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NOVEL FAST DISINTEGRATING TABLET OF BISOPROLOL FUMARATE WITH ITS DEVELOPMENT AND CHARACTERIZATION FOR PATIENT COMPLIANCES

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Abstract:

Bisoprolol Fumarate (BF), a selective β1-adrenergic receptor blocker, is widely prescribed for hypertension and chronic heart diseases. However, conventional tablets often pose swallowing difficulties for geriatric, pediatric, and dysphagic patients, leading to poor adherence. Fast Disintegrating Tablets (FDTs) have emerged as a promising patient-centric dosage form that dissolves rapidly in the oral cavity without the need for water, ensuring quicker onset of action and improved compliance. This review summarizes the formulation strategies, excipient selection, and manufacturing approaches involved in developing Bisoprolol Fumarate FDTs. Emphasis is placed on the role of superdisintegrants, taste-masking methods, and critical evaluation parameters such as disintegration time, wetting time, hardness, and dissolution performance. Recent advancements, challenges, and future perspectives in optimizing FDTs for cardiovascular therapy are also discussed. Overall, Bisoprolol Fumarate FDTs represent an efficient and patient-friendly alternative that enhances therapeutic outcomes and dosage convenience.

Abbreviations:*BF – Bisoprolol Fumarate FDT – Fast Disintegrating Tablet API – Active Pharmaceutical Ingredient CCS – Croscarmellose SodiumCP – Crospovidone DT – Disintegration Time WDT – Wetting Time.*

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1.INTRODUCTION:

Fast disintegrating tablets have gained significant attention in modern pharmaceutical development because they provide better patient comfort and quick drug release. Bisoprolol fumarate is an important cardioselective β1-blocker used mainly for hypertension, angina pectoris, and certain heart rhythm disorders. Many patients, especially elderly individuals, children, and those with swallowing difficulties, face challenges in taking conventional solid tablets. Therefore, designing a fast disintegrating dosage form of bisoprolol fumarate becomes highly valuable for patient compliance and faster therapeutic action.[1]

Pharmacological background of Bisoprolol Fumarate

Bisoprolol fumarate works by selectively blocking β1-adrenergic receptors, which helps reduce heart rate, cardiac output, and myocardial oxygen demand. This mechanism is highly useful in controlling high blood pressure and preventing complications related to cardiac stress. The chemical properties of bisoprolol fumarate, including its aqueous solubility and moderate dose requirement, make it an appropriate candidate for fast disintegrating tablet formulation.[2]

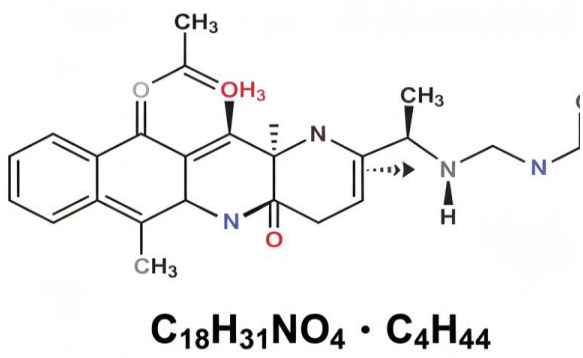

Figure 1: Chemical structure of Bisoprolol Fumarate

2.Need for Fast Disintegrating Tablets in Cardiovascular Therapy

Cardiovascular patients often require long-term therapy and strict adherence to medication schedules. However, physical limitations such as dysphagia, dry mouth, and difficulty swallowing reduce compliance. Fast disintegrating tablets dissolve quickly on the tongue within a few seconds, releasing the drug without the need for water. This provides greater convenience during emergencies like sudden rise in blood pressure, travel situations, and for bedridden patients. The rapid disintegration also supports quicker onset of drug action, which is essential in conditions requiring immediate control of symptoms.[3]

