Formulation Development and Evaluation for Mouth Dissolving Tablet Containing Bromelain

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ABSTRACT:

Bromelain is a proteolytic enzyme that is used as an anti-inflammatory drug. Administration of Bromelain through the oral route is a challenge in children, who have difficulty swallowing tablets. In the present study, six batches of Bromelain Mouth Dissolving tablets (MDT) dosage form at the dose of 100 mg were formulated and evaluated. Results showed that the thickness, weight variation, friability, hardness, and content uniformity of all six formulations were within acceptable limits. But in the in-vitro dissolution study formulation 3 demonstrated better cumulative drug release than other formulations. Hence the study concludes that Bromelain month dissolving tablets formulated using crospovidone (Formulation 3) showed better characteristics of mouth dissolving tablets.

KEYWORDS: Bromelain, Mouth dissolving tablets, Drug-Excipient Compatibility, Crospovidone.

INTRODUCTION:

Many patients, particularly old find it difficult in swallowing tablets, capsules, and fluids and subsequently do not comply with prescriptions, which results in a high frequency of resistance situated research has resulted in bringing out many secure, safe new drug delivery system. Among the several dosage forms developed to improve the difficulty of administration, the Mouth Dissolving Tablet (MDT) is the most favoured commercial product. [1] The oral cavity is an appealing site for the administration of drugs because of the simplicity of administration. Several dosage forms like Tablets, Capsules, and Liquid preparations are administered by oral route. During the most recent decade, Mouth Dissolving Tablet (MDT) advances that make tablets disintegrate in the mouth without chewing and additional water intake have drawn a lot of consideration. The MDTs are also known as fast liquefying, rapid dispersing, rapid dissolve, rapid melt, as well as speedy disintegrating tablets. [2-4] MDTs can be prepared by various conventional methods like direct compression, wet granulation, molding, spray drying, freeze-drying, and sublimation. Firstly, MDTs disintegrate and then dissolve quickly in the saliva without any need for solvents, releasing the drug. A few drugs are absorbed from the mouth, pharynx, and oesophagus as the saliva goes down into the stomach. In many cases, the bioavailability of these drugs is significantly more than those observed from conventional tablet dosage forms. [5,6]

Bromelain is a proteolytic enzyme with anti-inflammatory activity. It is found in pineapple juice and in the pineapple stem. Anti-inflammatory activity by activation of plasmin production from plasminogen and reduction of kinin via inhibition of the conversion of kininogen to kinin. Bromelain has low oral bio-availability because of high first pass metabolism rate. Hence, the formulation in orodispersible form of Bromelain upgrades the bioavailability, decreases side effects, low dosing, patient compliance, and rapid onset of action with great steadiness. In the present work, Orodispersible tablets of Bromelain were prepared by direct compression method using sodium starch glycollate, and crosspovidone as the superdisintegrants. The aim of the study was to evaluate the effect of the superdisintegrants on the wetting time, disintegration time, and drug release profile of the orodispersible tablets. The present investigation deals with the improvement of an effective and stable MDT of Bromelain having a sufficient hardness, low disintegration time, and pleasant taste.

MATERIAL AND METHODS:

Materials:

Bromelain was obtained from Arti Pharma, Mumbai, India. Crospovidone and sodium starch glycolate were obtained from Research Lab Fine Chemical Industries Pvt. Ltd. Mumbai. Microcrystalline cellulose and mannitol were also obtained from Research Lab Fine Chemical Industries Pvt. Ltd. Mumbai. All other chemicals of analytical grade were purchased from commercial sources.

Methods:

Preparation of Mouth Dissolving Tablets by Direct Compression Method:

Mouth dissolving tablets of Bromelain were prepared by direct compression. All the ingredients (except granular directly compressible excipients) were passed through # 60-mesh separately. The ingredients were then weighed and mixed in geometrical order and compressed into tablets of 250 mg using 6 mm round concave punches on an 8-station rotary tablet machine (Table 1).

Table 1: Formulation Table of Bromelain Mouth Dissolving Tablet

Formulations	**F1**	**F2**	**F3**	**F4**	**F5**	**F6**
Ingredient	**Unit Formula (mg per tablet)**					
Bromelain	100	100	100	100	100	100
Crosspovidone	5	10	15	-	-	-
Sodium starch glycolate	-	-	-	5	10	15
Mannitol	50	50	50	50	50	50
Menthol	10	10	10	10	10	10
Avicel PH 102	81	76	71	81	76	71
Sodium stearate	2	2	2	2	2	2
Talc	2	2	2	2	2	2
Total	250	250	250	250	250	250

Evaluation of Bromelain Mouth Dissolving Tablet:

Evaluation of pre-compression parameters of powder:

Preformulation study:

Angle of repose (Ɵ) [7]

The angle of repose was determined by using the funnel method. The accurately weighed blend was taken in a funnel. The height of the funnel was adjusted in such a way that the tip of funnel just touched the apex of the heap and the drug-excipient blend was allowed to flow through the funnel freely to the surface. The diameter of the powder cone was measured and angle of repose calculated using the following equation.

$$\mathbf{Tan\ \theta = h/r}$$

Different ranges of flowability in terms of angle of repose (Table II) are given below (Bikshapathi et al., 2011).

Table 2: Relationship Between Angle of Repose and Flowability

Flow property	Angle of repose
Excellent	25-30
Good	31-35
Fair (aid not needed)	36-40
Passable (may hang up)	41-45
Poor (must agitate, vibrate)	46-55
Very Poor	56-65
Very Very Poor	>66

Bulk Density [8]

Bulk density was determined by pouring presieved drug excipient blend into a 100 ml graduated cylinder. The sample occupied volume and its weight has been recorded It is expressed in g/mL and calculated by using following formula:

$$\mathbf{\rho b = M / Vp}$$

Where,

ρb = Bulk density

M = Weight of sample in grams

Vp = Final volumes of Powder in cm3

Tapped Density [9]

It was carried out by pouring powder blend in 100ml graduated cylinder. The cylinder was tapped mechanically by Tap density apparatus until a constant volume was obtained. Volume occupied by the sample after tapping were recorded and tapped density was calculated by using following formula:

$$\rho t = M / VT$$

Where,

ρt = Tap density

M = Weight of sample in grams

VT = final tap volume of powder in cm3

Hausner's ratio [10]

Hausner's ratio is the ratio of tapped density to bulk density. The lower the value of Hausner's ratio the better the flow property. The ratio is calculated by the following formula

$$\text{Hausner's ratio} = \frac{\text{Tapped density}}{\text{Bulk density}}$$

Lower Hausner's ratios (<1.25) indicate better flow properties than higher ratios (>1.25) (Sayeed et al., 2011).

