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# DEVELOPMENT AND EVALUATION OF MOUTH DISSOLVING TABLETS OF OMEPRAZOLE FOR ENHANCED BIOAVAILABILITY

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**Keywords:**

Mouth dissolving tablets, Omeprazole, Bioavailability, Hepatic first-pass metabolism, Wet granulation method, Carr's index

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**ABSTRACT:** The purpose of this research was to examine the development of a mouth-dissolving tablet formulation of omeprazole to enhance its rapid absorption through the buccal mucosa, which would facilitate the onset of therapeutic effects more quickly. Formulation was difficult for omeprazole because of its low solubility and permeability, which places it in the IV class of drugs according to the Biopharmaceutics Classification System. For the preparation of the tablets, the wet granulation method was utilized, which ensured that the drug-excipient ratios were consistent throughout. All of the formulations were able to satisfy the pharmacopeial standards for weight consistency, friability, thickness, and drug content. The results of the *in-vitro* tests showed that the disintegration and dispersion properties were outstanding, which indicated that the bioavailability and drug release kinetics were more favorable. Over four weeks at a temperature of 50°C, accelerated stability testing indicated consistent drug content, hardness, and *in-vitro* dispersion time. This indicates that the formulation has been stable for more than a year. Because the newly created formulation shows superior medicine release patterns, favorable disintegration time, hardness, and friability, it is a prospective candidate for the oral delivery of omeprazole that has enhanced therapeutic efficacy.

**INTRODUCTION:** Omeprazole is a member of the substituted benzimidazole group. It works by binding to H+, K+, and ATPase, which are all necessary for the secretion of stomach acid by parietal cells. As a result, omeprazole inhibits the formation of stomach acid. Moreover, the application of omeprazole results in the irreversible binding of protons to the proton pump.

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Omeprazole effectively inhibits the release of baseline stomach acid. Omeprazole is a compound with a chemical formula of $C_{17}H_{19}N_3O_3S$ and a molecular weight of 345.42 g/mol. Omeprazole can be described as 5-methoxy-2-[(4-methoxy-3,5-dimethyl-2 pyridinyl) methyl] sulfinyl] benzimidazole from a chemical standpoint.

Omeprazole is a medication that is utilised as an antiulcer agent and for the treatment of various acid-related disorders. Omeprazole exhibits the following chemical properties: it is a white to practically white powder, it undergoes breakdown when melted at temperatures between 150 and 160ºC, it is soluble in dichloromethane, somewhat

soluble in methanol and ethanol, and has extremely low solubility in water [1]. A novel drug delivery system is an innovative strategy that enhances our understanding of the pharmacokinetic and pharmacodynamic behaviour of drugs. It provides a more logical and efficient method for developing optimal drug delivery systems [2]. Aiming to improve patient compliance and create a more convenient dose form for administration, recent breakthroughs in novel drug delivery systems (NDDS) seek to increase the safety and effectiveness of therapeutic agents. People favour the oral form of administration due to its numerous benefits. Because of their small size, ease of manufacture, ability to allow for accurate doses, cost-effectiveness, and convenience for self-administration, pharmaceutical researchers and medical professionals choose tablets and capsules. As knowledge of compression physics and production variables has grown and the number of tablets produced has expanded, tablet production has become its own distinct scientific discipline [3]. Mouth dissolving tablets are solid dosage forms that quickly breakdown and dissolve in saliva in the oral cavity, forming a solution without the need for water for administration [4]. Oral fast-dissolving tablets are a novel form of solid oral medication that rapidly disintegrates or dissolves in saliva without the need for water. When the patient places this dosage form in their mouth, saliva will rapidly dissolve it, enabling the patient to ingest the drug in liquid form, which is advantageous for patients with dysphagia. When water penetrates the tablet matrix, it rapidly disintegrates, forming a porous structure and resulting in speedy disintegration [5].

## Material and Methods:

**Materials:** The materials listed below were acquired from the specified sources without further purification. Omeprazole was obtained from Yerrow Chem in Ghatkopr, West Mumbai, Maharashtra, India. The remaining chemicals utilized were of analytical reagent grade.

## Methods:

### Characterization of the Pure Active Ingredient:

**UV visible (Ultraviolet visible) spectro-photometer:** In identification investigations, UV spectrophotometry is utilized to verify the medicines' structural integrity. A certain range of frequencies of light can be absorbed by unsaturated molecules. When it comes to absorption capacity, the degree of unsaturation and the presence of chromophores determine whether visible light (800–400 nm) or ultraviolet (400–200 nm) light will be absorbed. Methanol was used to dissolve the medication, yielding solutions containing 10 µg/ml. I used a Shimadzu-1700 UV spectrophotometer to analyze the drug solution at a concentration of 10 µg/ml between 200 and 400 nm.

**Fourier-Transform Infrared spectroscopy (FTIR):** At IIT Kanpur, a Bruker FTIR spectrophotometer was used to analyze a magnesium omeprazole sample that was mixed with a potassium bromide dispersion pellet. Eight scans were performed, covering a range of 400 to 4000 cm-1, with a resolution of 4 $cm^{-1}$.

**Compatibility Studies:** FTIR will be used to determine the chemical compatibility of the medicine and excipients.

**FTIR Analysis:** The drug's compatibility with excipients is assessed using FTIR analysis. The scanners used were the Bruker FTIR spectrophotometers housed at IIT Kanpur. The measurements were taken in the 400–4000 cm–1 range using an aggregated resolution of 4 cm–1.

**Method of Preparation:** The components were precisely measured and passed through a 100-mesh sieve. A 10-minute consistent swirling of the liquid was performed. After adding and mixing, Acryflow L, talc, and Kyron 114 were combined. A conventional concave punch measuring 9mm was used on a single punch tableting machine to condense the tablets. The dimensions, weight variation, crushing strength, friability, and disintegration duration of the pills were among the several parameters examined [6].