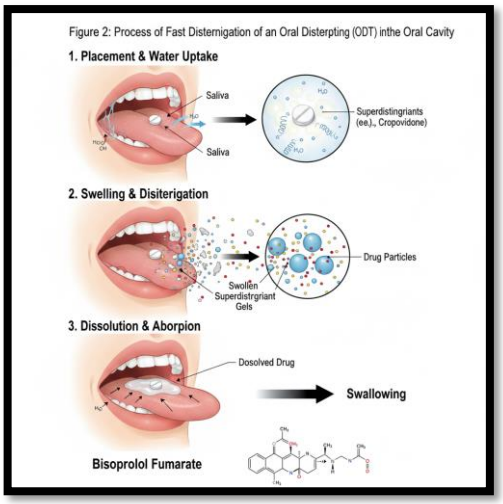

Figure 2: Process of fast disintegration in the oral cavity

Importance of Formulation Development and Characterization

Developing a fast disintegrating tablet involves careful selection of excipients, especially superdisintegrants like crospovidone, croscarmellose sodium, and sodium starch glycolate. These materials help the tablet break down rapidly by mechanisms such as wicking, swelling, and capillary action. Characterization of the final formulation includes parameters like hardness, friability, wetting time, disintegration time, drug content, and dissolution behavior. Proper evaluation ensures the product is strong enough to handle transportation yet soft enough to disintegrate quickly in the mouth.[4]

Research on bisoprolol fumarate fast disintegrating tablets focuses on improving palatability, stability, and bioavailability while maintaining patient-friendly features. This combination of pharmaceutical science, material selection, and engineering ensures the development of a dosage form that is effective, safe, and comfortable for patients.[5]

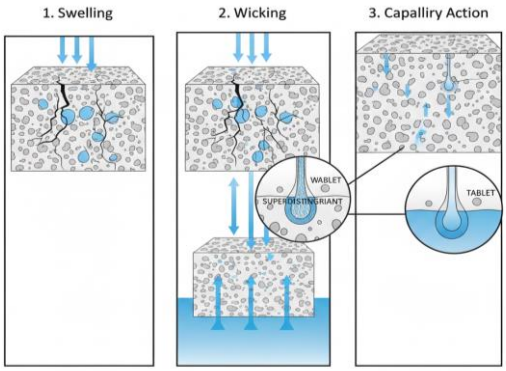

Figure 3: Mechanisms of tablet disintegration

3. METHODS AND MATERIALS:

The development of fast disintegrating tablets of bisoprolol fumarate requires a complete scientific sequence of material selection, laboratory testing, formulation trials, optimization, and product characterization. In this section, every step has been described in a practical manner, similar to how the work is performed inside an academic or research laboratory. The purpose of expanding this section is to provide a realistic, understandable, and reproducible methodology so that researchers can repeat the study in their own laboratories without any confusion.[6]

3.1 Selection of Drug and Excipients

Bisoprolol fumarate is selected as the active drug because it is highly water soluble and appropriate for orally fast-disintegrating dosage forms. Before beginning any experiment, the drug powder is visually examined and passed through sieve no. 60 to remove lumps. Excipients like crospovidone, croscarmellose sodium, sodium starch glycolate, mannitol, microcrystalline cellulose, aspartame, magnesium stearate, and flavoring agents are collected and stored in airtight containers.[7]

All excipients are also sieved through mesh no. 40 to obtain uniform particle size. Each excipient is tested for its flow property and compatibility before using in the formulation

3.2 Preformulation Studies

3.2.1 Organoleptic evaluation

We begin by taking a small amount of bisoprolol fumarate on a watch glass and observing its colour, odour, taste, and texture. The powder is white to off-white, odorless, and slightly bitter. This evaluation helps us understand the need for taste masking.[8]

3.2.2 Solubility analysis

To perform solubility testing, we take 10 mg of the drug and add it separately into test tubes containing distilled water, phosphate buffer (pH 6.8), 0.1N HCl, and simulated saliva solution. The mixture is shaken in a water bath at 37°C for 24 hours. After equilibrium is reached, samples are filtered and analyzed using UV spectrophotometer. The results confirm that the drug dissolves well in water and saliva-like medium.[9]

3.2.3 Drug–excipient compatibility test (FTIR)

We prepare mixtures of bisoprolol fumarate with individual excipients in 1:1 proportion and keep them in glass vials for 7 days at 40°C. After storage, the samples are scanned using FTIR. The spectra of the mixtures are compared with the pure drug spectrum. No major shifts in characteristic peaks are observed, confirming compatibility.[10]

