



## Research Article

# MECHANICAL AND DISSOLUTION PROPERTIES OF EUDRAGIT L100 AND S100 FILMS IN BUFFER SOLUTIONS

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MAA: MMA film, Mechanical properties, Dissolution rate, Buffer capacity, Enteric coating, Concentration gradients

### ABSTRACT

**Background:** Methacrylic acid (MAA) and methyl methacrylate (MMA) affect the mechanical and dissolution properties of enteric polymers, such as Eudragit L100 and S100. Their composition determines polymer flexibility, strength, and solubility, which are critical for pharmaceutical enteric coatings. This study examines the impact of the MAA: MMA ratio on the mechanical and dissolution properties of Eudragit L100 (1:1) and Eudragit S100 (1:2) films. **Methodology:** Mechanical testing assessed stiffness, tensile strength, and flexibility. Dissolution studies evaluated solubility at different pH levels, measuring peak dissolution rates. **Results and Discussion:** Eudragit L100, with more MAA, was stiffer and more brittle, while Eudragit S100 had higher tensile strength but reduced flexibility. Acidic conditions weakened both, due to water interactions with MAA. Eudragit L100 dissolved rapidly at pH 7.2 (90% mass loss in 60 min, peak 30.4 mg/g·min at 10 min), whereas Eudragit S100 showed minimal dissolution at lower pH, but dissolved significantly at pH 8.0 (64.5% at 180 min, peak 6.7 mg/g·min at 30 min). Larger dissolution volumes, maintained concentration gradients, enhancing dissolution, while high-capacity buffers stabilized pH and improved solubility. **Conclusion:** MAA: MMA composition critically affects the mechanical and dissolution properties of Eudragit L100 and S100, with concentration gradients playing a key role in dissolution, informing their application in enteric coatings.

### INTRODUCTION

Acrylic polymers, derived from acrylic acid or its esters, include poly (methyl methacrylate) (PMMA) and polyacrylates (PA). PMMA offers optical clarity, high tensile strength, and durability, while PA is softer and adhesive. Their ester groups enhance resilience and hydrolysis resistance, making them ideal for various applications such as nanotechnology, polymer

synthesis, and modification [1]. Biodegradable acrylic polymers play a crucial role in enteric coatings, protecting drugs from gastric degradation and facilitating their release in the intestine. This targeted delivery enhances therapeutic efficacy, reduces side effects, and improves oral drug absorption [2–4]. Eudragit polymers enable precise drug release in oral dosage forms,

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showcasing the methacrylic acid copolymer's role in healthcare sustainability at Evonik Health Care [5]. Acrylic polymers, Eudragit L100 [poly (methacrylic acid-co-methyl methacrylate), MAA: MMA 1:1] and S100 [poly (methacrylic acid-co-methyl methacrylate), MAA: MMA 1:2], are known for their pH-responsive properties. They are synthesized via free-radical polymerization of methyl methacrylate (MMA) with methacrylic acid (MAA) [6,7]. Their pH-dependent solubility arises from anionic carboxylic (-COOH) groups in MAA, insoluble in acid but soluble in alkali [8,9]. MAA: MMA 1:1, with 46.0–50.6% MAA, dissolves at pH levels above 6.0, while MAA: MMA 1:2, with 27.6–30.7% MAA, dissolves at pH levels above 7.0 [10–12]. These properties make them ideal for enteric coatings, ensuring gastric protection and precise intestinal drug release. Understanding the mechanical properties of MAA: MMA (1:1 and 1:2) polymers is crucial for optimizing drug delivery, as it enables balancing tensile strength and elasticity to prevent cracking and ensure durability for consistent drug release [13]. The dissolution behavior of MAA-MMA polymers under varying pH conditions is crucial for their performance as enteric coatings. It affects drug release in API formulations, such as tablets and pellets, with dissolution testing conducted according to pharmacopeial standards.