Carr's Index (Compressibility Index) [10]

It is also one of the simple methods to evaluate flow property of a powder by comparing the bulk density and tapped density. The percentage compressibility of a powder is a direct measure of the potential powder arch or bridge strength and stability. The grading of compressibility of powder according to carr's index is shown in table no.3. It can be calculated by following formula:

$$\text{Carr's Index} = \frac{\text{Tapped density} - \text{Bulk density}}{\text{Tapped density}} \times 100$$

Table 3: Relationship Between Carr's Index and Flowability

Carr's Index	Flow property
5-10	Excellent
12-16	Good
18-21	Fair to possible
23-35	Poor
33-38	Very poor
>40	Extremely poor

Drug-excipient compatibility study

Studies of drug-excipient compatibility are important to as certain drug and excipients are compatible with each other. IR spectra are used to study drug-excipient compatibility.

FTIR study [11]

The study was carried out to determine the molecular structure, serving as an identification test to ascertain the purity of the molecule. IR spectroscopy was obtained by a FTIR spectrophotometer (H400-84100, Shimadzu, Japan) using KBr pellets. The scanning range used was 4400 to 400 cm-1 at a scan period of 1min. Spectra of pure drug and the blend are shown in Figures 1 and 2. There is no change in the shape of the peak or shift of the peak, hence the drug and excipients are compatible (Prameela et al., 2010).

Evaluation of Post-Compression Parameters of Tablets:

Weight variation test [12]

Weight variation was calculated as per method described in Indian pharmacopeia (I.P.2007). Twenty tablets were weighted individually by using Electronic balance (Shimatzu) and the average weight is calculated. The tablets meet the test if no more than 2 tablets are outside the percentage limit and no tablet differs by more than 2 times the percentage limit. The limit of weight variation in tablet are listed in Table 4.

Table 4: Limits for Weight Variation in Tablet as Per I.P. 2007

Average weight of tablet (mg)	Percentage deviation allowed
80 mg or less	± 10
More than 80 mg but less than 250 mg	±7.5
or more	±5

Hardness test [13]

Hardness indicates the ability of a tablet to withstand mechanical shocks while handling. The hardness of the tablets was determined using Digital hardness tester. It is expressed in Kg/cm2. Digital hardness tester was used to measure hardness of the tablet. In which the tablet was placed in the tester and pressure needed to break the tablet was measured.

Thickness [14]

The thickness of the tablets was determined using a Vernier Caliper. Ten tablets from formulation batch were used and average values were calculated.

Friability [15]

Friability is the measure of tablet strength. It was carried out by using Roch friability apparatus, in which the accurately weighed 20 tablets was allowed to rolling and free fall at 25 rpm, after 100 revolutions weight of tablet was again measured and % friability was calculated by following formula

$$\% \text{ Friability} = \frac{\text{Initial weight of tablet} - \text{Final weight of tablet}}{\text{Initial weight of tablet}} \times 100$$

Disintegration time [16]

The disintegration time of tablet was determined by using Disintegration test apparatus. Tablets were placed in disintegration test assembly and disc was placed was placed on tablets in each glass tube of assembly. The assembly was dipped in a vessel containing 900 ml phosphate buffer 6.8 pH. The time for disappearance of tablet residue above mesh was noted as disintegration time.

Wetting time [17]

About 6-8 ml of phosphate buffer 6.8 pH was taken in 10 mL of measuring cylinder. Tablet was placed in the cylinder and complete dispersion of tablet in the cylinder was recorded as the disintegration time. Wetting time in that the tissue paper has been folded twice and placed in petri dish above that tablet is placed. A small quantity of amaranth red color was put on the upper surface of the tablet and 10 ml distilled water was added. The time required to get the tablet completely wet and indicate red color was measured.

Uniformity of drug content [18]

This method is performed as per Indian Pharmacopoeia. Two tablets were crushed and added to 30 ml of 0.1M NaOH in 100 ml volumetric flask sonicated to disintegrate, then diluted by acetonitrile, then this solution was filtered and diluted the filtrate with a mixture of seven volumes acetonitrile and three volumes of 0.1M NaOH. Absorbance was measured by UV spectroscopy at 280 nm and drug content was calculated.

In-vitro Dissolution study [16]

The dissolution study of selected Bromelain formulations was conducted by using USP dissolution apparatus Type – II (Electrolab Mumbai) by taking 900 ml phosphate buffer pH 6.8 as dissolution medium which maintained at 37 ± 0.5°C. At every 5 min interval upto 30 min 1 ml samples was withdrawn and the same volume was replaced to maintain the sink condition. The samples were analyzed using UV spectroscopy at wavelength maxima 280 nm. The % drug release was calculated and is reported in Table 10.11 and drug release profile of selected formulations tablets are depicted in Figure 12.

RESULTS AND DISCUSSION:

Spectroscopic Analysis:

UV spectroscopy:

Determination of λmax of Bromelain in Water:

In UV spectroscopy study, the maximum wavelength (λmax) of Bromelain in water was found to be 279.40 nm. The reported λmax value of Bromelain in water was also 279.40 nm respectively, so the values similar with the reported values indicates that the given sample of Bromelain was in pure form.