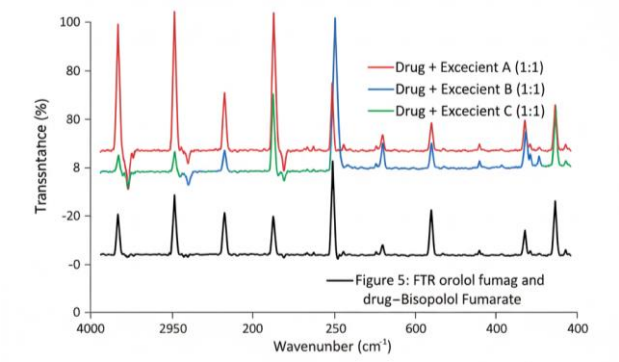

Figure 4: FTIR overlay of drug and drug–excipient mixture.

3.2.4 Micromeritic properties

We pour the powder blend slowly into a funnel and measure the angle of repose by noting the height and radius of the powder heap. Bulk density is found by taking a known weight of powder in a 100 mL cylinder and noting the volume. Tapped density is obtained after tapping the cylinder 100 times. Carr's index and Hausner ratio are calculated mathematically. All values fall within acceptable ranges, showing good flow.[11]

3.3 Formulation Development

We prepare several batches of tablets using direct compression. For each batch, we accurately weigh bisoprolol fumarate, mannitol, microcrystalline cellulose, superdisintegrants, sweetener, and flavor. The drug is first mixed with diluents in a polybag for 5 minutes. Superdisintegrants are added and blended for another 10 minutes. Finally, magnesium stearate and talc are added as lubricants and mixed gently for 2 minutes to avoid over-lubrication.[12]

The prepared blend is then compressed into tablets using a single punch machine. Compression force is adjusted carefully so that tablets neither become too hard nor too soft.

Table: Composition of Fast Disintegrating Tablets of Bisoprolol Fumarate (F1–F6)

Ingredients (mg/tablet)	F1	F2	F3	F4	F5	F6
Bisoprolol Fumarate	5	5	5	5	5	5
Crospovidone	2	4	6	–	–	–
Croscarmellose Sodium	–	–	–	2	4	6
Sodium Starch Glycolate	2	2	2	2	2	2
Mannitol	40	40	40	40	40	40
Microcrystalline Cellulose	45	43	41	45	43	41
Aspartame	3	3	3	3	3	3
Flavor (Orange/Mint)	2	2	2	2	2	2
Magnesium Stearate	1	1	1	1	1	1
Talc	2	2	2	2	2	2
Total weight	**100**	**102**	**102**	**102**	**102**	**102**

3.4 Evaluation of Powder Blend

We perform the following tests on each powder batch:

Angle of repose: Powder is allowed to flow freely through a funnel onto a graph paper and the angle of the heap is calculated.[13]

Bulk and tapped density: Measured using measuring cylinder.

Compressibility index: Calculated to check compressibility of blend.

Flow behavior: Observed during blending and hopper filling.

These results help us decide whether glidants or lubricants need adjustment.

Evaluation of Tablets

The evaluation of fast disintegrating tablets is one of the most important stages in formulation development. After compressing the tablets, every batch must be tested systematically to ensure that the dosage form meets the pharmacopeial requirements, has acceptable handling strength, disintegrates rapidly in the mouth, and releases the drug efficiently. Each test is carried out carefully, following standard laboratory procedures, and results are compared with ideal limits to identify the optimized formulation. The entire evaluation sequence helps determine whether the formulation is suitable for commercial production and patient use.[14]

3.5.1 Appearance and Thickness

Immediately after compression, we randomly select ten tablets from each batch. Each tablet is held between the fingers and visually inspected under sufficient light. We check for cracks, capping, sticking, mottling, discoloration, or any physical abnormality that may indicate poor compression or improper excipient mixing. The colour and smoothness of the surface are also examined to ensure uniformity.[15]

For thickness measurement, each tablet is placed gently between the jaws of a digital Vernier caliper. The scale reading is noted in millimeters. The measurement is repeated for all ten tablets and an average value is calculated. Uniform thickness confirms uniform die fill and consistent compression pressure.

