Design, Development and Characterization of Medicated Chewing Gum for Enhancing Therapeutic Efficacy of Drug

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Abstract*—Medicated chewing gum (MCG) of Montelukast sodium was developed by direct compression method with the goal to achieve quick onset of action and to improve patient compliance. Formulation development of MCG of Montelukast sodium and optimization of the formulation by screening of different excipients. Material and methods: MCG containing Montelukast sodium was prepared by screening different concentrations of sweeteners, flavouring agents, softening agents, lubricants and anti-adherents by changing one variable at a time. Performance evaluation was carried out by evaluating size, shape, thickness, taste, in vivo drug release study, ex vivo buccal permeation study and by studying statistical analysis for quality. Results and discussion: The statistical analysis showed significant improvement in organoleptic properties such as chewable mass, product taste, product consistency, product softness, total flavour lasting time and pharmaceutical properties like micromeritic properties after incorporation of appropriate excipients in an optimum amount in final optimized MCG formulation. In vivo drug release study showed 97% Montelukast sodium release whereas ex vivo buccal permeation study through goat buccal mucosa exhibited 11.27% Montelukast sodium permeation within 15 min indicating its potential for increasing bioavailability by decreasing time of onset. The optimized formulation showed good surface properties and the peak load required for drug release was found to be acceptable action. Conclusion: The developed formulation of medicated chewing gum can be a better alternative to mouth dissolving and conventional tablet formulation. It may be proved as a promising approach to improve the bioavailability as well as to improve patient compliance.

I. INTRODUCTION

Tablets are the most common dose form, and oral dr ug delivery is generally recommended for the admin istration of many drugs.
Solid dosage forms are widely used because they are simple to administer, allow for accurate dose, allow for self-medication, prevent pain, and—above all—ensure patient compliance.

However, swallowing difficulties are a major proble m that many patients encounter while utilizing tradit ional pill dosage forms.When a patient is taking med ication and does not have simple access to drinking water, this issue gets worse.

Dispersible pill delivery systems, which offer quick disintegration, quick dissolution, quick release, and enhanced patient compliance, have been developed t o solve this problem.

Dysphagia, or difficulty swallowing, is a widespread issue that affects people of all ages, although it is m ost prevalent in the elderly and young people due to physiological changes that are specific to these age groups (3,4).Patients with mental problems, those w ho are recalcitrant, and those who suffer from nause a, motion sickness, allergic reactions, or coughing fi ts are other groups of patients that struggle with trad itional oral dose forms.

Additionally, it may be challenging to swallow conv entional items if water is unavailable.
Due to these difficulties, a new kind of solid oral do sage form has been developed, highlighting the signi ficance of appealing tastemasking formulations in th e current situation.

1. Oral Cavity

Components or structural features of oral cavity:
Bounded by lips, cheeks, palate, and floor
The oral cavity consists of two regions:-1)Vestibule (outer) 2)Oral cavity proper (inner with tongue)

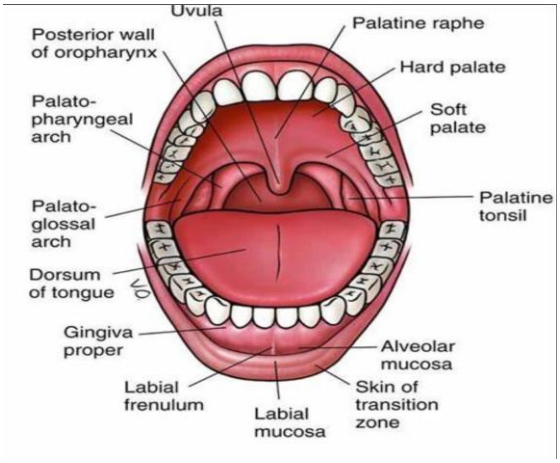

Figure 1: Structure of Oral Cavity

Anatomical Features

Lined by mucous membrane (epithelium + basement membrane + lamina propria + submucosa)

The mucosa divided into three types

1) Masticatory mucosa (gums, hard palate)
2) Lining mucosa, (lips, cheeks, soft palate)
3) Specialized mucosa (tongue)

Rich blood supply (external carotid branches)

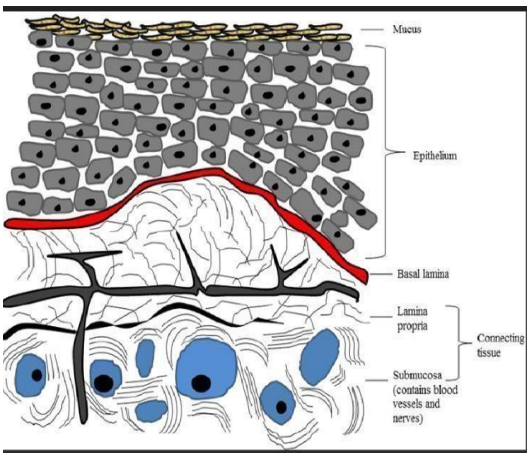

Figure 2: Cross-section of buccal mucosa

Absorption Pathways

a. Passive diffusion:

Transcellular or intracellular route (crossing the cell membrane and entering the cell).