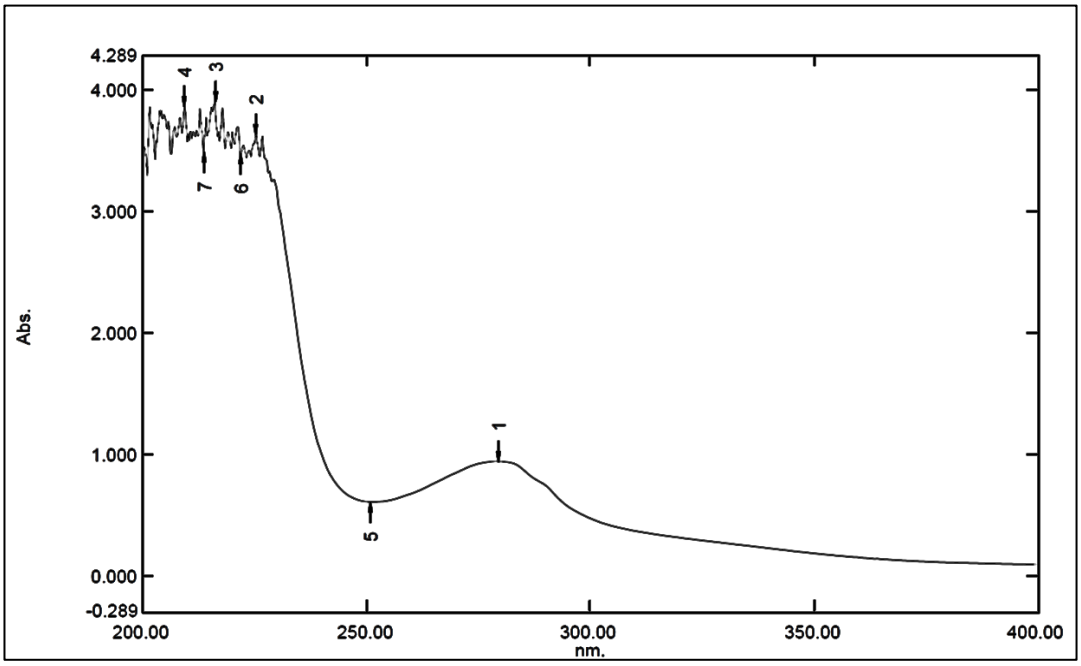

Figure 1: UV spectra of Bromelain in water at 279.40 nm

Calibration Curve of Bromelain in Water:

The linearity of the response of Bromelain was verified at 2–10 µg/ml concentrations. The calibration curve was obtained by plotting the absorbance versus the concentration data and was treated by linear regression analysis. The equation of the linearity curve for Bromelain was y = 0.0127x +0.0033. The linearity curve was found to be linear in the a for mentioned concentrations (the correlation coefficient (r^2) of determination was 0.9922) (Figure 2).

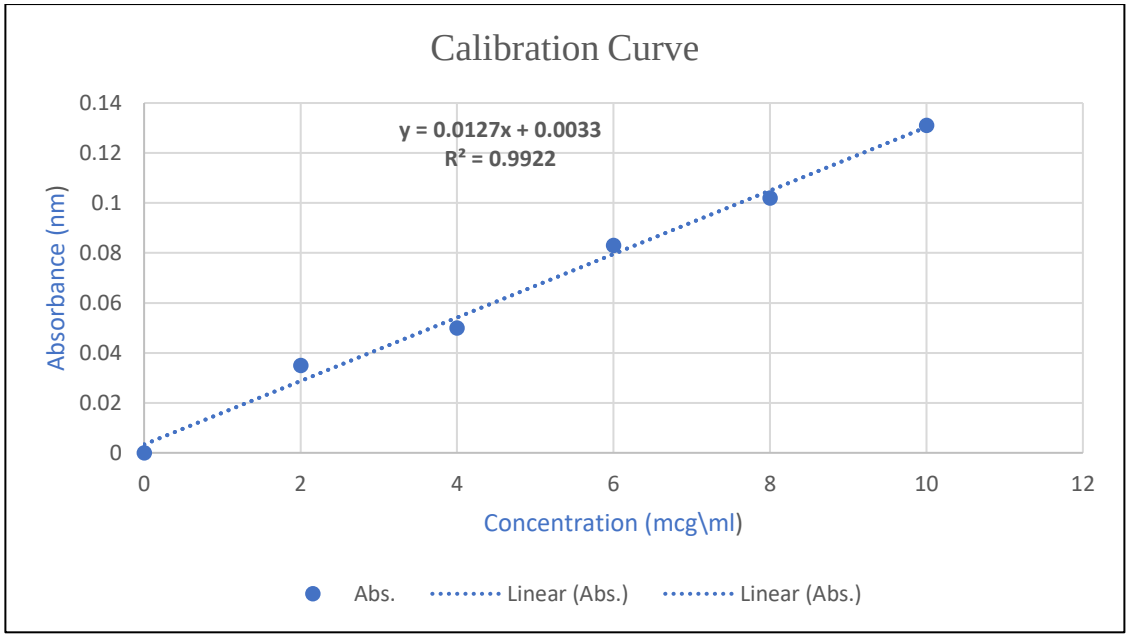

Figure 2: Calibration Curve of Bromelain in Water

FTIR spectroscopy:

The FTIR spectrums of pure Bromelain and physical mixtures of drugs and polymers were studied separately as per the excipients used in the formulation. It was observed that there were no major shifts in the main peaks of either drug. This indicates that there were no compatibility problems with the drug with the polymers and excipients used in the formulation. Bromelain had peaks at 3433 (-OH elongation), 1643 (CO elongation), 3487 (NH stretch), 1384 (C-N stretch), 2862 (C-H).

