



# Development and Evaluation of Eprosartan Immediate Release Tablet Physical Characterization and in Vitro Drug Release Studies

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## ABSTRACT:

A chronic cardiovascular disease, hypertension is one of the main causes of morbidity and death globally. Although eprosartan mesylate, a selective angiotensin II receptor blocker (ARB), is frequently recommended to treat hypertension, its low oral bioavailability (about 13%) and poor water solubility limit its clinical efficacy. Eprosartan mesylate immediate-release mouth dissolving tablets (MDTs) were developed and evaluated in this study in order to increase the drug's rate of dissolution, boost its bioavailability, and guarantee a prompt commencement of therapeutic activity. The suitability of drug–excipient combinations was confirmed by preformulation tests that included organoleptic characteristics, melting point, and solubility, loss on drying, partition coefficient, UV spectroscopic analysis, calibration curve development, and FTIR compatibility investigations. Using crospovidone as a superdisintegrant in different doses, MDTs were created using the direct compression approach. Mannitol, microcrystalline cellulose, sodium saccharin, HPMC, talc, and magnesium stearate were also used. While the prepared tablets were assessed for hardness, thickness, friability, weight variation, drug content uniformity, wetting time, water absorption ratio, and in vitro drug release, the powder blends were subjected to precompression parameters like angle of repose, bulk density, tapped density, Carr's index, and Hausner's ratio. When compared to traditional dose forms, optimised formulations demonstrated much better dissolving behaviour and quick disintegration within 30 seconds. While stability experiments carried out in accordance with ICH recommendations showed that the formulations were stable without any discernible changes in physicochemical attributes, FTIR analysis verified that there were no significant drug–excipient interactions. According to the study's findings, eprosartan mesylate mouth-dissolving tablets present a viable substitute for traditional tablets, enhancing patient adherence, treatment effectiveness, and the general control of hypertension.

## 1. Introduction:

### 1. 1 Hypertension

Hypertension or high blood pressure, is a very common and serious condition that can lead to or complicate many health problems. The risk of cardiovascular morbidity and mortality is directly correlated with blood pressure. Risks of stroke, MI, angina, heart failure, kidney failure or early death from a cardiovascular cause are directly correlated with BP. [1] Hypertension is often called "the silent killer" because it generally has no symptoms until

serious complications develop. There are three general types of hypertension. Essential or primary hypertension occurs when the condition has no known cause [2]. This form of hypertension cannot be cured, but it can be controlled. More than 90% of individuals with hypertension have essential hypertension. Genetic factor may play an important role in the development of essential hypertension. When hypertension is caused by another condition or disease process, it is called secondary hypertension. Fewer than 10% of patients have secondary hypertension; where either a co-morbid



disease or drug is responsible for elevating BP. In most of these cases renal dysfunction resulting from severe chronic kidney disease or renovascular disease is the most common secondary cause. Hypertension has a variety of causes. Blood pressure generally tends to rise with age. Hypertension can also be caused by other medical conditions, such as thyroid disease or chronic kidney disease. Hypertension may also be a side effect of certain medications, such as over-the-counter cold medications and oral contraceptives and other hormone drugs.

Hypertension is defined as abnormally high blood pressure (more than 120/80 mm Hg) in the arteries [3]. Persistent increase in systemic arterial blood pressure is known as hypertension. Usually a mean arterial pressure greater than 110 mm Hg under resting conditions is considered to be hypertensive; this level normally occurs when the diastolic blood pressure is greater than 90 mm

Hg and the systolic pressure is greater than about 135-140 mm Hg.

## 1.2 Mechanisms of Hypertension

The mechanisms underlying hypertension are multifactorial, involving various physiological systems, including the cardiovascular, renal, and neuroendocrine systems. Factors such as increased sympathetic nervous system activity, renal sodium retention, and dysregulation of the renin-angiotensin-aldosterone system (RAAS) contribute significantly to the pathogenesis of hypertension [4, 5]. Given its widespread prevalence and associated health risks, hypertension remains a major public health challenge, necessitating ongoing research and effective management strategies.

