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Development and Assessment of Taste-masked Paracetamol Chewable Tablets

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ABSTRACT

Patients often want to prevent medication use due to the extreme bitter taste of medicine. Medicated chocolates were made in order to resolve the disadvantages. Chocolate, consisting of fats such as cocoa butter and finely pulverized sugar to bake solid bakery products, is particularly a cocoa product. Chocolate bases blended with medications are medicated chocolates. The base of chocolate is an arid medium that resists growth microbe, making it favorable for medicinal reasons. Chocolate drug delivery systems are the use of medicated chocolate for drug transportation. The objective of this study is to develop paracetamol formulations using the delivery system for chocolate drugs. In the scientific paper, the nature, drug content and in vitro drug release activity was developed and tested for three separate drug formulations. The effect of the in vitro analysis of the formulations was that took 15 minutes more to release the drug relative to two other formulations. It was reported that there is no interaction between medical formulations and ingredients used for preparing chocolate.

Keywords: Chocolate, Drug delivery system, Medicated drug, Paracetamol

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INTRODUCTION

In pediatrics and geriatric dosage types, chewable supplements have been frequently used because they are helpful for children or adults who have trouble swallowing [1]. These dosage forms will disintegrate through the chewing process in the patient's mouth. After that a smooth consistency is consumed upon breakdown, and the drug is dissolved into the gastrointestinal tract. Consequently, by bypassing dissolution, the chewable supplements will enhance bioavailability (that increases dissolution). Moreover since water is not required for administration of drugs, it increases patient satisfaction and ease.

It may be crucial to select a suitable excipient to perform a particular function in supplement formulation, like dissolution or lubrication, to accomplish high production efficiency. For the flavoring of the active ingredients, another major excipient is a sweetening factor. Only a sweetening factor, however does not completely outweigh the drug's bitter aftertaste [2]. Several physical alteration procedures, including drug wrapping, may be carried out to prolong drug dissolution with in subject's mouth.

Chocolate, composed of fats such as cocoa butter and finely pulverized sugar to bake solid bakery products, is a particular cocoa product [3]. Chocolate contains significant quantities of compounds such as fats, polyphenols, and sterols, alcohols from di and tri terpenes and methylxanthines. The most impressive chocolate ingredients are caffeine and theobromine. The base of chocolate is an arid medium which resists microbial activity and hydrophilic agent association [4]. Medicated chocolate is developed by applying a medicine with a chocolate base. One of the efficient methods of delivering drugs is the chocolate drug delivery system [5]. In several

ways, chocolate has been used as a means to move ingredients. Chocolate's organoleptic properties are good for masking bad tastes correlated with main ingredients and offering a smooth and creamy texture.

The main focus of the research is to design and fabricate a paracetamol chocolate drug delivery system. In this research paper, the chocolate drug delivery system aims to improve patient compliance and drug release activity. The paper also discusses excipient interaction with drugs.

LITERATURE SURVEY

In a research paper by O. G. Bhusnure, methacrylic acid and methacrylic ester copolymer were used for flavor masking the drug with polymer coat levels ranging from 10 % to 40 %. [6]. In research paper titled "Development and Evaluation of Taste Masked Granular Formulation of Satranidazole", taste masked granules were developed for satranidazole using melt granulation technique. The developed granules were evaluated by FTIR studies, Scanning Electron Microscopy of drug and in vitro drug release study. The developed granules showed release of 87.65% release in 60 mins [7].

A paper by Tanikan Sangnim taste-masked paracetamol capsule using polymer and/or wax dispersion technique. The paper also evaluated taste-masked paracetamol capsule. The material used for coating were Eudragit, beeswax and cetyl alcohol. The coating material along with active ingredient and other excipients were used in different proportion to develop drug and the developed drug was physically evaluated by individuals [8].