Initially, drug release remains below 10% in acidic media (0.1 N HCl or acetate buffers, pH 4.5) for 1-2 hours, then exceeds 80% in buffer media (pH 6.0-7.2) within 30-60 minutes [14–16]. Buffer choice and its capacity impact the polymer dissolution rates and performance. Effective drug release relies on the stability of the enteric coating in acidic conditions and the dissolution rate of the polymer in the buffer phase. This study evaluates the dissolution behavior and mechanical properties of MAA: MMA (1:1 and 1:2) films. Uniform films were tested in various media, taking into account concentration gradients and buffer capacity. The findings aim to optimize enteric coatings by enhancing their flexibility and performance for targeted drug delivery.

## MATERIALS AND METHODS

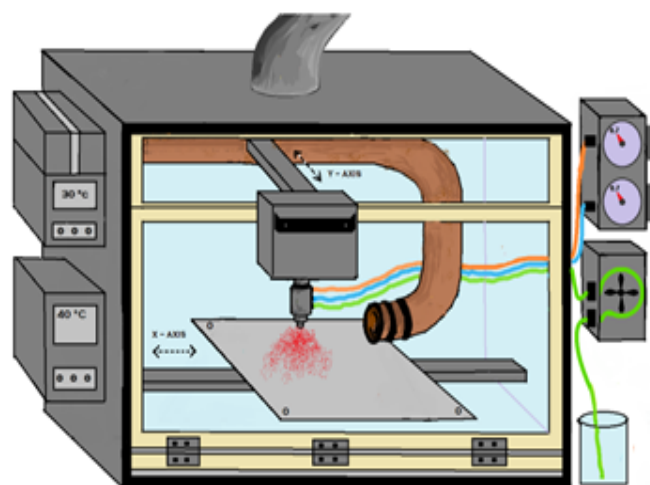
### Materials

MAA: MMA (1:1 and 1:2) sourced from Evonik Industries. Isopropanol (IPA,  $\geq 99\%$ , analytical grade, Merck) and water (Milli-Q type-1 water). Polystyrene flexible plastic board sheet (8 x 11 inches) for spray coating. Hydrochloric acid (HCl, 37%, analytical grade, Merck), Acetic acid ( $\geq 99\%$ , analytical grade,

Merck), Potassium dihydrogen phosphate monobasic (99%, analytical grade, Merck), Sodium hydroxide (97% pellets, analytical grade, Merck). Ammonium acetate (96%, analytical grade, Qualigens-Thermo Fisher), Acetonitrile ( $\geq 99.9\%$ , HPLC grade, Merck).

### Preparation of polymeric films

Polymeric films were prepared using the Automated Film Spray System (Profile Automation, UK) on 8 x 11-inch polystyrene films (90-110 microns) placed on a hot plate, as shown in Figure 1. A 5% MAA: MMA (1:1 and 1:2) solution in IPA: water (90:10 v/v) was sprayed at 17-20 g/min through a 1 mm nozzle, with atomizing and pattern air maintained at 0.7 bar. The hot plate was set at  $39^{\circ}\text{C} \pm 2^{\circ}\text{C}$ , and the drying unit at  $33^{\circ}\text{C} \pm 2^{\circ}\text{C}$ . After eight to nine cycles, the final film thickness was 95-100 microns, calculated by subtracting the original thickness of the polystyrene from the total thickness. The polymeric film was then peeled off using tweezers.



**Figure 1: Preparation of MAA: MMA (1:1 and 1:2) Polymeric Films Using an Automated Film Spray System**

### Mechanical Properties Testing of Polymeric Films

MAA: MMA (1:1 and 1:2) films (100 microns) were cut into 7.5 cm by 5 cm samples, conditioned at  $21^{\circ}\text{C} \pm 2^{\circ}\text{C}$  and  $50\% \text{RH} \pm 5\%$ . Mechanical properties were measured using an Instron 5942 with Bluehill-3 software, both for the films as prepared and after exposure to 0.1 N HCl at  $37^{\circ}\text{C} \pm 0.5^{\circ}\text{C}$  for 2 hours.

