, the hull opens and the seed separates easily. Almonds contain lipids (around 50%), proteins (around 25%) and carbohydrates (around 20%), and have a low moisture content and diverse minor bioactive compounds. The beneficial effects of almond consumption are associated with its composition of macro- and micronutrients. Among the compounds with beneficial properties for health, the lipid profile, predominantly monounsaturated fatty acids (MUFA, 60%), followed by polyunsaturated fatty acids (PUFA, 30%), fiber, vitamins, minerals, phytosterols and polyphenols, can be highlighted. The great diversity of varieties as well as the forms of cultivation and the climatic characteristics determine the remarkable differences in almonds' chemical composition. In addition, the form of consumption, mostly raw or roasted, adds additional changes to the composition of almonds. The roasting process induces chemical and microstructural changes, especially altering the lipid composition, favoring its oxidation and modifying antioxidant compounds. Moreover, the use of prebiotics to promote gut microbiota modulation towards a health-promoting profile is gaining attention. The fiber and polyphenols content in almonds could be a substrate for microbial fermentation in the gut, contributing to regulation of the microbiota composition. Considering the relevance of almonds from an agro-economical and nutritional point of view, the present review addresses the chemical composition of different almond varieties, the bioavailability and metabolism of its components, especially bioactive compounds, and their use as a source of functional foods and prebiotics.



Figure No. - 10 Almond

- Scientific Name:** *Prunus dulcis*
- Common Name:** Almond
- Parts Used:** Seed
- Family:** Rosaceae
- Use of Almond:** 1. Help to increasing brain activity.
2. Good for pregnant woman. 3. Make your heart healthy.
4. Low down bad cholesterol level.
5. Energy booster.

3. **Cashew:** Cashew is an evergreen perennial plant belonging to the family Anacardiaceae. This family consists of 400-600 species. Among the eight species in the genus Anacardium, the only cashew is valuable due to its nutritious kernel. Cashew is a tropical tree present in South America and Brazil. Plant height varies from 5 to 14

m. The trunk is usually short and irregular, starting branches close to the ground. Leaves are green that are placed in a spiral pattern towards the end of the stem. Leaves become mature after 20-25 days. Flowering can occur at any time; individual flowers are short in size consisting of five yellowish-green sepals and five white to reddish petals. In 2011, about 4.7million tons of raw nuts were produced worldwide, which were distributed between Asia and Africa, where 1.8 million cashew apples were produced



Figure No. - 11 Cashew

- **Scientific Name:** *Anacardium occidentale*
 - **Common Name:** Cashew Nut, Cashew, Jagus, Gandaria,
 - **Family:** Anacardiaceae
 - **Parts Used:**beans
 - **Use of Cashew:** 1. Builds blood.
 - 2. Figurehts migraines.
 - 3. Prevents gallstones.
 - 4. Makes the skin healthy
 - 5. Improves vision.
 - 6. Reduces stress. 7.Good for
- vegan diet.

8.Improves heart health.

❖ **FORMULATION AND OPTIMIZATION OF CHOCOLATE BASE: 1.Method of preparation of Chocolate base:**

Oven was set to 50°C. Sugar and water were taken in a beaker and kept in the oven for 4-5 min and syrup was prepared. Then sugar syrup was removed from the oven, and cocoa powder was added and. Careful attention is paid to the chocolate manufacturing process to ensure that the temperature of the mixture is not too high. Then above mixture of chocolate base was cooled up to semisolid consistency and then flavor was added.

7. **Formulation of herbal chocolate:**

Water bath was set in such a way that water become hot having temperature about 50°C. Then chocolate

base was melted in porcelain dish till it become free flowing. On another side, sugar syrup was prepared by taking sugar in appropriate quantity with distilled water in beaker on water bath. Then add prepared sugar syrup in required quantity into melted chocolate base. After above step, appropriate quantity of drug extract i.e., crude extract of Tulsi 250mg was added. And add some prunus dulcis, Anacardium occidentale and stirred continuously. Then whole mass of chocolate base was poured in a silicon chocolate mould and refrigerated till it become solid form approximate 3- 6Hrs.

Table 1: Formulation Table

s.no	Ingredients	Batch 1	Batch 2
1	Chocolate base	5gm	5gm
2	Jagree	3gm	3gm
3	Tulsi Extract	3gm	3gm
4	Peppermint oil	5gm	5gm
5	Cashew oil	150gm	150gm
6	Almond	q.s	q.s

❖ CHARACTERIZATION OF CHOCOLATE BASE

1. **Determination of viscosity of chocolate base:** - Viscosity of the chocolate base plays an important role in maintaining proper consistency. Brookfield Rotational digital viscometer (DV I+) was used to measure the viscosity (in cps) of the prepared chocolate base. The spindle (LV1) was rotated at 50rpm. Samples of chocolate base were heated at 50°C before the measurements were taken.

