Review

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Medicated Chocolate Formulation: A Review

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Abstract

Chocolate is everyone's favorite food, especially for children. Chocolate contains phytonutrients called antioxidants, which provide antioxidant activity. Chocolates are also associated with health benefits such as reduction in metabolic and cardiovascular disorders and so on. Conventional dosage forms are associated with some limitations such as bitter taste and difficulty in swallowing *etc.,* especially for paediatrics. To overcome these limitations a novel drug delivery system has been developed by the researchers *i.e* medicated chocolate. Medicated chocolate increases the aesthetic texture and patient compliance and is more attractive to paediatrics. This type of delivery system is also beneficial for geriatrics and patients with *dysphagia*.

Keywords: Conventional dosage forms; Paediatrics; Medicated chocolate; Patient compliance.

Introduction

The oral route remains the most preferred route of drug delivery. The non-invasive nature, ease of administration, safety, and cost-effectiveness makes oral drug delivery system acceptable for all populations [1-3]. Even though tablets and capsules are reported to be the most preferred solid oral dosage forms, they do not possess high patient compliance among the paediatric and geriatric population or those with dysphagia. Liquid dosage forms, which are comparatively preferred among paediatrics and geriatrics, are associated with poor dose accuracy, poor stability, and inability to mask the bitterness of the drug [4]. So there is a requirement for the development of a novel oral dosage form that can be therapeutically effective, safe, cost-effective, and patient-friendly with paediatrics, geriatrics, and patients with dysphagia. Chocolate is considered to be highly palatable and well accepted among the paediatric population. The organoleptic characteristics of chocolate make them ideal for masking the bitter taste of drugs. Also being an anhydrous medium, they are resistant to microbial growth and hydrolytic degradation of sensitive drugs. Cocoa, the principle constituent of chocolate is rich in polyphenols which possess many potential health benefits and these properties make the chocolate suitable to use as a drug delivery system [5,6]. Chocolate can be ideally incorporated with bitter-tasting drugs. Medicated chocolates are a novel drug delivery system consisting of bitter drug incorporated chocolates. Bitter taste, fear of choking, lack of aesthetic texture had made conventional solid oral formulations less acceptable among paediatrics hence these medicated chocolates may be the suitable dosage form to enhance patient compliance among the paediatrics.

Benefits of chocolate

For the cardiometabolic disorder

The cocoa product containing flavanols can prevent cardiometabolic disorder.

For the blood sugar

Dark chocolate helps to make the blood vessels healthy and unimpaired circulation will protect them from type II diabetes. The flavonoids present in dark chocolate also help to reduce insulin resistance.

For cardiovascular disease

Chocolate, cocoa, and flavanols are used to lower cardiovascular disease. Consumption of flavanol-rich food will be helping to improve cardiovascular outcomes. Dark chocolate will also minimize the risk of atherosclerosis. It helps to prevent the sticking of WBCs to the blood vessel walls.

In magnesium deficiency

Decreased magnesium levels may be responsible for some cardiovascular changes, kidney, digestive, nervous, and muscular disorders. The use of cocoa has not been explored to treat or prevent magnesium deficiency in humans.

For brain

Dark chocolate increases blood flow to the brain and heart. Dark chocolate consists of several chemical compounds which have a stimulating action. Phenylethylamine (PEA) present in the chocolates will stimulate the brain to release endorphins and also contains a mild stimulant known as caffeine. A small quantity of caffeine present in the chocolate will make it an ingredient for the treatment of mood disorders.

For oral hygiene

Dark chocolate reduces the risk of tooth decay. Theobromine is also a mild stimulant present in the chocolate that helps to overcome cough by suppressing the vagus nerve activity.

The Rich source of antioxidants

Chocolate is a good source of antioxidants responsible for inhibiting plasma lipid oxidation.

Anti-cancer and anti-inflammatory properties

Dark chocolate is a rich source of antioxidants like flavonoids and polyphenols. These compounds are responsible for anti-cancer and anti-inflammatory properties. It acts by suppressing excessive and uncontrolled cell division and also reducing inflammation by neutralizing the free radical formation [6].

Advantages of medicated chocolates

- Bypassing first-pass metabolism and pre-systemic elimination in the GIT
- Chocolate is resistant to microbial growth and hydrolysis degradation of water-sensitive drugs.
- Improve patient compliance, well accepted by children.
- Drug absorption is rapid.
- Exhibit local as well as systemic effect
- Easy to administer
- Suitable during traveling
- A simple method of preparation

Disadvantages of medicated chocolates

- Melting at high temperature
- Should require proper storage condition
- Packaging is costly

Ingredients	Use
Cocoa powder	Principle ingredient
Cocoa butter	Solidifying agent
Soy Lecithin	Emulsifier
Simple syrup	Sweetening agent
Pineapple flavor	Flavoring agent

Table 1: Commonly used ingredients in medicated chocolates.