### Selection of Dissolution Media

Dissolution media were prepared following USP, IP, and EP guidelines. The media included 0.1 N HCl, acetate buffer (AB) (pH 4.5), phosphate buffers (PB) (pH 6.0, 6.8, 7.2, and 8.0), and

purified water [17–21]. Buffer capacity was assessed to determine its impact on dissolution. Dissolution testing of MAA: MMA 1:1 and 1:2 films was conducted using Phosphate Buffer Mixed (PBM) pH 6.8 IP and phosphate buffer (PB) pH 7.2 EP, and results were compared to phosphate buffers of identical pH but differing in preparation and buffer capacities.

### Dissolution Testing

Dissolution tests of MAA: MMA (1:1 and 1:2) polymeric films (n=3) were conducted using the paddle method on an Electrolab dissolution apparatus (EDT-08LX) at 75 rpm and 37±0.5°C. Films were cut into 4 × 4 cm pieces weighing 250 mg. Samples were collected at specific time intervals and analyzed using Size-Exclusion Chromatography (SEC). Percent dissolution and dissolution rate (mg/g/min) were calculated.

To assess the impact of the concentration gradient, additional tests were performed using larger dissolution volumes (375 mL and 500 mL) of phosphate buffers (PB) at pH levels of 7.2 and 8.0. SEC analysis was performed using an Agilent 1200 Infinity Series system with Waters Ultrahydrogel columns, maintained at 40°C. The mobile phase consisted of 44.75 mM ammonium acetate buffer (pH 6.6) and acetonitrile.

### Buffer Capacity Assessment

The buffer capacities of PB pH 6.8 USP, PBM pH 6.8 IP, PB pH 7.2 EP, and PB pH 7.2 USP were evaluated. Each buffer solution (1000 mL) was prepared, and its initial pH was measured. Then, 1N HCl and 1N NaOH were added separately to determine the volume required to change the pH by one unit, with the pH described using the Henderson-Hasselbalch equation 1 [22].

$$pH = pKa + \log \frac{[A^-]}{[HA]} \text{----- eq 1}$$

[A<sup>-</sup>] is the concentration of the conjugate base, [HA] is the concentration of the weak acid. When a small amount of acid or base (Δn) is added to the buffer [A<sup>-</sup>] and [HA] change as follows:

### Adding acid:

$$[A^-]_{new} = [A^-] - (\Delta n) \text{----- eq 2}$$

$$[HA]_{new} = [HA] + (\Delta n) \text{----- eq 3}$$

### Adding base:

$$[A^-]_{new} = [A^-] + (\Delta n) \text{----- eq 4}$$

$$[HA]_{new} = [HA] - (\Delta n) \text{----- eq 5}$$

Change in pH (ΔpH), calculated using the modified Henderson-Hasselbalch equation.

$$\Delta pH = \log \frac{[A^-]_{new}/[HA]_{new}}{[A^-]_{initial}/[HA]_{initial}} \text{----- eq 6}$$

Buffer capacity (β) is defined as the ratio of acid or base added (in gram-equivalents/L) to the change in pH units [23]:

$$(\beta) = \frac{\Delta n}{\Delta pH} \text{----- eq 7}$$

## RESULT AND DISCUSSION

### Mechanical Properties of Polymeric Films

Key mechanical properties, including tensile strength (σ<sub>max</sub>), Young's modulus (E), and elongation (ε<sub>max</sub>), were derived and are summarized in Table 1. Both polymeric films were brittle, exhibiting zero toughness, with high E but low σ<sub>max</sub> and ε<sub>max</sub>. The high modulus indicates stiffness and resistance to deformation, while the low elongation and toughness highlight brittleness. MAA: MMA 1:2 demonstrated higher tensile strength than MAA: MMA 1:1, attributed to its higher MMA content (~70%), which contributes to greater rigidity [12].

Both films maintained appearance after 2 hours in 0.1N HCl but showed reduced E and σ<sub>max</sub>, with increased thickness due to water uptake and plasticization. This effect is due to polymer chain solvation, weakening intramolecular forces, and increasing free volume [24]. The increase in film thickness indicates absorption of the acidic medium, contributing to mechanical changes and reduced stiffness.