Paracellular or intercellular route (passing between the cells).

b. Carrier mediated transport.
c. Endocytosis

Physiological aspects and functions of oral cavity

- Food intake & chewing
- Lubrication & bolus formation
- Taste sensation
- Digestion initiation
- Speech & breathing
- Antimicrobial action (saliva)

Secretions of Oral Cavity

- Saliva: digestion, lubrication, buffering (pH 6.5–7.5)
- Crevicular fluid: gingival secretion
- Mucus: protection & lubrication

2. Drug Delivery via Oral Cavity

Used for local + systemic delivery

The two main-routes for administration with oral cavity are:

1) Sublingual: fast, but poor retention
2) Buccal: better retention, sustained action

3. Buccal Absorption

Mainly passive diffusion of non-ionized drugs

Lipophilic drugs absorb better

Intercellular route predominant

Advantages of Buccal Absorption

- No first-pass metabolism
- Rapid absorption
- Suitable for peptides/proteins
- No GI degradation

Limitations of Buccal Absorption

- Small surface area
- Saliva dilution
- Swallowing risk
- Taste/irritation issues

4. Medicated Chewing Gum

Modified release dosage forms are developed to deliver drugs to the specific part of the body wherever it will be absorbed, to change dosing schedules, associated to assure that concentration of drug is maintained over an acceptable interval

Drug released during chewing → absorbed buccally or via GIT

Need of Medicated Chewing Gum as a drug delivery system

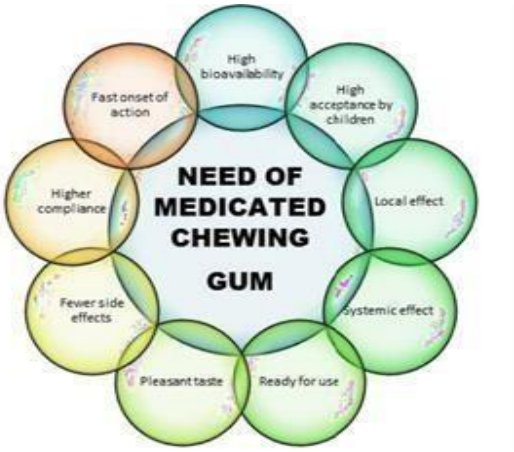

Figure 3: Need of Medicated Chewing Gum

Advantages

- No water needed
- Fast onset
- Better bioavailability
- Patient-friendly
- Less gastric irritation

Limitations

- GI side effects (e.g., sorbitol)
- Excipient-related issues

Mechanism

During the mastication process, the drug is released into saliva and are either absorbed through buccal mucosa or swallowed and absorbed through GIT.

Drug transport across buccal mucosa follows simple Fickian diffusion.

$$J = DKp/\text{o}\ ce$$

Where: J=Drug flux, D=Diffusivity, Kp= Partition Coefficient, Ace= Concentration gradient.

The drug permeation across the oral mucosa is by 2 pathways

1. Transcellular/ intracellular route
2. Paracellular/ intercellular route

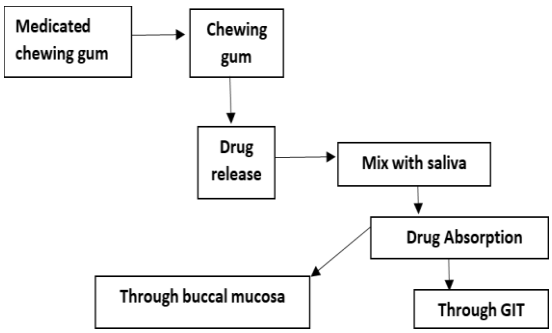

Figure 4: Schematic Sequence of Mechanism of drug release from MCG

The pathway of drug transport across oral mucosa may be studied using:

a. Microscopic techniques using fluorescent dyes
b. Autoradiography and
c. Confocal laser scanning microscopic procedures

5. Composition of MCG

- Water-insoluble: gum base, elastomers
- Water-soluble: sweeteners, flavors

Other components:

- Plasticizers, fillers, antioxidants, colorants

6. Manufacturing Methods

1. Melting method
2. Cooling & grinding
3. Direct compression (best modern method)

7. Factors Affecting Drug Release

Formulation factor: Composition and gum base amount used in the preparation affects the release rate of drug from the chewing gum. If amount of lipophilic fraction of gum is high, the release rate is decreased.

