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Formulation and Evaluation of Rapid Dissolving Tablet of Bilastine

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Abstract: The demand for fast dissolving tablets has been growing during the last decade especially for elderly and children who have swallowing difficulties. In the present work fast dissolving tablets of Bilastine were prepared with Plantago ovata seed powder, Tulsion 33 and Locust bean gum as superdisintegrants by direct compression method. The tablets were evaluated for various parameters including weight variation, hardness, friability, drug content, *In vitro* drug release and FTIR. The tablets prepared by direct compression method had a weight variation in the range of 118.35 to 122.31, hardness of 2.36 to 3.25 Kg/cm^{2,} percentage friability of 0.33 to 0.52 % is with in the limits, drug content uniformity between 97.21 to 99.83 % and *In vitro* drug release of B4 formulation was 99.25% for 30mints. The FTIR spectral analysis showed no drug interaction with formulation additives of the tablet and the formulation indicated no significants.

Keywords: Bilastine, Plantago ovata seed powder, Tulsion 33 and Locust bean gum

1. INTRODUCTION

The Fast route of administration is considered as the most widely accepted route because of its convenience of self administration, compactness and easy manufacturing. But the most evident drawback of the commonly used Fast dosage forms like tablets and capsules is difficulty in swallowing, leading to patients incompliance particularly in case of paediatric and geriatric patients, but it also applies to people who are ill in bed and to those active working patients who are busy or travelling, especially those who have no access to water.

For these reasons, tablets that can rapidly dissolve or disintegrate in the Fast cavity have attracted a great deal of attention. Fast dispersible tablets are not only indicated for people who have swallowing difficulties, but also are ideal for active people. [1]

An Fast disintegrating tablet (FDT) is a solid dosage form that contains medicinal substances and disintegrates rapidly (within seconds) without water when placed on the tongue. The drug is released, dissolved, or dispersed in the saliva, and then swallowed and absorbed across the GIT. [2]

US FDA defined FDT tablets as “A solid dosage form containing medicinal substances which disintegrates rapidly usually within a matter of seconds, when placed upon the tongue”.

Recently European Pharmacopoeia used the term ‘Fastdispersible tablet’ as a tablet that is to be placed in the Fast where it disperses rapidly before swallowing.

Fastly disintegrating tablets are also called as Fast-dissolving tablets, fast disintegrating tablets, fast dissolving tablets, Fastdispersible tablets, rapimelts, pFastus tablets, quick dissolving tablet .

The US Food and Drug Administration responded to this challenge with the 2008 publication of Guidance for Industry: Fastly Disintegrating Tablets (Rosie et al., 2009).Three main points stand out in the final guidance:

- FDTs should have an *in vitro* disintegration time of approximately 30sec or less.
- Generally, the FDT tablet weight should not exceed 500 mg, although the combined influence of tablet weight, size, and component solubility all factor into the acceptability of an FDT for both patients and regulators.
- The guidance serves to define the upper limits of the FDT category, but it does not supersede or replace the original regulatory definition mentioned. In other words, disintegration within a matter of seconds remains the target for an FDT.

1.1 NEED TO DEVELOP FDT:

The need for one of the non-invasive delivery system i.e., Fastly disintegrating tablets persists due to patients' poor acceptance of, and compliance with, existing delivery regimes, limited market size for drug companies and drug uses, coupled with high cost of disease management.

PATIENT FACTORS:

Fastly disintegrating dosage forms are particularly suitable for patients, who for one reason or the other; find it inconvenient to swallow tablets and capsules with an 8-oz glass of water. These include the following:

- Paediatric and geriatric patients who have difficulty in swallowing or chewing solid dosage forms.
- Patients who are unwilling to take solid preparation due to fear of choking.
- Very elderly patients who may not be able to swallow a daily dose of antidepressant.
- An eight-year old with allergies who desires a more convenient dosage form than antihistamine syrup
- A middle-aged woman undergoing radiation therapy for breast cancer may be too nauseous to swallow her H2- blocker.
- A schizophrenic patient in an institutional setting who may try to hide a conventional tablet under his or her tongue to avoid their daily dose of an atypical antipsychotic.
- A patient with persistent nausea, who may be journey, or has little or no access to water

EFFECTIVENESS FACTORS:

- Increased bioavailability and faster onset of action 0are a major claim of these formulations.
- Dispersion in saliva in Fast cavity causes pregastric absorption from some formulations in those cases where drug dissolves quickly.
- Buccal, pharyngeal and gastric regions are all areas of absorption for many drugs**.**
- Any pregastric absorption avoids first pass metabolism and can be a great advantage in drugs that undergo a great deal of hepatic metabolism.
- Furthermore, safety profiles may be improved for drugs that produce significant amounts of toxic metabolites mediated by first-pass liver metabolism and gastric metabolism, and for drugs that have a substantial fraction of absorption in the Fast cavity and pregastric segments of GIT**.**

MANUFACTURING AND MARKETING FACTORS:

- Developing new drug delivery technologies and utilizing them in product development is critical for pharmaceutical industries to survive, regardless of their size.
- As a drug nears the end of its patent life, it is common for pharmaceutical manufacturers to develop a given drug entity in a new and improved dosage form.
- A new dosage form allows a manufacturer to extend market exclusivity, unique product differentiation, value-added product line extension, and extend patent protection, while offering its patient population a more convenient dosage form.

- This leads to increased revenue, while also targeting underserved and under-treated patient populations.

7. METHODOLOGY

Buffer Preparation:

Preparation of 0.2M Potassium dihydrogen orthophosphate solution: Accurately weighed 27.218 gm of monobasic potassium dihydrogen orthophosphate was dissolved in 1000 mL of distilled water and mixed.

Preparation of 0.2M sodium hydroxide solution: Accurately weighed 8 gm of sodium hydroxide pellets were dissolved in 1000 mL of distilled water and mixed

Preparation of pH 6.8 phosphate buffer: Accurately measured 250 mL of 0.2M potassium dihydrogen ortho phosphate and 112.5 mL of 0.2M NaOH was taken into the 1000 mL volumetric flask. Volume was made up to 1000 mL with distilled water.

Analytical method development for Bilastine:

a) Determination of absorption maxima

A solution containing the concentration 10 µg/ ml drug was prepared in 6.8 phosphate buffer UV spectrum was taken using Lab India Double beam UV/VIS spectrophotometer (Lab India UV 3000+). The solution was scanned in the range of 200 – 400 nm.

b) Construction of standard graph

100 mg of Bilastine was dissolved in 100 ml of pH 6.8 phosphate buffer to give a concentration of 1mg/ml (1000 µg/ml). From the above standard solution (1000 µg/ml) 1ml was taken and diluted to 100ml with pH 6.8 phosphate buffer to give a concentration of 0.01mg/ml (10µgm/ml). From this stock solution aliquots of 0.5ml, 1.0ml, 1.5ml, 2.0ml and 2.5ml were pipette out in 10 ml volumetric flask and the volume was made up to the mark with pH 6.8 phosphate buffer to produce concentration of 5, 10, 15, 20 and 25µg/ mL respectively. The absorbance (abs) of each conc. was measured at respective (λ_{max}) i.e., 275 nm.

Formulation Development:

- Drug and different concentrations of super Disintegrates (Plantago ovata seed powder, Tulsion 339, Locust bean gum) and required ingredients were accurately weighed and passed through a 40-mesh screen to get uniform size particles and mixed in a glass mortar for 15 minutes.
- The obtained blend was lubricated with Magnesium stearate and glidant (Aerosil) was added and mixing was continued for further 5 minutes.
- The resultant mixture was directly compressed into tablets by using punch of rotary tablet compression machine. Compression force was kept constant for all formulations.

Table: Formulation table showing various compositions

INGREDIANTS	B1	B2	B3	B4	B5	B6	B7	B8	B9
Bilastine	20	20	20	20	20	20	20	20	20
Plantago ovata seed powder	20	40	60	-	-	-	-	-	-
Tulsion 339	-	-	-	20	40	60	-	-	-
Locust bean gum	-	-	-	-	-	-	20	40	60
Aerosil	7	7	7	7	7	7	7	7	7
Magnesium stearate	5	5	5	5	5	5	5	5	5
Aspartame	3	3	3	3	3	3	3	3	3
Spraydried lactose	65	45	25	65	45	25	65	45	25
Total Weight	120	120	120	120	120	120	120	120	120

The tablets were prepared by using Tablet Compression machine. The hardness of the tablets was maintained as 2.36 to 3.25 kg/cm^2.