Method of preparation medicated chocolate

Preparation of chocolate base

Oven set at 50°C. Place the beaker containing sugar and water to prepare the simple syrup. Melt the cocoa butter and lecithin in a beaker and add the simple syrup. To the above mixture add the cocoa powder and mix well until it becomes free-flowing. After cooling add the flavoring agent. The mixture is then poured into a polycarbonate set mould then allow to solidify in a refrigerator.

Preparation of Medicated chocolate

The oven is preheated at 500C. Melt the chocolate base. Add the required quantity of the drug to the chocolate base. Mix well by using a magnetic stirrer. Then add the required quantity of the preservatives. Then pour the above mixture into a polycarbonate set mould and allow it to solidify in a refrigerator [7-9].

Evaluation of medicated chocolate

Viscosity

Brookfield viscometer is used to determine the viscosity of the chocolate base.

Melting point

A glass beaker half-filled with water was placed on a tripod stand. The burner was set below the tripod stand to heat the water of the beaker. A porcelain disc containing medicated chocolate was placed on the top of the beaker. To the porcelain disc, a thermometer was placed. Contents of the porcelain disc were melted due to the generated steam. By using the thermometer the melting temperature was measured [10].

Weight variation

Ten formulations were randomly selected and weighed individually. Calculate the average weight.

Thickness

The thickness of the formulation is determined by using Vernier calipers.

Hardness

Chocolate crushing strength is the force required to break the chocolate. It is measured by using a Monsanto tablet hardness tester.

Friability

Roche friabilator is used to measure the friability of the medicated formulation. It is expressed in percentage (%). The percentage friability is calculated by

$$F = \frac{W_{initial} - W_{final}}{W_{initial}} \times 100$$

Moisture content determination

This test is carried out to check the moisture present in the chocolate in dry conditions. Moisture content is determined by using a Desiccator. The medicated chocolate weighed accurately and was kept in a desiccator containing anhydrous silica gel. After 24 hrs, the formulations were taken out, weighed and % moisture loss was calculated by using formula

$$\%Moisture\ loss = \frac{Initial\ weight - Final\ weight}{Initial weight} \times 100$$

Disintegration test

A disintegration test for the prepared formulation was carried out as per USP until it disintegrates using the Disintegration tester (at 37±0.5 °C) and 60 rpm speed using pH 6.8 phosphate buffer.

Invitro **dissolution study**

USP dissolution apparatus type II (paddle) is used. 900 ml of 0.1 N HCl is filled in the vessel and the temperature is maintained at 37 ± 0.5°C and 50 rpm. The medicated chocolate is placed in the dissolution medium and samples are withdrawn at regular time intervals. The samples are analyzed using spectrophotometry

Blooming test

Fat bloom: Fat bloom is the presence of a light color spot or a thin layer of fat crystal on the surface of the chocolate formulation. Fat bloom will cause the chocolate to lose its gloss and make the chocolate an unappetizing look. The fat recrystallization or migration of filling fat to the chocolate layer will lead to the formation of fat bloom. Storage at a constant temperature will help to overcome the appearance of fat bloom

Sugar bloom: It is the result of the contact of chocolate with moisture and dissolves the sugar present on the surface of the chocolate. The dissolved sugar crystallizes and settles on the surface of the chocolate, when the water dries. These small sugar crystals cause the chocolate layer a dusty appearance. Storage at a constant temperature will prevent the appearance of sugar bloom.

Stability

The formulation is packed in suitable packing materials such as aluminium foil, wax paper, and double wrapper. Stability studies were done at room temperature (25 ± 20C) and refrigerated condition (20C ± 80C) for 1 month. Then the samples were analyzed for the evaluation test.

Conclusion

Medicated chocolates may be the suitable dosage form for delivering drugs that have an unpleasant and obnoxious taste. The chocolate delivery system could be an organoleptically acceptable formulation for the paediatric and patient with dysphagia. The chocolate contains the principle constituent cocoa which has so many health benefits. They are expected to acquire more demand in pharmaceutical production as innovative dosage forms for the paediatric population. Medicated chocolates will achieve the most wanted position among the paediatric population very soon.

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