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COMPARATIVE DISSOLUTION PROFILES OF OLMESARTAN MEDOXOMIL MONOTHERAPY AND FIXED-DOSE COMBINATION TABLETS

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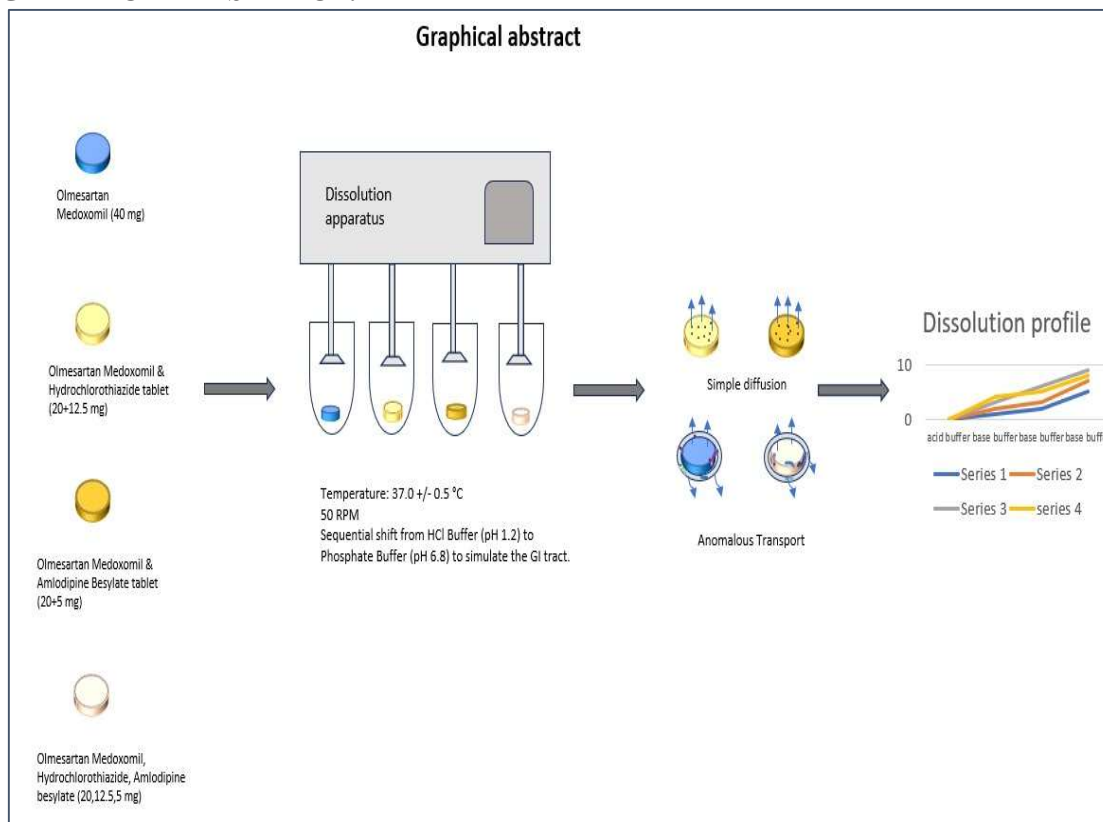
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ABSTRACT

Dissolution studies play a major role in evaluating solid dosage forms. It is one of the official tests. In-vitro-in-vivo correlation (IVIVC) is based on dissolution studies [4, 5]. Olmesartan Medoxomil (OM) is an Angiotensin-II receptor blocker given for the treatment of hypertension [10, 11]. This was selected to compare dissolution profiles of monotherapy tablets (OLMO-40) and fixed-dose combinations (FDCs): OLMO-AM (with Amlodipine), OLMO-H (with Hydrochlorothiazide), and OLMO-AH (triple combination). **Method:** Dissolution testing was performed using the USP apparatus type II (paddle method) at 50 rpm in 900 mL medium. The LABINDIA D5 8000-8-stage apparatus was employed. Since OM and its FDCs are enteric-coated, two buffers were used: HCl buffer (pH 1.2) and phosphate buffer (pH 6.8), maintained at 37.0 ± 0.5 °C. Samples were analysed with a UV spectrophotometer at 256 nm. Release kinetics were studied using zero-order, first-order, Higuchi, Korsmeyer-Peppas, and Hixon-Crowell models, with R^2 values computed in Excel. **Results:** Both monotherapy and FDC tablets showed rapid release of OM in phosphate buffer (pH 6.8). The dissolution profiles of OM API reference and FDC formulations were statistically compared, revealing close similarity. The release kinetics confirmed consistent drug release patterns across formulations. **Conclusion:** Across all biorelevant media, the in-vitro dissolution profiles of OM in the FDC tablet and the monotherapy are regarded as statistically comparable. This finding confirms the pharmaceutical equivalence between the formulations, ensuring that the superior (critical) quality attribute of API release is maintained in the combination product [17-20].