Evaluation of tablets:

Pre compression parameters:

Measurement of Micromeritic Properties of Powders

1. Angle of repose

The angle of repose of API powder is determined by the funnel method. The accurately weight powder blend are taken in the funnel. The height of the funnel is adjusted in a way that, the tip of the funnel just touched the apex of the powder blend. The powder blend is allowed to flow through the funnel freely on to the surface. The diameter of the powder cone is measured and angle of repose is calculated using the following equation.

$$\tan \theta = h/r \quad (1)$$

Where, h and r are the height and radius of the powder cone.

Table: Flow Properties and Corresponding Angle of Repose

Flow Property	Angle of Repose (^{0})
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

2. Bulk density

The powder sample under test is screened through sieve No.18 and the sample equivalent to 25 gm is weighed and filled in a 100 ml graduated cylinder and the power is leveled and the unsettled volume, V_0 is noted. The bulk density is calculated in g/cm^3 by the formula.

$$\text{Bulk density} = M/V_0 \quad (2)$$

M = Powder mass

V_0 = apparent unstirred volume

3. Tapped density

The powder sample under test is screened through sieve No.18 and the weight of the sample equivalent to 25 gm filled in 100 ml graduated cylinder. The mechanical tapping of cylinder is carried out using tapped density tester at a nominal rate for 500 times initially and the tapped volume V_0 is noted. Tappings are proceeded further for an additional tapping 750 times and tapped volume, V_b is noted. The difference between two tapping volume is less the 2%, V_b is considered as a tapped volume V_f. The tapped density is calculated in g/cm^3 by the formula.

$$\text{Tapped density} = M/V_f \quad (3)$$

M =weight of sample power taken

V_f=tapped volume

4. Compressibility Index

The Compressibility Index of the powder blend is determined by Carr's compressibility index to know the flow character of a powder. The formula for Carr's Index is as below:

$$\text{Carr's Index (\%)} = [(TD-BD)/TD] \times 100 \quad (4)$$

5. Hausner's ratio

The Hausner's ratio is a number that is correlated to the flowability of a powder or granular material. The ratio of tapped density to bulk density of the powders is called the Hasner's ratio. It is calculated by the following equation.

$$H = \rho T / \rho B \quad (5)$$

Where ρT = tapped density, ρB = bulk density

Table : Scale of Flowability

Compressibility Index (%)	Flow Character	Hausner Ratio
≤ 10	Excellent	1.00-1.11
11-15	Good	1.12-1.18
16-20	Fair	1.19-1.25
21-25	Passable	1.26-1.34
26-31	Poor	1.35-1.45
32-37	Very Poor	1.46-1.59
> 38	Very, very Poor	> 1.60

Post compression parameters:

a) Thickness

The thickness of tablets was determined by using Digital micrometer. Ten individual tablets from each batch were used and the results averaged.

b) Weight variation

Twenty tablets were randomly selected from each batch and individually weighed. The average weight and standard deviation three batches were calculated. It passes the test for weight variation test if not more than two of the individual tablet weights deviate from the average weight by more than the allowed percentage deviation and none deviate by more than twice the percentage shown. It was calculated on an electronic weighing balance.

c) Friability

The friability values of the tablets were determined using a Roche-type friabilator. Accurately weighed six tablets were placed in Roche friabilator and rotated at 25 rpm for 4 min.

Percentage friability was calculated using the following equation.

$$\text{Friability} = ([w_O - w] / w_O) \times 100$$

Where; w_O = weight of the tablet at time zero before revolution.

w = weight of the tablet after 100 revolutions.

d) Drug content

The content of drug carried out by five randomly selected tablets of each formulation. The five tablets were grinded in mortar to get powder; this powder was dissolved in pH 6.8 phosphate buffer by sonication for 30 min and filtered through filter paper. The drug content was analyzed spectrophotometrically at 275 nm using UV spectrophotometer. Each measurement was carried out in triplicate and the average drug content was calculated.

e) Disintegration test

Six tablets were taken randomly from each batch and placed in USP disintegration apparatus baskets. Apparatus was run for 10 minutes and the basket was lift from the fluid, observe whether all of the tablets have disintegrated.

f) Dissolution test of Bilastine tablets

Drug release from Bilastine tablets was determined by using dissolution test United States Pharmacopoeia (USP) 24 type II (paddle). The parameters used for performing the dissolution were pH 6.8 medium as the dissolution medium of quantity 900 ml. The whole study is being carried out at a temperature of 37^0 C and at a speed of 50rpm. 5ml aliquots of dissolution media were withdrawn each time at suitable time intervals (5, 10, 15,20, 30, 45, 60minutes.) and replaced with fresh medium. After withdrawing, samples were

filtered and analyzed after appropriate dilution by UV spectrophotometer. The concentration was calculated using standard calibration curve.

