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Formulation And Evaluation Of Medicated Chewing Gum

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Abstract: Medicated chewing gum represents an innovative and practical approach to drug delivery. Medicated chewing gum (MCG) containing Domperidone Maleate (DM) was developed using the direct compression method, aiming to provide a rapid onset of action and enhance patient compliance. This study focused on formulating the medicated chewing gum to speed up the onset of action and improve bioavailability, ensuring quicker relief from nausea and vomiting while increasing patient adherence. The results suggest that chewing gum containing Domperidone Maleate could be an effective dosage form for treating chemotherapy-induced nausea and vomiting.

Keywords : Drug delivery , Patient compliance , Bioavailability , Buccal absorption , Anti-emetic therapy

I. INTRODUCTION

Modified release dosage forms are designed to alter dosing schedules and ensure that the drug's concentration is maintained over an acceptable interval while delivering medication to the precise area of the body where it will be absorbed. When it comes to product design and formulation development, modified release dosage forms are much more palatable than conventional dosage forms. Globally, modified dosage forms are becoming more and more approved, and a lot of researchers are expressing interest in this area. [1]

Even more sophisticated technologies are being developed to modify conventional standard tablets in order to improve bioavailability and achieve greater acceptance. [2] Oral disintegrating tablets, lozenges, prescription chewing gum, effervescent tablets, sublingual and buccal tablets, extended-release tablets, etc. are examples of tablets that fall within modified release dosage forms. Chewing gum is a unique and handy way to distribute drugs.

Prescription Chewing Gums are made to a similar high grade as pills these days, and their development allows for the possibility of varied medication release patterns depending on the patient populations they are intended for. From ancient times man has a habit of chewing the chewing gum. These days it is one among the foremost popular dosage forms used for delivering the numerous active substances. [3-5]

when the medication was chewed, some of it was released into saliva, which was subsequently absorbed through the oral mucosa, and the rest was ingested for gastrointestinal absorption. When the medication was released, the leftover bulk was spat out. [11-13]. Chewing gums are used to treat oral illnesses locally or to have a systemic effect. Chewing gums are a recently licensed medication delivery method that may find application in the pharmaceutical, over-the-counter, and nutraceutical industries.

II. AIM AND OBJECTIVES

Aim: The current study's objective was to formulate and assess a modified release dosage form, such as Medicated Chewing Gum.

Objective : Investigating a unique compression technique was the main goal of the study in order to solve the problem of chewing gum manufacture and generate a high-quality product. Different methods for creating and evaluating therapeutic chewing gum.

Rationale of Research : Increasing patient compliance.

Convenient most importantly by pass first pass effect. 40% - 60% of drug is absorbed in the oral cavity nearly 1-10 % is absorbed in the stomach region so the best site of delivery is oral and Intestine for instant action enteric coated tablet will not give instant action to buccal region delivery will give you instant action.

III. MATERIALS AND METHODS

Table 1. Materials used

Sr. No.	Name of Chemical	Name of Supplier
1	Domperidone maleate	KGRDCP,Karjat
2	Gum base	Silk route international, Delhi
3	Glycerol	KGRDCP,Karjat
4	Sucrose	KGRDCP,Karjat
5	Mannitol	KGRDCP,Karjat
6	Calcium Carbonate	KGRDCP,Karjat

Instruments used: Digital balance, water bath, Digital Ph meter, heating mantle, thermometer, FT-IR, UV

3.1.Methodology and Preparation

Medicated chewing gums of Domperidone were prepared by direct compression method by using gum base, and glycerol as plasticizers. All the ingredients including the drug, plasticizer, and all other excipients were weighed accurately according to the batch formula. In an inflated polyethylene pouch, the medication, and every ingredient aside from lubricants were combined in ascending weight order and blended for ten minutes. Using a compression machine, the prepared blend of each recipe was compressed.

3.2.Formulation table

Table 2: Composition of Medicated Chewing Gums of Domperidone formulations with synthetic gum base

Name of the ingredients	Formulation Code					
Qty in mg	F1	F2	F3	F4	F5	F6
Domperidone maleate	10	10	10	10	10	10
Gum base	300	300	350	350	400	400
Glycerol	10	15	20	10	15	20
Sucrose	200	200	200	200	200	200
Mannitol	148	143	88	98	43	38
Calcium Carbonate	30	30	30	30	30	30
Orange flavour	2	2	2	2	2	2
Total wt. (mg)	700	700	700	700	700	700

3.3.Analytical method development

Determination of the maximum absorption wavelength (λmax) of Domperidone:

The prepared solutions were scanned in the ultraviolet region (200-400 nm) to determine the wavelength of maximum absorption (λmax) in each medium.