Keywords: Olmesartan Medoxomil, Amlodipine, Hydrochlorothiazide, UV-spectrophotometer,
Dissolution test apparatus, Monotherapy, Fixed dose combinations

GRAPHICAL ABSTRACT:**INTRODUCTION**

Dissolution studies are crucial for in-vitro research and are used to assess the drug's bioavailability. In order to analyse their quality, these studies are typically conducted batch by batch. It is an essential parameter for drug efficiency, as the absorption of drugs takes place after the dissolution only. Hence, it acts as a rate-limiting step for the therapeutic activity, mainly for drugs that belong to the BCS class II&IV. This study aims to compare in vitro dissolution profiles of Olmesartan Medoxomil tablets IP (OLMO-40) and other fixed-dose combinations, such as double combinations: Olmesartan Medoxomil and Amlodipine

Besylate tablets IP (OLMO-AM), Olmesartan Medoxomil and Hydrochlorothiazide tablets IP (OLMO-H), and triple combination: Olmesartan Medoxomil, Amlodipine Besylate, and Hydrochlorothiazide tablets IP (OLMO-AH). For most dosage forms, the USP defines acceptance criteria as the Q value (e.g., Not Less Than $Q = 80\%$ dissolved in 45 minutes). The product must meet the acceptance criteria at each stage to pass the quality control test.

The drug Olmesartan Medoxomil is an antihypertensive drug that is widely used both as monotherapy and fixed-dose

combinations [1, 2]. OM is generally a prodrug. During absorption, esterases in the liver and digestive system transform it into the active ingredient, Olmesartan. It is very pH-dependent and has poor water solubility. It has high permeability and crosses the membrane immediately after dissolution. Particularly, its low solubility makes dissolution testing a crucial quality control step. Film-coated immediate-release pills of this medication are available as monotherapy and FDC [1, 2, 3].

The primary goal of this study is to compare the release rate of the medicine Olmesartan Medoxomil in FDC and monotherapy. As the drug belongs to class II, it is quite challenging to make a formulation that can dissolve quickly. Additionally, it is pH-dependent and insoluble at acidic pH levels [6-8]. We employed two buffers, HCl (pH 1.2) and pH 6.8 phosphate buffer, to simulate the stomach and intestine to preserve a human gastrointestinal environment. Tablets remained undissolved in 0.1N HCL even after 60 minutes due to the acidic pH. After the replacement of the buffer with phosphate buffer, the tablets immediately started to dissolve and were completely dissolved within 60 minutes. The dissolution medium is 900 mL at 37 $\pm$ 0 °C, and the paddle type (Type-II) is utilized.

To reduce errors, all of the tablets were positioned simultaneously, and samples

were collected at the same time. To analyze the disintegration pattern, many graph types are plotted. Zero-order and first-order plots were plotted to determine which of the kinetics the drug follows. The Higuchi plot tells whether drug release is primarily driven by diffusion from a porous or insoluble matrix. Korsmeyer Peppas define the transport mechanism of a drug. In order to ascertain whether or not the dissolution pattern of OM varies for combination tablets, the Hixon-Crowell plot is used to test whether the drug release is proportionate to the cubic root of the remaining amount of drug, which happens when the tablet dissolves uniformly, and the surface area changes over time.

MATERIALS AND METHODOLOGY:

Materials:

Olmesartan Medoxomil and the combination of Olmesartan Medoxomil and Amlodipine, Olmesartan Medoxomil and Hydrochlorothiazide, a triple combination of Olmesartan, Amlodipine, and Hydrochlorothiazide. All these tablets were from Knoll Healthcare Pvt Ltd. – New Delhi.

UV-Visible spectroscopy – LABINDIA D5 8000 - Maharashtra

Solvent (methanol), Hydrochloric Acid, Potassium dihydrogen phosphate, Sodium hydroxide, Purified water.