**TABLE 1: FORMULATION CHART**

| Ingredients | FS1 | FS2 | FS3 | FC1 | FC2 | FC3 | FP1 | FP2 | FP3 | FK1 | FK2 | FK3 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Omeprazole magnesium | 20 | 20 | 20 | 20 | 20 | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| Kyron 314 | 15 | 25 | 15 | --- | --- | --- | --- | --- | --- | --- | --- | --- |

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| PolyKoVidone XL | --- | --- | --- | 10 | 20 | 20 | --- | --- | --- | --- | --- | --- |
| Croscarmellose | --- | --- | --- | --- | --- | --- | 15 | 20 | 15 | --- | --- | --- |
| SSG | --- | --- | --- | --- | --- | --- | --- | --- | --- | 15 | 20 | 15 |
| Acryflow L | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| Talc | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
| Kyron 114 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
| Microcrystalline cellulose up to | 200 | 200 | 200 | 200 | 200 | 200 | 200 | 200 | 200 | 200 | 200 | 200 |

**Evaluation of Mouth Dissolving Tablets:**

**Evaluation of Blend:** The physicochemical characteristics of the blend used to make the tablet are the primary determinants of its quality. The characteristics of the mixes created can be impacted by several formulation and process variables that are considered throughout the mixing stage.

**The angle of Repose (θ):** The angle of repose (θ) can be used to calculate the frictional forces in a loose powder. It indicates the properties of the powder's flow. The definition is the maximum angle that exists between a powder pile's surface and the horizontal plane. The funnel method was used to calculate the angle of repose. An adjustable funnel was used to disburse the powder to achieve the highest cone height [7, 8].

$$\theta = \tan^{-1} h/r$$

Whereas, θ- Angle of repose, h- Height of pile and r is the radius of the base pile.

**Bulk Density (DB):** The term refers to the ratio of the entire mass of powder to the overall volume of powder. The powder was sifted through a standard sieve #20 and then transferred to a measuring cylinder to record the starting volume. The following formula is utilized to calculate the bulk density. The value is denoted in grams per milliliter and is determined by [8].

$$Db = M/Vb$$

Where, M- Mass of powder, Vb- Bulk volume of the powder.

**Tapped Density (DT):** The whole mass of the powder divided by the tapped volume of the powder is found. One hundred taps on the powder were used to determine its volume. The following volumes were tapped until a bulk density instrument revealed a difference of less than 2%. The value is calculated and expressed in grams per milliliter [8].

$$Dt = M/Vt$$

Where, M- Mass of powder, Vt- The tapped volume of the powder.

**Compressibility Index (Carr's Consolidation Index):** By measuring its density, a free-flowing powder's compressibility can be ascertained. The formula was used to carry out the computation [8].

$$\% \text{ Compressibility} = (\text{Tapped Density} - \text{Bulk Density}) / (\text{Tapped Density}) \times 100$$

**Hausner Ratio:** As an indirect measure, the Hausner ratio assesses the flowability of a particle. A Hausner ratio in the vicinity of 1.25 indicates enhanced particle flow. The formula is employed to ascertain the calculation [8].

$$\text{Hausner Ratio} = Dt/Db$$

Where, Db- Bulk density of the powder, Dt- Tapped density of the powder.

**Post Compression Parameters:**

**Appearance:** Uncoated tablets were visually examined for their form and color under light exposure.

**Dimension:** Measurements of thickness and diameter were taken using a calibrated vernier caliper. Measurements were taken from six tablets of each formulation randomly to determine their dimensions.

**Hardness Test:** Hardness refers to the capacity of a tablet to endure mechanical forces that may occur during its usage. To determine the pills' hardness, a Monsanto hardness analyzer was utilized. Kg/cm2 is the unit of measurement in kilograms per square centimeter. Examined the hardness of six tablets selected at random. Calculation of the mean and standard deviation occurred [9].

**Friability Test:** Friability is the reduction in tablet mass within the container or package as a result of

microscopic particle elimination from the tablet's surface. The purpose of this quality control examination is to validate the tablets' resistance to disturbances that may occur throughout the stages of processing, handling, transportation, and delivery. The acceptable threshold for friability is 1.0%. The friability of the tablets was assessed utilizing the Roche friabilator. Following the collective weighing of ten tablets, they were transferred to the friabilator chamber. The tablets within the friabilator rolled due to their unrestricted descent within the chamber. The velocity of the object's rotation was 25 revolutions per minute. Following a cycle of 100 revolutions lasting 4 minutes, the pills were extracted from the friabilator and their remaining undamaged weight was recalculated. The percentage of friability was ascertained by employing the formula [9].

$$\text{Friability} = (W1 - W2) / W1 \times 100$$

Where, W1 = weight of the tablet before the test, W2 = weight of the tablets after the test

**Weight Variation Test:** A total of twenty tablets were subjected to individual and group weighing. To determine the average weight, the sum of the weights of all tablets was divided by the quantity of tablets. The weights of each individual were compared to the mean weight. The percentage variation in weight fluctuation must fall within a range of ±7.5%. To determine the percentage deviation, the subsequent formula was applied [10].

$$\text{Percentage Diviation} = (\text{Individual weight} - \text{Average weight}) / (\text{Average weight}) \times 100$$

Any change in the weight of the tablet has the potential to cause an overdose or underdose. Each tablet in a batch needs to weigh the same amount. For a 200 mg pill, a variation of 7.5% from the advertised weight is acceptable. To ensure consistent weight, the tablets were compressed.