Drug-Excipients compatibility studies:

Drug Excipients compatibility studies were carried out by mixing the drug with various excipients in different proportions (in 1:1 ratio were prepared to have maximum likelihood interaction between them) was placed in a vial, and closed with rubber stopper and sealed properly. Fourier Transform Infrared Spectroscopy (FTIR) studies were performed on drug, optimized formulation using Bruker FTIR. The samples were analyzed between wave numbers 4000 cm^{-1} and 550 cm^{-1}.

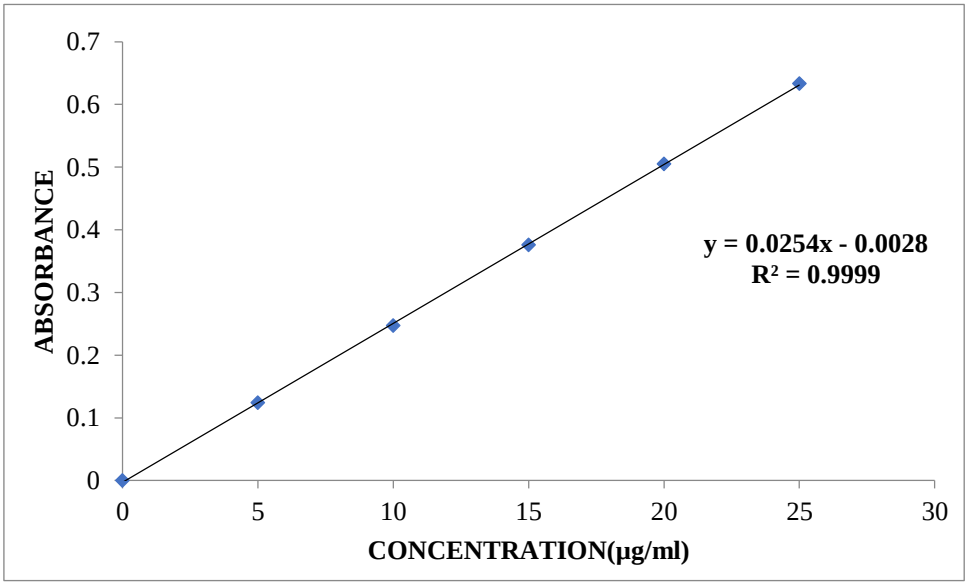
8. RESULTS AND DISCUSSION:

Preparation of Calibration Curve of Bilastine:

The Regression Coefficient was found to be 0.999 which indicates a linearity with an equation of y = 0.0254x - 0.0028. Hence beer - Lambert's law was obeyed.

Table: Calibration curve data of Bilastine in ph 6.8 phosphate buffer

Concentration (µg/mL)	Absorbance
0	0
5	0.124
10	0.247
15	0.376
20	0.505
25	0.633



EVALUATION OF PRE - COMPRESSION PARAMETERS OF POWDER BLEND

Table: Evaluation of pre-compression parameters of powder blend

Formulation Code	Angle of Repose (°)	Bulk density (gm/mL)	Tapped density (gm/mL)	Carr's index (%)	Hausner's Ratio
B1	27.52	0.52	0.65	18	1.21
B2	28.87	0.51	0.62	17	1.21
B3	30.02	0.53	0.63	15	1.20
B4	30.01	0.53	0.64	17	1.20
B5	28.43	0.50	0.63	20	1.26
B6	28.26	0.55	0.65	15	1.14
B7	28.85	0.51	0.62	17	1.21

B8	30.14	0.52	0.63	17	1.21
B9	28.04	0.54	0.65	16	1.20

- For each formulation blend of drug and excipients were prepared and evaluated for various pre compression parameters described earlier in methodology chapter.
  - The bulk density of all formulations was found in the range of (0.50 - 0.55**)** and tapped density was in range of (0.62 - 0.65).
- The carr's index and hausner's ratio was calculated from tapped density and bulk density.