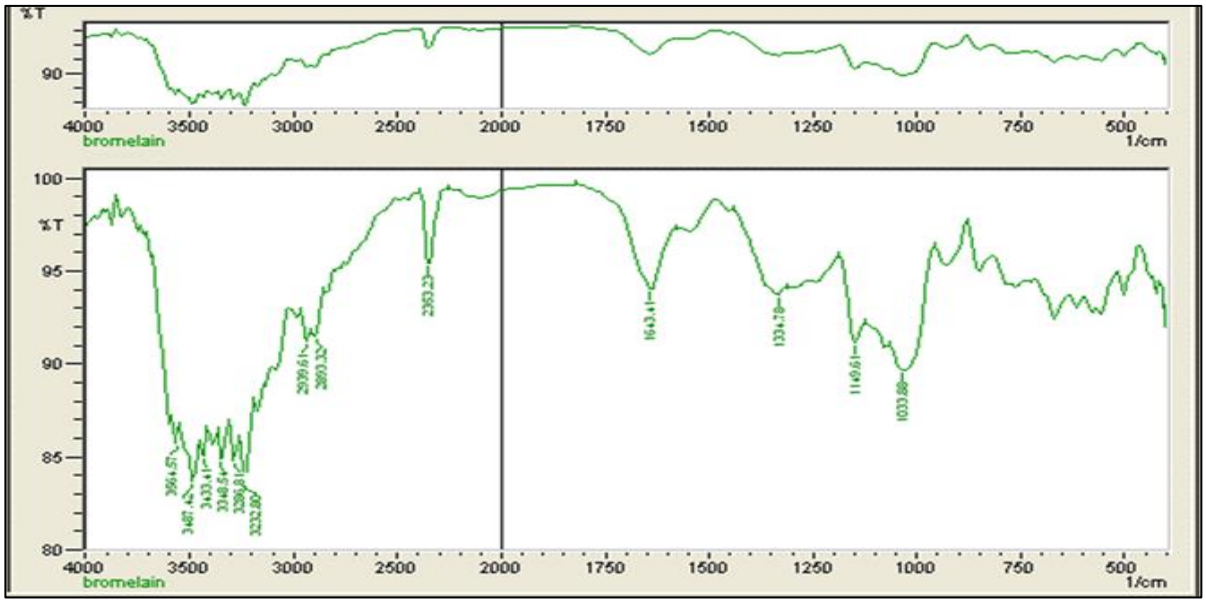

Figure 3: FTIR Studies of Bromelain

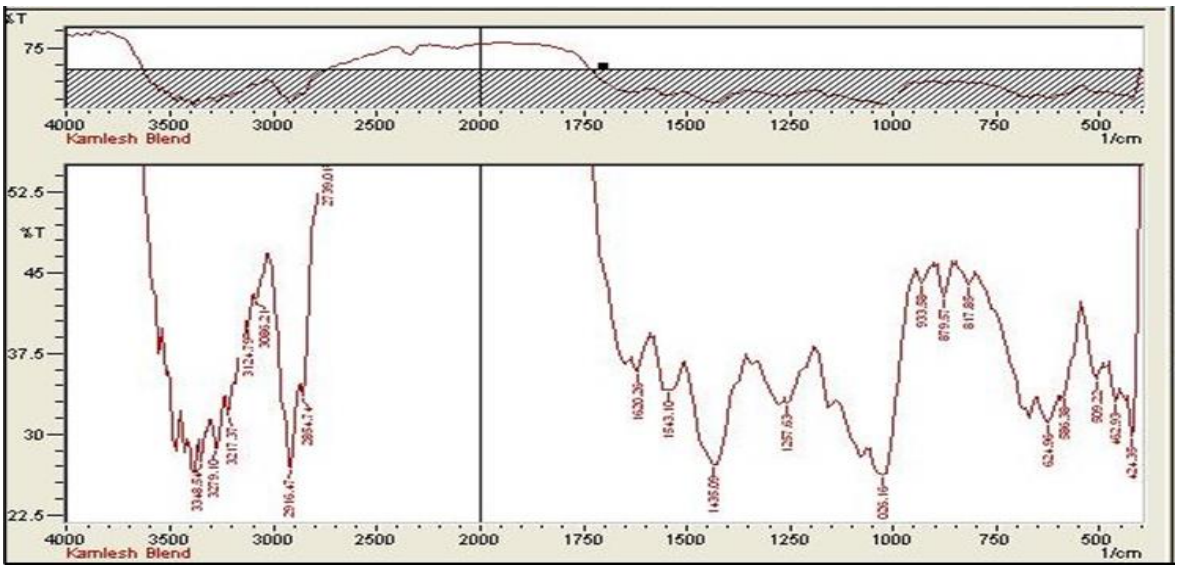

Figure 4: FTIR Studies of Bromelain Tablet Blend

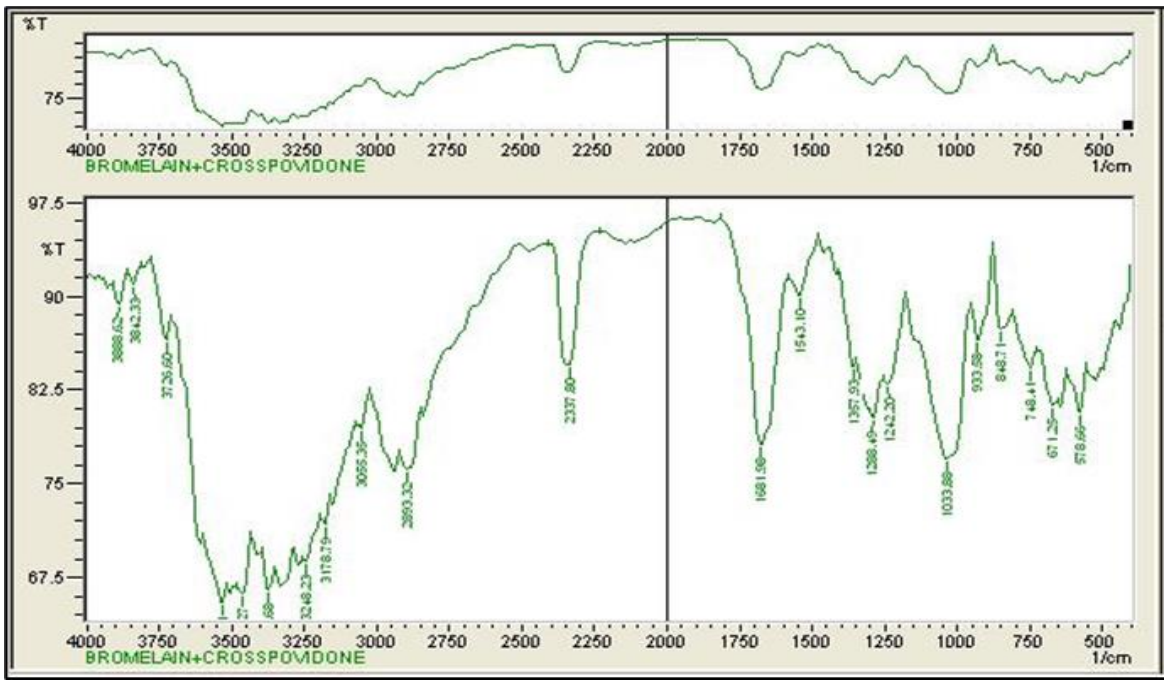

Figure 5: FTIR Studies of Bromelain + Crospovidone

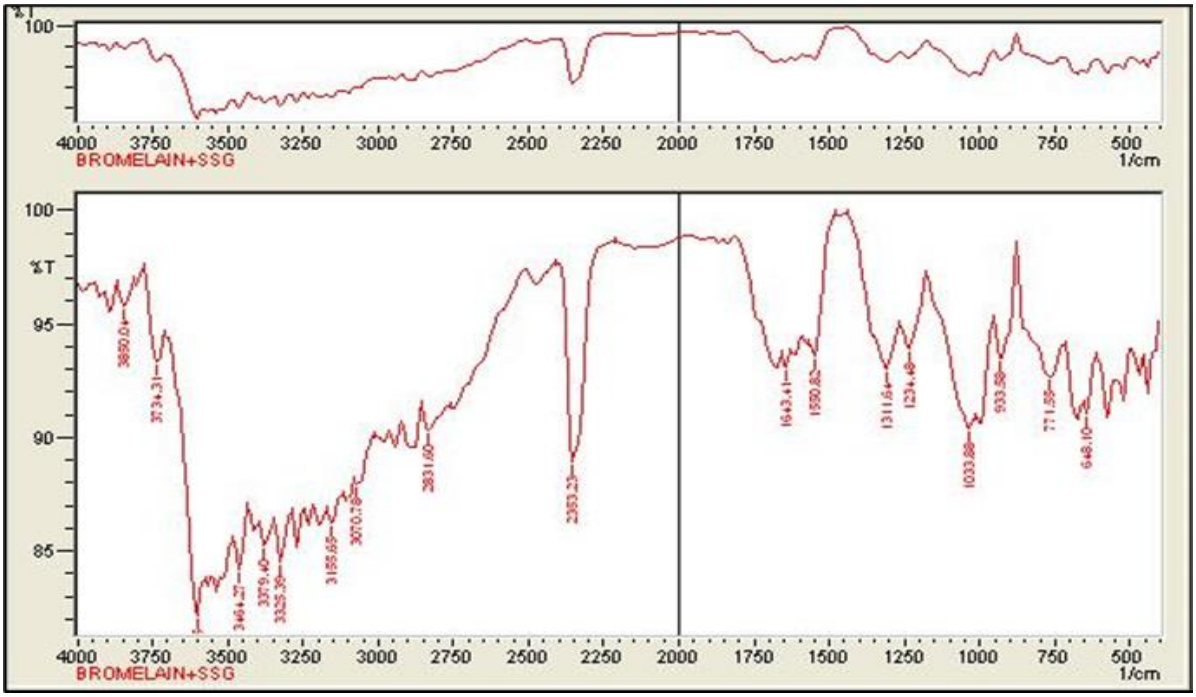

Figure 6: FTIR Studies of Bromelain + SSG

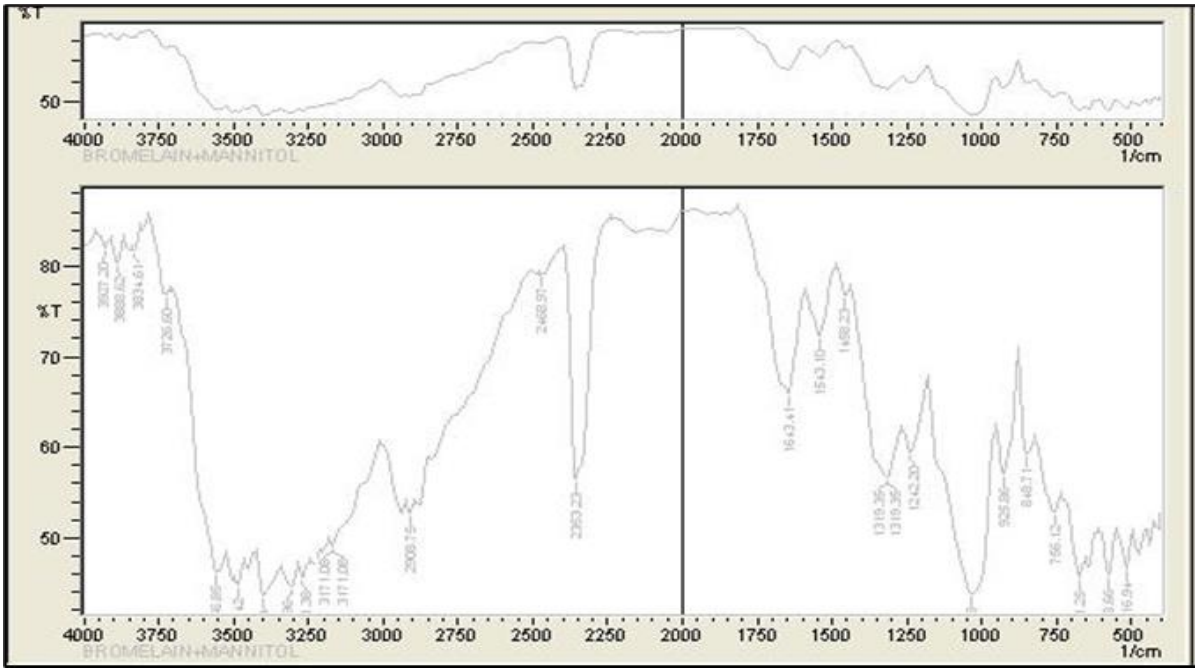

Figure 7: FTIR Studies of Bromelain + Mannitol

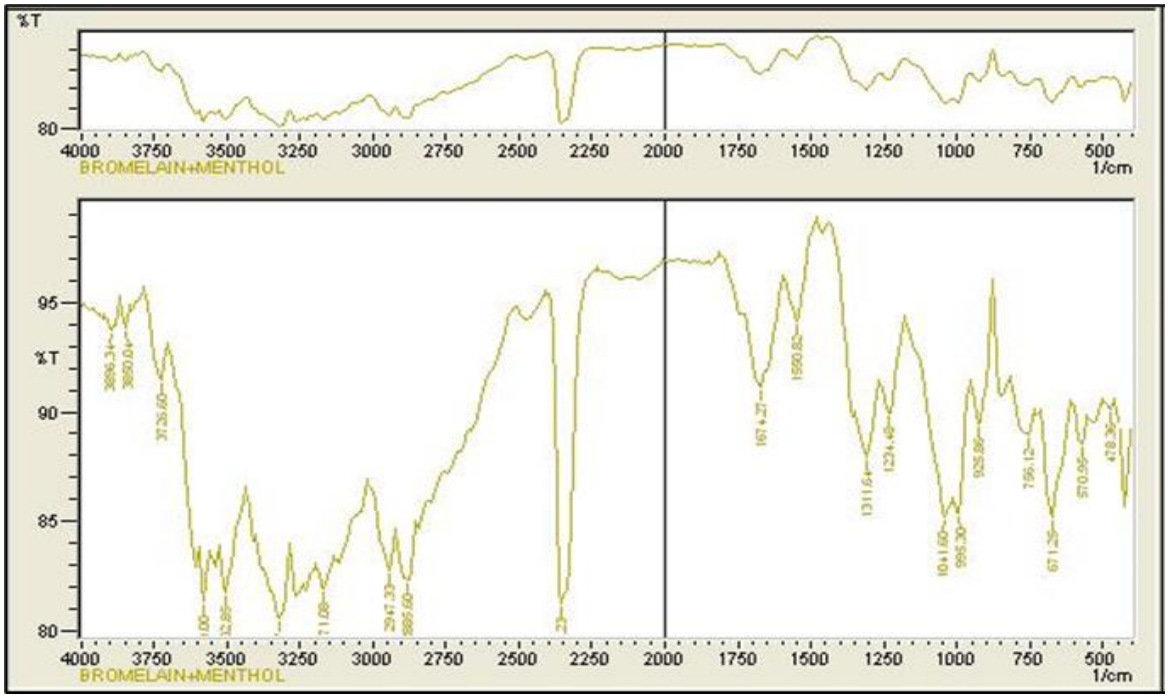

Figure 8: FTIR Studies of Bromelain + Menthol

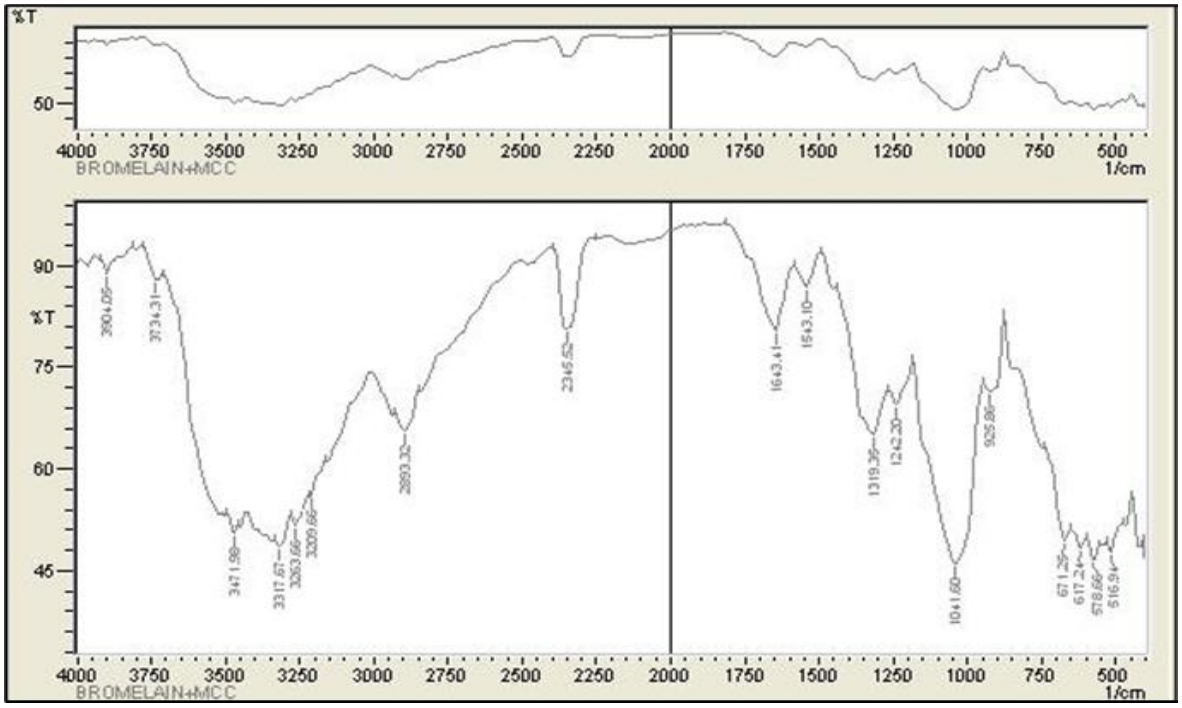

Figure 9: FTIR Studies of Bromelain + MCC

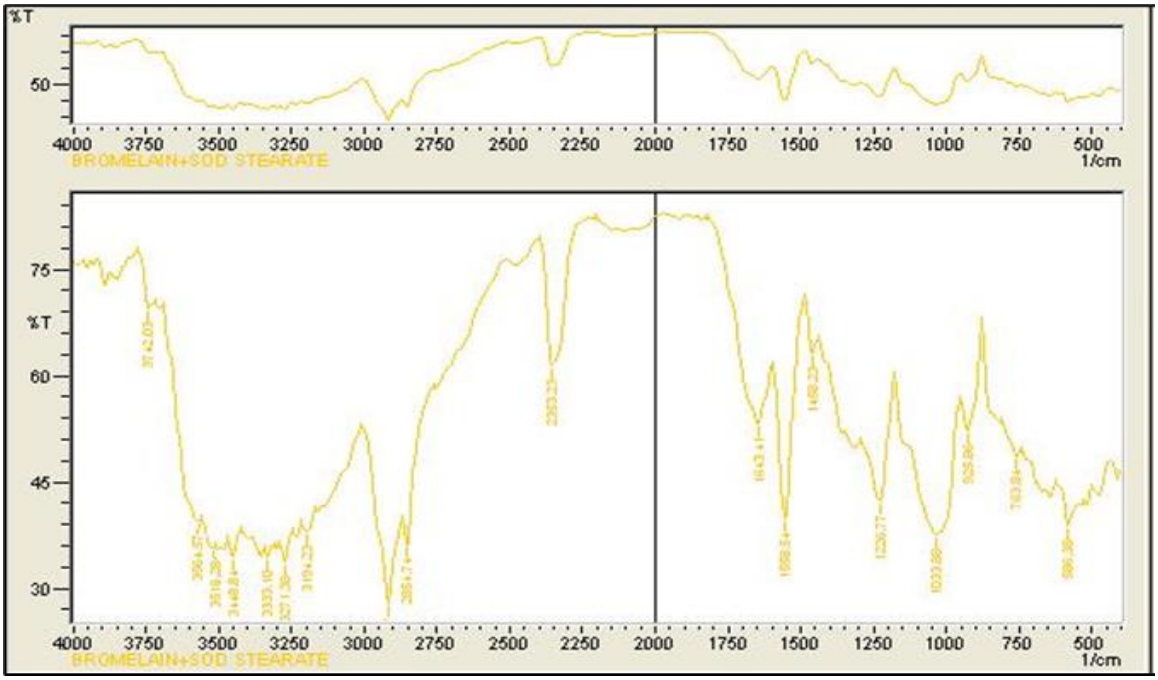

Figure 10: FTIR Studies of Bromelain + Sodium Stearate

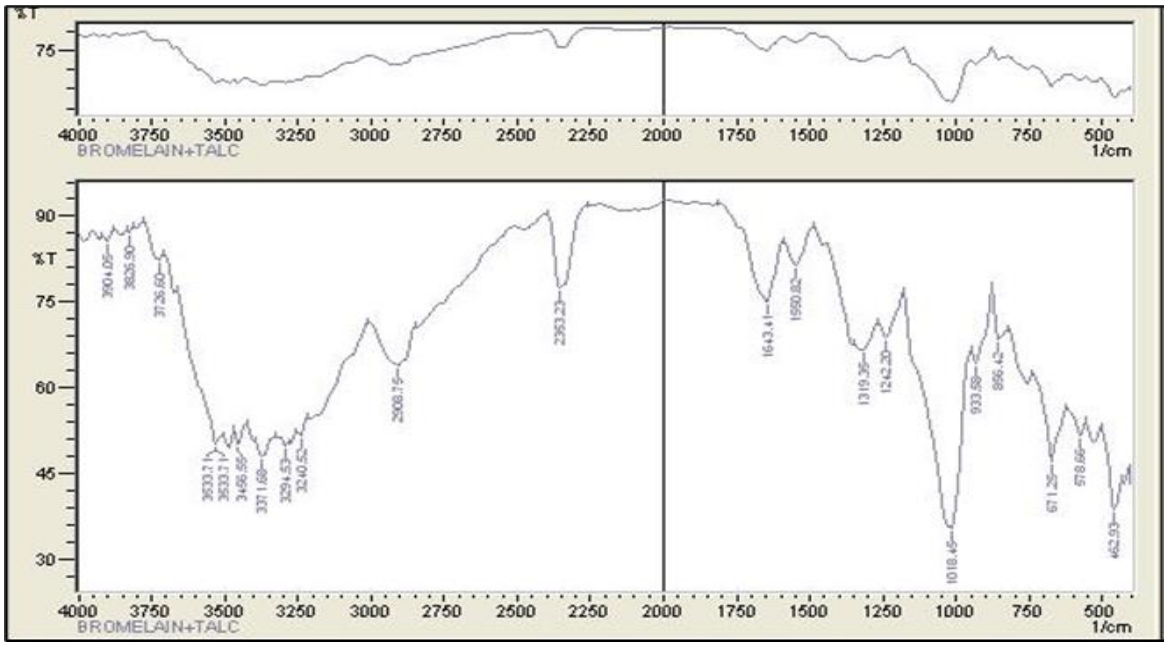

Figure 11: FTIR Studies of Bromelain + Talc

Evaluations:

Mouth dissolving tablets of Bromelain were prepared by a method employing crospovidone and sodium starch glycolate as super-disintegrants at different ratios. A total of six formulations were designed. The flow properties of the powder mixture are important for the uniformity of mass of the tablets; the flow of the powder mixture was analysed before compression to tablets.

Low Hausner`s ratio (≤1.18), compressibility index (≤14.81) and angle of repose (≤ 29.04) values indicated fairly good flowability of the powder mixture (Table 5).

Table 5: Evaluation of Tablet Blend of Mouth Dissolving Tablet of Bromelain.

Batches	Angle of Repose (Ɵ)	Bulk Density (gm/cm^3)	Tapped Density (gm/cm^3)	Housner's Ratio (H_R)	Carr's Compressibility Index
F1	21.78±1.88	0.45±0.12	0.50±0.23	1.18±0.10	10.00±0.20
F2	20.67±0.95	0.43±0.16	0.49±0.09	1.13±0.21	12.24±0.33
F3	23.59±0.47	0.43±0.17	0.48±0.26	1.11±0.20	10.41±0.10
F4	28.42±1.27	0.41±0.10	0.47±0.20	1.14±0.32	12.76±0.63
F5	23.78±1.45	0.45±0.90	0.52±0.21	1.15±0.28	13.46±0.39
F6	29.04±1.14	0.47±0.12	0.54±0.21	1.14±0.18	14.81±0.91

As the tablet powder mixture was free flowing, tablets produced were of uniform weight with acceptable weight variation in the range from 251 mg to 254 mg due to uniform die fill. Hardness (3.2 ± 0.05 - 3.4 ± 0.1 kg/cm2) and friability loss (0.8 ± 0.090 - 0.9 ± 0.117 %) indicated that tablets had good mechanical resistance. Drug content was found to be high (≥ 98.25 %) in all the tablet formulations (Tables 6).

Table 6: Evaluation of Mouth Dissolving Tablets of Bromelain

Batches	Thickness (mm)	Hardness (Kg/cm^2)	Friability (%)	Drug Content (%)	Weight Variation (mg)	Disintegration time (sec)
F1	4.04±0.10	3.26±0.05	0.8±0.05	98.50±0.11	252± 0.93	49±3.28
F2	4.35±0.17	3.36± 0.11	0.8±0.15	98.75±0.01	251±0.32	44±1.41
F3	4.27±0.25	3.26± 0.15	0.9±0.1	98.75±0.13	251±0.70	41±1.41
F4	4.35±0.10	3.36± 0.15	0.9±0.13	98.25±0.06	252± 0.93	50±1.89
F5	4.01±0.17	3.33± 0.25	0.8±0.07	98.70±0.23	251±0.17	48±1.41
F6	4.20±0.10	3.43± 0.10	0.8±0.09	98.75±0.14	254±0.51	45±1.91

The most important parameter that needs to be optimized in the development of mouth dissolving tablets is the disintegration time of tablets. In the present study. The faster disintegration of crospovidone tablets may be attributed to its rapid capillary activity and pronounced hydration with low capacity for gel formation. Thus, these results suggest that disintegration times can be reduced by using a wicking type disintegrant (crospovidone). Thus, disintegration times of tablets with crospovidone were found to be less than those with sodium starch glycolate. IR shows the drug interaction study, indicating that the drug is compatible with all the excipients (Figures 3 to 11).