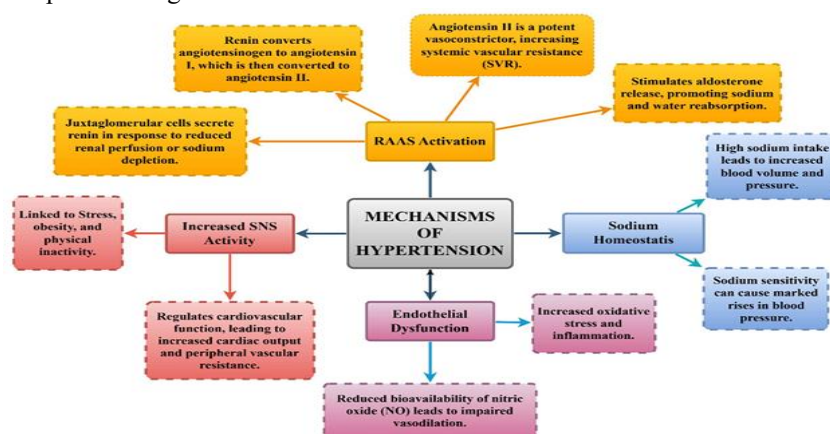


Figure 1. Mechanisms of hypertension

## 1.3 Pathophysiology of hypertension

The pathophysiology of hypertension is complex and multifactorial, involving genetic, environmental, and lifestyle factors. The regulation of blood pressure is primarily mediated by the interplay between the autonomic nervous system, the renin-angiotensin-aldosterone system (RAAS), and the kidneys [6].

- **Genetic Factors:** Genetic predisposition plays a critical role in the development of hypertension. Family history of hypertension significantly increases the risk of developing the condition, suggesting that multiple genes contribute to blood pressure regulation.
- **Environmental Factors:** Environmental

influences, such as high sodium intake, obesity, physical inactivity, and excessive alcohol consumption, are well-established contributors to hypertension. Sodium retention leads to increased blood volume, which elevates blood pressure.

- **Hormonal Regulation:** The RAAS is a key regulator of blood pressure. Renin, released from the kidneys, converts angiotensinogen to angiotensin I, which is subsequently converted to angiotensin II by angiotensin-converting enzyme (ACE). Angiotensin II is a potent vasoconstrictor that raises blood pressure by increasing systemic vascular resistance and stimulating aldosterone secretion, leading to sodium and water retention.



- **Sympathetic Nervous System:** Increased sympathetic nervous system activity contributes to hypertension by promoting vasoconstriction and increasing heart rate. This heightened sympathetic tone is often observed in patients with essential hypertension.

## 1.4 Ideal features of a MDT

The ideal features that a MDT should be able to cater include [7]

- Should disintegrate and dissolve in mouth within 30 seconds
- Should not require water to swallow them
- Should have a pleasant feel in the mouth
- Should be able to mask the unpleasant taste of drugs
- Should not leave behind any residue in the mouth
- Should not be sensitive to environmental conditions like temperature and humidity
- Should allow for manufacturing using the conventional process of tablet manufacturing

## 1.5 Advantages of MDT

- Ease of administration especially for geriatric, pediatric and uncooperative patients
- No need of water is especially helpful for patients with motion sickness
- Rapid dissolution and absorption of the drug lead to quick onset of action
- Increased bioavailability due to bypassing the first pass metabolism

## 2 Material and Methods

### 2.1 Preformulation Studies [8]

#### 1 Organoleptic properties

#### 6. Determination of Ultraviolet Absorption Maxima

For the determination of the absorption maxima, a stock solution was prepared by dissolving 10 mg of accurately weighed Eprosartan mesylate in 10 mL of methanol to obtain a 1 mg/mL solution. Then, 1 mL of this solution was pipetted into a 10 mL volumetric flask and diluted to 10 mL with phosphate buffer pH 6.8 to achieve a 100 µg/mL solution. The solution was scanned using a UV-visible double beam spectrophotometer (Labtronics, LT-2201) in the range of 200 nm to 400 nm, using phosphate

A small quantity of pure ebrosartan powder was taken in a butter paper and viewed in well illuminated place to observe its color; the taste and odor were observed using tasting and smelling the drug.