1. Contact time: The local or systemic effect is dependent on time of contact of MCG in the oral cavity.

2. Physicochemical properties of active ingredient: The saliva soluble ingredients will be immediately released within a few minutes whereas lipid soluble drugs are released first into the gum base and then released slowly.

3. Inter individual variability: The chewing frequency and chewing intensity which affect the drug release from MCG may vary from person to person (inter-individual variability).

4. Formulation factors: Composition and amount of gum base also affects the release rate of active ingredient(s).

5. Chewing time and rate: A self-reporting questionnaire technique was developed to determine the length of chewing time.

6. Aqueous solubility: The release of water-soluble drugs (aqueous solubility > 1:10) in general is about 75% or more during the first 5 min of chewing and 90% or more during 15 min of chewing at a rate of 60 chews/min (Andersen, et al. 1990).

8. Applications:

1. Dental caries - Prevention and cure of oral disease are obvious targets for chewing gum formulations.

2. Systemic therapy- chewing gum as a drug delivery system is beneficial to several indications, some of which are discussed below:
a. Pain
b. Smoking cessation
c. Obesity

The aim of the present study was Design, Development and Characterization of Medicated Chewing Gum for Enhancing Therapeutic Efficacy of Drug.

Chewing Gum drug delivery system is an amalgamation of science and dexterity with therapeutic prospect and presentability. It is a potentially convenient means of administering medications either locally or systemically via the oral cavity.

II. MATERIALS AND METHODS

Materials:

Sr. No.	Materials	Source
1	Montelukast Sodium	Ajanta Pharma Ltd., Mumbai
2	Bees Wax	Loba Chem Mumbai India Pvt..
3	Glycerol	Research-Lab Fine Chem Industries, Mumbai
4	Castor Oil	Panama Products, Nagpur
5	Dextrose	Thomas Baker Chem Pvt. Ltd.
6	Calcium Carbonate	Merk Ltd. Shiv Sagar Estate, Worli, Mumbai
7	PVP	Research-Lab Fine Chem Industries, Mumbai
8	Mannitol	Thomas Baker Chem Pvt. Ltd.
9	Flavour	FMC- Ireland
10	Magnesium Stearate	S. Kanth Health Care Ltd.
11	Aerosil	Venus Enterprises

Table No.05: List of Reagents and Chemicals

Methods:

A. Preformulation Studies of Drug

Preformulation studies involve examining the physical and chemical properties of a drug substance, both individually and in combination with excipients. These studies form the foundation for the rational design of dosage forms. The main objectives include:

- Determining the physicochemical properties of the drug
- Assessing its compatibility with different excipients

Characterization of Montelukast

1. Organoleptic properties: The drug powder was evaluated for its color, odor, and taste.
2. Description: The physical appearance and nature of the powder were observed.
3. Melting point: Determined using the open capillary method, which helps assess purity. A decrease or broadening in melting range indicates possible impurities.

Solubility Characteristics

Solubility was assessed by gradually adding the drug to a fixed volume of phosphate buffer (pH 6.8). Montelukast sodium is freely soluble in ethanol, methanol, and water, but practically insoluble in acetonitrile.

A standard solution was prepared by dissolving 100 mg of drug in 100 mL buffer. Further dilutions were made to obtain different concentrations. The absorbance of each solution was measured at 285 nm using a UV-Visible spectrophotometer, and a calibration curve of absorbance versus concentration was constructed.

Drug–Excipient Compatibility Study

Compatibility studies are essential to ensure stability of the formulation. Incompatible excipients may lead to drug degradation.

FT-IR spectroscopy was used to analyze the drug and excipients. Samples were prepared using KBr pellets and scanned over a range of 400–4000 cm^{-1}. Any significant change in characteristic peaks indicates possible interaction or incompatibility.

Preparation of Medicated Chewing Gum

Montelukast medicated chewing gum was prepared using the direct compression method. Plasticizers such as beeswax, glycerol, and castor oil were used.

All ingredients were accurately weighed. The drug and excipients (except lubricants) were mixed in ascending order of weight and blended for 10 minutes. The final blend was then compressed into chewing gum using a tablet compression machine.

