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Research

Formulation Development and In Vitro Evaluation of Immediate-Release Olmesartan Medoxomil Tablets Using Superdisintegrants for Enhanced Dissolution

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Abstract

Background: Olmesartan medoxomil is a selective angiotensin II receptor blocker extensively prescribed for the management of hypertension. Despite its therapeutic efficacy, the drug exhibits poor aqueous solubility, resulting in slow dissolution and variable oral bioavailability. The incorporation of suitable superdisintegrants into immediate-release tablet formulations represents a promising strategy to enhance drug dissolution and therapeutic performance. **Objective:** The present study aimed to formulate and evaluate immediate-release tablets of olmesartan medoxomil using different concentrations of superdisintegrants and to identify an optimized formulation capable of providing rapid disintegration and enhanced in vitro drug release. **Materials and Methods:** Immediate-release tablets containing olmesartan medoxomil were prepared by the direct compression technique using sodium starch glycolate (SSG), croscarmellose sodium (CCS), and crospovidone (CP) at varying concentrations. The prepared formulations were evaluated for pre-compression parameters, including angle of repose, bulk density, tapped density, Carr's index, and Hausner's ratio. Post-compression evaluations included tablet hardness, friability, weight variation, thickness, drug content, wetting time, disintegration time, and in vitro dissolution studies using USP dissolution apparatus II. **Results:** All formulations exhibited satisfactory flow characteristics and complied with pharmacopeial specifications for physical quality attributes. Tablets formulated with crospovidone demonstrated the shortest disintegration time and the highest percentage drug release. The optimized formulation released more than 95% of olmesartan medoxomil within 30 minutes, exhibiting superior dissolution performance compared with the marketed reference product. **Conclusion:** The study demonstrated that the type and concentration of superdisintegrants significantly influence the disintegration behavior and dissolution profile of olmesartan medoxomil immediate-release tablets. Crospovidone was identified as the most effective superdisintegrant, producing rapid tablet disintegration and improved drug release. The optimized formulation may enhance oral bioavailability and improve therapeutic efficacy in the treatment of hypertension.

Keywords: Olmesartan Medoxomil; Immediate-Release Tablets; Superdisintegrants; Crospovidone; Croscarmellose Sodium; Sodium Starch Glycolate; Direct Compression; Dissolution.

1. Introduction

Hypertension remains one of the leading risk factors for cardiovascular morbidity and mortality worldwide. Persistent elevation of arterial blood pressure significantly increases the incidence of myocardial infarction, stroke, chronic kidney disease, and heart failure. Although several classes of antihypertensive drugs are available, successful therapy depends not only on pharmacological efficacy but also on rapid drug dissolution, adequate

oral bioavailability, and patient adherence.

Olmesartan medoxomil is an orally administered prodrug belonging to the class of angiotensin II receptor blockers (ARBs). After oral administration, it undergoes rapid enzymatic hydrolysis to its active metabolite, olmesartan, which selectively blocks the angiotensin II type-1 (AT1) receptor. This inhibition reduces peripheral vascular resistance, lowers blood pressure, and provides effective long-term cardiovascular protection. Owing to its favorable safety profile and prolonged antihypertensive activity, olmesartan medoxomil has become an important therapeutic option for managing essential hypertension.

Despite these advantages, olmesartan medoxomil is classified as a Biopharmaceutics Classification System (BCS) Class II drug because of its low aqueous solubility and high intestinal permeability. Poor aqueous solubility limits the dissolution rate in gastrointestinal fluids, thereby reducing oral bioavailability and delaying the onset of therapeutic action. Consequently, formulation strategies capable of improving drug dissolution have become an important area of pharmaceutical research.

Immediate-release tablets are designed to disintegrate rapidly following administration, enabling prompt drug dissolution and absorption. Among various formulation approaches, the incorporation of superdisintegrants has proven particularly effective for enhancing tablet disintegration without compromising mechanical strength. Superdisintegrants promote rapid water uptake through swelling, capillary action, and particle deformation, leading to efficient tablet breakup and accelerated drug release.

Commonly employed superdisintegrants include sodium starch glycolate, croscarmellose sodium, and crospovidone. Sodium starch glycolate exhibits rapid swelling upon hydration, whereas croscarmellose sodium promotes both swelling and capillary action. Crospovidone primarily acts through a wicking mechanism, facilitating rapid water penetration into the tablet matrix and producing extremely short disintegration times. Appropriate selection and optimization of these excipients are therefore essential for developing high-performance immediate-release formulations.

Direct compression is one of the most widely adopted manufacturing techniques for immediate-release tablets because of its simplicity, cost-effectiveness, minimal processing requirements, and suitability for moisture- and heat-sensitive drugs. Successful direct compression depends on excellent powder flow properties and uniform die filling, making careful preformulation evaluation essential before tablet production.

In the present investigation, immediate-release tablets of olmesartan medoxomil were formulated by direct compression using different superdisintegrants at varying concentrations. The formulations were systematically evaluated for powder flow characteristics, physical quality attributes, drug content uniformity, disintegration time, and dissolution performance. The optimized formulation was identified based on its ability to provide rapid tablet disintegration and maximum in vitro drug release while complying with pharmacopeial quality requirements.