#### 2 Solubility analysis

Solubility of ebrosartan was determined in methanol, ethanol, water and phosphate buffer. Solubility studies were performed by shaking small amount of DC in test tubes containing the solvent and observing for undissolved particles (if any).

#### 3 Melting point

The melting point of ebrosartan was determined by capillary method. The capillary tube was sealed from one end by heating on burner. The pure drug was filled in a capillary tube placed in the cavity of the melting point apparatus. The capillary tube was heated electrically by gradual increase in temperature and the temperature at which the sample melted was observed and recorded.

#### 4. Loss on drying

The loss on drying was determined by drying the pure drug in an oven at 100°C to 105°C for 3 h. The percent loss of moisture was calculated by the difference between the initial and final weight of the drug.

#### 5. Partition Coefficient

The partition coefficient of the drug was performed by using octanol as oil phase (10 mL) and water as aqueous phase (10 mL). Both the phases were mixed by shaking vigorously in a separating funnel and then 5 mg of drug was added. The drug was allowed to dissolve in both the phases by shaking and allowing for equilibration. Both phases were taken in a conical flask and then analyzed against their respective blank solution and the partition coefficient was calculated.

buffer pH 6.8 as the blank. The  $\lambda$  max of Eprosartan mesylate was determined to be 231 nm.

#### 7. Construction of Calibration Curve

For the quantitative estimation of Eprosartan mesylate, a stock solution was prepared by dissolving 10 mg of accurately weighed Eprosartan mesylate in 10 mL of methanol to obtain a 1 mg/mL solution. From this solution, 1 mL was pipetted into a 50 mL volumetric flask and diluted to 50 mL with methanol to prepare a 20



µg/mL solution. Aliquots of 1, 2, 3, 4, 5, 6, 7, 8, 9, and 10 mL of the second stock solution were pipetted into separate 10 mL volumetric flasks to achieve concentrations of 2, 4, 6, 8, 10, 12, 14, 16, 18, and 20 µg/mL. The volume in each flask was made up to the mark with methanol. The absorbance of the prepared solutions of Eprosartan mesylate was measured at 231 nm using methanol as the blank.

### 8. Compatibility Study

To evaluate the compatibility of Eprosartan mesylate with excipients in a formulation, infrared (IR) spectra were recorded using a Shimadzu FTIR 8400 spectrophotometer. The potassium bromide (KBr) pellet method was employed. The drug and excipients were thoroughly mixed with dry powdered potassium bromide, and the mixture was compressed into a disc. This disc was placed in the FTIR spectrophotometer, and the spectrum was recorded over a wavelength range of 4000–400 cm<sup>-1</sup>. This analysis was conducted to detect any potential interactions between the drug and excipients, ensuring formulation stability.

### 2.2 Formulation of Mouth Dissolving Tablets

#### A. Direct Compression method [9]

The fast dissolving tablets of eprosartan were prepared by direct compression method according to the batch formula given in Table II.C.1.

All the ingredients were separately sifted through 60 mesh sieve. The drug and microcrystalline cellulose were mixed in small portions of both and blending it to get a uniform mixture. This mixture was kept aside for blending. All the other ingredients were accurately weighed and mixed in geometrical order and tablets and blended in a double cone blender. The blend was compressed to tablets of 8 mm sizes using flat round punch using Tablet compression Machine.

**Table 1. Batch formula per tablet using direct compression method**

Ingredient (mg)	Formulation code					
	EF1	EF2	EF3	EF4	EF5	EF6
Eprosartan Mesylate	100	100	100	100	100	100

Crospovidone	5	10	15	20	25	30
Saccharin Sodium	12	12	12	12	12	12
D-mannitol	50	45	40	35	30	25
Avicel PH-102	25	25	25	25	25	25
HPMC	3	3	3	3	3	3
Talc	3	3	3	3	3	3
Magnesium stearate	2	2	2	2	2	2
<b>TOTAL</b>	<b>200</b>	<b>200</b>	<b>200</b>	<b>200</b>	<b>200</b>	<b>200</b>

### 2.3 Precompression evaluation the formulation blends

All the prepared blends (EF1–EF6) were subjected to determination of the powder flow properties. The angle of repose was determined by allowing the powder mixture to flow through a funnel fixed at a definite height (h), and the angle (θ) was calculated by measuring the height and radius (r) of the heap of powder formed using the formula  $\tan[\theta] = [h/r]$  [10].