INGREDIENTS IN MCG s	F1	F2	F3	F4	F5	F6
Montelukast	5	5	5	5	5	5
Beeswax	240	240	240	240	240	240
Glycerol	32	48	64	0	0	0
Castor Oil	0	0	0	32	48	64
Dextrose	94	94	94	94	94	94
Caco3	72	72	72	72	72	72
PVP	250	250	250	250	250	250
Mannitol	100	100	100	100	100	100
Flavour	3	3	3	3	3	3
Magnesium Sterate	1	1	1	1	1	1
Aerosil	3	3	3	3	3	3

Evaluation of Formulation

Flow Properties of Mixture

1. Bulk and tapped density: Determined using a graduated cylinder to evaluate packing behavior
Then Bulk density and tapped density were calculated.

$$\text{Bulk density} = \frac{\text{Weight of sample}}{\text{Final volume of sample contained in cylinder}}$$

$$\text{Tapped density} = \frac{\text{Weight of sample in gram}}{\text{Final volume after tapping in cylinder}}$$

2. Carr's compressibility index: Indicates flowability; lower values suggest better flow
3. Hausner ratio: Another parameter to assess flow characteristics The flow properties of blend, granules or powder are measured by this ratio.
4. Angle of repose: Angle of repose is used to determine the flow properties of powders, pellets or granules. angle of repose of different formulations was measured by fixed standing methods.

Quality Control Tests

1. Weight variation: 20 samples were weighed individually and compared to the average weight as per USP standards.

2. Hardness: Measured using Monsanto hardness tester and expressed in kg/cm².

3. Thickness: Determined using vernier calipers; deviation within ±5% was considered acceptable.

Drug Content
Ten chewing gum samples were crushed, and a quantity equivalent to 5 mg drug was dissolved in phosphate buffer (pH 6.8). After sonication and filtration, absorbance was measured at 285 nm. Drug content was calculated using a calibration curve.

$$\text{Drug Content} = \frac{\text{Concentration x volume x DF}}{1000}$$

In-vitro Drug Release Study

A modified disintegration apparatus was used to simulate chewing action. The chewing gum was placed in 500 mL phosphate buffer (pH 6.8). Samples were collected at intervals (5, 10, 15, 20, 25, and 30 minutes), and absorbance was measured at 285 nm. Results were recorded as mean ± standard deviation.

Chewing gum frequency	60 strokes per min
No. of chewing gum tested	1
Temperature	37°c± 0.5°c
Time	30 min
Test medium	Phosphate buffer pH 6.8
Volume of test medium	500 ml in each vessel
Sampling time	5-30 min

Table12. Parameter of in-vitro release test

Stability Studies of Montelukast

Stability studies are essential for dosage form design and evaluation. They ensure the preservation of the active drug, prevent toxic byproduct formation, and maintain bioavailability. Accelerated stability studies under extreme conditions expedite the process.
The studies will take a longer time and hence it would be convenient to carry out the accelerated stability

studies where the product is stored under extreme conditions of temperature. In the present study, stability studies were carried out on optimized formulation.

The formulations were subjected to storage at 25±2°C/60+5% RH and 40°±2°C/75%+5% RH for 45 days. The evaluation included assessments of physical deformities (such as thickness and hardness), drug content, and in-vitro drug release studies.

III. RESULT AND DISCUSSION

A. Characterization of Montelukast

1.Organoleptic Characterization and Melting Point determination

The physicochemical characteristics of Montelukast are described in Table 13.

Sr.No.	Characterization	Observation
1.	Colour	Yellowish white
2.	Odour	Odourless
3.	Taste	Bitter
4.	pH	6.5-6.8
5.	Melting Point	115 ℃

Table 13. Physiochemical Characteristics of MCG

The organoleptic character and melting point were found as per the standard drug, so the drug used in the formulation was found to be pure according to I.P. specifications.

2. Solubility analysis

Sr. No.	Solvent	Solubility
1	Water	Soluble
2	Buffer solution 6.8	Soluble
3	Ethanol	Soluble

Table 14. Solubility profile of Montelukast

The solubility of pure drug in 10mg/10ml of solvent was carried out and it reveals that it is soluble in methanol, sparingly soluble in water, soluble in phosphate buffer pH 6.8.

3. Micromeritic characterization of drug:

The micromeritic characterization of drug were carried out and the following observation were made.

Sr. No.	Parameter	Result
1	Bulk density (gm/ml)	0.58± 0.4
2	Tapped Density (gm/ml)	0.67± 0.13
3	Carr's Index	13.43± 0.72
4	Haunser's ratio	1.15± 0.12
5	Angle of repose	28.68± 0.72

Tablet 15. Micromeritic Characterization of Montelukast

Based on micromeritic properties it was confirmed that the drug montelukast possessed sufficient flowability to be used for direct compression.