Construction of a calibration curve of Olmesartan Medoxomil:

10mg of Olmesartan Medoxomil was dissolved in 10ml of methanol. Name it as stock solution-1(1000 $\mu\text{g/ml}$). From that stock solution, 1ml was taken and made up to 10ml with pH 6.8 phosphate buffer, which is stock solution-2(100 $\mu\text{g/ml}$). Stock solution-2 is used to make serial dilutions of concentrations 2,4,6,8, and 10 $\mu\text{g/ml}$ by taking 0.2, 0.4, 0.6, 0.8, and 1.0 mL of stock and adding up to 10 mL.

These dilutions were observed in a UV-Spectrophotometer at 256nm, and absorbances were noted. The calibration curve was drawn by taking time on the X-axis and absorbance on the Y-axis.

Preparation of Dissolution Medium:

(pH 1.2) HCl Buffer: 2.0 g of Sodium chloride dissolved in purified water to which 7ml of HCl is added and made up to the final volume of 1000ml using purified water. As per IP. pH 6.8 phosphate Buffer: 6.85 g of Potassium dihydrogen phosphate and 0.896

g of Sodium hydroxide dissolved in purified water and made up to the final volume of 1000ml using purified water. As per IP.

Procedure for Dissolution:

0.1N HCL buffer of 900ml each was taken in 4 vessels of the dissolution apparatus. The temperature of the vessel was maintained to be 37 ± 0.5 °C. Stirrer depth was set to 25 cm, and rpm was 50. After the temperature was set, Olmesartan Medoxomil tablet and other combination tablets were placed in a separate vessel. 5ml of sample was taken from 4 vessels for 5, 10, 15, 30, 45, 60 minutes, and 5ml of buffer was added every time to maintain sink condition. The samples were observed under UV at 256nm, and absorbances were noted. By using these values, different plots were drawn, such as zero-order plot, first-order plot, Higuchi plot, Korsmeyer Peppas plot, and Hixon Crowell plot, and by using these values, release kinetics are compared [9, 12, 14].



Fig. 1

Fig. 1: Dissolution apparatus with 4 different tablets.



Fig. 2

Fig. 2: Checking the temperature during the progress of the experiment.

RESULTS:

In the HCl buffer, the tablets do not dissolve.

Subsequently, dissolution started in

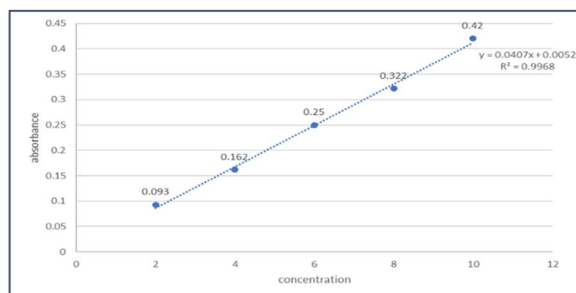
phosphate buffer, and the outcomes are as follows:

Calibration curve and its values of Olmesartan API:

Absorption values of API Olmesartan from UV- Visible spectroscopy and the Calibration curve Graph

Concentration	Absorbance
2	0.093
4	0.162
6	0.25
8	0.322
10	0.42

Slope	Y intercept
0.0407	0.0052

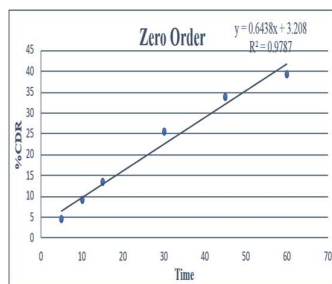


Dissolution studies:

1. OLMESARTAN MEDOXOMIL 40mg

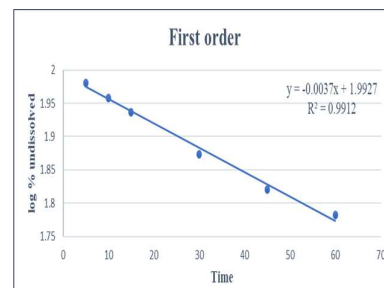
Zero-order values and their graph:

Time	% CDR
5	4.4112
10	9.1657
15	13.4775
30	25.308
45	33.7662
60	39.35



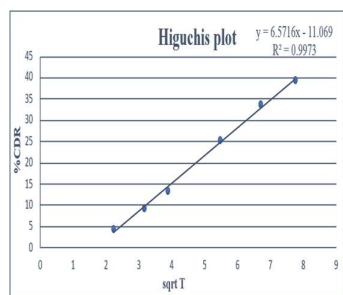
First-order values and their graph:

Time	log% undissolved
5	4.4112
10	9.1657
15	13.4775
30	25.308
45	33.7662
60	39.35



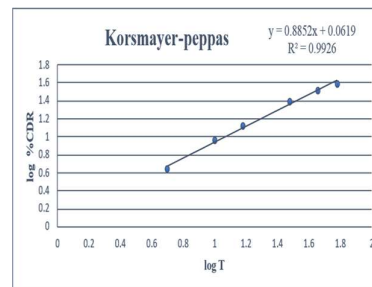
Higuchi's values and their graph:

Sqrt Time	% CDR
2.236	4.4112
3.162	9.1657
3.872	13.4775
5.477	25.308
6.708	33.7662
7.745	39.35



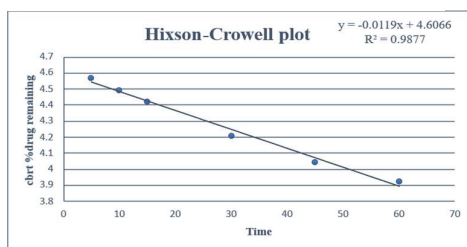
Korsmeyer-Peppas Values and plot:

Log time	log% CDR
0.698	0.6445
1	0.9621
1.176	1.1296
1.477	1.4032
1.653	1.5254
1.778	1.5949



Time	Cbdt drug remaining
5	4.5723
10	4.4952
15	4.4229
30	4.2113
45	4.046
60	3.9289

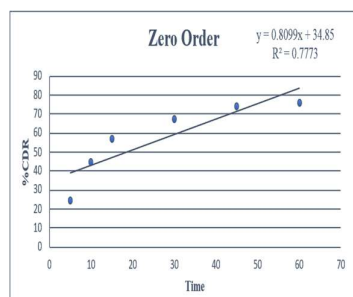
Hixson-Crowell values and their graph:



2. OLMESARTAN MEDOXOMIL + AMLODIPINE BESYLATE (20+5 mg)

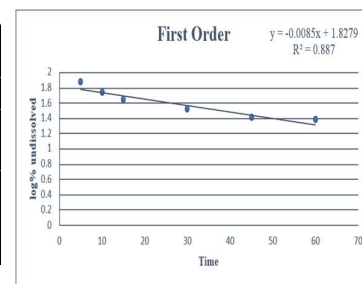
Zero-order values and their graph:

Time	% CDR
5	24.304
10	44.645
15	56.697
30	67.090
45	74.166
60	75.82



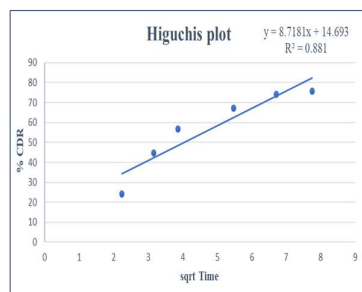
First-order values and their graph:

Time	log% undissolved
5	1.879
10	1.7431
15	1.6365
30	1.5173
45	1.4121
60	1.3833



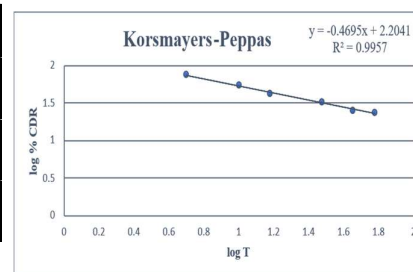
Higuchi's values and their graph:

Sqrt Time	% CDR
2.236	24.304
3.162	44.645
3.872	56.697
5.477	67.090
6.708	74.166
7.745	75.82



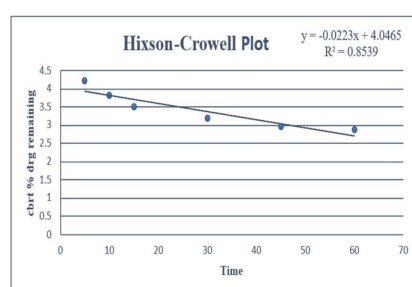
Korsmayer-Peppas Values and plot:

Log time	log% CDR
0.698	0.6445
1	0.9621
1.176	1.1296
1.477	1.4032
1.653	1.5254
1.778	1.5949



Hixson-Crowell values and plot:

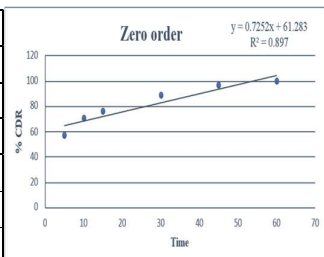
Time	Cbdt drug remaining
5	4.2301
10	3.8111
15	3.5115
30	4.2113
45	2.9561
60	2.8914



3. OLMESARTAN MEDOXOMIL + HYDROCHLOROTHIAZIDE (20+ 12.5 mg)

Zero-order values and their graph:

Time	% CDR
5	56.9185
10	70.0835
15	75.7145
30	88.54
45	96.39
60	99.707



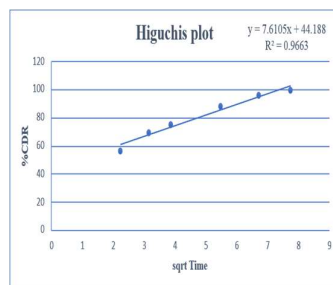
First-order values and their graph:

Time	log% undissolved
5	1.6342
10	1.4759
15	1.3853
30	1.0591
45	0.5575
60	0.5331



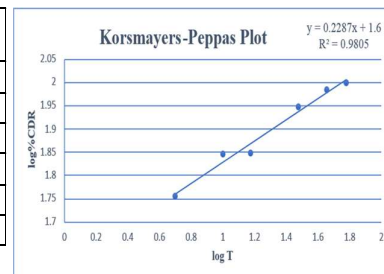
Higuchi's values and their graph:

Sqrt Time	% CDR
2.236	56.9185
3.162	70.0835
3.872	75.7145
5.477	88.54
6.708	96.39
7.745	99.707



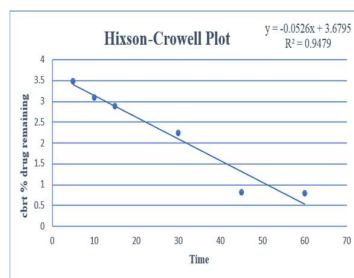
Korsmayer-Peppas Values and plot:

Log time	log% CDR
0.698	1.7552
1	1.8456
1.176	1.8491
1.477	1.9471
1.653	1.984
1.778	1.9987



Hixson-Crowell values and plot:

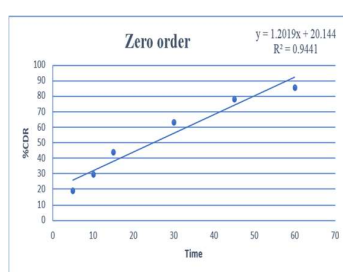
Time	Cbrt drug remaining
5	3.5056
10	3.1043
15	2.8958
30	2.2545
45	0.823
60	0.8108



4. OLMESARTAN MEDOXOMIL + AMLODIPINE + HYDROCHLOROTHIAZIDE (20+ 5+12.5 mg)

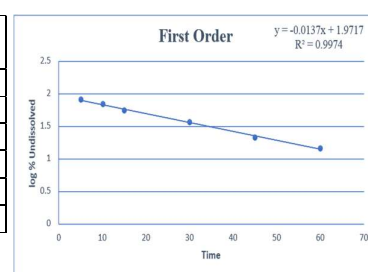
Zero-order values and their graph:

Time	% CDR
5	18.9945
10	29.7195
15	43.6505
30	63.11
45	78.368
60	85.3335



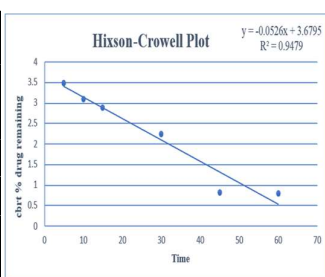
First-order values and their graph:

Time	log% undissolved
5	1.9085
10	1.8468
15	1.7508
30	1.5669
45	1.335
60	1.1663

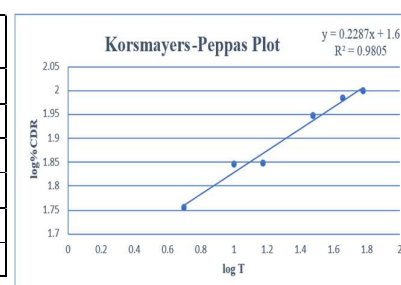


Higuchi's values and their graph:

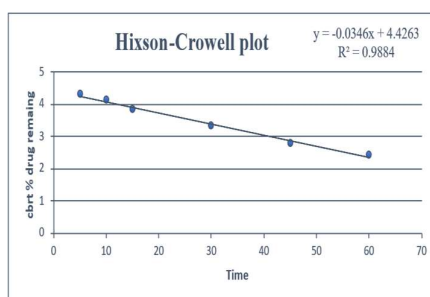
Sqrt Time	% CDR
2.236	18.9945
3.162	29.7195
3.872	43.6505
5.477	63.11
6.708	78.368
7.745	85.3335

**Korsmayer-Peppas Values and plot:**

Log time	log% CDR
0.698	1.2786
1	1.473
1.176	1.6399
1.477	1.8
1.653	1.8941
1.778	1.9311

**Hixson-Crowell values and plot:**

Time	Cbdt drug remaining
5	4.3268
10	4.1267
15	3.8338
30	3.3289
45	2.7863
60	2.4477

**DISCUSSION:****1. For Olmesartan Medoxomil 40 mg (OLMO-40):**

- We can conclude that the drug release rate is concentration-dependent based on the zero-order and first-order plots. The release rate lowers as the medication concentration in the dose form drops.
- The formulation follows the Higuchi model ($R^2 = 0.9973$). This suggests that the medication is released from a matrix system through a diffusion-controlled method.
- The formulation follows the Korsmeyer-Peppas model with a high linearity of $R^2 =$

0.9926. The release exponent (n) of 0.8852 (the slope) indicates an anomalous (non-Fickian) transport mechanism. This confirms that drug release is governed by a combination of both diffusion and polymer swelling/erosion.

- The data fit the Hixson-Crowell model, indicating that drug release is governed by the diminishing surface area and diameter of the particles over time.
- This implies that the dosage form experiences uniform erosion or dissolution, with the geometric shape staying the same as it contracts.

Observation table:

Time (min)	Absorbance	Conc. (mg)	Amount dissolved	%CDR	%drug remaining	Log %drug remaining	Cube root of the drug remaining	Log %CDR
5	0.085	1.906	1.7645	4.4112	95.588	1.9804	4.5723	0.6445
10	0.171	4.0737	3.6663	9.1657	90.8343	1.9582	4.4952	0.9621
15	0.249	5.9901	5.391	13.4775	86.5235	1.9371	4.4229	1.01296
30	0.463	11.2481	10.1232	25.308	74.692	1.8732	4.2113	1.4032
45	0.616	15.0073	13.5065	33.7662	66.2338	1.821	4.0460	1.5284
60	0.717	17.4889	15.74	39.35	60.65	1.7828	3.9289	1.5949

2. For Olmesartan Medoxomil + Amlodipine Besylate (20+5 mg) (OLMO-AM):

- The medication is released after A concentration-dependent release mechanism is indicated by first-order kinetics ($R^2 = 0.887$) more precisely than zero-order kinetics ($R^2 = 0.7773$).
- The drug release data demonstrates an excellent fit to the Higuchi model ($R^2 = 0.881$), confirming that the release mechanism is primarily diffusion-controlled.

With an $R^2 = 0.9957$, the Korsmeyer-Peppas plot demonstrates an outstanding linear fit, suggesting that it is the most accurate model for characterizing the release data. It explains how Fickian transport controls the drug's release.

The Hixson-Crowell plot for this data shows a lower correlation ($R^2 = 0.8539$), indicating that drug release is not primarily governed by surface erosion. This suggests that the geometric shape and surface area of the particles do not diminish uniformly, and other release mechanisms are likely more dominant.