Standard calibration curve of Domperidone maleate by UV spectrophotometry

Accurately weighed 30 mg drug was dissolved in a solvent containing 20 mL DMSO: ethanol (1:4) to form a 1500 µ/l solution. Using this stock, a solution of 150 ppm was made using phosphate buffer (pH). Further concentration was prepared using 150 ppm stock solution to 5 ppm,10 ppm, 20 ppm, and 25 ppm, 30 ppm, 40 ppm,50 ppm. The λ max was obtained at 285 nm on UV spectrophotometry. The concentration vs absorbance plot was made to obtain a linear equation.

3.4.Evaluation

Organoleptic properties

Formulated chewing gum is studied for Organoleptic properties such as color and taste.

Hardness test

After formulating the preparation, they may require certain strength, so the hardness of medicated chewing gums was measured using Monsanto Hardness Tester and expressed in kg/cm^2.

Thickness

The thickness of randomly selected medicated chewing gums from each formulation series was determined in mm using a Screw gauge.

Friability

Six medicated chewing gums were produced and randomly selected. They were weighed, put in the Friabilator, and rotated for 100 revolutions for four minutes. The formulas were then removed, cleaned, and reweighed. The percentage loss was then calculated using the formula below.

$$\%\text{Loss} = \frac{\text{initial wt.} - \text{final wt.}}{\text{initial wt.}} \times 100$$

% Friability of tablets less than 1 % is considered acceptable.

Uniformity of weight

The weight variation test was determined by randomly selecting 20 medicated chewing gums, their weights were determined using electronic balance initially and the average weight was calculated from the total weight.

Stickiness

The prepared medicated chewing gums are placed on a plain surface, A Teflon hammer weight of 250 gm collides on preparations for 10 min, and after 10 min sticking of mass to the hammered surface was visually observed.

Uniformity of drug content

A 100 mL conical flask with a stoppered lid was filled with the powdered drug equivalent of five medicated chewing gums, which had been ground up in a mortar. 40 mL of distilled water was used to extract the medication, and it was shaken vigorously for an hour at 100 rpm on a mechanical shaker. After 30 minutes of intermittent shaking in a water bath, the mixture was heated and filtered into a 50 mL volumetric flask. The filtrate was then increased to the necessary volume by adding more distilled water to the filter, dilutions were made, and absorbance at a particular wavelength was measured using a UV spectrophotometer in comparison to a blank.

3.5.In-vitro in-vivo studies

Upon the extensive literature survey, the disintegration apparatus was slightly modified. The apparatus consists of a beaker of 1000 mL capacity and two rods welded with two plates attached to the apparatus's main stand, which acts as a lower chewing surface and an upper chewing surface. The chewing gum was placed on the lower surface and there is a provision to move the upper surface of the rod towards upward and downward motion at a chewing frequency of 60 strokes per minute and observe for the drug release in 6.8 pH phosphate buffer for 30 min to ensure the maximum drug release from the formulation

IV. RESULT AND DISCUSSION

Preformulation Study:

Identification of Drug:

Identification of the procured drug sample and ensuring its purity is a prerequisite before proceeding with the formulation development. The identification tests and the inferences for the drug sample based on its appearance and melting point determination are summarized in Table No. 3

Table 3: Identification of Domperidone maleate

Parameters	Observations	Reported
Appearance	White to Off-White Solid	White to Off-White Solid
Melting point	238 ^{o}C	241 ^{o}C

Solubility Determination

The solubility of Domperidone maleate was determined in water, 0.1N HCl, methanol, phosphate buffer 6.8 pH. Solubility of drug in solvents so obtained compiled in.

Table 4: Solubility Determination

Sr. No.	Solvent	Solubility
1	Distilled water	Insoluble
2	0.1 N HCl	4.67 µg/ml
3	pH 6.8 Phosphate buffer	5.30 µg/ml
4	Methanol	Slightly soluble
5	Ethanol	Slightly soluble
6	Dimethyl formide	Soluble

Calibration Curve of Domperidone maleate in phosphate buffer pH 6.8

UV- Spectra of pure Domperidone maleate was obtained from UV- Spectrophotometer and the absorption maximum was found to be 285 nm.