B. Standard Calibration Curve of Montelukast

Sr. No.	Concentration (µg/ml)	Mean Absorbance* ± S.D
1	2	0.0776 ± 0.00046
2	4	0.1466 ± 0.00011
3	6	0.2136 ± 0.00013
4	8	0.2816 ± 0.00026
5	10	0.3506 ± 0.00029

Table 16. Standard calibration curve of Montelukast.

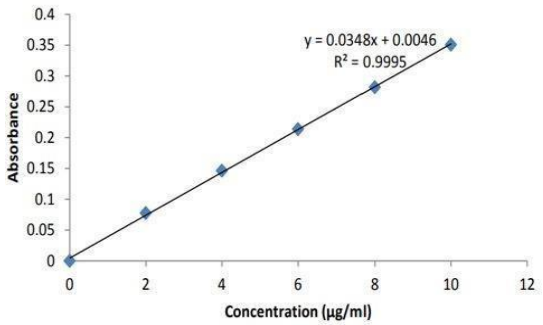

Figure 6: Calibration curve of Montelukast

C. Determination of λ max:

The UV spectrum of Montelukast in phosphate buffer showed maximum absorption at 285nm. Hence drug used in the formulation was found to be pure according to I.P. specification. The UV spectrum of the Montelukast in phosphate buffer is given in figure:

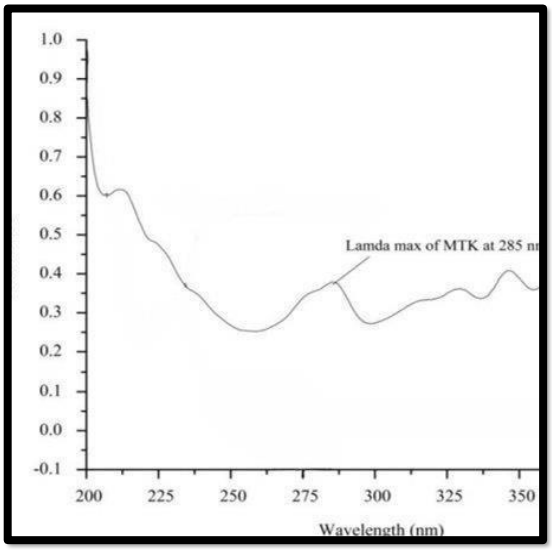

Figure 7: λ max of Montelukast

D. IR analysis:

Compatibility of drug and polymers was studied using Fourier Transform Infrared (FTIR) spectroscopy. FTIR Spectrum was recorded between 400- 4000 cm-1 by KBR pellet using Shimadzue 206-7350038 FT-IR spectrophotometer. The FTIR spectra of montelukast sodium and its physical mixtures are shown in figure 11. The FTIR spectrum of montelukast depicts a characteristic absorption band at 3437 cm-1 representing the presence of OH group. The CH2, C-N vibrations showed a characteristic absorption band in the region of 2926 cm-1 and 1265 cm-1. The spectrum of montelukast-polymer physical mixtures showed absorption bands at 3414 cm-1, 2926 cm-1 and 1266 cm-1 OH, The CH2 and C-N. It indicates drug and drug containing physical mixture absorption bands were near that there was no chemical and physical change in the functional groups present in montelukast sodium.

1. IR spectra of Montelukast:

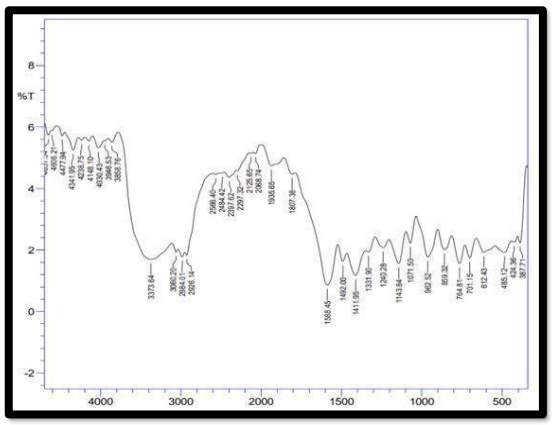

Figure 8: IR spectra of Montelukast.

2. IR spectra of castor oil:

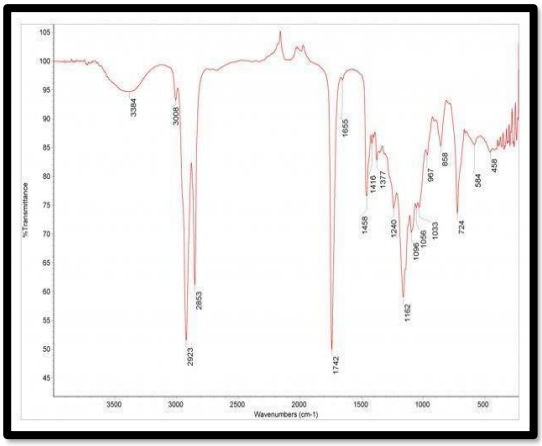

Figure 9: IR spectra of Castor Oil.