**Drug Content Estimation:** The dosage of Omeprazole magnesium was 20 milligrams, which was achieved by weighing and crushing 20 tablets and then mixing them with 100 milliliters of pH 6.8 phosphate buffer. Filtration, proper dilution, and drug concentration testing were performed on the solution using a UV-spectrophotometer (UV 1800 Shimadzu, Japan) at 302 nm [11].

**Wetting Time:** By the contact angle, the saturation time of a dosage form follows. It is critical to assess the absorption time of orally disintegrating tablets to gain a comprehensive understanding of their disintegration properties. A shortened wetting time is associated with a more rapid disintegration of the pill. The determination of the pill's soaking time can be achieved through a straightforward procedure.

**Method:** Five circular tissue papers, each measuring 10 cm in diameter, are positioned inside a petri dish with the same dimension. In a petri dish, 10 ml of an aqueous solution containing 2% w/v methylene blue, a water-soluble dye, is added. With caution, a tablet is positioned on the tissue paper. Wetting time is the duration required for water to reach the upper surface of the tablet [12, 13].

**Water Absorption Ratio:** A tiny petri dish containing 10 milliliters of 6.8 pH phosphate buffer solution was filled with folded tissue paper. A tablet was placed on the paper, and the amount of time needed to reach full saturation was noted. After absorbing moisture, the tablet was weighed. The ratio of water absorption, R, was determined using the provided equation:

$$R = (Wa - Wb) / Wb) \times 100$$

Where, Wa = weight of tablet after absorption, Wb = weight of tablet before absorption.

Six tablets from each formulation were analyzed and the standard deviation was also determined [12].

***In-vitro* Dispersion Time:** By adding 6 ml of artificial saliva (pH 6.8) to a 10 ml measuring cylinder, the dispersion time of the pill was determined. It was noted how long it took the tablet to completely scatter [14].

***In-vitro* Disintegration Time:** When a tablet breaks down into smaller bits, the process is referred to as disintegration. A modified dissolving test was used to determine how long the pill would take to dissolve *in-vitro*.

**Disintegration Test:** When a tablet breaks down into smaller bits, the process is referred to as disintegration.

A modified dissolving test was used to determine how long the pill would take to dissolve *in-vitro* [15].

**Modified Disintegrating Test:** A centimeters diameter Petri plate filled with ten milliliters of pH 6.8 phosphate buffer is used for the experiment. The pill is precisely placed in the middle of the petri dish, and the amount of time needed for it to completely dissolve into particles is recorded [12, 16].

Analysis was performed on five pills from each formulation, and the standard deviation was computed.

***In-vitro* Dissolution Studies:** The drug release of omeprazole magnesium mouth dissolving tablet was assessed *in-vitro* utilizing the USP Dissolution Apparatus II (Paddle type) (Electrolab TDT-08L, India). The dissolution test was conducted at a temperature of 37±0.50C using 900 cc of Phosphate buffer SSF with a pH of 6.8. The rotational speed of the paddle was 50 revolutions per minute (rpm). At 2, 4, 6, 8, and 10-minute intervals, 2 ml samples were collected and corresponding volumes were replaced with fresh media. Following the filtration process, 1 mL of the filtered solution was combined with 10 mL of pH 6.8 phosphate buffer. At a wavelength of 302 nm, the absorbance of the solution was measured using a UV-spectrophotometer (UV 1800 Shimadzu, Japan), and the amount of substance released was quantified utilizing a reference curve [8, 17].

**Stability Studies:** Stability refers to the capacity of a specified medication or dosage form to maintain its physical, chemical, therapeutic, and toxicological attributes while contained in a designated container. Drug degradation during the stability period transpires as a result of product instability or chemical modification of the active ingredients, which ultimately diminishes the drug concentration in the dosage form [18].

**RESULT & DISCUSSION**:

**By UV-visible (Ultraviolet-visible) spectrophotometer: Fig. 1** shows the absorption maxima (λ max) of omeprazole sodium in methanol.

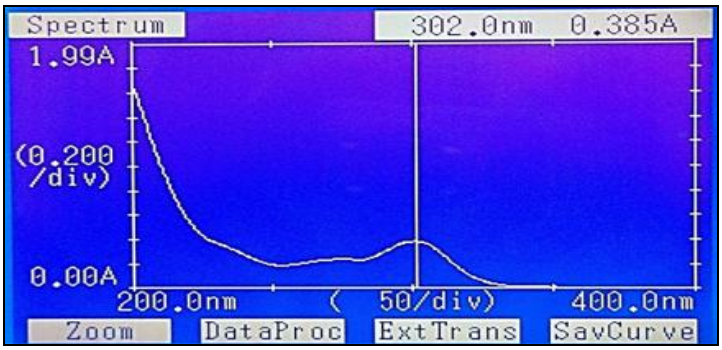


**FIG. 1: THE UV SPECTRUM OF THE DRUG OMEPRAZOLE MAGNESIUM**

Using methanol, the calibration curve for magnesium omeprazole was established; it is shown in **Table 2** and **Fig. 2.** The Y-intercept is 0.0035, the regression coefficient is 0.9995, and the slope is 0.0379. The relationship between absorbance and concentration is demonstrated to be direct.

