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Research Article

Development and Evaluation of Azilsartan Medoxmil Novel Fast Dissolving Tablet Using Magnesium Aluminium Silicate for the Treatment of Hypertension

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ABSTRACT

In the current study, magnesium aluminium silicate, microcrystalline, and cellulose crospovidone will be used to make fast-dissolving tablets of azilsartan medoxomil 40 mg. The effects of each material at various concentrations will be compared, and the best formulation will be created. The preparation of 8 formulations will involve the use of various super disintegrants at various concentrations. Formulation F-6, which contains the following ingredients: drug (40 mg), Mg-Aluminium Silicate (12 mg), crospovidone 15 mg, MCC (75 mg), mannitol (87 mg), Sodium Starch Glycolate (15 mg), and magnesium stearate (6 mg), showed the best disintegration time within 14 seconds. Among these, formulation F-8 showed the maximum effect. Studies on in vitro dissolution revealed that the formulation F6 provided he highest within 8 minutes, the medication was released to its fullest extent (98.96%). Utilizing magnesium aluminium silicate to reduce acidity, relieve heartburn, and improve patient compliance. For the formulation F-6, stability investigations are also carried out. For this formulation, tests on a number of physio-chemical parameters produced positive outcomes. The innovative formulations are capable of avoiding first-pass metabolism and has a speedier onset of effect, according to the findings of the release research.

Keywords: Fast dissolving tablet, Azilsartan Medoxomil, Magnesium Aluminum Silicate.

INTRODUCTION

Oral Routes Drug Delivery System:

The highest mode of transport of all dosage types, oral administration accounts for up to 50–60%, which are well accepted. Solid dosage forms are preferred because they are simple to administer, precise in their amount, allow for self-medicating alleviate suffering, and, to decrease discomfort, prevent self-medication, and most significantly, boost Patient adherence. Tablets and capsules are the two most widely used solid dose forms; yet, for some individuals, these dosage forms are challenging to swallow. Water consumption is crucial to successfully ingesting oral dose forms. Many people find it difficult to take traditional dosage forms like tablets when water is not available, when they get motion sickness (kinetics), or when they suddenly start coughing due to a cold, an allergy, or bronchitis.

Oral administration is the most typical mode of dosage since it is simple to consume, pain-free, versatile (to accommodate a variety of medication options), and most importantly, patient-compliant. Additionally, since they are not necessarily manufactured under sterile circumstances, solid oral administration devices are less expensive. Recently, several innovative oral administration techniques have made able to address the pharmacokinetic and physicochemical properties of medications while enhancing Patient adherence. Additionally, recently developed technologies include computer assisted 3DP: three-dimensional printing tablet production and electrostatic drug deposition and coating.

For juvenile and elderly patients who have usual swallowing difficulties oral solid-tablets are examples of dose types, capsules, and syrups, distribution of drugs that dissolve quickly devices were initially created late around the 1970s. Oral fast-dispersing dose forms, a revolutionary technique referred as quickly disintegrate, quickly melt, and quickly dissolve pills. However, all of these dosage forms share a similar purpose and conceptual framework.[1,2]

A fast-acting oral dose form is a way to administer medicines that, by definition, quickly disintegrates or dissolves in the mouth to produce a solution or suspension without the need to administer water. Dysphagia, or trouble swallowing, affects people of all ages, but it is more prevalent among the elderly. It also affects people who take regular tablets and capsules. Many medical illnesses, such as AIDS, a stroke, and Parkinson's, thyroid cancer, radiation treatment for the head and neck and other neurological conditions like a cyptic palsy, are linked to dysphagia. Tablet size was the most often mentioned issue, followed by surface, form, and flavour. Patients with geriatric and paediatric conditions, as well as those who were. When traveling, having access to water may be difficult, had more difficulty taking tablets.[3,4]