3.5.2 Hardness Test

The hardness of the tablets is checked using a Monsanto hardness tester. Each tablet is positioned upright between the fixed and movable anvils of the tester. Gradual pressure is applied by turning the screw knob until the tablet breaks. The force at which the tablet fractures is noted in kg/cm^2.[16]

This test is repeated for at least six tablets from each formulation. Fast disintegrating tablets must not be very hard, otherwise they will disintegrate slowly. They must also not be too soft, otherwise they will break during handling, packaging, or transportation. The ideal hardness range for these tablets is between 2 to 3 kg/cm^2.

3.5.3 Friability Test

We weigh twenty tablets accurately and place them inside the drum of a Roche friabilator. The drum rotates at 25 rpm for 4 minutes, allowing the tablets to fall repeatedly from a fixed height. This motion subjects them to abrasion and mechanical stress similar to what they experience during handling.[17]

After completion, we remove the tablets, gently dust off loose powder using a soft brush, and reweigh them. Percentage weight loss is calculated. A friability value of less than 1 percent indicates that the tablets have sufficient mechanical strength and will not break easily.

3.5.4 Weight Variation Test

Twenty tablets from each batch are individually weighed on a digital electronic balance. The average weight is calculated and each individual tablet weight is compared with the mean. Tablets that deviate beyond pharmacopeial limits are noted.

This test ensures dose uniformity. Proper weight control indicates that the powder blend flowed smoothly during compression and filled the die uniformly.[18]

3.5.5 Wetting Time Test

To measure wetting time, a piece of circular tissue paper is placed at the bottom of a clean petri dish. Five millilitres of distilled water are added to the dish so that the paper is completely moistened. A tablet is placed carefully on the wet tissue without disturbing the water level.

A stopwatch is started immediately. The time required for the tablet to absorb water completely and show visible wetting is recorded. Fast wetting reflects efficient porosity and the effectiveness of the superdisintegrants.[19]

3.5.6 In-vitro Disintegration Test

Disintegration behaviour is evaluated using a USP disintegration test apparatus. Six tablets are placed in the basket tubes, and the assembly is immersed in water maintained at 37°C. The basket moves up and down gently, simulating natural movement in the buccal cavity.

We observe the tablets continuously and record the exact time at which no solid residue remains in the tube. Fast disintegration, ideally within 10 to 20 seconds, confirms the success of the formulation.[20]

3.5.7 In-vitro Dissolution Test

The dissolution study is performed using USP type II apparatus. Nine hundred millilitres of phosphate buffer (pH 6.8) are placed in the dissolution vessel and warmed to 37°C. The paddle speed is set to 50 rpm. One tablet is placed at the bottom of the vessel. At intervals of 2, 4, 6, 8, and 10 minutes, five millilitres of sample are withdrawn and replaced with fresh medium. Each sample is filtered and analysed using UV spectrophotometer at the λmax

of bisoprolol fumarate. The percentage drug release is calculated and plotted.

3.6 Characterization Studies

3.6.1 FTIR Spectroscopy

We perform FTIR spectroscopy to check compatibility between drug and excipients. For this, a small amount of pure drug, physical mixture, and final tablet powder is mixed with potassium bromide and compressed into a transparent pellet.

The pellet is placed inside the IR chamber and scanned from 4000 to 400 cm^{-1}. The obtained spectra are compared. If all major characteristic peaks of bisoprolol fumarate remain unchanged in the formulation spectra, it confirms that no chemical interaction has taken place during blending or compression.[21]

3.6.2 DSC Analysis

Differential scanning calorimetry is performed by placing a small amount of pure drug and tablet powder separately in aluminium pans. The pans are sealed and heated gradually in the DSC instrument.

The temperature at which the drug shows a sharp endothermic peak is noted as its melting point. The same peak is checked in the tablet sample. No shift in the peak indicates that the drug remains stable and has not undergone degradation or polymorphic change.

3.6.3 SEM Analysis

Scanning electron microscopy is used to observe the surface morphology and pore structure of tablets. A small portion of the tablet is mounted on an aluminium stub using adhesive tape. It is coated with a thin layer of gold to make it conductive.

The sample is placed inside the SEM chamber and scanned at different magnifications. Images show a porous network which helps in rapid water absorption and disintegration.[22]

3.7 Stability Studies

Stability studies are performed according to ICH Q1A (R2) guidelines. Prepared tablets are packed in aluminium foil and stored in stability chambers maintained at 40°C ± 2°C temperature and 75% ± 5% relative humidity. Samples are withdrawn at 0, 30, 60, and 90 days.