The bulk and tapped density were measured by taking a weighed quantity of blend (1g) into a graduated cylinder (10 mL) and recording the volume; bulk density (ρ bulk) was calculated by the formula ρ bulk = weight of the powder/initial volume [11].

The cylinder was tapped until no further volume change occurred, and the tapped density (ρ tap) was calculated using the formula ρ tap = weight of the powder/final volume. Hausner's ratio, defined as the ratio of tapped density to bulk density, was calculated by  $HR = \rho \text{ tap} / \rho \text{ bulk}$ , and the compressibility index, also known as Carr's Index, was calculated using the formula Carr's Index =  $(\rho \text{ tap} - \rho \text{ bulk}) / (\rho \text{ tap}) \times 100$ .

### 2.4. Evaluation of MDTs

The MDTs prepared using both the methods were subjected to evaluation of the post compression parameters (tablet evaluation) according to guidelines [12].

#### A. Hardness test



The hardness of the formulated tablets was tested using Monsanto type hardness tester. Three tablets from each batch of formulation were randomly taken and the force required to break the tablets was measured using hardness tester.

### B. Friability test

The friability test of the formulations was performed using a Roche type friability test apparatus. Twenty tablets were initially weighed ( $W_{\text{initial}}$ ) and transferred into friabilator. The friabilator was operated at 25 rpm for 4 minutes or run up to 100 revolutions. The tablets were weighed again ( $W_{\text{final}}$ ). The percentage friability was then calculated by the formula

$$\% \text{ Friability} = \frac{W_{\text{initial}} - W_{\text{final}}}{W_{\text{initial}}} \times 100$$

### C. Weight variation test

20 tablets were randomly taken and weighed to calculate the average weight of the tablets. Each of these tablets was individually weighed and the difference from average weight was calculated. The percent weight variation was calculated to determine the deviation from the average weight.

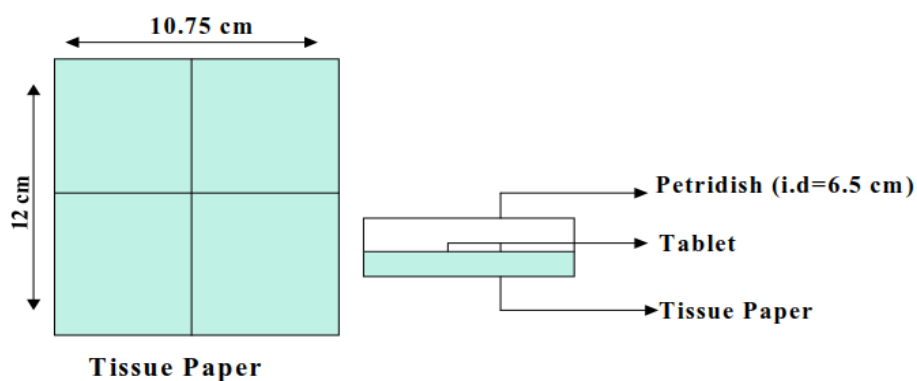


Figure 2 Diagrammatic representation of determination of wetting of tablet

### E. Water Absorption ratio [13]

A piece of tissue paper was folded twice and placed in a Petri dish containing 6 mL of 0.5% v/v amaranth solution (as a coloring agent) in water. A tablet was placed gently on the tissue paper, and the wetted tablet was reweighed. The water absorption ratio R was determined according the following equation

$$R = \frac{W_a - W_b}{W_b} \times 100$$

Where  $W_a$  is the weight of tablet after water absorption and  $W_b$  is the weight of tablet before water absorption.

### F. In vitro disintegration time

The in-vitro disintegration time of a tablet was determined using disintegration test apparatus as per I.P. specifications. One tablet was placed in each of the 6



tubes of the basket and a perforated disc was placed over each tablet. The assembly was raised and lowered at 30 cycles per minute in the pH 6.8 buffer maintained at  $37 \pm 2^\circ\text{C}$ . The time required for complete disintegration of the tablet with no palpable mass remaining in the apparatus was recorded. [14]

### G. In-vitro dissolution

The USP type II paddle apparatus with a paddle speed of 50 rpm was used for dissolution testing for the formulated MDTs. The dissolution media used consisted of 900 mL of 0.1 N HCl and distilled water. 5 mL of samples were collected at time points of 5, 10, 15, and 30 min and the media was replenished with the same volume of fresh media. The free drug concentration was estimated using a UV spectrophotometer at a wavelength of 231 nm.