These factors have led to a lot of interest in drugs that can quickly disintegrate or disappear in the mouth. Or dispersible pills are recommended for active people in addition to those who have trouble swallowing. Fast-dissolving pills are also known as melt-in-your-mouth pills, Oro dispersible pills, Rapi melts, porous pills, quick-dissolving pills, like, when placed fast-acting pills that

dissolve on the tongue instantly dissolve, releasing the medication that will dissolve or disperse in the saliva.[5] Saliva enters the stomach as it flows, several drugs are taken in through the mouth, throat, and the oesophagus. The quicker a drug enters solution, the accelerated absorption and beginning of clinical impact. In these circumstances, the drug's bioavailability is substantially higher than what is often seen with dosage forms of regular tablets. Academics and industry are increasingly recognizing the benefits of mouth-dispersing dose formulations.[6]

Recent adoption of the phrase "Orodispersible tablet "as published by the European Pharmacopoeia designates a tablet to be dissolved quickly in the mouth before being swallowed, serves to highlight their expanding significance. Less than three minutes should pass before the ODT disperses or breaks up, per European Pharmacopoeia. Utilizing superdisintegrants such cross-linked carboxymethyl cellulose, sodium starch glycolate, polyvinylpyrrolidone, etc., is the primary method for producing FDT. They allow tablets to instantly dissolve when placed on the tongue, releasing the drug in saliva. The oral cavity and pregastric absorption of saliva containing certain drugs may increase their bioavailability scattered medications that enter into the stomach. Even more so, the dosage of the medicine that the first pass metabolism is lower than with a regular pill. Fast-dissolving tablets are made using the techniques of tablet compression, sublimation, sugar-based excipients, freeze-drying, spray-drying, tablet molding, and addition. The elderly now make up a sizable segment of the world's population as a result of longer life expectancies. These people's physiological and physical capabilities will gradually deteriorate.

Tablets:

The best dose plan for treating any condition with medication is one that quickly achieves the targeted therapeutic medication level at the point of activity, in plasma, and keeps it there during the whole course of therapy. This is accomplished by administering a standard dosage form in a certain dose and on a regular basis. Therefore, a medicine may be supplied using a variety of routes and dose formulations. The more typical way to administer medication is orally. Although the majority of oral drugs are ingested, a small minority are made to dissolve in the mouth. When compared to other the most popular and has been utilized successfully for the traditional delivery of medications is the oral route. It is recognized as the most organic, easy, useful, and secure way to provide drugs. Additionally, it provides greater design flexibility for dose forms, is natural, and costs nothing to make. Various pharmacological dose forms are used to give medications orally. Tablets, capsules, suspensions, and various pharmaceutical solutions are the most often used. Solid dose forms are the most popular type of medication among those that are taken orally. They are adaptable, adjustable in dosage strength, reasonably stable, pose fewer formulation and packaging issues, and are simple to produce, store, handle, and utilize. The medicine is better protected during shipment in solid dosage form against light, temperature, humidity, oxygen, and stress19. Tablets are a common form of solid oral dose.[7]

Benefits of Tablets:

The following are some potential benefits of tablets.

- They are the oral dosage form unit with the best capabilities for dose accuracy and the least amount of content fluctuation.
- They are the least expensive oral dose forms
- They are the most portable and lightweight oral dose form available.
- They are the simplest and least expensive to transport and package.
- They suit some products with unique release profiles, such enteric or delayed release products.
- When compared to other unit oral dose forms, tablets are more suitable for mass manufacture.
- They display the finest combination of chemical, mechanical, and microbiological stability of all oral dosage forms.

The drawbacks of tablets:

- it is challenging to incorporate a highly efficient, insufficiently compressible API into a tablet safe for human ingestion.
- A medication with poor wettability and sluggish disintegration is challenging to manufacture into a tablet.
- A slower onset of effect than parenterals, liquid oral medications, and capsules.
- There is relatively little liquid medication (such as simethicone or vitamin E) that can be contained inside a tablet.
- Difficult for children, the terminally ill, and elderly patients to swallow.
- Patients receiving radiation therapy are unable to swallow tablets.