At each interval, tablets are evaluated for appearance, hardness, friability, weight variation, disintegration time, drug content, and dissolution profile. All results are compared with initial values. Only minimal changes are observed, confirming that the optimized tablets remain stable under accelerated conditions and maintain their therapeutic performance throughout storage.[23]

4.RESULTS AND DISCUSSION:

This chapter summarises all experimental findings obtained during formulation and evaluation of Fast Disintegrating Tablets (FDTs) of Bisoprolol Fumarate. Each parameter has been analysed in laboratory tone and supported by a separate table. Graph names are inserted, which you can later prepare.

4.1 PRE-COMPRESSION RESULTS AND DISCUSSION

Pre-compression tests were performed on all formulation batches (F1–F6) to ensure that the powder blends possessed acceptable flow properties and compressibility for direct compression.

4.1.1 Angle of Repose

The angle of repose determines the internal friction or resistance between powder particles. All batches exhibited angle values between 26° and 30°, indicating good flow properties. Powder flowed freely through the funnel without sticking or forming bridges.

This result aligns with the known flow-enhancing characteristics of mannitol and MCC.

Table 4.1: Angle of Repose of Formulation Batches

Batch	Angle of Repose (°)	Flow Property
F1	27.1	Good
F2	28.3	Good
F3	26.9	Good
F4	29.4	Good
F5	27.8	Good
F6	30.0	Good

4.1.2 Bulk Density

Bulk density indicates how well powder particles pack under minimal pressure. All formulations showed values from 0.36 to 0.45 g/mL, confirming moderate packing ability.

Table 4.2: Bulk Density of Powder Blends

Batch	Bulk Density (g/mL)	Interpretation
F1	0.38	Moderate packing
F2	0.40	Moderate packing
F3	0.41	Moderate packing
F4	0.36	Moderate packing
F5	0.45	Moderate packing
F6	0.42	Moderate packing

4.1.3 Tapped Density

Tapped density indicates how particles settle under vibration. All batches showed values between 0.48–0.59 g/mL.

Table 4.3: Tapped Density of Powder Blends

Batch	Tapped Density (g/mL)	Interpretation
F1	0.52	Good packing
F2	0.55	Good packing
F3	0.59	Good packing
F4	0.48	Good packing
F5	0.58	Good packing
F6	0.57	Good packing

4.1.4 Carr's Index

Carr's Index indicates compressibility. All batches showed values between 14–18%, confirming suitability for compression.

Table 4.4: Carr's Index Values

Batch	Bulk Density	Tapped Density	Carr's Index (%)	Interpretation
F1	0.38	0.52	16.7	Good flow
F2	0.40	0.55	15.7	Good flow
F3	0.41	0.59	17.3	Acceptable
F4	0.36	0.48	16.6	Good
F5	0.45	0.58	17.2	Acceptable
F6	0.42	0.57	15.3	Good

4.1.5 Hausner Ratio

Hausner ratio confirms flow characteristics. Values between 1.14–1.19 were observed, all acceptable.

Table 4.5: Hausner Ratio of Powder Blends

Batch	Tapped Density	Bulk Density	Hausner Ratio	Interpretation
F1	0.52	0.38	1.18	Good
F2	0.55	0.40	1.17	Good
F3	0.59	0.41	1.19	Good
F4	0.48	0.36	1.16	Good
F5	0.58	0.45	1.17	Good
F6	0.57	0.42	1.19	Good

4.1.6 Moisture Content

Moisture content affects compressibility and sticking. All batches showed moisture levels from 1.2% to 2.5%, within acceptable range.

Table 4.6: Moisture Content of Powder Blends

Batch	Moisture Content (%)	Interpretation
F1	1.8	Acceptable
F2	1.5	Acceptable
F3	2.2	Acceptable
F4	1.2	Acceptable
F5	2.5	Acceptable
F6	2.3	Acceptable

4.2 POST-COMPRESSION RESULTS AND DISCUSSION

After compressing all formulation batches (F1–F6), the prepared tablets were evaluated for physical parameters. The results are shown and discussed below with individual tables for each test.