However, these are frequently ineffective, and the bitter taste stays in the mouth or as a prolonged aftertaste if small particles of medication stay in the mouth. Thus, it can be concluded from literature survey that various new techniques are developing for effective masking of the unpleasant taste of medicines in oral drug delivery system. The aim of this research was to mask the extreme bitter taste of the drug with help of chocolate. In the present research paper, a method of preparation and evaluation for paracetamol formulation used in chocolate drug delivery systems has been discussed.

METHODOLOGY

Materials

Paracetamol, polysorbate, pharmaceutical grade sugar was bought from Sigma-Aldrich. Cocoa butter was bought from Jindal cocoa. All the reagents such as vanilla and saffron flavor were of analytical grade.

Formulations

Chocolate base: Chocolate base was prepared with fat content of 20%-30% from cocoa liquor and butter with a total 30% of cocoa composition [9]. Formulation is given in Table 1.

Table 1. Formulation I.

S. No.	Contents	Role	Amount (mg)
1	Paracetamol	Drug	12
2	Cocoa powder	Principle ingredient	1546
3	Cocoa butter	Solidifying agent	600
4	Polysorbate 60	Emulsifier	80

Medicated chocolate: Prepared chocolate bases having paracetamol in appropriate quantities are referred as medicated chocolate.

Method of preparation

Chocolate base: At 50°C, the microwave was preheated. Sugar and water were taken into the beaker just after oven was preheated and placed in the microwave for 4 min- 5 min to obtain syrup. The cocoa butter was softened for 1 min in the microwave. Both of the solutions were appropriately blended. This procedure has been properly carried out so that the temperature of the solution is not too high. The ingredient composition is given in Table 2.

Table 2. Preparation of chocolate base.

S. No.	Contents	Role	Amount (mg)
1	Cocoa powder	Principle ingredient	1546
2	Cocoa butter	Solidifying agent	600
3	Polysorbate 60	Emulsifier	80
4	Pharmaceutical grade sugar	Sweetening agent	1150

Medicated chocolate: At 50°C, the microwave was preheated. The chocolate base previously prepared was dissolved to obtain a semi-liquid texture. In addition, a sufficient amount of medication was applied to the base of molten chocolate, combining the paste with homomixer to produce a consistent solution. The above mixture was transferred into a polypropylene mold and held for 15 minutes in the refrigerator until it became

solid. Ten formulation I units (Table 1) containing cocoa powder, cocoa butter, polysorbate 60 and sugar of pharmaceutical grade were made. But a strong aroma of cocoa powder was detected when processing the mixture. The compound was disguised with flavors to mask the noticeable aroma of the cocoa powder.

Ten units of formula II (Table 3) containing cocoa powder, cocoa butter, polylobate 60 and vanilla flavor of pharmaceutical grade sugar were made. In addition, ten units of formula III (Table 4) containing cocoa powder, cocoa butter, polysorbate 60 and saffron flavor of pharmaceutical grade sugar were also made. The distinction is the variation in taste in formulations II and III. However, due to improved taste and flavor, vanilla flavor is more appropriate than saffron flavor. In certain cases, medicated chocolate will turn into an inappropriate shape after solidification. Dicalcium phosphate, together with cocoa butter, may be used as an absorbent if this issue occurs.

Table 3. Formulation II.

S. No.	Contents	Role	Amount (mg)
1	Paracetamol	Drug	12
2	Cocoa powder	Principle ingredient	1541
3	Cocoa butter	Solidifying agent	600
4	Polysorbate 60	Emulsifier	80
5	Pharmaceutical grade sugar	Sweetening agent	1150
6	Vanilla flavor	Flavor	17
7	Total		3380

Table 4. Formulation III.

S. No.	Contents	Role	Amount (mg)
1	Paracetamol	Drug	12
2	Cocoa powder	Principle ingredient	1541
3	Cocoa butter	Solidifying agent	600
4	Polysorbate 60	Emulsifier	80
5	Pharmaceutical grade sugar	Sweetening agent	1150
6	Saffron flavor	Flavor	17
7	Total		3380

EVALUATION

Chocolate base

A survey was used to estimate the flavor, texture and quality of the chocolate base. In this analysis, 10 individuals were chosen to rate the characteristics of chocolate based on a rating scale of 1-5.