**Table 1: Mechanical Properties of Polymeric Film**

Polymer Type	Conditions	E(Gpa)	σ <sub>max</sub> (Mpa)	ε <sub>max</sub> (%)	Film thickness (mm)
MAA: MMA 1:1	As such a film	491.202± 40.140	891± 238	0.69± 1.10	108± 10.3
	After 2 hr in 0.1 N HCl USP	0.032± 0.006	0.22± 0.05	1.00± 0.42	116± 12.1
MAA: MMA 1:2	As such a film	524.548± 60.519	3144± 687	0.65± 0.17	107± 9.3
	After 2 hr in 0.1 N HCl USP	0.113± 0.012	0.66± 0.08	0.90± 0.17	110± 10.5

MAA: MMA 1:1 / 1:2 – Film ratios of methacrylic acid to methyl methacrylate., E (GPa) – Young's modulus (gigapascals)., σ<sub>max</sub> (Mpa) – Maximum tensile strength (megapascals)., ε<sub>max</sub> (%) – Elongation at break (percentage)

## Dissolution Testing

The dissolution profiles of MAA: MMA 1:1 and 1:2 films were analyzed in various buffer solutions (Table 2). MAA: MMA 1:1 remained intact in acidic media (0.1 N HCl, AB pH 4.5, PB pH 6.0) due to non-ionized carboxyl groups, but dissolved rapidly above pH 6.8 as MAA ionized. MAA: MMA 1:2 showed no

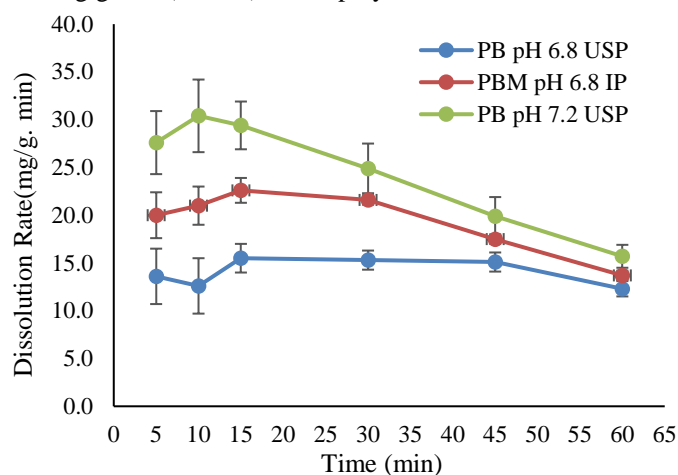
dissolution up to pH 6.8, with slow dissolution above this point, releasing significantly in PB pH 8.0. Water-insolubility was due to the lack of buffering capacity. MAA: MMA 1:1 achieved 90% dissolution in PB pH 7.2 within 60 min due to higher MAA content, whereas MAA: MMA 1:2 reached 64.9% at PB pH 8.0 in 180 min, as ionization increased.

**Table 2: Release Profiles of MAA: MMA Films in Various Buffer Media**

Time (min)	MAA: MMA 1:1 Film			MAA: MMA 1:2 Film		
	PB pH 6.8 USP	PBM pH 6.8 IP	PB pH 7.2 USP	PB pH 7.2 USP	PB pH 7.2 EP	PB pH 8.0 USP
5	6.8% ± 1.5	10.0% ± 1.4	13.1% ± 1.6	0	0	0
10	12.5% ± 2.9	21.1% ± 1.7	29.0% ± 2.8	0	0	0.8% ± 0.1
15	23.3% ± 2.4	33.9% ± 2.4	42.0% ± 2.2	0	6.0% ± 1.7	7.1% ± 1.5
30	45.7% ± 3.0	65.0% ± 2.5	71.0% ± 3.4	2.2% ± 1.6	18.2% ± 2.8	20.2% ± 1.1
45	67.7% ± 4.0	79.0% ± 2.7	85.0% ± 4.2	5.1% ± 1.9	25.1% ± 3.3	29.0% ± 1.9
60	73.5% ± 4.4	82.1% ± 3.8	90.0% ± 4.2	7.0% ± 2.0	32.1% ± 3.3	40.2% ± 3.7
90	-	-	-	9.8% ± 1.7	41.0% ± 2.6	57.0% ± 3.5
120	-	-	-	15.0% ± 3.2	44.0% ± 3.6	63.2% ± 3.5
180	-	-	-	20.9% ± 2.0	49.0% ± 3.4	64.9% ± 4.5