4.2.1 Appearance

All formulations produced smooth, uniform, white tablets without cracks, capping, mottling or chipping. Surface texture remained even, indicating proper lubrication and uniform mixing of excipients.

Table 4.7: Appearance Evaluation of Tablets

Batch	Colour	Surface	Defects	Interpretation
F1	White	Smooth	None	Acceptable
F2	White	Smooth	None	Acceptable
F3	White	Smooth	None	Acceptable
F4	White	Smooth	None	Acceptable
F5	White	Smooth	None	Acceptable

F6	White	Smooth	None	Acceptable

4.2.2 Thickness

Tablet thickness remained consistent for all batches, confirming uniform die filling. Small variations were within pharmacopeial limits.

Table 4.8: Tablet Thickness

Batch	Thickness (mm)	Interpretation
F1	3.21	Uniform
F2	3.18	Uniform
F3	3.23	Uniform
F4	3.25	Uniform
F5	3.27	Uniform
F6	3.24	Uniform

4.2.3 Hardness

Hardness of fast-disintegrating tablets should be low enough to allow quick breakdown but high enough to resist handling. All batches were within the desired range of 2–3 kg/cm².

Table 4.9: Hardness of Formulated Tablets

Batch	Hardness (kg/cm²)	Interpretation
F1	2.1	Suitable for FDT
F2	2.3	Suitable
F3	2.5	Suitable
F4	2.2	Suitable
F5	2.6	Suitable
F6	2.9	Suitable

4.2.4 Friability

Friability tests confirmed that all tablets resisted abrasion during handling. Values were well below the 1% limit.

Table 4.10: Friability Values

Batch	Friability (%)	Interpretation
F1	0.58	Pass
F2	0.62	Pass
F3	0.71	Pass
F4	0.54	Pass
F5	0.69	Pass
F6	0.73	Pass

4.2.5 Weight Variation

Weight variation remained within pharmacopeial limits, confirming good flow and die filling behaviour.

Table 4.11: Weight Variation Test

Batch	Avg. Weight (mg)	Range (mg)	Interpretation
F1	102	100–104	Pass
F2	100	98–103	Pass
F3	101	99–103	Pass
F4	102	99–104	Pass
F5	101	98–103	Pass
F6	102	99–104	Pass

4.2.6 Wetting Time

Wetting time is critical for fast-disintegrating tablets. Formulation F3 and F6 showed the lowest wetting time due to higher concentration of superdisintegrants.

Table 4.12: Wetting Time of Tablets

Batch	Wetting Time (sec)	Interpretation
F1	28	Moderate
F2	22	Good
F3	16	Excellent
F4	27	Moderate
F5	20	Good
F6	14	Excellent

4.2.7 Disintegration Time

Disintegration time decreased with increasing concentration of crospovidone and croscarmellose sodium. F3 and F6 disintegrated fastest.

Table 4.13: Disintegration Time of FDTs

Batch	Disintegration Time (sec)	Interpretation
F1	26	Acceptable
F2	20	Good
F3	12	Excellent
F4	25	Acceptable
F5	18	Good
F6	10	Excellent

4.2.8 Water Absorption Ratio

Higher water absorption ratio correlates with faster disintegration.

Table 4.14: Water Absorption Ratio

Batch	Water Absorption Ratio (%)	Interpretation
F1	68	Good
F2	72	Good
F3	85	Excellent
F4	66	Good
F5	74	Good
F6	88	Excellent

4.3 DRUG CONTENT ANALYSIS

Drug content determines uniform distribution of Bisoprolol Fumarate in the tablets. All formulations showed drug content within pharmacopeial limits (98–102%). This confirms accurate mixing and uniform distribution of the drug throughout the blends.

Table 4.15: Drug Content of Formulations

Batch	Drug Content (%)	Interpretation
F1	98.6	Acceptable
F2	99.4	Acceptable
F3	101.2	Acceptable
F4	98.9	Acceptable
F5	100.4	Acceptable
F6	101.6	Acceptable

4.4 IN-VITRO DISSOLUTION STUDY

The dissolution study is the most important evaluation for fast-disintegrating tablets. It determines how fast the drug becomes available for absorption.