Medicated chocolate

General appearance: For acceptability, the outward look of medicated chocolate is very important. Some criteria that may be color, scent, taste and consistency include the general appearance. The criteria were observed.

Physio-chemical properties: Compatibility tests of drug excipients, like Differential Scanning Calorimetry (DSC), were carried out for both paracetamol and medicated chocolate. Using Vernier calipers, the thickness of each formulation was determined. The thickness limit permitted varies by ± 5 per cent of the formulation size. As per USP, variation was performed in the weight and disintegration test. The weight and standard deviation were noted. A UV spectrometer at 260 nm against the blank was used to determine the drug content. 5 ml of aliquot sample was removed for dissolution studies and instantly replaced with fresh culture.

The sample was diluted and 260 nm was analyzed spectrophotometrically. It measured the total percentage and deviations.

RESULT AND DISCUSSION

General appearance

The taste and consistency were determined using surveys and the results were satisfactory as shown in the table 5. The prepared formulation appears to be gloomy and shiny with length, width and height of 26.5, 19 and 16 mm respectively. The characteristic is outlined in table 6.

Table 5. Assessment of parameters such as taste, texture and consistency.

S. No.	Character	Specification	Scale
1	Appearance	No spots, gleaming and upmarket appearance	1-5 with 5 being the best.
2	Aroma	No pungent smell of the chemical with lots of cocoa powder smell and a little smell of flavors	1-5 with 5 being the best.
3	Snap	Clean cut without falling into pieces	1-5 with 5 being the best.
4	Taste	Chocolaty, good to taste	1-5 with 5 being the best.
5	Texture	Smooth with good consistency and melts in mouth	1-5 with 5 being the best.

Table 6. General appearance.

S. No.	Characteristics	Result
1	Color	Brown
2	Aroma	Good
3	Taste	Mild sweet
4	Consistency	Smooth

Differential scanning calorimetry

The DSC spectra of paracetamol showed a sharp curve at 230°C while DSC spectra of medicated chocolate showed a blunt curve [10]. It can be studied from the spectra that there is no interaction between drug and drug-excipient (as shown in Figure 1 and 2), thereby retaining properties of the medicine to the user providing effective medication to the user.

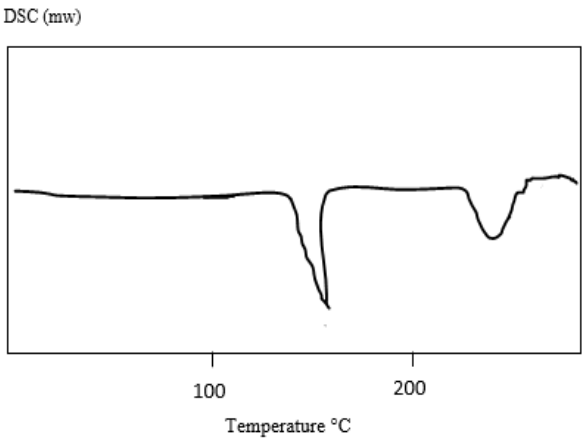

Figure 1. Differential Scanning Calorimetry (DSC) spectra of Paracetamol. The DSC spectra of paracetamol depicted a sharp curve at 230°C.

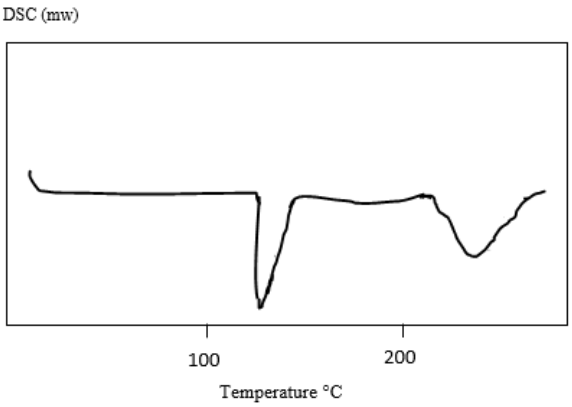

Figure 2. DSC spectra of Medicated chocolate. The spectrum is obtained to measure characteristic properties of the chocolate by using fusion and crystallization events.