### H. Short term stability study

The formulated MDTs were randomly selected and subjected to three month stability study at  $25^\circ\text{C}/60\%$  and  $40^\circ\text{C}/75\%$  RH. After the end of the study period, some critical parameters were evaluated.

## 3. Results and Discussion

### 3.1 Results of Preformulation Studies

The preformulation studies was carried out using the previously reported methods and the results are presented underneath.

**Table 2: Physicochemical properties of Eprosartan**

Test	Observation
Color	White
Odor	Odorless
Melting Point	245-247°C

The partition coefficient of Eprosartan was calculated using octanol and water and the  $K_o/w$  value was found to be 3.6.

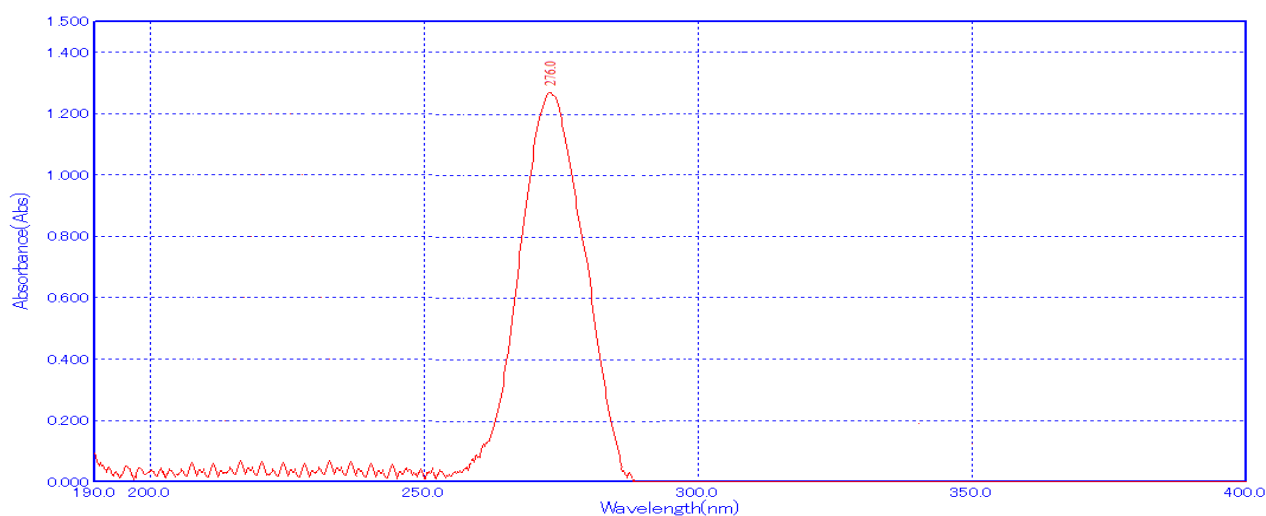
The percent loss on drying of Eprosartan was found to be 0.17%.

**Table 3: Solubility of Eprosartan**

Solvent	Observation
Water	Insoluble
Ethanol	Soluble
Methanol	Soluble
Phosphate Buffer	Slightly Soluble

### 1. Calibration Curve of Eprosartan

The UV spectrum of eprosartan showed absorption maximum at 231.0 nm. Calibration curve of eprosartan was plotted as absorbance versus concentration ( $\mu\text{g/ml}$ ) at 231.0 nm.