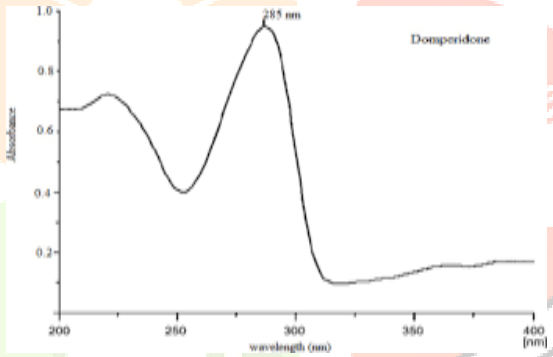

Figure 1: UV Absorption spectra of Domperidone maleate in Phosphate buffer 6.8 Ph

Table 4: Organoleptic Characteristics of Formulations

SR. NO.	Formulation	Colour	Stickiness
1	**F1**	Off -White	Nil
2	**F2**	Off -White	Nil
3	**F3**	Off -White	Nil
4	**F4**	Off -White	Nil
5	**F5**	Off -White	Nil
6	**F6**	Off -White	Nil

Evaluation of Prescription Chewing Gum

DSC Study

The DSC thermogram of Domperidone maleate showed a sharp endothermic peak at 528.25˚C and The DSC thermogram of optimized formulation showed an endothermic peak at 529.43˚C. °C. It indicates that there was no interaction found between drug and all other excipients used in the formulation of Prescription Chewing Gum .

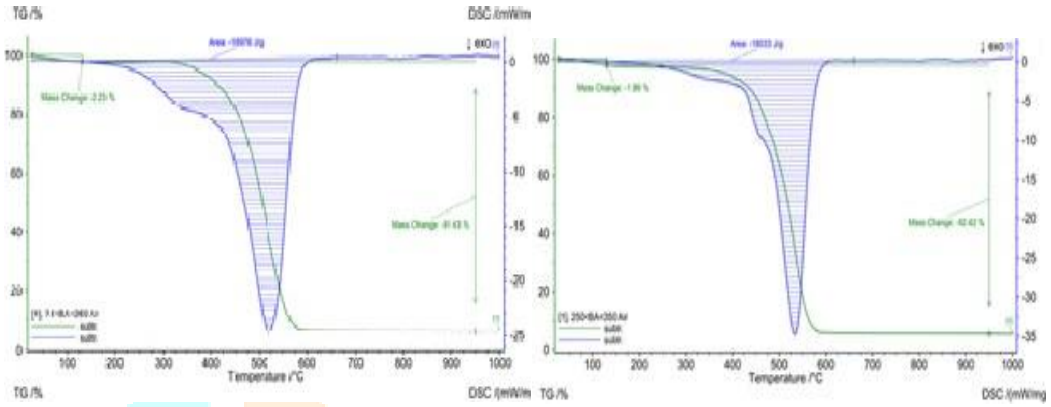

Figure 2 : DSC of pure Domperidone maleate and optimized formulation

Stability studies for optimized formulation:

Optimized formulations were kept for stability studies as per ICH guidelines at 25±2°C/60±5 %RH, 40±2°C/75±5 %RH. Following 90 days, the percentage of medication release from the optimal formulation was measured for 30 minutes and

compared to the preliminary findings, which were displayed in Table 7.9. It was shown that there was little change in the drug release from the enhanced formulations.

Table 5: In vitro drug release profile of stability batches

Cumulative percentage of drug release			
Formulation Code	Initial	25°C/60%RH	40°C/75%RH
		90 days	90 days
F2	98 ± 3.44	98.53 ± 1.12	98.66 ± 1.33

V . CONCLUSION

From the results obtained the following conclusions can be drawn:

I. Results of preformulation studies i.e., FTIR and conclude that there was no drugexcipient interaction.

II. Results of physical characteristics of formulations prepared with direct compression method showed values with in specifications.

III. The in vitro drug releases of optimized formulations of the drug shows highestdrug release.

IV. The directly compressed method is much simpler, cheaper

V. All optimized formulations were kept for stability studies according to ICH guidelines. Results revealed that all optimized formulations were stable and there was no change in the drug release.

VI. In general, it might be concluded that formulation such as chewing gum might be a proper drug delivery system for fast onset of action due to the rapid release of drug in the oral cavity.

VII. Thus, it was concluded that Prescription Chewing Gums could be prepare with drug candidates to improve the patient acceptability and bioavailability.

VIII. A unique method for treating nausea and vomiting linked to motion sickness and other pathophysiological disorders is the MCG formulation of DM. Due to its substantial penetration into the buccal mucosa, MCG has been shown to improve patient acceptance and compliance additionally the bioavailability of DM.

IX. It was discovered that the synthetic gum base was insoluble at salivary pH (6.4). Because it minimizes the chance of gum base dissolving in saliva, this feature is crucial for chewing gum bases.

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