Physio-chemical parameters

Table 7 indicates the difference in thickness and weight, the disintegration test, and the content of the drug. It should be noted that uniformity is preserved in the table. The weight and minimum standard deviation of all the formulations were standardized. The weight uniformity in the table shows that the medication and excipients are appropriately combined with no sticking.

Table 7. Thickness, weight variation, disintegration and drug content of medicated chocolate.

Formulation	Thickness (mm)	Weight variation (g)	Disintegration (mins)	Drug content (%)
F1	9.37± 0.05	3.78± 0.19	21± 4	91.12± 0.4
F2	9.12±0.03	3.56±0.21	24±7	94.23±0.17
F3	9.89±0.07	3.67±0.17	26±3	96±0.33

Dissolution studies

Medicated chocolate with a 6.8 pH buffer was subjected to a dissolution analysis of various formulations. An *in vitro* drug release data showed that it took 60 mins for formula I to disperse completely. The drug release was found to be 27% in 5 minutes, 39% in 10 minutes, 50.12% in 15 minutes, 64% in 20 minutes, 79.05% in 30 minutes, 89% in 45 minutes, and finally 100.00% in 60 minutes. The *in vitro* drug release data demonstrated that formulation II took 45 mins. The drug release in 5 min was found to be 27%, in 10 min it was 48.25%, in 15 mins it was 67.32%, in 20 mins it was 79.13%, in 30 mins it was 93.87%, and at last in 45 mins it was 100.00%. The *in vitro* drug release data demonstrated that formulation II took 45 mins.

The *in vitro* drug release data demonstrated that formulation III took 45 mins. The drug release in 5 min was found to be 44%, in 10 min it was 51.73%, in 15 mins it was 69.64%, in 20 mins it was 79.11%, in 30 mins it was 90.99% and at last in 45 mins it was found to be 100%. The *in vitro* drug release data demonstrated that formulation III took 45 mins. The percentage cumulative drug release profile of paracetamol in all formulations is shown in Figure 3.

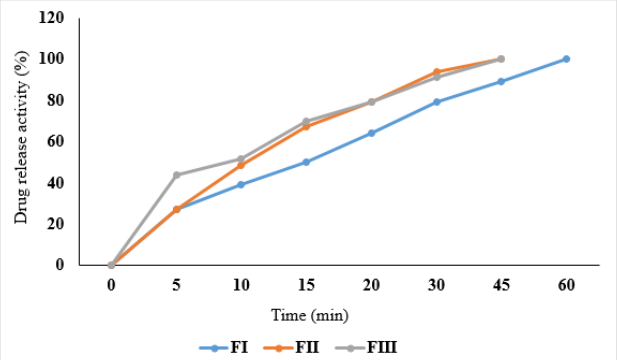

Figure 3. Drug dissolution study of different formulations. It can be concluded that F1 formulation dissolves in 60 mins whereas FII and FIII takes 45 mins for releasing drug.

CONCLUSION

The paper summarizes that paracetamol chocolate drugs demonstrated strong drug release at 100% at 60 minutes of Formulation I, 100% at 45 minutes of Formulation II and 100% at 45 minutes of Formulation III, respectively. Also, no contact between drug excipients. It may also be used by diabetic patients, as an artificial sugar agent is linked to the formulation. This paper eliminates the bitter taste of paracetamol so that it is possible to reduce fever in a sweet way. The acquired framework has greater market potential because it is cost-effective was observed. However for the transportation of pharmaceutical or nutraceutical agents, the chocolate drug delivery system has not been commercially approved.

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