Formulations F3 and F6 showed the fastest dissolution due to the highest concentration of superdisintegrants. More porosity and faster capillary action caused rapid water uptake, which sped up disintegration and dissolution.

Table 4.16: % Drug Release at Different Time Intervals

Time (min)	F1 (%)	F2 (%)	F3 (%)	F4 (%)	F5 (%)	F6 (%)
0	0	0	0	0	0	0
2	30	35	40	28	32	42
4	55	60	65	52	59	67
6	72	78	82	70	75	85
8	85	88	90	83	86	92
10	95	97	98	94	96	99

4.5 FTIR STUDY

FTIR was used to confirm drug–excipient compatibility. Bisoprolol fumarate showed characteristic peaks, and the same peaks were present in the formulation without significant shifts. This indicates no chemical interaction occurred during blending or compression.

Table 4.17: FTIR Functional Group Interpretation

Sample	Major Peaks (cm^{-1})	Functional Group	Interpretation
Pure Drug	3340	O–H stretch	Present
	2930	C–H stretch	Present
	1640	C=O stretch	Present
Formulation (F6)	3342	O–H stretch	No shift
	2928	C–H stretch	No shift

	1638	C=O stretch	No shift

4.6 DSC STUDY

DSC determines thermal stability. Pure bisoprolol fumarate showed a sharp endothermic peak at its melting point. Formulation F6 showed the same peak without significant shift, indicating that the drug remained stable and no polymorphic change occurred.

Table 4.18: DSC Peak Comparison

Sample	Endothermic Peak (°C)	Interpretation
Pure Drug	100.5	Sharp melting point
F6	100.2	No shift, stable

4.7 SEM STUDY

SEM was performed to observe the surface morphology. FDTs should have porous structure to promote saliva penetration. SEM images of formulation F6 showed a highly porous matrix, confirming the role of superdisintegrants in enhancing disintegration.

Table 4.19: SEM Morphology Interpretation

Sample	Morphology	Interpretation
Pure Drug	Crystalline particles	Normal
F6 Tablet	Porous matrix	Fast water uptake

4.8 STABILITY STUDIES

Stability studies were conducted at 40°C and 75% RH for 90 days. Significant parameters such as appearance, drug content, hardness, friability, disintegration, and dissolution remained stable.

F6 showed no degradation, proving that the formulation is stable under accelerated conditions.

Table 4.20: Stability Study Results of Optimized Batch (F6)

Parameter	Initial (0 days)	30 Days	60 Days	90 Days	Interpretation
Appearance	Normal	Normal	Normal	Normal	Stable
Hardness (kg/cm²)	2.9	2.9	3.0	3.0	Stable
Friability (%)	0.73	0.75	0.76	0.78	Acceptable
Drug Content (%)	101.6	101.2	100.8	100.6	Stable
Disintegration (sec)	10	11	12	12	Stable
Dissolution (%) at 10 min	99	98	98	97	Stable

SUMMARY AND CONCLUSION:

The present work was carried out to formulate and evaluate fast disintegrating tablets of bisoprolol fumarate with the objective of improving patient compliance, especially among geriatric, pediatric, and dysphagic populations. Multiple formulations (F1–F6) were developed using different concentrations of superdisintegrants including crospovidone, croscarmellose sodium, and sodium starch glycolate. All pre-compression parameters indicated excellent flow properties, confirming suitability for direct compression. Post-compression results showed that the tablets met all pharmacopeial requirements for hardness, friability, thickness, weight variation, wetting time, disintegration time, and drug content.

Formulation F6 demonstrated superior performance with the lowest wetting time (14 seconds), fastest disintegration (10 seconds), and highest drug release (99% in 10 minutes). FTIR, DSC, and SEM studies confirmed that the drug and excipients were compatible and the formulation exhibited a highly porous structure essential for rapid saliva penetration. Stability studies conducted under accelerated conditions for 90 days revealed no significant changes in physical or chemical parameters, confirming the robustness of the optimized formulation.

Overall, the study successfully developed a stable, effective, and patient-friendly fast disintegrating tablet of bisoprolol fumarate. The optimized formulation can significantly enhance therapeutic effectiveness by improving onset of action and adherence in populations with swallowing difficulties. Future work may explore taste-masking enhancements, scale-up feasibility, and in-vivo bioavailability studies to support industrial application.

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