Fast-dissolving medication delivery system concept:

Fast-Acting delivery of drugs Method was conceived as a way to give patients access to traditional drug administration methods. Dysphasia, or difficulty swallowing, is a common issue among patients of all ages due to physiological changes linked with, particularly, aging and pediatric patients, geriatrics and pediatrics populations, as well as those Patients who like easily swallowable medications dose forms, can benefit significantly from solid dose forms for oral medications fragmented, Saliva in the mouth dissolves or suspends food. When placed on the tongue, this tablet instantly

dissolves, releasing the medication in saliva that dissolves or disperses.[8]

Pharmaceutical treatments for elderly individuals have recently been looked into to increase their treatment compliance and quality of life. Rapidly dissolving tablets are an appealing dosage form and patient-focused pharmaceutical preparation that can quickly dissolve in saliva.[9]

The mouth-dissolving tablets have attracted the attention of several researchers. Many older people find it difficult to swallow tablets, pills, and powders. To address this problem, these pills are made to dissolve or disintegrate in the mouth without the use of water. Saliva helps the dissolved material travel down the oesophagus smoothly so that even those with swallowing or chewing issues can easily absorb it.[10]

whereas the other tablet formulation may easily be dissolved in water to create a dispersion, making it easy for the patient to consume.[11] Dispersible tablets come in two different

variations that need to be acknowledged varieties that need to be acknowledged. Particularly in young patients, the decent mouth feelcharacteristic helps to alter how people view drugs as an unpleasant tablet. A single dose form dissolves instantaneously in the tongue so that it can be consumed without being chewed.

By removing physical barriers, the usual formulation's oral administration reduces the possibility of choking or suffocating., boosting safety.

Fast-dissolving Drug Delivery System Requirements:

Without the need for water to be swallowed, the pills should instantly dissolve or disintegrate in the mouth. accept taste masking with grace. Be flexible and unafraid to break. Feel pleasing in your mouth. little to no aftertaste should remain after oral delivery. low environmental sensitivity elements like Thermodynamics and humidity Let the tablet be to be produced at a low cost using common processing and packaging equipment.

The key characteristic of a fast-acting drug delivery system is:

Simplicity of treatment for mental illness ill, handicapped, and uncooperative patients.

- Don't need water.
- The unpleasant taste of the medications is over.
- Can be made to leave little to No aftertaste left behind ingestion while yet feeling good in the mouth.
- Capability of delivering liquid medicinal benefits in the form of an effective formulation; adaptable to and compatible with current packaging and processing techniques methods.
- Reasonably priced
- some medicines are taken by mouth, throat, and oesophagus with rapid dissolving and absorption, producing a speedy onset of action varieties that must be recognized. One dosage form dissolves instantly in the tongue so that it can be eaten without Especially in pediatric patients, the decent mouth feel feature helps to modify how people view medicine as an unpleasant tablet.
- The risk of choking or suffocation is decreased by minimizing physical obstacles during administering via mouth the conventional formulation, increasing safety.
- A higher bioavailability as a result of the tablets' quick breakdown and dissolving, especially in the case of insoluble and hydrophobic medicines. Stability over a longer period of time because the medication is ingested in solid dose form.[11]

Fast-Dissolving Tablet Benefits:

- Fast dissolving tablets (FDTs) are unit dose forms that are solid with high drug loading and precision dosing. They are also an excellent dose option for elderly and pediatric patients and a great replacement for traditional tablets.
- It causes fast action as soon as the person takes it, starts melting as it involves contact with saliva, quickly absorbs within the mouth, and quickly melts.
- The bioavailability of the medications is altered by pregastric absorption, and fewer dosages are needed, which alters patient compliance and clinical reports.
- Fast-dissolving tablets are ideal for people on the go and conscientious people who don't always have access to water because they dissolve quickly in the mouth and may be taken anytime, anywhere. As a result, patient compliance is improved.
- Due to their solid unit dosage form, they are exceedingly simple and practical to administer, making them especially useful for elderly, juvenile, recalcitrant, and people with dysphasia. Fast-dissolving pills are extremely safe and easy to use because there is no danger of physical impediment obstructing the airways during swallowing
- Tablets that dissolve quickly have few leaves and completely dissolve in the tongue without leaving any trace, giving the tablet a pleasing mouthfeel and enhancing its palatability.
- Fast-dissolving tablets are particularly stable because they are less sensitive to environmental factors.
- Fast-dissolving tablets are inexpensive because they are packaged in straightforward blister packing rather than in special, pricey packaging.
- Fast dissolving tablets open up potential business opportunities for line expansion, product diversification, product promotion, life cycle management and uniqueness.