MAA: MMA 1:1 / 1:2 – Film ratios of methacrylic acid to methyl methacrylate., PB / PBM – Phosphate Buffer / Phosphate Buffer Mixed., USP / IP / EP – Buffer standards (United States, Indian, and European Pharmacopeia), % ± SD – Percentage of film material dissolved ± standard deviation., - Data not measured.

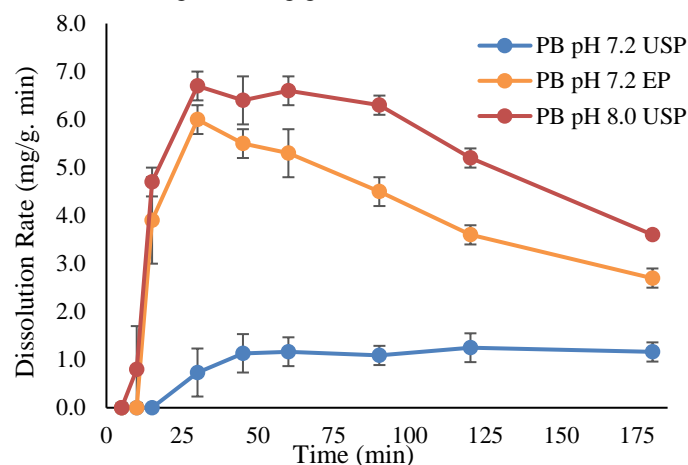
Figure 2 shows that the dissolution rates of MAA: MMA 1:1 film exhibit a clear pH-dependent trend. MAA: MMA 1:1 dissolved fastest in PB pH 7.2 USP, peaking at 30.4 mg/g-min at 10 min and dropping to 15.7 mg/g-min by 60 min. In PB pH 6.8 USP, it started at 15.5 mg/g-min (15 min) and declined to 12.3 mg/g-min (60 min) due to polymer saturation.



**Figure 2: Dissolution Rate of MAA: MMA 1:1 Film in Various Buffer Media Over Time. Data are presented as mean ± SD (n=3). PB – Phosphate Buffer; PBM – Phosphate Buffer Mixed; USP/IP – United States/Indian Pharmacopeia.**

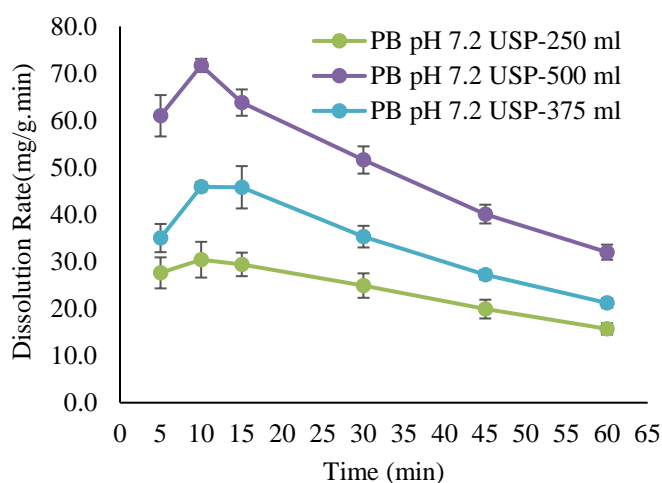
Figure 3 shows that MAA: MMA 1:2 films exhibited minimal dissolution rates. In PB pH 7.2 USP, it reached 1.3 mg/g-min at

120 min, stabilizing at 1.2 mg/g-min (180 min). In PB pH 8.0 USP, dissolution was higher, peaking at 6.7 mg/g-min (30 min) before decreasing to 3.6 mg/g-min (180 min).