Observation table:

Time (min)	Absorbance	Conc. (mg)	Amount dissolved	%CDR	%drug remaining	Log %drug remaining	Cube root of drug remaining	Log % CDR
5	0.255	5.4009	4.8608	24.304	75.696	1.879	4.2301	1.3856
10	0.409	9.9213	8.9291	44.6455	55.3545	1.7431	3.8111	1.6497
15	0.518	12.5995	11.3395	56.6975	43.3025	1.6365	3.5115	1.7535
30	0.612	14.9090	13.4181	67.0905	32.9095	1.5173	3.2045	1.8266
45	0.676	16.4815	14.833	74.1665	25.8335	1.4121	2.9561	1.8702
60	0.691	16.8501	15.165	75.825	24.175	1.3833	2.8914	1.8798

3. For Olmesartan Medoxomil + Hydrochlorothiazide (20+ 12.5mg) (OLMO-H):

- A concentration-dependent release process is indicated by the fact that the drug release more closely resembles first-order kinetics

($R^2 = 0.9576$) than the zero-order model ($R^2 = 0.897$). This shows that as the amount of medicine in the formulation is reduced over time, the rate of drug release is not constant.

- The Higuchi plot for this data shows a strong linear correlation ($R^2 = 0.9663$), indicating that drug release is primarily a diffusion-controlled process.
- The Korsmeyer-Peppas plot shows a high linear correlation ($R^2 = 0.9805$), and the release exponent ($n = 0.2287$) indicates a Fickian diffusion mechanism since the value is below 0.45.
- The drug release data fit the Hixson-Crowell model with strong linearity, suggesting that the particles' decreasing diameter and surface area over time control the release rate. This implies that as the dose form dissolves, it experiences homogeneous erosion while retaining its original geometric shape.

Observation table:

Time (min)	Absorbance	Conc. (mg)	Amount dissolved	%CDR	%drug remaining	Log %drug remaining	Cube root drug remaining	Log %CDR
5	0.520	12.6486	11.3837	56.9185	43.0815	1.6342	3.5056	1.7552
10	0.639	15.5742	14.0167	70.0835	29.9165	1.4759	3.1043	1.8456
15	0.69	16.8255	15.1429	75.7145	24.2855	1.3853	2.8958	1.8791
30	0.806	19.6756	17.7080	88.54	11.46	1.0591	2.2545	1.9471
45	0.877	21.4201	19.278	96.39	3.61	0.5575	0.823	1.984
60	0.907	22.1527	19.9414	99.707	0.293	0.5331	0.8101	1.9987

4. For Olmesartan Medoxomil + Amlodipine + Hydrochlorothiazide (20+5+12.5mg) (OLMO –AH)

- The release data of the drug exhibits nearly perfect linearity and first-order kinetics ($R^2 = 0.9974$), indicating that the release rate is concentration-dependent.
- The drug release mechanism is predominantly diffusion-controlled, as confirmed by the Higuchi plot's extremely good linear correlation ($R^2 = 0.989$).
- The Korsmeyer-Peppas plot shows high linearity ($R^2 = 0.9957$), and the release exponent ($n = 0.6165$) identifies the mechanism as anomalous (non-Fickian) transport.
- The Hixson-Crowell plot shows an excellent linear fit with an $R^2 = 0.9884$, confirming that drug release is governed by surface erosion. This shows that the uniform dissolution of the particles, where the dosage form's diameter and surface area decrease proportionately over time, limits the release rate.

Observation table:

Time (min)	Absorbance	Conc. (mg)	Amount dissolved	%CDR	%drug remaining	Log %drug remaining	Cube root drug remaining	Log %CDR
5	0.177	402211	3.7898	18.9945	81.0055	1.9085	4.3268	1.2786
10	0.274	606044	5.9439	29.7195	70.2805	1.8468	4.1267	1.473
15	0.4	9.7002	8.7301	43.6505	56.3495	1.7508	308338	1.6933
30	0.576	14.0245	12.622	63.11	36.86	1.5669	3.3289	1.8
45	0.714	17.4152	15.6736	78.368	21.632	1.335	2.7863	1.8941
60	0.777	18.9631	17.0667	85.3335	14.6665	1.1663	2.4477	1.9311

CONCLUSION:

While all tablets are diffusion-influenced, the Olmesartan 40 mg and Triple Combination tablets are more complex, utilizing both diffusion and matrix erosion. The double combinations are simpler, relying almost entirely on concentration-driven diffusion.

ACKNOWLEDGEMENT:

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UV-Visible spectroscopy and a Dissolution apparatus were used to complete this work. We are also grateful to the anonymous peer reviewers for their constructive feedback, which significantly improved the manuscript.

AI Disclosure: During the preparation of this manuscript, the authors used ChatGPT-4o, Perplexity, and Gemini AI for grammar editing and literature summarization. The

authors have reviewed and edited the output and take full responsibility for the final content of the article.

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