- Tablets that dissolve quickly save money because they don't need expensive ingredients. Natural polymers can be packaged in straightforward blister packs and are readily and inexpensively available when used as excipients. They do not require specific packaging materials.
- They are a multifaceted field of technology since they are used to create veterinary, over-the-counter (OTC), and prescription (Rx) medications
- They require no water to be swallowed and are easily portable because They are reliable dose form that has lower environmental sensitivity.[12,13]

Limitations of Mouth Dissolving Tablets:-

The mechanical strength of the tablets is typically insufficient. As a result, careful handling is necessary. If the tablets are not made properly, they may leave a bad taste and/or a metallic taste in the tongue.

MATERIALS AND METHODS

Azilsartan Medoxomil was obtained as a gift sample from New Delhi's Care Formulation Labs Pvt. Ltd., Narela. Magnesium Aluminium Silicate from TIPER Meerut and Microcrystalline Cellulose from Kayel medichem pvt ltd delhi. Crospovidone, Mannitol, Talc and Magnesium Stearate from TIPER Meerut, Sodium Starch Glycolate from sigma Aldrich.

Preparation of Fast Dissolving Tablets of Azilsartan Medoxomil:

AzilsartanMedoxomil-containing Tablets that dissolve quickly were made using the method of direct compression by Using a mortar and pestle, a compound containing 40 mg of azilsartan medoxomil and polymers including magnesium aluminium silicate, crospovidone, microcrystalline cellulose, mannitol, and sodium starch glycolate was well blended. The Super disintegrants were used in various ratios and combinations. With the exception of magnesium stearate, all the ingredients were weighed and blended well according to the specification. The mixture was then run through sieve number 60, which was used to assess the flow qualities. Magnesium stearate is then added to the powder and excipient mixture after it has been blended for 5 minutes. 9.5mm flat punches with a break line were used in an eight-station tablet punching machine to compress the mixed mixture. The remaining four punches in the 9.5mm station compressor are fitted with dummy punches, and four are fastened with die cavities.[14,15]

Table 1: Composition of Azilsartan Medoxomil Fast Dissolving Tablets

Ingredients	Quantity for tablet(mg)						
	F1	F2	F3	F4	F5	F6	F7
Azilsartan Medoxomil	40	40	40	40	40	40	40
Mg-Aluminum Silicate	2	4	6	8	10	12	14
Crospovidone	5	10	15	5	10	`15	5
Micro-crystalline Cellulose	75	75	75	75	75	75	75
Mannitol	89	88	87	89	88	87	90
Sodium Starch Glycolate	2.5	5	7.5	10	12.5	15	17.5
Magnesium stearate	2	4	6	2	4	6	2
Talc	2	2	2	2	2	2	2

Test variables for compressed tablets:

Tablet abrasion:

A Monsanto abrasion Tester was used to gauge the tablet's ability to be crushed. The Monsanto hardness test apparatus's fixed and moving jaws are used to hold the test tablets, and the examining the indicated tabletsthe value zero. The screw knob was advanced until the tablet broke, at which point the force needed to do so was recorded. Each formulation batch's three pills were tested at random, and the average reading was noted.[16]

Tablet Thickness:

Five fast-dispersing tablets were intentionally utilized, and the average Using a Vernier calliper, thickness was measured.[17]

Friability:

Using a Roche Friability tester, the friability of the tablet served as a stand-in for estimating solidity. 20 tablets are first ingested, and then they are carefully weighed and placed in the Friability tester. The tester was run up to100 times, or for 4 minutes at 25 rpm. The formula below merited % damage in mass friability

F = Initial wt. - Final wt./Initial wt × 100 ……. (2.7)

Weight Dispersion:

This procedure uses a weight-based several tablet types. There were 20 pills weighed (grams) individually on an electronic balance. then determined the average tablet weight and looked for variations in tablet weight.

% weight deviation calculation:

% Variation = Individual wt. - Average wt./Average wt × 100 ……. (2.8)

Wetting Time:

A small Petridis measuring 6.5 cm in diameter anda piece of tissue paper folded twice is placed inside the container, which is 6 ml of water. On top of tissue paper, a pre-weighed pill was put, and it was given time to soak up all the water. The amount of time that it took for water to completely wet the tablet's upper surface was recordedas the time of wetness. After that, the wet weight of the pill. The following equation was used to obtain the water absorption ratio R.[18]

$$R = Wa\text{-}Wa/Wb \; X \; 100 \quad \ldots\ldots \quad (2.9)$$

Where,

Wb - Weight of tablet before wetting.