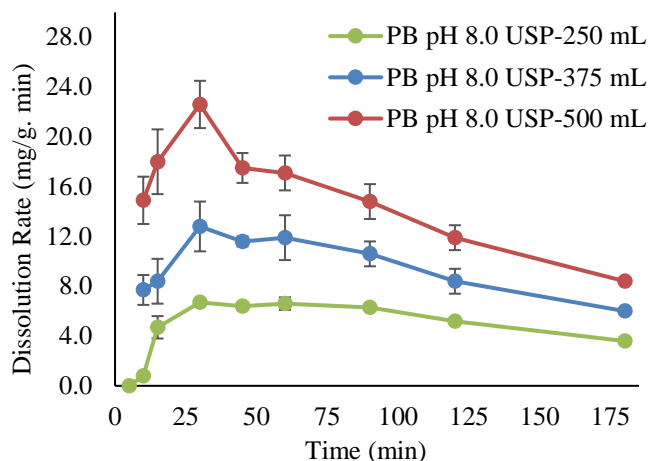
**Figure 3: Dissolution Rate of MAA: MMA 1:2 Film in Various Buffer Media Over Time. Data are presented as mean ± SD (n=3). PB – Phosphate Buffer; USP/EP – United States/European Pharmacopeia.**

Figure 4 shows that larger medium volumes enhance the concentration gradient, thereby increasing dissolution rates by reducing saturation effects. For MAA: MMA 1:1, the peak rate is highest at 500 mL (72.3 mg/g-min at 10 min), followed by 375 mL (~50 mg/g-min) and 250 mL (~30 mg/g-min).



**Figure 4: Impact of Medium Volume on MAA: MMA 1:1 Film Dissolution Rate.** Data are presented as mean  $\pm$  SD (n = 3), PB – Phosphate Buffer. USP phosphate buffer was used at three dissolution volumes: 250 mL, 375 mL, and 500 mL.

Similarly, Figure 5 for MAA: MMA 1:2 shows that rates peak at 22.6 mg/g·min (500 mL), decreasing to 12.8 mg/g·min (375 mL) and 6.7 mg/g·min (250 mL). Dissolution is pH- and time-dependent, with MAA: MMA 1:1 dissolving faster due to its higher MAA content (50%) compared to MAA: MMA 1:2 (30%).



**Figure 5: Impact of Medium Volume on MAA: MMA 1:2 Film Dissolution Rate.** Data are presented as mean  $\pm$  SD (n = 3), PB – Phosphate Buffer. USP phosphate buffer pH 8.0 was used at three dissolution volumes: 250 mL, 375 mL, and 500 mL.

#### Statistical Evaluation of pH-Dependent Dissolution

To quantitatively assess the influence of buffer pH on the dissolution behaviour of MAA: MMA copolymer films, one-

way analysis of variance (ANOVA) was conducted for both 1:1 and 1:2 films. For the MAA: MMA 1:1 film, the study revealed a highly significant difference among groups ( $F = 33.79$ ,  $p = 1.14 \times 10^{-6}$ ), indicating that dissolution rates varied substantially across the different pH buffer media tested. The F-value significantly exceeded the critical value at the 95% confidence level, and the very low p-value strongly rejected the null hypothesis that all group means are equal. This statistical evidence confirms that buffer pH has a pronounced and measurable effect on the dissolution behaviour of the 1:1 film. In comparison, MAA: MMA 1:2 film exhibited a moderate but statistically significant difference, with a one-way ANOVA result of  $F = 3.65$  and  $p = 0.0107$ . This indicates that while the extent of pH responsiveness is lower in the 1:2 films—likely due to reduced methacrylic acid content—the effect of pH on dissolution remains significant. Higher dissolution rates were consistently observed in pH 8.0, with minimal release in USP pH 7.2. Overall, the analysis of variance confirms that both film types exhibit pH-dependent dissolution, with the effect being stronger in the 1:1 composition. ANOVA enables a reliable comparison across buffer groups, supporting informed decisions in designing pH-responsive film formulations.