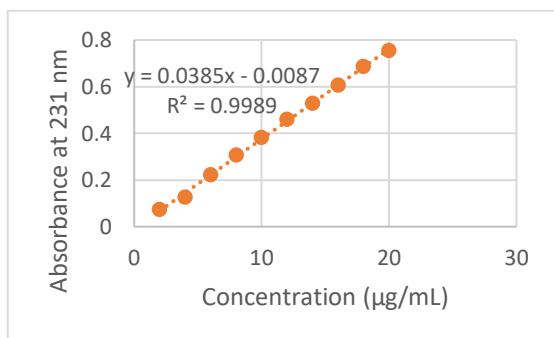


**Figure 3: UV spectrum of Eprosartan**

**Table 4: Standard curve absorbance data**

Concentration ( $\mu\text{g/mL}$ )	Absorbance
2	0.074
4	0.127
6	0.223
8	0.306
10	0.381
12	0.459
14	0.528
16	0.605
18	0.685
20	0.755

The linear regression analysis for the calibration curve was  $\text{Abs} = 0.0385(\text{conc}) - 0.0087$  with a regression coefficient of 0.9989.

**Figure 4: Calibration curve of Eprosartan**

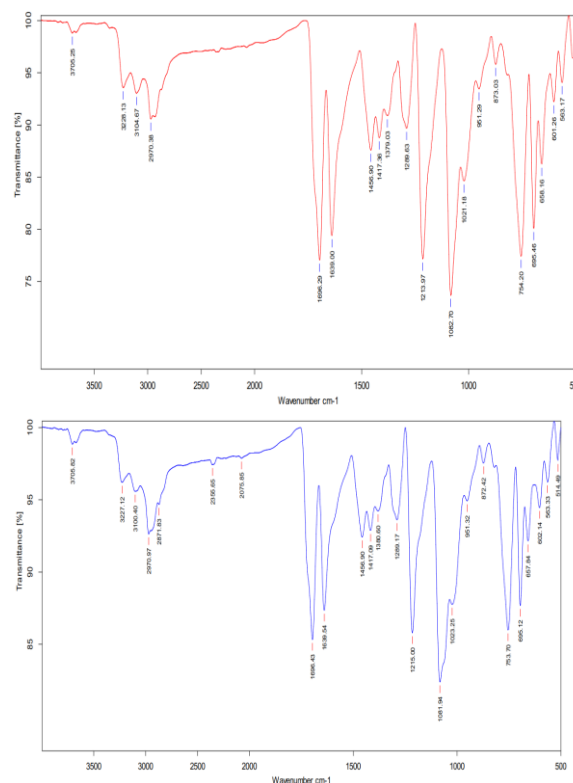
## 2. FT-IR Spectral study

### 3.2 Precompression Parameters of the formulation blends

**Table 5: Precompression parameters of blends**

Formulation Code	Bulk density ( $\text{g/cm}^3$ )	Tap density ( $\text{g/cm}^3$ )	Angle of repose ( $^\circ$ )	Carr's Index (%)	Hausner's Ratio
EF1	0.526	0.588	$23^\circ 65'$	10.54	1.12

The FT-IR spectra of eprosartan and a physical mixture of eprosartan and mannitol, HPMC and crosspovidone was obtained and the stretching and bending vibrations due to various functional groups was compared in order to confirm the compatibility of the components.

**Figure 5: FTIR spectra of Eprosartan and physical mixture respectively**

The peaks of hydroxyl ( $3600\text{-}3700\text{ cm}^{-1}$ ), and carbonyl ( $1680\text{-}1720\text{ cm}^{-1}$ ) were prominently present in both the spectra suggesting compatibility among the ingredients. The other peaks present in the spectra were of C-H, C-C and C-O stretching and bending.



EF2	0.555	0.625	23°98'	11.20	1.13
EF3	0.588	0.625	22°73'	5.92	1.06
EF4	0.625	0.666	22°44'	6.16	1.07
EF5	0.625	0.666	22°24'	6.16	1.07
EF6	0.666	0.714	22°09'	6.72	1.07