3. IR spectra of Glycerol:

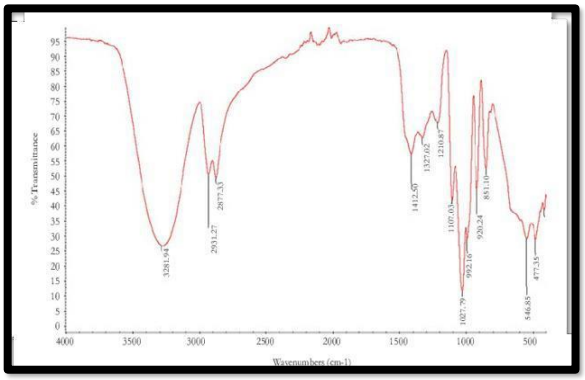

Figure 10: IR spectra of Glycerol.

4. Compatibility study of Montelukast and polymers.

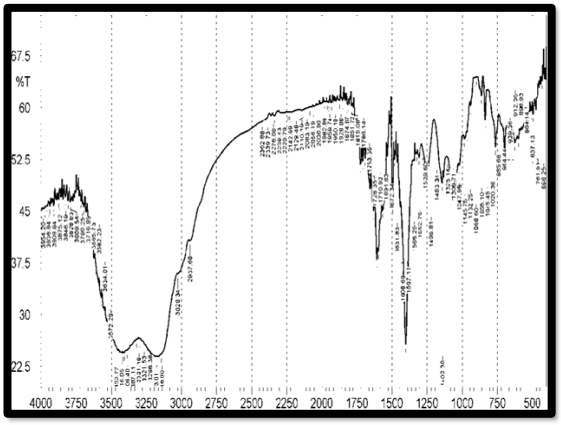

Figure 11: IR Spectra of drug and polymers.

E. Evaluation of Montelukast medicated chewing gum:

1. Precompression evaluation of powder blend:

i. Bulk density:

It has been stated that the bulk density values less than 1.2 g/cm2 indicate good packing and values greater than 1.5 g/cm2 indicate poor packing. The loose bulk density and tapped bulk density values for all the formulation varied in range of 0.384 ± 0.02 g/cm^3 to 0.454 ± 0.04 g/cm^3 respectively. The values obtained lies within the acceptable range.

Batch	Bulk Density (g/ml)	Tapped Density (g/ml)	%Compressibility Index	Haausner's Ratio	Angle of Repose
F1	0.384±0.02	0.421±0.02	8.79±0.03	1.10±0.02	32.67 ±0.03
F2	0.401±0.01	0.434±0.01	7.60±0.02	1.08±0.04	32.82±0.01
F3	0.454±0.03	0.493±0.01	7.91±0.03	1.09±0.06	28.77±0.02
F4	0.384±0.01	0.432±0.03	11.11±0.01	1.13±0.03	32.34±0.03
F5	0.416±0.03	0.453±0.01	8.17±0.02	1.09±0.02	29.53±0.02
F6	0.454±0.04	0.515±0.04	11.84±0.03	1.13±0.01	32.77±0.03

Table 17: Precompression evaluation of powder blend.

ii. Compressibility Index:

The percent compressibility of was determined by Carr's compressibility index, The percent compressibility for all formulation lies within the range of 7.60± 0.02% to 11.84 ± 0.03% indicates acceptable flow property.

iii. Hausner ratio:

Hausner ratio was found to be in a range of 1.08 ± 0.04 to 1.13 ± 0.01 which shows acceptable flow property and good packing ability.

2. Evaluation of prepared MCG:

Formulation	Hardness (kg/cm2)	Thickness (mm)	Weight Variation (mg)	Friability (%)	Drug Content (%)
F1	3.6±0.31	6.08±0.17	813.05±1.48	0.39±0.12	96.51±0.12
F2	3.6±0.15	5.83±0.25	814.8±0.41	0.25±0.22	96.34±0.23
F3	3.5±0.30	6.84±0.66	815.7±0.83	0.20±0.35	98.35±0.13
F4	3.4±0.60	6.46±0.71	812.08±0.61	0.41±0.42	96.32±0.16
F5	3.4±0.44	6.32±0.25	817.11±0.44	0.55±0.37	95.38±0.15
F6	3.5±0.40	6.79±0.80	814.1±0.54	0.64±0.54	95.04±0.10

Table 18: Standard physical evaluation of MCGs.

iv. Angle of repose:

The results of angle of repose of all the formulations were found to be in range of 28.77 ± 0.02 to 32.82 ± 0.01 indicating good flow property

Supported by lower compressibility index values. Thus, it can be concluded that the granules for all the batches possessed good flow characteristics.