Wa - Weight of tablet after wetting.

Disintegration Test:

The disintegration apparatus was used for the tablet study. Six tubes in the basket were filled with one tablet each, and there was a basket rack placed for one-liter beaker of water that was set to 37°C (2°F). The apparatus was run until the tablets were totally destroyed.

In-vitro Dissolution Studies:

Using a dissolve test device (electro lab) at 50 rpm, an in-vitro dissolution study was carried out. As a 900 cc of phosphate buffer, pH 6.8, was used as the dissolving medium utilized at a 2-min time interval and was filtered. By measuring the sample's absorbance at Selegiline at 252 nm in phosphate buffer at pH 7.4 using the UV spectroscopy method, the amount of medicine that was dissolved was calculated using a UV spectrophotometer (Shimadzu 1800, Japan). A precise amount of the dissolving medium (5 ml), which was kept at 37.50 °C, was removed. The following method was used to calculate the in vitro dissolution rate for each formulation throughout the investigation.[19]

Dissolution parameters:

Equipment used - Electro lab.

Temperature - 37± 0.50C

RPM - 50 rpm

Volume withdrawn - 5ml for 5 minutes

λ max - 252nm

Stability studies:

According to ICH guidelines, stability tests of the optimized formulation were conducted. For 90 days, the right formulation was tested for stability at 40°C and 75°RH. After that time, the product's colour, hardness, In-vitro release and disintegration time were assessed.[20]

RESULTS AND DISCUSSION

Preformulation Studies:

Melting Point:

A melting point apparatus was used to ascertain the melting point of Azilsartan Medoxomil, which was discovered to be..

Parameter	Standard	Observed
Melting Point	160℃-161℃	159-160℃

Solubility:

Azilsartan Medoxomil's solubility in various solvents was examined.

Table 2: Determination of drug solubility in various solvents

S. No.	Solvent	Descriptive Term
1	Alcohol	Soluble
2	Water	Slightly Soluble
3	Dimethyl Formamide	Soluble
4	Dichloromethane	Soluble
5	Benzyl alcohol	Not very Soluble
6	Phenolic	Not very Soluble

Standardization of Drug:

UV Spectrophotometric Method for Azilsartan Medoxomil:

The calibration curve for azilsartan medoxomil in phosphate buffer at pH 6.8 is shown in the table. The UV technique was used to evaluate the medication quantity. The standard solution of azilsartan medoxomil, with a concentration of 0–7 g/ml in a medium, produced relationship in a straight line as shown in Fig. The calculated coefficient for the phosphate buffer at pH 6.8 in a straight line is shown in Fig.

Table 3: Standard calibration curve of Azilsartan Medoxomil in pH 6.8 phosphate buffer

S. No.	Conc.(µg/ml)	Abs.at 264nm
1	0	0
2	5	0.308
3	10	0.382
4	15	0.454
5	20	0.564
6	25	0.622
7	30	0.748

IR Spectra of Pure Drug:

Pure FTIR spectrum data drugs with various polymers employed in formulation are shown in the figures under "IR Spectra of Pure Drugs.