**TABLE 2: CALIBRATION CURVE OF OMEPRAZOLE SODIUM METHANOL AT $\Lambda_{MAX}$ 302 NM**

| S. no. | Concentration (µg/ml) | Absorbance |
|---|---|---|
| 1. | 0 | 0 |
| 2. | 1 | 0.043 |
| 3. | 2 | 0.081 |
| 4. | 3 | 0.121 |
| 5. | 4 | 0.154 |
| 6. | 5 | 0.195 |
| 7. | 6 | 0.23 |
| 8. | 7 | 0.267 |
| 9. | 8 | 0.302 |
| 10. | 9 | 0.347 |
| 11. | 10 | 0.385 |

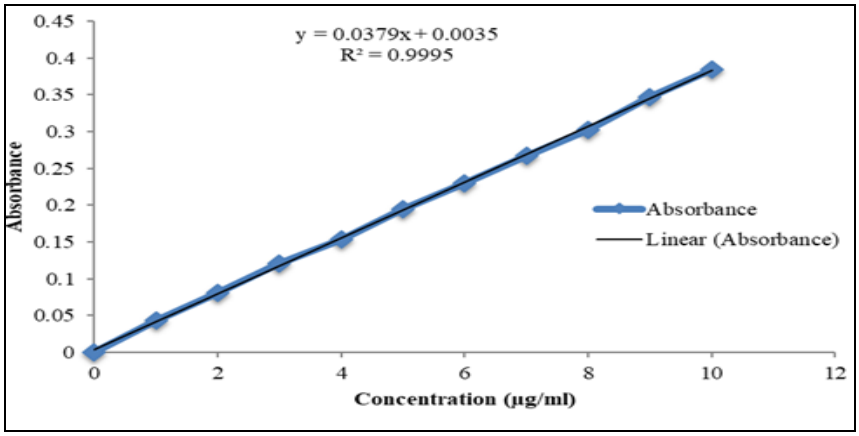


**FIG. 2: LINEARLY REGRESSED CALIBRATION CURVE OF OMEPRAZOLE SODIUM METHANOL AT $\Lambda_{MAX}$ 302NM**

**FTIR Studies:** As shown in **Table 6** and **Fig. 3**, the analysis shows the presence of functional groups in omeprazole magnesium and the distinct IR peaks of the pure drug.

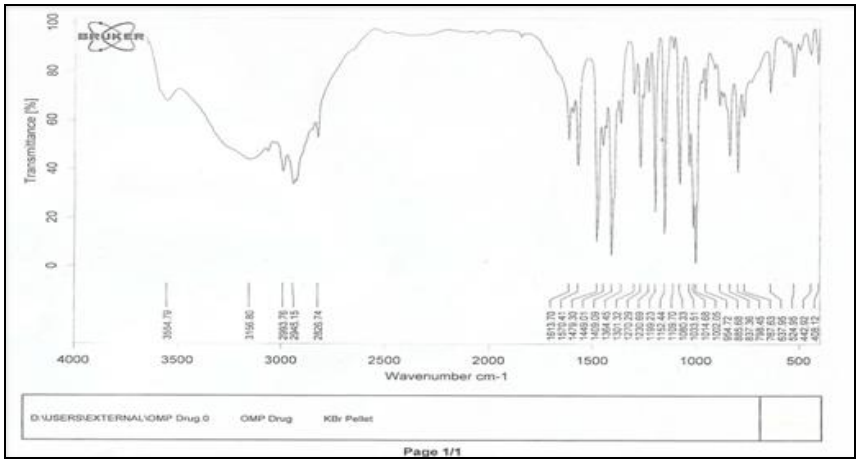


**FIG. 3: FTIR SPECTRUM OF OMEPRAZOLE MAGNESIUM**

**TABLE 3: CHARACTERISTIC PEAKS OF FTIR SPECTRUM OF OMEPRAZOLE MAGNESIUM**

| Peak $cm^{-1}$ | Groups |
|---|---|
| 767 & 798 | Aromatic meta Di-substitution |
| 3156 | Aromatic |
| 2945 | $-CH_3$ |
| 1364 | Ar-N Str. |
| 1230 | Ar-O-R |
| 1409 | S=O |