EVALUATIONS OF POST COMPRESSION PARAMETERS OF MAPROTILINE FDTs

Table: Evaluation of post compression parameters of Bilastine Fast dissolving tablets

Formulation codes	Average Weight (mg)	Hardness (kg/cm^2)	Friability (% loss)	Thickness (mm)	Drug content (%)	*In vitro* Disintegration Time (min)
B1	119.49	2.36	0.45	1.25	99.38	3.12
B2	118.85	2.88	0.34	1.37	98.08	3.44
B3	121.37	3.14	0.41	1.55	97.21	3.28
B4	119.74	2.75	0.33	2.12	98.39	2.36
B5	120.88	3.25	0.64	1.89	99.42	3.57
B6	122.31	2.45	0.52	1.45	99.83	3.89
B7	121.63	2.59	0.39	1.44	98.47	2.77
B8	119.44	2.88	0.48	1.62	97.31	3.15
B9	118.35	3.11	0.37	1.75	98.22	2.44

Weight variation and thickness: All the formulations were evaluated for uniformity of weight using electronic weighing balance and the results are shown above. The average tablet weights of all the formulations were noted down.

Hardness and friability: All the FDT formulations were evaluated for their hardness, using monsanto hardness tester and the results are shown above. The average hardness for all the formulations was found to be between (2.36 to 3.25) Kg/cm^2 which was found to be acceptable.

Friability was determined to evaluate the ability of the tablets to withstand the abrasion during packing, handling and transporting. All the FDT formulations were evaluated for their percentage friability using roche friabilator and the results are shown above. The average percentage friability for all the formulations was between 0.33 to 0.52, which was found to be within the limit. Addition of Aerosil resulted in appreciable decrease in friability.

Drug content: All the formulations were evaluated for drug content according to the procedure described in methodology section and the results were shown above. The assay values for all the formulations were found to be in the range of **(**97.21 to 99.83**).** According to IP standards the tablets must contain not less than 95% and not more than 105% of the stated amount of the drug. Thus, all the FDT formulations comply with the standards given in IP.

In vitro **disintegration time:** *In vitro* disintegration studies showed from 2.36 to 3.89Minutes. The B4 Formulation showed Very Less *In vitro* Disintegration Time i.e., 2.36 Minutes.

IN VITRO DRUG RELEASE STUDIES OF BILASTINE

Table: Dissolution data of Bilastine

Time (Minutes)	B1	B2	B3	B4	B5	B6	B7	B8	B9

0	0	0	0	0	0	0	0	0	0
5	34.6	53.26	56.38	55.42	46.34	55.18	47.51	53.69	56.67
10	47.36	66.86	64.99	67.87	61.49	67.85	63.45	67.12	68.44
15	69.32	75.97	80.12	75.43	79.15	81.49	78.86	81.16	77.56
20	75.58	84.67	88.2	87.86	86.25	93.23	86.2	87.45	84.69
30	86.36	90.49	92.52	99.25	98.22	96.79	94.64	97.27	95.61