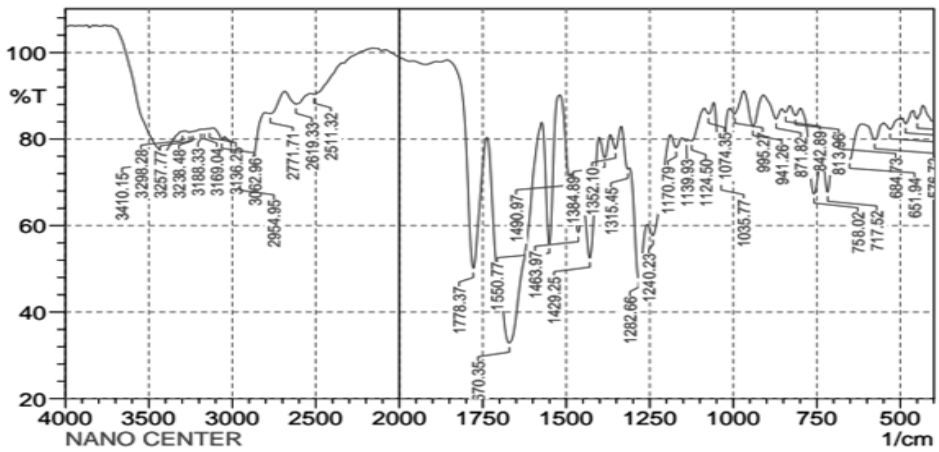

Figure 1: FTIR Spectrum of Azilsartan Medoxomil

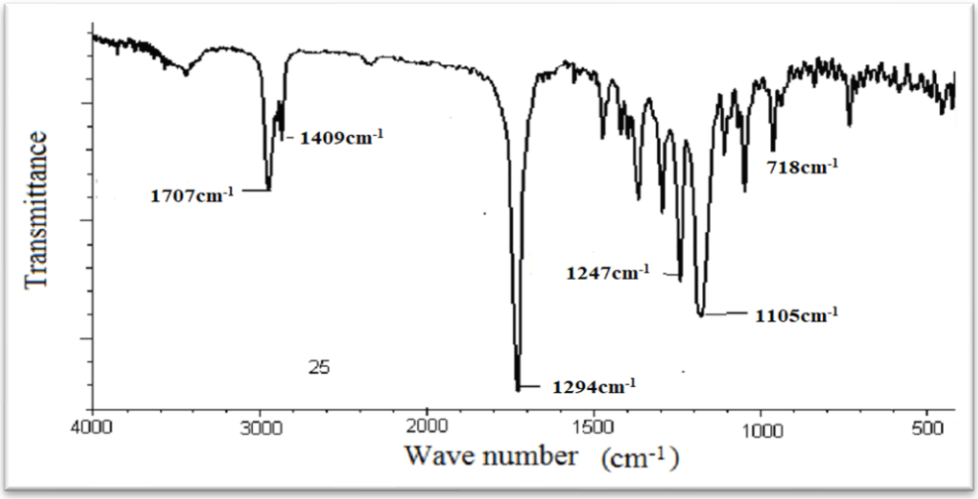

Figure 2: FTIR Range of a Pure Drug+ Magnesium Aluminum Silicate

DISCUSSION

FTIR spectrum:

The formulation's IR spectra showed that there was little to no evidence of a drug-polymer interaction. Peaks of both drugs were observed to be identical, as were their formulations. This strongly shows that the drug did not interact with the polymer during formulation because there was no change in the locations of the medication's distinctive absorption bands in the composition.

DSC, or differential scanning calorimetry:

A precise melting start temperature is provided by DSC. The DSC thermograms of Azilsartan Medoxomil and Microcrystalline Cellulose while Azilsartan Medoxomil had an endothermic peak at 280.48°C, which corresponds the Polymer until its melting point had a peak at 330.62°C. The identification of a novel phase is supported by the finding that the endothermic peaks of the drug and the polymer differ in co-crystals.

Micrometry Study:

Before beginning the formulation process, the medication powder components and other excipients used to make Azilsartan Medoxomil Fast Dissolving the physical and flow characteristics of the tablets were evaluated. These characteristics included Angle of repose, Carr's index, bulk density, tapering density, Hausner's ratio, and Carr's index. The results are shown in the Table and were in line with predictions.

Hardness:

The hardness ratio was found to range from 3.60 to 0.35 to 3.86 to 0.20, the thickness ratio from 2.72 to 0.22 to 2.79, and the friability ratio from 0.31 to 0.22 to 0.68, showing potential assessment feature.

A weight difference was discovered to range from 186.42 to 199.26, and the tablet wetting time ratio was found to range from 24.86 to 94.46 for all batches, pointing to potential assessment properties.

Water absorption:

The Water Absorption was found 28.5± 1.52 to 40.41± 2.0 and Disintegration time (Sec) 12 to 17 for each batch, showing potential assessment properties.