In vitro, drug release studies were carried out in phosphate buffer pH 6.8 and the dissolution profile is depicted in Table 7 and Figures 12. The drug release from the optimized batch (F3) was 97.67 % at 30 min.

Table 7: In vitro Cumulative % Drug Release from Tablets

Time (In Min)	**Cumulative % Drug Release**					
	F1	**F2**	**F3**	**F4**	**F5**	**F6**
0 min	0	0	0	0	0	0
05 min	30.88±0.97	32.47±1.76	33.34±1.06	30.75±1.46	32.89±1.92	34.55±2.11
10 min	46.76±1.55	41.13±1.23	51.34±1.88	49.98±1.65	42.18±1.54	44.8±0.94
15 min	54.35±1.89	55.04±0.76	61.37±1.46	53.24±2.45	58.6±1.98	61.35±1.56
20 min	75.52±2.63	75.14±1.89	84.21±1.23	75.14±1.33	72.55±1.17	72.55±2.35
25 min	83.29±1.44	83.09±1.27	91.06±0.89	83.29±1.39	81.69±1.43	81.25±1.34
30 min	95.17±1.93	96.59±1.09	97.67±1.98	94.47±1.47	95.88±2.78	96.95±1.89

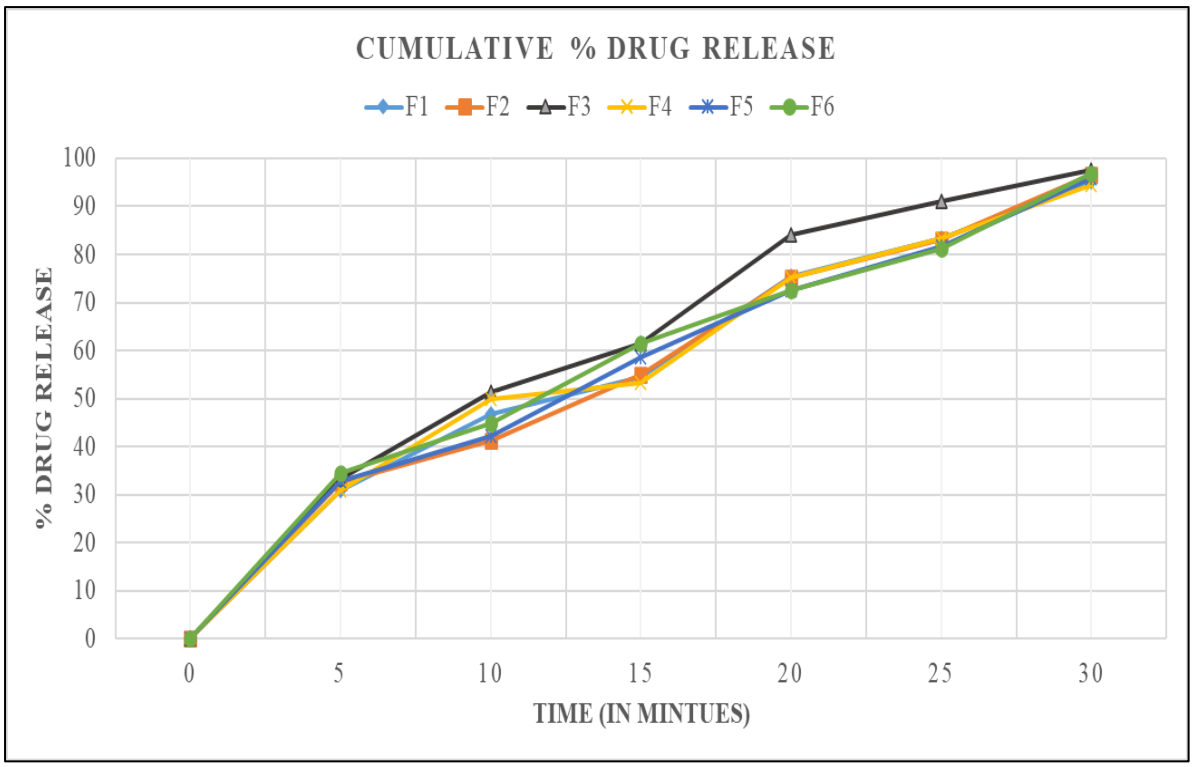

Figure 12: Cumulative % Drug Release

CONCLUSION:

In the present work, mouth dissolving tablets of Bromelain were prepared by direct compression method using superdisintegrants such as sodium starch glycolate and crospovidone. All the tablets of Bromelain were subjected to tests for weight variation, hardness, friability, drug polymer interaction, drug content uniformity, water absorption ratio, wetting time, and in vitro drug release**.**

Based on the above studies, the following conclusions can be drawn:

Tablets prepared by direct compression methods were found to be good and free from chipping and capping.

- The low values of the standard deviation of average weight of the prepared tablets indicated weight uniformity within the batches prepared.
- The hardness of the prepared tablets was found to be in the range of 3.2 ± 0.05 - 3.4 ± 0.1 kg/cm2. The friability values of the prepared tablets were found to be less than 1%.
- IR spectroscopic indicated that the drug is compatible with all the excipients.

- The in vitro disintegration time of Bromelain MDT prepared by the direct compression method was found to be in the range of 41 sec. to 50 sec. fulfilling the official requirements.
- Based on the in vitro disintegration time, formulation F3 (crospovidone) was found to be promising and showed a disintegration time of 41 sec, facilitating faster dispersion in the mouth.
- The drug content of tablets was uniform across all batches, ranging from 98.25 ± 0.06 - 98.75 ± 0.14 %w/w
- The drug release from the optimized batch (F3) was about 97.67 % at 30 min.

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CONFLICT OF INTEREST

All authors declared no conflicts of interest.

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