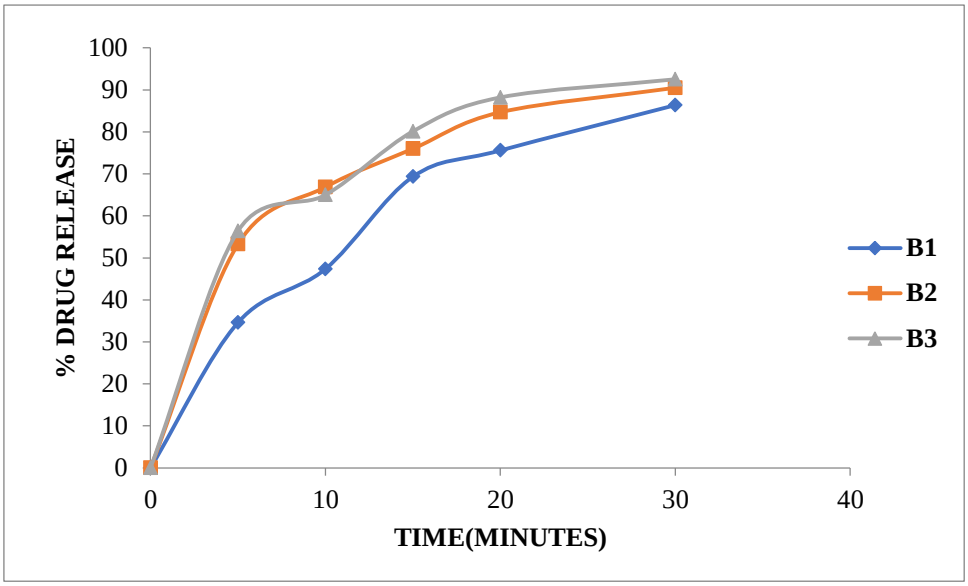


Fig: Dissolution profile of formulations B1, B2, and B3

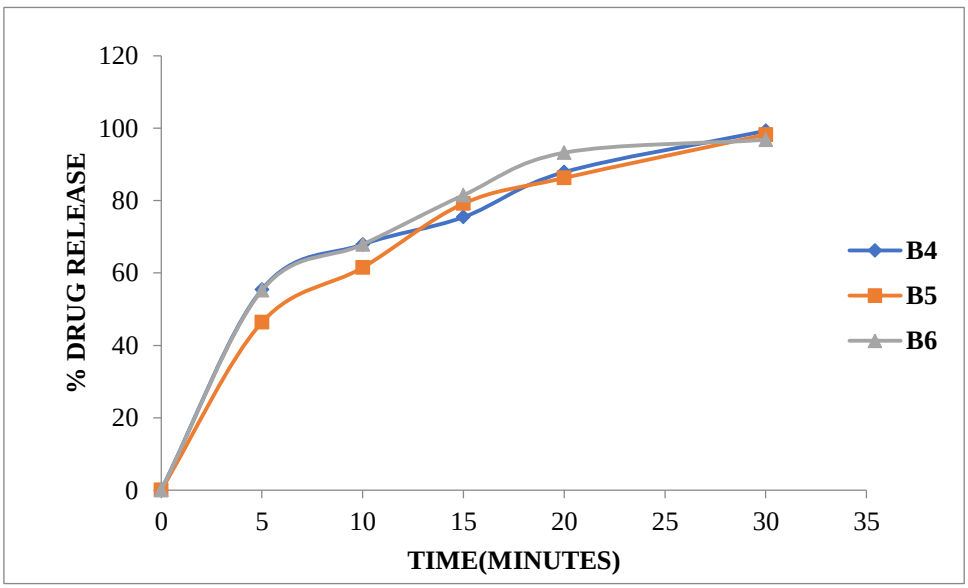


Fig: Dissolution profile of formulations B4, B5, and B6

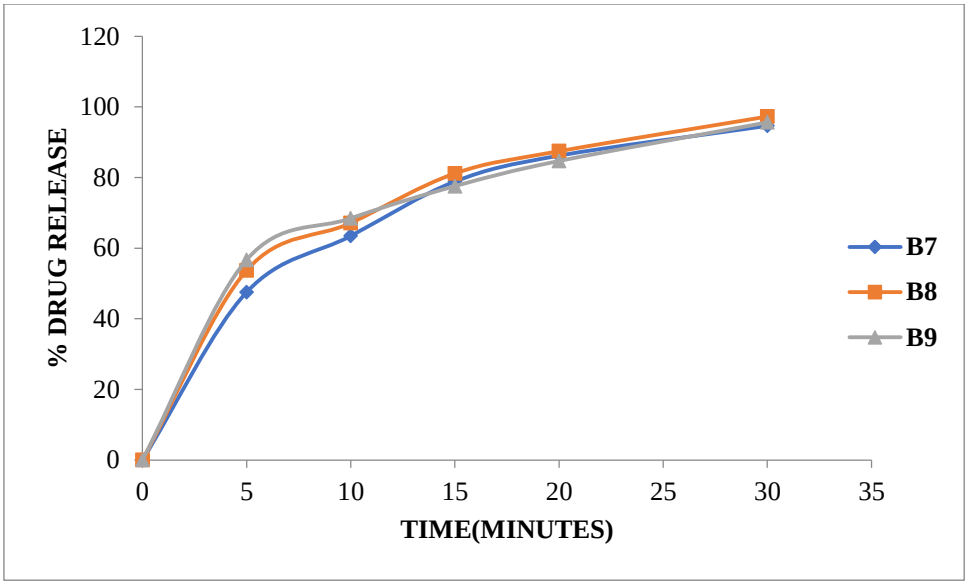


Fig : Dissolution profile of formulations B7, B8 and B9

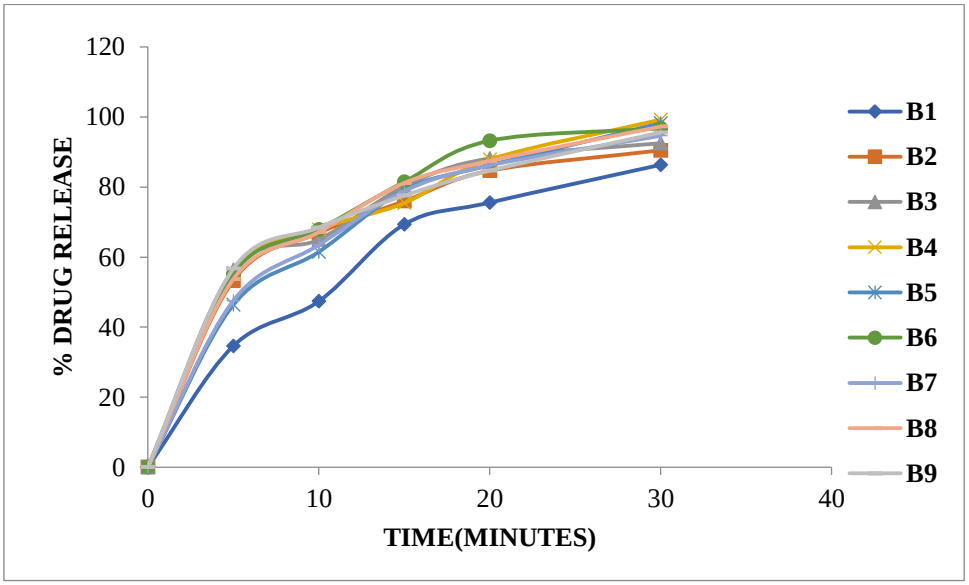


Fig : Dissolution profile of all formulations B1- B9

Formulations prepared with Plantago ovata seed powder showed maximum drug release i.e., 92.52 % (B3Formulation) at 30 min in 60 mg of blend. Formulations prepared with Tulsion 339 showed maximum drug release i.e., 99.25 % (B4Formulation) at 30 min in 20mg of blend. Formulations prepared with Locust bean gum powder showed maximum drug release i.e., 97.27% (B8 Formulation) at 30 min in 40mg of blend. Among all formulations B4 formulation(Contains Tulsion 339) was optimised better formulation.

FTIR RESULTS:

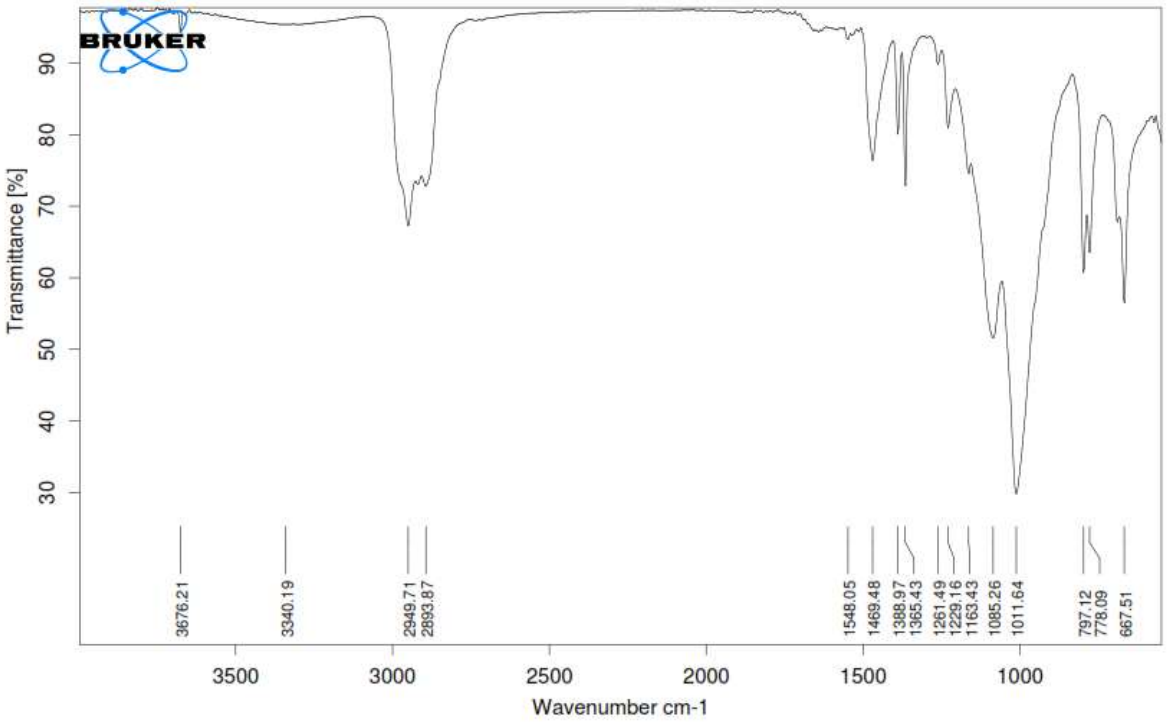


Fig: FTIR of Bilastine Pure drug

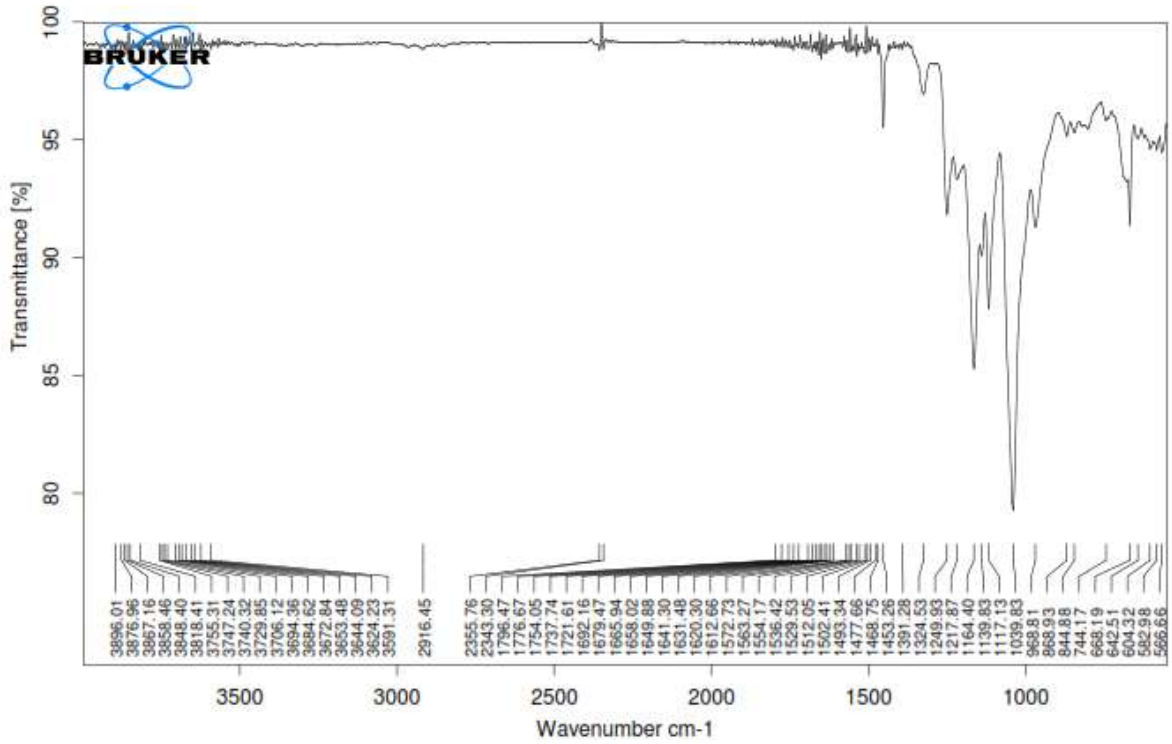


Fig: FTIR of Bilastine optimized Formulation

Bilastine was mixed with various proportions of excipients showed no colour change, providing no drug-excipient interactions.

9. CONCLUSION

In the present work fast dissolving tablets of Bilastine were prepared by direct compression method using superdisintegrants such as Plantago ovata seed powder, Tulsion 339 and Locust bean gum. All the tablets of Bilastine were subjected to tests for weight variations, hardness, friability, drug content uniformity and *In vitro drug release.* Based on the above studies the following conclusion can be drawn.

- Tablets were prepared by direct compression methods were found to be good and free form chipping and capping.
- The low values of standard deviation of average weight of the prepared tablets indicated weight uniformity with in the batches prepared.
- The hardness of the prepared tablets were found to be 2.36 to 3.25 $Kg/cm^{2.}$
- The Friability values of the prepared tablets were found to be less than 1%.
- IR spectroscopic studies indicated that the drug is compatible with all the excipients.
- The drug content of tablets was uniform across all batches ranging from 97.21 to 99.83 %
- The drug release from the optimized batch B4 was about 99.25 % at 30min.

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