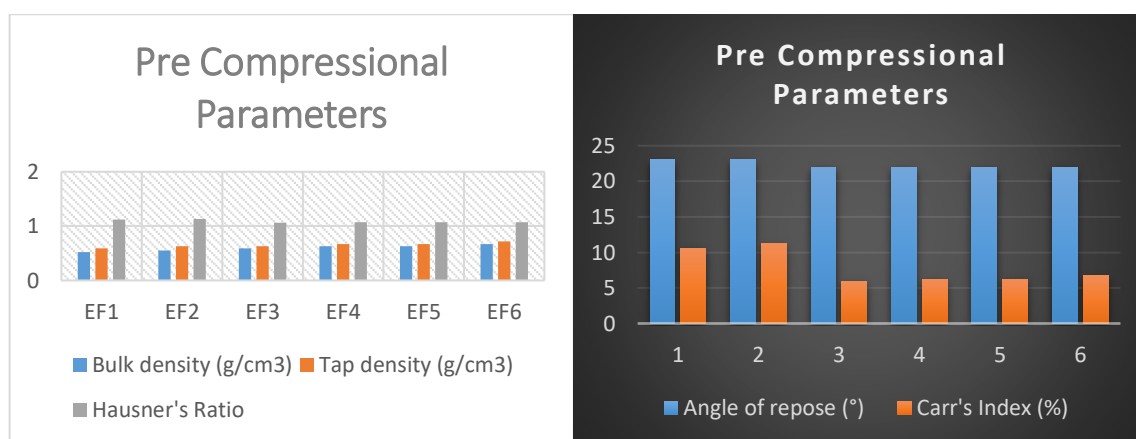


Figure 6: Precompressional studies of blends

### 3.3 Evaluation of MDTs

Table 6: Post compression parameters of MDT formulations

Formulation Code	Hardness (Kg/cm <sup>2</sup> )	Thickness (mm)	Average Weight variation (%)	Friability (%)	Drug content (%)
EF1	3	7.98	5.1	0.43	98.10
EF2	3	8.01	5.2	0.52	98.30
EF3	3	8.05	4.6	0.64	98.70
EF4	3	8.02	5.2	0.69	98.10
EF5	3	8.01	5.1	0.72	97.80
EF6	3	7.99	5.4	0.77	97.90

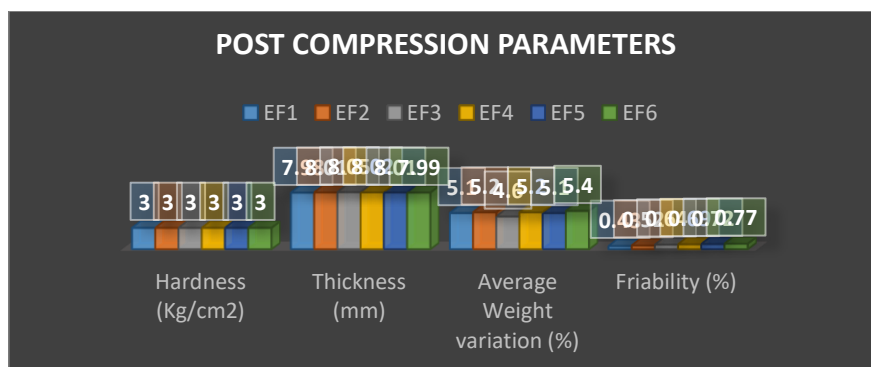


Figure 7: Comparison of Post compression parameters of MDT formulations

Table 7: wetting, water absorption, disintegration and drug release of MDTs

Formulation Code	Wetting time (seconds)	Water absorption ratio	Disintegration time (seconds)	Drug release (%)
EF1	47	74.6	25.1	80.80
EF2	45	80.2	23.7	84.10
EF3	36	73.5	21.5	89.60
EF4	29	85.7	20.7	90.40
EF5	24	75.7	18.5	92.30
EF6	19	86.8	16.1	95.50