Medicated chewing of all formulations (F1 to F6) was evaluated for different parameters such as thickness, hardness, weight variation, drug content and friability

i. Hardness:

Hardness values of the formulation ranged from 3.4-3.6 kg/cm2, which indicate good strength of Mcg.

ii. Friability:

Friability values of all the formulation were less than 1%, indicating good strength of Mcg.

iii. Weight variation:

In weight variation test, the weight variation values of prepared mcg ranged between 813-817 mg. all formulation passes the weight variation test.

iv. Thickness:

Examination of Mcg from each batch showed flat circular shape with no cracks having orange colour. The thickness of Mcg ranged from 5.83 - 6.79mm. All formulations showed uniform thickness.

v. Content uniformity:

The drug content was found to be uniform among all formulation and ranged from 95.04 -98.35%.

vi. In-vitro drug release studies:

The study was carried out in modified dissolution apparatus with 500 ml. of phosphate buffer pH 6.8 as dissolution medium is taken in beaker and maintained at 37 ± 0.5^{o}C. The prepared chewing gums are placed in apparatus, at different time intervals like 5, 10, 15, 20, 25, 30 min, 11 ml. of sample was withdrawn and replaced with fresh medium. All experiments were done in triplicate and average values were taken. The samples were filtered through 0.25 µm membrane filter paper and analysed for drug concentration after appropriate dilution at specific wavelength using UV-Visible spectrophotometer.

In-vitro dissolution study of batch F1 to F3:

Time (min)	F1	F2	F3
0	0	0	0
5	28.34	30.89	43.35
10	38.83	41.24	55.35
15	45.18	49.05	65.75
20	55.5	58.12	79.86
25	67.78	68.04	90.19
30	77.89	80.12	95.12

Table 19: In-vitro drug dissolution data of F1 to F3 formulation.

All the values are represented as Mean ± S.D. (standard deviation)

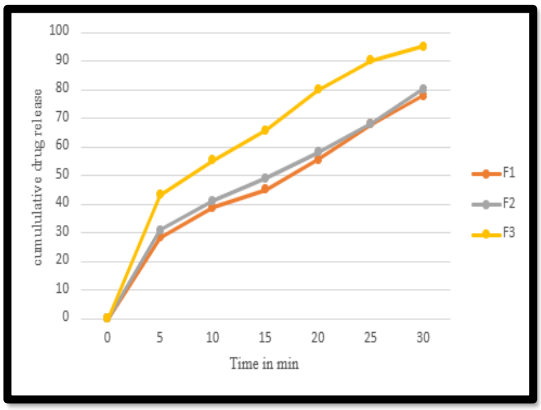

Figure 13: In-vitro dissolution profile of F4 to F6 formulation

In-vitro dissolution study of batch F4 to F6:

Time (min)	F4	F5	F6
0	26.14	33.05	39.15
5	36.65	53.13	48.06
10	42.14	62.05	60.13
15	52.13	73.13	75.12
20	65.25	80.06	86.21
25	73.12	88.1	90.16
30	F4	F5	F6

Table 20: In-vitro dissolution data of F4 to F6 formulation.

All the values are represented as Mean ± S.D. (standard deviation)

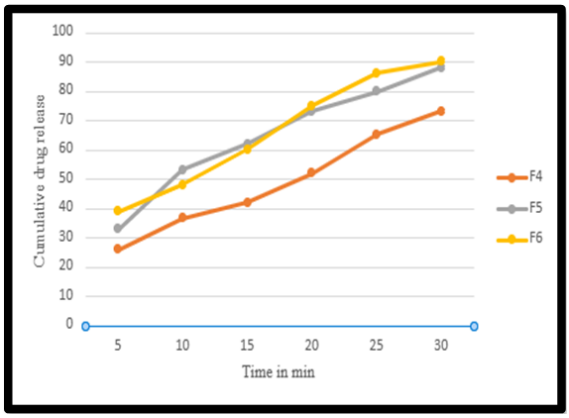

Figure 13: In-vitro dissolution profile of F4 to F6 formulation

Optimized Batch:

All the formulation prepared were subjected to in-vitro release study. In-vitro drug release profiles of

all the formulations of montelukast prepared by direct compression method was performed by dissolution apparatus. For different time interval, sample was withdrawn and cumulative drug release was calculated. The temperature was maintained at 37 ± 0.5 ^{O}C. The % cumulative drug release graphs shown in figure (12-13) shows that as the amount of glycerol increases there is an increase in the drug release because of smooth consistency provided by the glycerol to the formulation. Glycerol shows better consistency as compared to castor oil. In all these formulations F3 showed the drug release of 95.12 % within 30 min. It means that the maximum drug release was observed using this formulation. So, F3 batch is considered as optimized formulation containing glycerol as plasticizer.