❖ CHARACTERIZATION OF HERBAL CHOCOLATE:

1. **Physical Observation:** First medicated chocolate was weighed and observed physically to study the surface characteristics and shape. Surface characteristics and shape of the herbal chocolate was evaluated by physical observation. It is important to check for the absence of pitting, fat blooming, sedimentation and migration of active ingredients.

2. **Weight Variation** A non-destructive test that compares the individual weights of a sample of tablets with the average weight of the selected sample.^[31]

3. **Thickness and diameter:** The thickness and diameter of the herbal chocolate is the only dimensional variable related to the molding process. Thickness and diameter of the dosage form were measured by Vernier caliper. The deviation of each is calculated and the deviation of individual unit from the mean diameter should not exceed $\pm 5\%$.^[32]

4. **Drug content determination:** Drug content of medicated chocolate by thin layer chromatography. Here control was taken as aqueous tulsi extract and test as melted chocolate sample. TLC plates were prepared by using silica G and plates were activated for

½ Hr. Spotting was carried out on both plates i.e., control and test plate by using capillary. Run both the plates in mobile phase i.e., Toluene: Ethyl acetate: Water having ratio 7:3:2. After running of both plates air drying of plates was carried out. Further, visualization of both plates was carried out by using iodine chamber. By comparing the RF value of both the plates i.e., control and test, Drug content in Medicated chocolate was determined.

5. Determination of Moisture content: Moisture content of medicated toffee was determined by keeping it inside the desiccator under reduced pressure by applying vacuum for 24 hours. Initial weight and the final weight after 24 hrs. were noted and the moisture content was determined by using formula.

Moisture content [% W/W] = $\frac{\text{Initial weight} - \text{Final weight}}{\text{Initial weight}} \times 100$

Initial weight

❖ **Determination of Blooming test:**

1. Fat Bloom - When the thin layer of fat crystals forms on the surface of chocolate formulation. This will cause the chocolate to lose its gloss and a soft white layer will appear, giving the finished article an unappetizing look. Fat bloom is caused by the recrystallization of fat and/or a migration of a filling fat to the chocolate layer. Storage at a constant temperature will delay the appearance of fat bloom.^[1]

2. Jaggery Bloom – This is rough and irregular layer on top of chocolate formulation. This is caused by condensation (when chocolate is taken out of the refrigerator). This moisture will dissolve the sugar in the chocolate. When the water evaporates, sugar recrystallizes into rough, irregular crystals on surface. This results into unpleasant look. Test sample of chocolate was subjected to treatment cycles contains. 30 °C for 11 hours Shifting of temperature for 1 hour 18 °C for 11 hours Shifting of temperature for 1 hour Observed the test sample of chocolate whether blooming has taken place. ^[1]

6. Stability studies: Since the period of stability testing can be as long as two years, it is time consuming and expensive. Therefore, it is essential to devise a method that will help rapid prediction of long-term stability of drug. The stability may be predicted defined as the validated method by which the product stability may be predicted by storage of the product under conditions that accelerate the change in defined and predictable manner. The stability studies of formulated formulations were carried out at 25 °C / 75 % RH and 2-8 °C for one month. The effects of temperature, humidity and time on the general appearance of chocolate and drug content were evaluated for assessing the stability of the prepared formulation.

7. RESULT AND DISCUSSION

: -Determination of viscosity of chocolate base: -Viscosity helps in determining flow behaviour, which is an indirect measure of product consistency and quality. The thickness of chocolate base in a

melted state directly relates to how it will harden, too. High chocolate viscosity (thicker chocolate) is ideal for molding where it is needed the chocolate to hold its specific shape. Viscosity was measured by Brookfield rotational digital viscometer and the spindle was rotated at 60 rpm. The results are tabulated in Table No.2 which indicates molten chocolate base has high viscosity which is ideal for moulding into medicated herbal chocolate.

Table No. 2: Determination of Viscosity of Chocolate Base

CHOCOLATE BASE	VISCOSITY (CPS)
Trial 1	58264
Trial 2	58365
Trial 3	58573

: - CHARACTERIZATION OF HERBAL CHOCOLATE

Physical observation: -The general appearance of a chocolate formulation, its visual identity and overall elegance is essential for consumer acceptance and to control lot to lot uniformity. The control of the general appearance of a chocolate involves the measurement of number of attributes such as chocolate's color, presence or absence of an odor, taste, surface texture and physical flaws. Randomly selected ten medicated toffees were inspected visually and the results were listed in Table No.3.