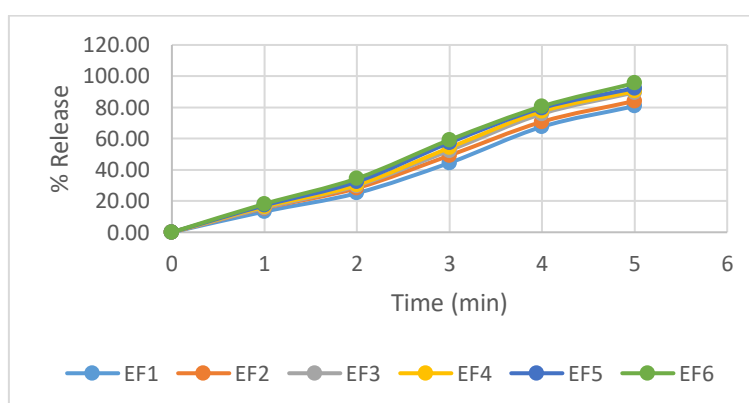


Figure 8: *In vitro* drug release from formulations

The post-compression assessment of the MDT formulations (EF1–EF6) demonstrated consistent hardness values of 3 Kg/cm<sup>2</sup> across all batches, signifying uniform tablet strength. The tablets exhibited a thickness ranging from 7.98 mm to 8.05 mm, indicating negligible variation, while the average weight fluctuation was maintained within acceptable parameters (4.6–

5.4%), so guaranteeing dose consistency. Friability values were minimal (0.43–0.77%), indicating robust mechanical integrity, whereas drug content was elevated across all formulations (97.80–98.70%), and affirming effective drug loading. The wetting time diminished progressively from 47 seconds in EF1 to 19 seconds in EF6, indicating improved tablet wettability in



subsequent formulations. Correspondingly, the water absorption ratio exhibited elevated values in EF4 (85.7%) and EF6 (86.8%), signifying enhanced water uptake capability. The disintegration time decreased from 25.1 seconds in EF1 to 16.1 seconds in EF6, indicating accelerated tablet dissolution. Consequently, drug release enhanced with increased water absorption and reduced disintegration times, with a peak of 95.50% in EF6 compared to 80.80% in EF1. Formulations with reduced wetting and disintegration time's demonstrated superior drug release patterns, underscoring the

influence of formulation characteristics on MDT performance.

#### Stability Study

Accelerated stability testing was performed on 15 tablets of all formulations by storing them in amber colored stoppered vials at specified conditions of temperature and humidity for a period of 3 months. At intervals of one month, the tablets were visually examined for any physical changes, changes in drug content and *in vitro* dispersion time. The results of stability study are presented in Table III.A.4.

**Table 8: Results of accelerated stability study**

S.NO	Time (days)	40°C/75% RH				25°C/60% RH			
		Hardness (Kg/cm <sup>3</sup> )	Friability (%)	Drug content (%)	DT (SEC)	Hardness (Kg/cm <sup>3</sup> )	Friability (%)	Drug content (%)	Disintegrati on time (seconds)
EF1	30	3	0.42	98.10	25.1	3	0.42	98.10	25.1
	60	3	0.42	98.00	24.8	3	0.42	98.10	25.1
	90	3	0.43	98.00	24.5	3	0.43	98.00	25.1
EF2	30	3	0.52	98.30	23.7	3	0.52	98.30	23.7
	60	3	0.53	98.20	23.6	3	0.53	98.30	23.7
	90	3	0.55	98.20	23.4	3	0.55	98.20	23.7
EF3	30	3	0.64	98.70	21.5	3	0.64	98.70	21.5
	60	3	0.65	98.50	21.2	3	0.65	98.70	21.5
	90	3	0.67	98.50	21.1	3	0.67	98.60	21.5
EF4	30	3	0.69	98.10	20.7	3	0.69	98.10	20.7
	60	3	0.70	98.00	20.6	3	0.70	98.10	20.7
	90	3	0.70	98.00	20.4	3	0.70	98.10	20.7
EF5	30	3	0.72	97.80	18.5	3	0.72	97.80	18.5
	60	3	0.73	97.70	18.4	3	0.73	97.80	18.5
	90	3	0.74	97.70	18.2	3	0.74	97.70	18.5
EF6	30	3	0.77	97.90	16.1	3	0.77	97.90	16.1
	60	3	0.79	97.70	16	3	0.79	97.80	16.1
	90	3	0.80	97.70	15.8	3	0.80	97.80	16.1



A very small change in disintegration time, drug content and friability was observed in almost all the formulations under the conditions of the study.

## Conclusion

It can be concluded from the study that mouth dissolving tablets of eprosartan could be easily formulated using super-disintegrants and sublimating agents in order to achieve a rapid onset of drug action and peak plasma concentration over short period of time. The MDTs formulated using could be highly beneficial for the management of hypertensive crisis that require immediate attention.

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