#### Buffer Capacity Assessment

The buffer capacities of PB pH 6.8 USP, PBM pH 6.8 IP, PB pH 7.2 USP, and PB pH 7.2 EP were assessed using 1N HCl and 1N NaOH. PB pH 6.8 USP exhibited the lowest acid resistance (16 mL, 0.0162 mol/L/pH unit), while PBM pH 6.8 IP (64 mL, 0.0634 mol/L/pH unit) and PB pH 7.2 EP (84 mL, 0.0840 mol/L/pH unit) showed higher stability. In base stability, PB pH 6.8 USP (25 mL, 0.0250 mol/L/pH unit) and PB pH 7.2 USP (15 mL, 0.0149 mol/L/pH unit) had lower resistance, whereas PBM pH 6.8 IP (71 mL, 0.0703 mol/L/pH unit) demonstrated the highest. These findings highlight the differences in buffer resistance to pH changes and their impact on the dissolution of polymeric films.

#### Buffer Composition Influence

**MAA: MMA 1:1 Films:** PBM pH 6.8 IP showed higher buffer capacity than PB pH 6.8 USP, maintaining a stable pH and minimizing fluctuations. As a result, MAA: MMA 1:1 film had faster dissolution in PBM pH 6.8 IP, achieving 82.1% dissolution in 60 minutes, compared to 73.5% in PB pH 6.8 USP (Table 2). The dissolution rate in PBM pH 6.8 IP reached a peak of 22.6 mg/g·min within 15 minutes. In contrast, PB pH 6.8 USP

showed a reduced rate of 15.5 mg/g·min, likely due to its lower buffer capacity, which limits dissolution efficiency (Figure 2).

**MAA: MMA 1:2 Films:** PB pH 7.2 EP showed higher buffer capacity than PB pH 7.2 USP, leading to more consistent and improved dissolution of MAA: MMA 1:2 films. After 180 minutes, dissolution reached 49.0% in PB pH 7.2 EP, while PB pH 7.2 USP only achieved 20.9% (Table 2). The dissolution rate was highest in PB pH 7.2 EP, peaking at 6 mg/g·min in the first 30 minutes (Figure 3). In contrast, PB pH 7.2 USP had a slower dissolution rate due to pH fluctuations, which affected its dissolution performance.

### CONCLUSIONS

This study evaluates the mechanical and dissolution properties of Eudragit L100 and S100 films as enteric coatings. Both films exhibited high stiffness and brittleness, with MAA: MMA 1:2 films being more rigid due to higher MMA content. Acidic exposure reduced mechanical strength, indicating a plasticizing effect. The dissolution study revealed that MAA: MMA 1:1 films dissolved faster and more completely at higher pH levels, while MAA: MMA 1:2 films showed minimal dissolution at lower pH levels, improving only in alkaline conditions. Larger medium volumes enhanced dissolution by reducing saturation effects and maintaining favorable concentration gradients. Buffers with higher capacities (PBM pH 6.8 IP, PB pH 7.2 EP) facilitated faster dissolution by stabilizing pH. In contrast, lower-capacity buffers (PB pH 6.8 USP, PB pH 7.2 USP) caused slower dissolution due to pH fluctuations. A one-way ANOVA confirmed statistically significant pH-dependent dissolution for both film types across the buffer media. The findings highlight the critical role of buffer capacity and media volume in dissolution performance, offering insights for optimizing enteric coating formulations. MAA: MMA 1:1 film suits intestinal release, while 1:2 films are better suited for colon-targeted delivery due to their higher pH requirement for dissolution. These results are particularly valuable for designing robust delayed-release drug products, aiding in the development of more consistent and predictable oral dosage forms. In today's context, such improvements are essential for enhancing patient compliance and ensuring effective therapeutic outcomes.

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### FINANCIAL ASSISTANCE

NIL

### CONFLICT OF INTEREST

The authors declare no conflict of interest.

### AUTHOR CONTRIBUTION

Vaibhav Ambudkar conducted the experimental work and was involved in data interpretation and manuscript writing. Rashmi Chauhan was involved in conceiving the idea, interpreting the data, and writing the manuscript. All authors read and approved the final manuscript.

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