Table No .3: Physical Observation

S. No	CHARACTERISTIC S	RESULT
1	Color	Dark brown
2	Odor	Chocolate with no brunt, no smoky smell
3	Taste	sweet
4	Texture	Smooth

Dimension: - It was measured by Vernier's calipers. -

Table No.4: Dimension & Hardness

S.no	Batch I	Batch II
1	Height: 8.97 ±0.12	Height: 8.47 ±0.049
2	Diameter: 31.05 ±0.03	Diameter: 31.13 ±0.021
3	Hardness: 0.2 Kg/cm ²	Hardness :0.3 Kg/cm ²

Thickness and diameter: - Thickness of the medicated toffee is influenced by the diameter and the amount of fill in the mold. Six medicated toffees were used to evaluate the average thickness by

measuring Vernier caliper. Results shows in the Table No.5 thickness of the medicated toffee was controlled within $\pm 5\%$ variation.

Table No.5: Thickness of herbal chocolate

S.no	F1	F2	F3
1	8.99	8.36	9.18
2	8.97	8.35	9.16
3	8.96	8.40	9.12
4	8.99	8.36	9.14
5	8.96	8.35	9.18
Average Thickness	8.97	8.36	9.16

Determination of fat bloom & sugar bloom: -Fat bloom and sugar bloom were evaluated to see the change in texture of the medicated chocolate. It was observed by exposing the medicated chocolate to different temperature cycles [40°C for 8 hour and an intermediate shift to 20°C] temperature for 8 hr. Absence of light colour spots or dusty appearance on the medicated toffee indicates the absence of fat bloom and sugar bloom.



Figure No. - 13 : - Image of fat bloom sugar bloom test

: - Stability studies: - Medicated toffee were evaluated for physical and chemical stability for over a period of month at room temperature. No significant changes in the physical and chemical properties were observed which indicates that formulated medicated toffee is stable and results were shown in Table No.6.

Table No .6: Stability Study Data of Medicated Toffee at room temperature

Parameter	7 days	15 days	30 days
Color	Dark brown	Dark brown	Dark brown
Odor	Pleasant	Pleasant	Pleasant
Appearance	Glossy	Glossy	Glossy
Fat bloom	Absence	Absence	Absence

Sugar bloom	Absence	Absence	Absence
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8. Summary

Formulating herbal pediatric chocolate involves combining a chocolate base with herbal extracts, sugar syrup, and other ingredients, followed by evaluation for appearance, taste, texture, and stability.

Here's a more detailed breakdown of the process:

1. Preparation of Herbal Extracts:

- * Herbal ingredients, like Tulsi (Holy Basil) or other herbs with beneficial properties, are collected and prepared.
- * The herbs are crushed or powdered, then boiled with distilled water to extract the active compounds.
- * The extract is then filtered to remove solid particles. ®

2. Chocolate Base Preparation:

- * A chocolate base is prepared using ingredients like cocoa powder, cocoa butter, lecithin, and pharmaceutical-grade sugar.
- * The chocolate base is melted in a water bath until it becomes free-flowing. & Sugar syrup is prepared separately by dissolving sugar in distilled water in a beaker placed in the water bath.

3. Combining Ingredients:

- * The prepared sugar syrup is added to the melted chocolate base.
- * The herbal extract is then added to the mixture, which is stirred continuously. o

4. Pouring and Setting:

- * The prepared chocolate mixture is poured into molds.
- * The molds are then placed in a freezer to allow the chocolate to set and solidify. &

5. Evaluation and Quality Control:

- * The prepared herbal chocolates are evaluated for various parameters, including:
- * Visual Evaluation: Appearance, color, and overall look.

- * Physical Properties: Texture, hardness, and moisture content.
- * Taste and Odor: Sensory evaluation of taste and smell.
- * Stability: Physical stability over time, including blooming test (formation of white patches on the chocolate). Drug Content: Ensuring the presence and stability of the herbal extract within the chocolate.
- * Phytochemical Analysis: Identifying and quantifying the presence of beneficial compounds from the herbal extracts.

8. CONCLUSION

When most medications are bitter, oral delivery of these formulation results in patient noncompliance, particularly in children. To solve this restriction, it is suggested that a dosage form be developed that is most suitable to pediatrics and adult patients. Nowadays, most pharma companies are coming out with numerous alteration formulations such as dissolving tablets, dry syrups, lozenges, oral films, and so on, having this universal challenge. In this topic we tried to find formulation which can be best compatible with the patient. As a chocolate provides formulations a smooth and creamy texture, and it's great for hiding the unpleasant flavors of some medication's excipients. Thus, it can be concluded that the chocolate formulations are attractive way to administer medications to patients via oral drug delivery.

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