For all batches the Uniform Drug Content ranged from 96.56 1.20 to 98.76 1.18, indicating potential evaluation properties**.**

Table 4: Results of derived and flow properties

	Derived Properties		Flow Properties		
Formulation Code	**Bulk Density (mean±SD)**	**Tapped Density (mean±SD)**	**Angle of Repose (mean±SD)**	**Carr's Index (mean±SD)**	**Hausner's Ratio (mean±SD)**
F1	0.28±0.02	0.26±0.014	34.2±0.4	12.42±1.95	1.15±0.04
F2	0.26±0.010	0.25±0.012	33.3±0.3	13.20±1.92	1.14±0.02
F3	0.27±0.012	0.27±0.011	30.4±0.10	10.47±3.94	1.16±0.04
F4	0.29±0.011	0.30±0.010	34.3±0.08	13.02±1.78	1.14±0.03
F5	0.24±0.04	0.28±0.014	38.01±0.09	14.87±2.20	1.12±0.04
F6	0.25±0.02	0.29±0.007	36.07±0.07	12.38±3.11	1.14±0.06
F7	0.23±0.025	0.27±0.025	29.9±0.15	10.46±1.19	1.12±0.02

Test variables for compressed tablets:

Table 4: Evaluation of Compressed Azilsartan Medoxomil Fast Dissolving Tablets

Formulation Code	Hardness (Kg/cm^2)	Thickness (mm)	Friability (%)	Weight variation Average wt. in (mg)	Wetting Time (Sec)
F1	3.60±0.35	2.72±0.22	0.31±0.22	186.42	12.3
F2	3.10±0.50	2.24±0.12	0.44±0.13	190.51	11.4
F3	2.98±0.61	2.76±0.03	0.68±0.13	200.48	9.3
F4	4.03±0.68	2.78±0.02	0.52±0.21	196.47	15.1
F5	4.15±0.36	2.42±0.06	0.58±0.14	202.48	12.5
F6	4.25±0.20	2.76±0.14	0.74±0.14	198.50	10.4
F7	3.86±0.20	2.79±0.04	0.68±0.14	199.26	14.5

Values are intimate as design ± SD (n = 3)

Table 5: Evaluation Parameters of Water Absorption & Disintegration time (Sec)

Formulation Code	Water Absorption	Disintegration time (Sec)	Drug Content Uniformity
F1	28.5± 1.52	16	96.56±1.20
F2	32.5± 1.52	15	97.86±1.90
F3	32.5± 2.0	13	98.24±1.86
F4	30.94± 1.12	15	96.78±1.35
F5	39.28± 1.23	12	97.96±1.25
F6	38.16± 1.21	14	99.86±1.18
F7	40.41± 2.0	17	98.76±1.18

Values are intimate as design ± SD (n = 3)

Table 6: Release Studies F1-F7

Time/Mins	% Release Drug						
Formulation	**F1**	**F2**	**F3**	**F4**	**F5**	**F6**	**F7**
0.5	41.75±2.4	40.30±0.28	46.65±0.24	46.04±0.96	47.40±0.72	48.42±1.30	42.42±1.30
1	46.56±2.2	45.55±0.99	54.46±0.48	52.52±1.33	56.85±0.88	57.78±1.25	54.78±1.25
2	51.78±2.3	54.04±0.90	59.52±0.76	63.13±1.28	60.58±1.24	63.47±1.20	60.47±1.20
3	59.25±0.2	60.56±0.36	65.32±0.82	69.49±1.22	67.44±1.45	75.89±1.18	72.89±1.18
4	66.52±0.5	69.78±1.25	76.70±0.91	72.21±0.98	77.98±1.20	87.45±0.78	82.45±0.94
5	76.48±0.8	78.65±1.09	79.46±0.52	78.16±0.88	80.43±1.40	92.25±1.77	88.45±0.76
6	84.89±0.3	85.44±1.17	86.24±0.78	88.29±0.68	88.78±1.48	95.67±1.57	94.45±1.24
8	92.34±0.9	93.13±1.18	90.76±0.34	94.90±0.48	96.38±1.26	98.96±0.82	97.45±1.82

Points are communicate as mean ±standard deviation (n = 3)