PARAMETERS	EVALUATIONS
Hardness	3.5±0.30 Kg/cm^2
Thickness	6.84±0.66 mm
Weight Variation	815.7±0.83 mg
Friability	0.20±0.35 %
Drug Content	98.35±0.13 %
Drug Release	95.12 %

Table 21: Optimized batch -F3

3. Stability Studies of optimized batch: (F3)

a. Parameters studied before and after stability study:

Parameters	Before Stability study	After Stability Study
Thickness	6.84±0.66	6.84±0.66
Hardness	3.5±0.30	3.4±0.30
Drug Content	98.35%	98.03%

Table 22: Parameters studied on batch F3 after and before stability studies.

All the values are represented as Mean ± S.D. (standard deviation)

b. Cumulative % drug release of batch F3 before and after stability studies:

Time (min)	Before Stability Studies	After Stability Studies
5	43.35±0.06	42.95±0.04
10	55.35±0.03	54.80±0.09
15	65.75±0.15	65.45±0.31
20	79.86±0.17	79.35±0.20
25	90.19±0.31	90.02±0.61
30	95.12±0.16	94.89±0.29

Table 23: Cumulative % drug release of batch F3 before and after stability studies.

All the values are represented as Mean ± S.D. (standard deviation)

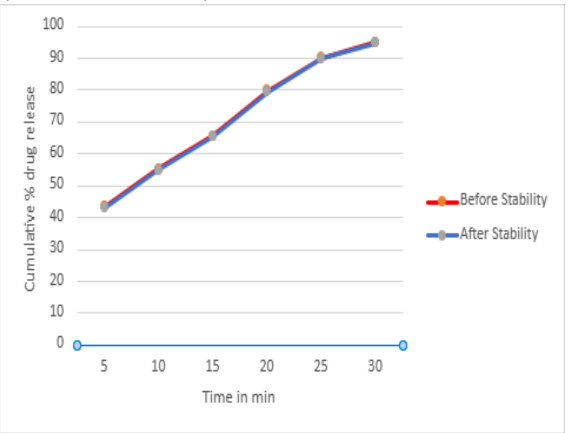

Figure 14: In-vitro dissolution profile of batch F3 before and after stability studies.

VII. CONCLUSION

The literature survey on medicated chewing gum as a drug delivery system indicates promising results for low-dose, high acceptability, and bioavailability. Montelukast, a drug with anti- inflammatory activity used for the treatment of asthma, as well as exercise-induced bronchoconstriction (EIB) and allergic rhinitis, belongs to BCS-class III. It has solubility and stability properties that are pH-dependent, degrading in highly acidic and basic environments. However, due to its high lipid solubility and low dose, Montelukast is a suitable candidate for incorporation into medicated chewing gum as a drug delivery system.

Based on the literature survey on polymers, it is evident that the polymers selected in this study possess strong plasticizing properties. Different formulations of medicated chewing gum containing Montelukast were prepared using various polymers in different proportions and combinations. The prepared formulations were evaluated for various parameters, including content uniformity, friability, weight variation, hardness, and in-vitro release.

All the formulations complied with the official compendia for physical characterization. Among the formulations, F3 emerged as the most promising

formulation, exhibiting a higher degree of in-vitro drug release compared to other formulations. The dissolution data for batch F3 demonstrated greater drug release compared to batches formulated using castor oil.

The in-vitro drug release study conducted for 30 minutes with the optimized formulation F3 showed a satisfactory release rate of 95.12%, indicating superior drug release compared to other formulations.

A stability study was conducted on medicated chewing gum formulation F3 under stress conditions for 45 days. After 45 days, the physical characteristics, in-vitro drug release, drug content, thickness, and hardness properties of the chewing gum were evaluated. No significant changes were observed, suggesting that the formulation remained stable.

In conclusion, the medicated chewing gum formulation F3, containing glycerol, PVP, Mg stearate, mannitol, and dextrose, exhibited promising results with Montelukast. The formulation demonstrated adequate thickness, hardness, drug content, friability, weight variation, and consistent drug release from the chewing gum, thereby enhancing the bioavailability of Montelukast and reducing dose-dependent side effects. Hence, the objective of the present study has been achieved.

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