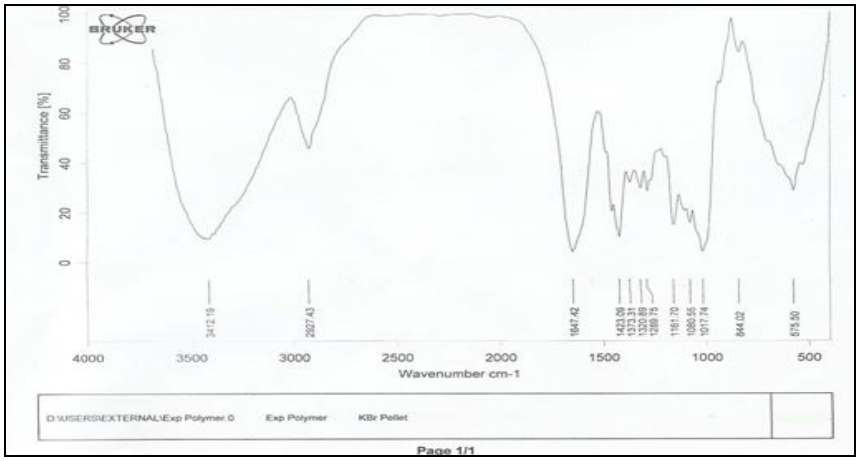


**FIG. 4: IR-SPECTRUM OF CROSCARMELLOSE SODIUM + POLYKOVIDONE XL + KYRON 314 + SSG**

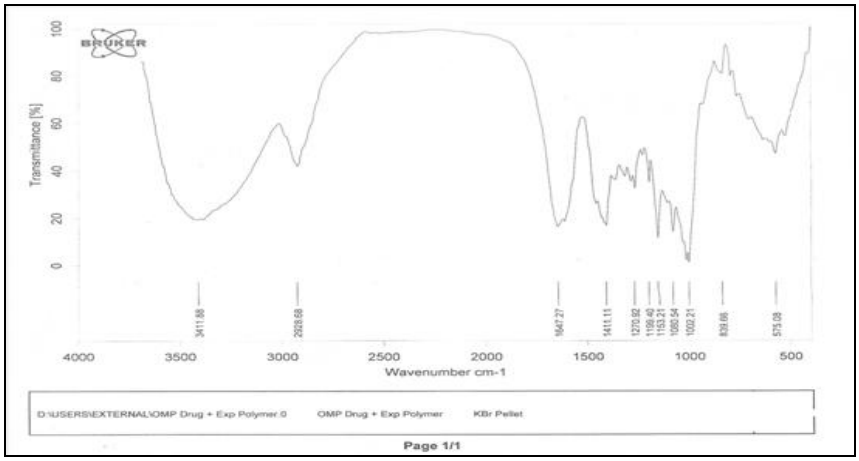


**FIG. 5: I R SPECTRUM OF MILOXICAM+ CROSCARMELLOSE SODIUM + POLYKOVIDONE XL + KYRON 314 + SSG**

**Evaluation of Mouth Dissolving Tablets:**

**Precompression:** The batches were assessed based on parameters such as angle of repose, which ranged from 32.16±0.90 to 35.16±1.10, showing acceptable flow characteristics. The bulk density ranged from 0.49±0.01 to 0.57±0.02 g/cm3, and the tapped density varied between 0.066±0.01 and 0.72±0.02 g/cm$^3$. The Hausner's ratio ranged from 1.18±0.04 to 1.39±0.02. Values below 1.25 indicate superior flow characteristics compared to values over 1.25. The Compressibility index varied between 14.01±3.10 to 28.16±1.36. Those under 15% suggest better flow qualities than those beyond 25%. All formulations exhibited favorable blend qualities for direct compression, enabling the manufacturing of tablets using the direct compression method specified in **Table 4.**

**TABLE 4: EVALUATION OF POWDER (BLEND)**

| Batch code | Angle of Repose* | Bulk Density* | Tapped Density* | % Compressibility* | Hausner ratio* |
|---|---|---|---|---|---|
| FS1 | 35.16±1.10 | 0.49±0.01 | 0.69±0.02 | 28.16±1.36 | 1.39±0.02 |
| FS2 | 34.87±1.64 | 0.51±0.01 | 0.70±0.01 | 27.86±2.48 | 1.38±0.04 |
| FS3 | 34.54±2.47 | 0.55±0.01 | 0.72±0.02 | 24.28±2.77 | 1.32±0.04 |
| FC1 | 33.62±1.10 | 0.53±0.01 | 0.69±0.04 | 23.06±2.57 | 1.30±0.04 |
| FC2 | 33.52±1.72 | 0.53±0.02 | 0.67±0.03 | 21.48±4.15 | 1.27±0.07 |
| FC3 | 32.99±0.90 | 0.55±0.01 | 0.68±0.02 | 19.98±1.83 | 1.25±0.03 |
| FP1 | 34.21±0.82 | 0.54±0.03 | 0.66±0.02 | 17.65±4.48 | 1.21±0.06 |
| FP2 | 32.44±0.64 | 0.56±0.01 | 0.67±0.05 | 15.85±6.95 | 1.19±0.10 |
| FP3 | 32.16±0.90 | 0.57±0.02 | 0.66±0.03 | 14.01±3.10 | 1.16±0.04 |
| FK1 | 34.74±1.22 | 0.54±0.02 | 0.67±0.03 | 17.97±3.77 | 1.22±0.05 |
| FK2 | 33.76±2.87 | 0.55±0.01 | 0.66±0.03 | 16.23±1.92 | 1.19±0.02 |
| FK3 | 33.12±0.86 | 0.57±0.01 | 0.68±0.02 | 15.75±2.90 | 1.18±0.04 |

**Post Compression:**

**Thickness:** The tablet's thickness was measured using Vernier calipers. The orally dissolving pill maintained a consistent thickness ranging from 3.16 to 3.38mm. As all tablets were punched using a die punch with a 9.00 mm diameter, they all had the same diameter, as indicated in **Table 5.**

**Weight Uniformity:** There were no significant weight variations among the different formulations, as all alterations fell below acceptable limits. The weight of each formulation ranged from 185 mg to 215 mg. The weight varied between 199.25±8.47 and 201.25±9.30, meeting the pharmacopeial parameters as displayed in **Table 5.**

**% Drug Content:** The drug concentration in the orally disintegrating tablets ranged from 97.13±2.40 to 99.12±2.10%, as shown in **Table 5.**

**Hardness:** The firmness of orally dissolving pills differed based on the polymer ratios and types employed. When Sodium starch glycolate was added, the tablet's hardness reduced to 5.74±1.20kg/cm3, but increased with higher amounts of microcrystalline cellulose. PolyKoVidone XL showed higher hardness at 6.60±0.80kg/cm3 compared to other formulations and increased further with higher microcrystalline cellulose concentration.

The formulations' hardness was evaluated by the quantity of the diluent, microcrystalline cellulose, which exhibited better hardness properties in comparison to other polymers such as SSG, Croscarmellose, PolyKoVidone XL, and Kyron T-314, as indicated in **Table 5.**

**Friability:** The friability test of the matrix tablets was conducted using a Roche Friabilator. The tablets experienced a weight loss ranging from 0.59±0.05 to 0.94±0.07% as a result of friability. The weight loss falls within the acceptable range for conventional oral pills as specified in the Indian Pharmacopeia (1996), as indicated in **Table 5.**

**Water Absorption Ratio:** A little piece of tissue paper folded twice was placed in a small Petri dish with 10ml of water. A tablet was placed on the paper, and the time taken to reach complete saturation was recorded. Afterward, the pill that had absorbed moisture was weighed again.