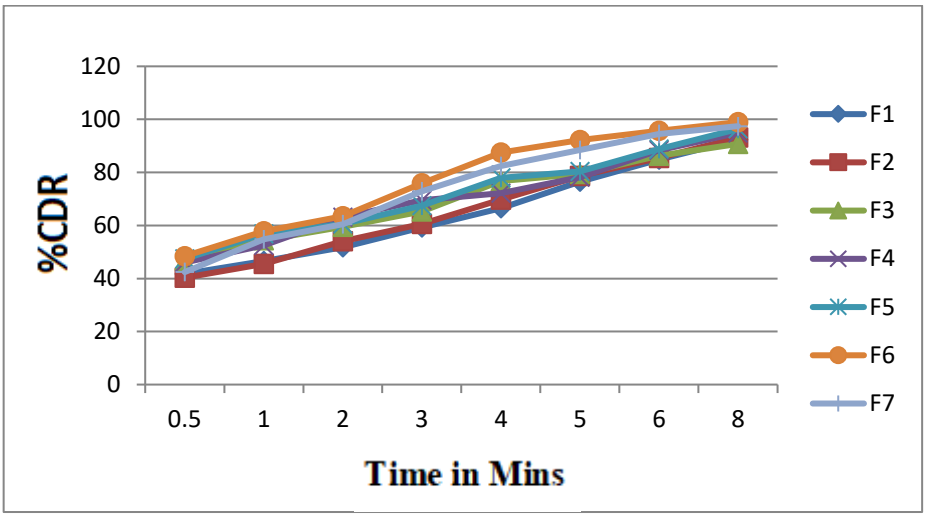

Figure 3: % Release Drug Represented Diagramatically

Table 7: Study of Stability for the Best Formulation F6

S. No.	Parameters	Initial	1 Month	2 Months	3 Months
2	Hardness	4.25±0.20	4.64±0.30	4.90±0.74	5.05±0.14
3	Friability	0.74±0.14	0.72±0.14	0.65±0.14	0.60±0.15
4	*In-Vitro* Drug Release	98.96±0.82	98.90±0.76	98.68±0.22	98.10±0.34
5	Drug Content Uniformity	99.86±1.18	99.81±1.12	99.10±1.09	98.90±1.11
6	Water Absorption	38.16± 1.21	38.12± 1.20	37.01± 1.09	37.50± 1.00
7	*In-vitro* drug release	98.96±0.82	98.90±0.76	98.46±0.20	98.00±0.10

***In-Vitro* Drug Release Studies:**

The in vitro drug release investigation's Formulations F1 through F7 were successfully completed. F6's formulation pharmaceutical release time of 8 minutes for 98.96% of patients was found to be the most efficient when compared to another formulation.

Stability Studies:

Based on the results it was Formulation F6 judged the seven formulas to be the most effective. As a result, stability tests on formulation F6 were carried out. For Formulation F6, Drug Content, In Vitro Drug Release, and Percentage Yield, and water absorption were assessed every month for up to three months. The Formulation 6 stability studies were conducted over a 90-day period, and while there are some small differences in the homogeneity of the drug content, hardness, friability, and in vitro drug release, and water absorption, all data were evaluated in accordance with ICH guidelines at 40°C and 75% RH.

CONCLUSION

Pre-formulation studies are conducted on the pharmaceutical ingredient Azilsartan Medoxomil, which includes a study on the drug's compatibility with excipients. The results with particular excipients revealed the drug's compatibility with Azilsartan Medoxomil. Using Mg-Aluminum Silicate, Crospovidone, and Microcrystalline Cellulose as super disintegrates, fast-dissolving tablets of Azilsartan Medoxomil 40mg are created in the current study. The effects of each ingredient at various concentrations are compared, and the best formulation is finally reached. Seven alternative formulations are created by varying the concentrations of various super disintegrant. The formulation F-6, which comprises the medication (40 mg), crospovidone (15 mg), MCC (75 mg), Mg-Aluminum Silicate (12 mg), Sodium Starch Glycolate (15 mg), and magnesium stearate (6 mg), is chosen as the best formulation among them due of its amazing mouth feel. For the formulation F-6, stability investigations were also carried out. When different physico-chemical parameters were examined for this formulation, the results were promising. According to the results of the release study and mathematical simulations, the innovative formulation can avoid the first pass metabolism and result in a speedier onset of action.

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