A water absorption ratio test was conducted to examine the moisture sorption and water uptake characteristics of super disintegrants. Greater amounts of super disintegrants led to higher water absorption, reduced disintegration time, and wetting time. The tablets exhibited water absorption rates ranging from 161.41±16.23 to 265.40±11.84, as indicated in **Table 5.**

**Disintegration Test:** Disintegration is the process of a tablet breaking down into smaller pieces. The tablet's disintegration time in an artificial environment was evaluated using a specialized dissolution test. The experiment is conducted in a Petri dish with a 10 cm diameter, containing 10 ml of phosphate buffer at pH 6.8. The tablet is positioned accurately at the center of the petri dish, and the time taken for the tablet to completely break down into particles is noted.

Analysis was conducted on five pills from each formulation, and the standard deviation was calculated. The disintegration time of the mouth-dissolving tablets ranged from 23.78±2.90 to 103.48±3.60 seconds, meeting the standard requirement of 3 minutes for mouth-dissolving pills. The rapid disintegration of the mouth-dissolving tablets occurs when saliva penetrates the pores of the tablets, allowing the super disintegrants to swell and provide enough hydrodynamic pressure for a quick and complete breakdown of the tablets. The optimized formulation, FP3, includes PolyKoVidone XL at a 10% concentration. The disintegration time was 23.78±2.90 seconds, as reported in **Table 5** and **Fig. 7.**

**Wetting Time:** The wetting time of the pills was determined using a fundamental method. Five circular tissue papers, each with a diameter of 10 cm, were immersed in a Petri dish containing 3 ml of a 0.2% w/v methylene blue dye solution. A tablet was carefully placed on the tissue paper. The soaking time was measured as the duration it took for the blue hue to appear on the top surface of the tablets.

The dissolution of a tablet is affected by moisture and subsequent disintegration. It is logical to infer that soaking by itself could be the main factor causing disintegration. This indicates that the liquid medium penetrates the tablet, displacing the air adsorbed on the particles, leading to a weakening of the intermolecular bonds and causing the tablet to break into smaller particles. The wetting time of the pills varied from 13.2±1.30 to 80.2±1.30 seconds, as shown in **Table 5** and **Fig. 6.**

***In-vitro* Dissolution Studies:** Analyzed the drug release of Omeprazole magnesium mouth dissolving tablet through in vitro testing using USP Dissolution Apparatus II (Paddle type) (Electrolab TDT-08L, India). The dissolution test was performed using 900 cc of Phosphate buffer SSF with a pH of 6.8 at a temperature of 37±0.50C.

The paddle was rotating at a speed of 50 revolutions per minute (rpm). 2 ml samples were collected at time points of 2, 4, 6, 8, and 10 minutes, and an equivalent volume was replaced with a new medium. The samples underwent filtration, and 1ml of the resulting filtrate was then diluted to 10ml using pH 6.8 Phosphate buffer.

The absorbance of the solution was determined using a UV-spectrophotometer (UV 1800 Shimadzu, Japan) at a wavelength of 302 nm. The drug release was calculated using the standard curve provided in **Table 6** and **Fig. 8, 9, 10**, and **11.**

**Stability Studies:** The stability investigations are conducted in phosphate buffer solutions with a pH

similar to that of physiological fluids. The mouth dissolving tablets were stored at temperatures of 25 ± 2°C and 45 ± 2°C for 45 days.

The oral dissolving tablets were examined based on their visual qualities, including color and shape, as well as their pharmacological makeup in a phosphate buffer solution. The oral dissolving pills exhibited no alteration in color or form, showing the drug's stability. The mouth-dissolving tablets exhibited a modest increase in their physical properties, such as thickness and diameter, due to swelling in the body fluid (phosphate buffer 6.8 pH).

The tablets were regarded as satisfactory in terms of color and Omeprazole magnesium content, as reported in **Table 7** and **8.**

**TABLE 5: EVALUATION OF TABLETS**

| Batch code | Uniformity of Weight # | Drug content uniformity (%) | Friability* | Hardness* (kg/cm$^2$) | Thickness * (mm) | Wetting Time* (Sec) | Disintegration Time*(Sec) | *In-vitro* Dispersion Time*(Sec) | Water absorption ratio* |
|---|---|---|---|---|---|---|---|---|---|
| FS1 | 202.25±8.34 | 97.13±2.40 | 0.79±0.04 | 5.74±1.20 | 3.16±0.08 | 80.2±1.30 | 103.48±3.60 | 43.76±3.31 | 221.33±14.90 |
| FS2 | 200.75±8.62 | 97.67±2.25 | 0.63±0.05 | 5.94±1.16 | 3.30±0.12 | 66.0±1.58 | 93.52±4.10 | 36.65±2.29 | 242.44±12.11 |
| FS3 | 201.25±8.40 | 98.56±1.89 | 0.61±.0.02 | 5.96±1.13 | 3.26±0.11 | 58.6±1.14 | 83.99±5.50 | 31.66±1.96 | 265.40±11.84 |
| FC1 | 199.25±8.47 | 96.10±2.29 | 0.90±0.08 | 5.68±0.85 | 3.28±0.10 | 165±3.93 | 203.64±3.31 | 84.29±1.65 | 181.16±14.23 |
| FC2 | 199.75±9.52 | 97.56±2.05 | 0.79±0.01 | 5.80±1.24 | 3.38±0.13 | 140 ±2.91 | 164.18±5.96 | 62.49±2.72 | 203.11±13.17 |
| FC3 | 201.00±8.82 | 97.78±2.89 | 0.69±0.06 | 6.20±0.54 | 3.34±0.15 | 103±1.92 | 139.58±2.06 | 50.01±5.29 | 219.33±20.26 |
| FP1 | 202.50±8.35 | 98.78±1.90 | 0.94±0.07 | 6.34±0.95 | 3.38±016 | 45.6±1.14 | 69.21±4.50 | 27.55±3.11 | 161.41±16.23 |
| FP2 | 199.75±9.93 | 99.12±2.10 | 0.89±0.09 | 6.56±0.58 | 3.30±0.15 | 32.4±1.14 | 46.07±3.72 | 18.69±2.64 | 188.10±11.18 |
| FP3 | 200.75±9.90 | 98.89±2.91 | 0.59±0.05 | 6.60±0.80 | 3.22±0.13 | 13.2±1.30 | 23.78±2.90 | 14.41±1.74 | 192.40±21.98 |
| FK1 | 201.25±9.30 | 98.72±2.04 | 0.89±0.04 | 5.86±1.25 | 3.28±0.16 | 60.2±1.30 | 80.40±2.73 | 34.08±2.00 | 167.50±12.18 |
| FK2 | 200.75±8.62 | 98.17±.1.90 | 0.74±0.04 | 6.00±1.30 | 3.18±0.08 | 33.8±1.92 | 46.12±4.61 | 28.39±3.27 | 182.01±17.05 |
| FK3 | 200.50±9.72 | 98.32±2.12 | 0.64±0.04 | 6.44±0.58 | 3.26±0.11 | 26.6±1.40 | 30.82±1.28 | 19.46±2.50 | 197.80±11.36 |

*Each value was an average of five determinations and # Results of one batch, n = 20 tablets.

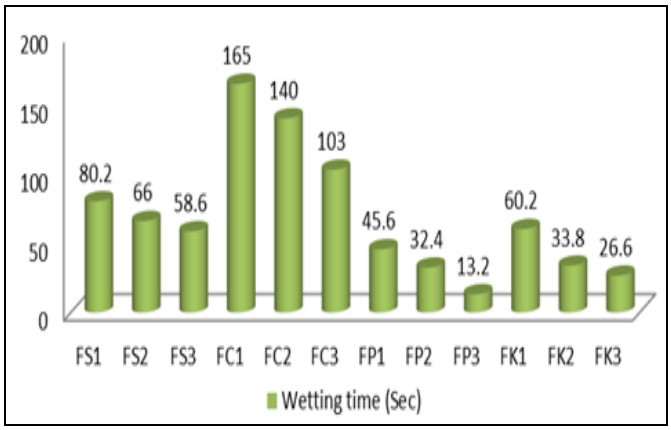


**FIG. 6: WETTING TIME (SEC) OF FORMULATIONS**

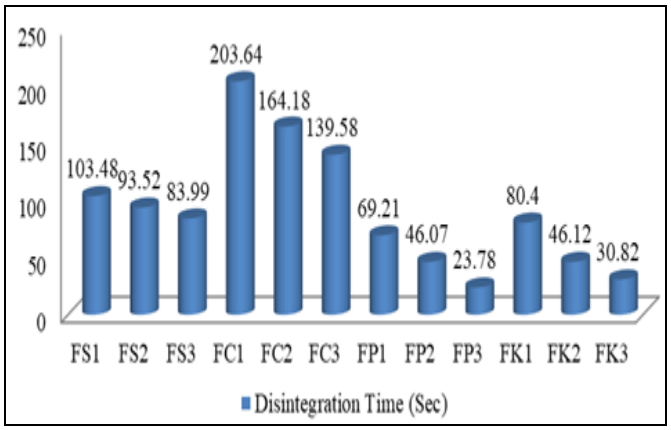


**FIG. 7: DISINTEGRATION TIME (SEC) OF FORMULATIONS**

**TABLE 6: *IN-VITRO* DRUG RELEASE STUDIES OF THE FORMULATIONS**

| Formulation Code | Cumulative % drug release | | | | | |
|---|---|---|---|---|---|---|
| Time (Sec) → | 0 | 2 | 4 | 6 | 8 | 10 |
| FS1 | 0 | 33.26 | 50.94 | 73.44 | 81.48 | 89.51 |
| FS2 | 0 | 30.05 | 52.55 | 75.05 | 86.30 | 92.73 |
| FS3 | 0 | 34.87 | 54.16 | 76.66 | 87.91 | 94.33 |
| FC1 | 0 | 28.44 | 49.33 | 68.62 | 78.26 | 84.69 |
| FC2 | 0 | 30.05 | 47.73 | 70.23 | 81.48 | 89.51 |
| FC3 | 0 | 31.66 | 52.55 | 67.01 | 83.08 | 91.12 |
| FP1 | 0 | 34.87 | 54.16 | 73.44 | 87.91 | 95.94 |
| FP2 | 0 | 36.48 | 55.76 | 78.26 | 91.12 | 97.55 |
| FP3 | 0 | 42.91 | 67.01 | 79.87 | 92.73 | 99.16 |
| FK1 | 0 | 33.26 | 58.98 | 75.05 | 86.30 | 94.33 |
| FK2 | 0 | 38.08 | 62.19 | 73.44 | 87.91 | 95.94 |
| FK3 | 0 | 41.30 | 65.41 | 78.26 | 89.51 | 97.55 |

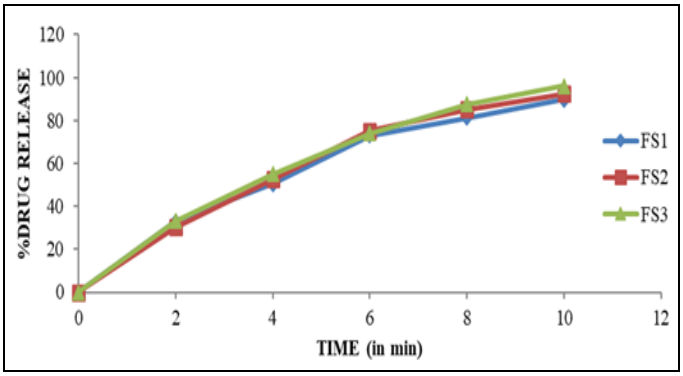


**FIG. 8: CUMULATIVE % DRUG RELEASE PROFILE OF FS1, FS2, FS3**

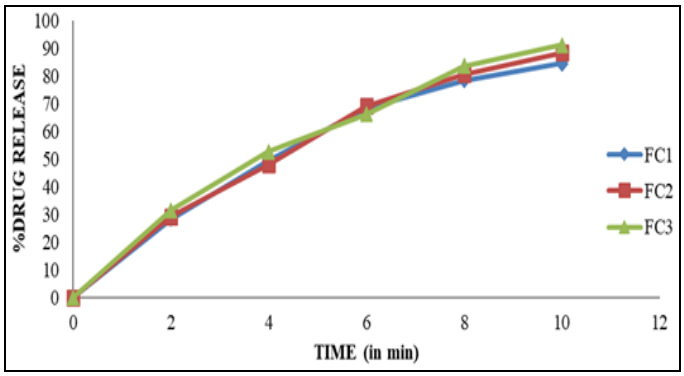


**FIG. 9: CUMULATIVE % DRUG RELEASE PROFILE OF FC1, FC2, FC3**

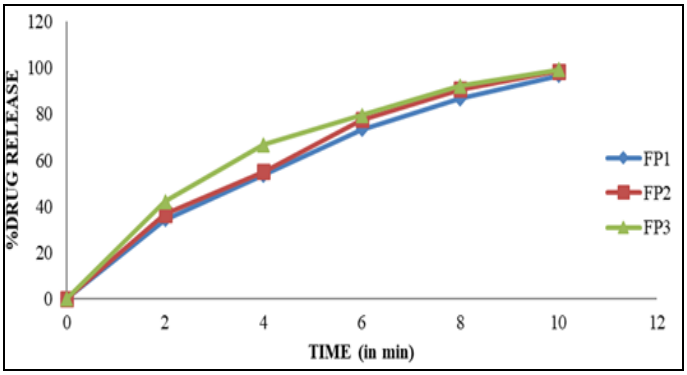


**FIG. 10: CUMULATIVE % DRUG RELEASE PROFILE OF FP1, FP2, FP3**

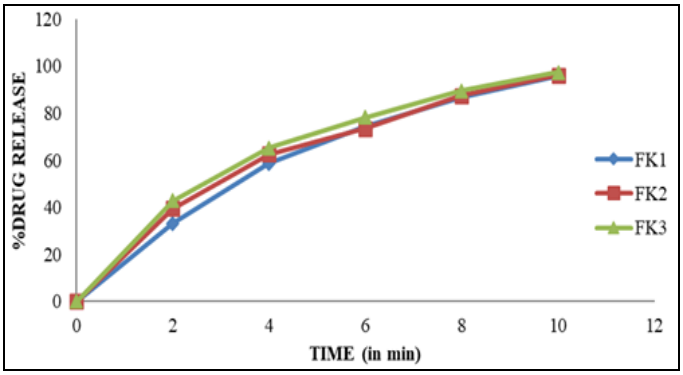


**FIG. 11: CUMULATIVE % DRUG RELEASE PROFILE OF FK1, FK2, FK3**

**TABLE 7: ACCELERATED STABILITY STUDIES OF OMEPRAZOLE SODIUM MOUTH DISSOLVING TABLETS STORED AT ROOM TEMPERATURE (RT)**

| Evaluation parameters | Time (in days) | | | |
|---|---|---|---|---|
| | 0 | 15 | 30 | 45 |
| Crushing strength | 6.6±0.80 | 6.6±0.89 | 6.5±0.93 | 6.5±0.85 |
| Disintegration time | 23.78 | 23.80 | 23.50 | 23.00 |
| Time required for complete drug release (Sec) | 10 | 10 | 10 | 10 |
| Drug content (%) | 98.89 | 98.92 | 98.02 | 97.20 |

**TABLE 8: ACCELERATED STABILITY STUDIES OF OMEPRAZOLE SODIUM MOUTH DISSOLVING TABLETS STORED AT $45^0$C TEMPERATURE**

| Evaluation parameters | Time (in days) | | | |
|---|---|---|---|---|
| | 0 | 15 | 30 | 45 |
| Crushing strength | 6.7±0.70 | 6.7±0.66 | 6.6±0.88 | 6.6±0.84 |
| Disintegration time | 23.08 | 23.00 | 22.96 | 22.90 |
| Time required for complete drug release (Sec) | 10 | 10 | 10 | 10 |
| Drug content (%) | 98.78 | 98.70 | 98.00 | 97.14 |

**CONCLUSION:** The study concentrated on creating and assessing mouth-dissolving tablets of omeprazole magnesium by utilizing several super disintegrants and other excipients. The formulations were created and assessed for different pre-compression and post-compression characteristics. The pre-compression study involved examining the flow characteristics of the powder blend, which demonstrated satisfactory results, indicating excellent flowability. Post-compression evaluation included analyzing several parameters like thickness, weight consistency, drug content, hardness, friability, wetting time, disintegration time, water absorption ratio, and in-vitro dissolution experiments. The results showed that all formulations had consistent thickness, weight within permissible limits, and uniform medication content. Hardness fluctuated depending on the ratios and types of polymers used but always stayed within acceptable limits. The friability of the standard oral pills was within acceptable norms. The wetting time, disintegration time, and water

absorption ratio were appropriate for mouth-dissolving tablets, suggesting fast disintegration and dissolution characteristics. The *in-vitro* dissolution investigations demonstrated a sustained release pattern that met the pharmacopeial standards over a specific timeframe. The mouth-dissolving tablets were shown to be stable in phosphate buffer solutions during the study period, with no noticeable alterations in color or shape. The study found that the mouth-dissolving tablets of omeprazole magnesium had good physical and chemical qualities, which could help improve patient compliance, particularly for those with dysphagia.

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