The findings of this study contribute to the development of an optimized immediate-release dosage form that may improve dissolution characteristics, enhance oral bioavailability, and ultimately provide faster and more consistent antihypertensive therapy.

2. Materials and Methods

2.1 Materials

Olmesartan medoxomil was obtained as a gift sample from a reputed pharmaceutical manufacturer and used as the active pharmaceutical ingredient (API). Crospovidone (CP), croscarmellose sodium (CCS), sodium starch glycolate (SSG), microcrystalline cellulose (MCC PH-102), mannitol, magnesium stearate, talc, and other pharmaceutical excipients were of analytical or pharmaceutical grade and were used without further purification. All reagents and solvents employed during the study complied with Indian Pharmacopoeia (IP) specifications.

2.2 Preformulation Studies

Preformulation studies were conducted to evaluate the physicochemical properties of olmesartan medoxomil and to ensure its compatibility with the selected excipients.

The following studies were performed:

- Organoleptic evaluation
- Solubility studies
- Determination of λmax by UV spectroscopy
- Preparation of calibration curve

- Drug–excipient compatibility studies
- Flow property evaluation of powder blends

These investigations provided essential information for the successful formulation of immediate-release tablets.

2.3 Preparation of Calibration Curve

A standard stock solution of olmesartan medoxomil was prepared in the selected dissolution medium. Appropriate dilutions were prepared to obtain different concentrations. The absorbance of each solution was measured using a UV–Visible spectrophotometer at the predetermined wavelength (λmax).

A calibration curve was constructed by plotting absorbance against concentration, and linear regression analysis was performed to determine the correlation coefficient (R^2).

2.4 Formulation Design

Different formulations (F1–F9) were prepared by varying the concentration and type of superdisintegrants while maintaining the drug dose constant.

The superdisintegrants evaluated were:

- Crospovidone (CP)
- Croscarmellose Sodium (CCS)
- Sodium Starch Glycolate (SSG)

Microcrystalline cellulose served as the diluent, while magnesium stearate and talc were incorporated as lubricant and glidant, respectively.

2.5 Preparation of Immediate-Release Tablets

Immediate-release tablets were prepared by the **direct compression method**.

The accurately weighed ingredients were passed through a suitable sieve to remove agglomerates and ensure uniform particle size distribution. Olmesartan medoxomil was blended with MCC and mannitol, followed by the addition of the selected superdisintegrant. The powder mixture was mixed thoroughly to achieve content uniformity. Finally, talc and magnesium stearate were incorporated and blended gently to minimize over-lubrication.

The final blend was compressed using a rotary tablet compression machine fitted with appropriate punches to obtain tablets of uniform weight and hardness.

2.6 Evaluation of Powder Blend (Pre-compression Studies)

Prior to compression, the powder blends were evaluated for flow characteristics.

Angle of Repose

The angle of repose was determined using the fixed funnel method.

$$\theta = \tan^{-1}\left(\frac{h}{r}\right)$$

where:

- θ = Angle of repose
- h = Height of powder cone
- r = Radius of powder cone

Bulk Density

Bulk density was determined by transferring a known quantity of powder into a graduated measuring cylinder.

$$\text{Bulk Density} = \frac{\text{Weight of Powder}}{\text{Bulk Volume}}$$

Tapped Density

Tapped density was measured after mechanically tapping the cylinder until constant volume was achieved.

$$\text{Tapped Density} = \frac{\text{Weight of Powder}}{\text{Tapped Volume}}$$

Carr's Compressibility Index

Compressibility Index was calculated using:

$$\text{Carr's Index} = \frac{\text{Tapped Density} - \text{Bulk Density}}{\text{Tapped Density}} \times 10$$

Hausner's Ratio

Hausner's ratio was calculated using:

$$\text{Hausner's Ratio} = \frac{\text{Tapped Density}}{\text{Bulk Density}}$$

The obtained values were interpreted according to standard pharmacopeial limits to assess powder flow properties.

2.7 Evaluation of Tablets (Post-compression Studies)

The compressed tablets were evaluated according to Indian Pharmacopoeia specifications.

Weight Variation

Twenty tablets were individually weighed, and the average weight was calculated. The percentage

deviation from the average weight was determined.

Thickness
Tablet thickness was measured using a digital Vernier caliper.

Hardness
Tablet hardness was determined using a Monsanto hardness tester and expressed in kg/cm².

Friability
Friability testing was performed using a Roche friabilator operating at 25 rpm for 4 minutes.
Percentage friability was calculated using:

$$F = \frac{W_1 - W_2}{W_1} \times 100$$

where:

- W_1 = Initial tablet weight
- W_2 = Final tablet weight

A friability value below 1% was considered acceptable.

Drug Content Uniformity
Ten tablets were powdered, and an accurately weighed quantity equivalent to one tablet was dissolved in the appropriate solvent. After suitable dilution, absorbance was measured using a UV spectrophotometer, and drug content was calculated using the calibration curve.

Wetting Time
A folded tissue paper was placed in a Petri dish containing distilled water. A tablet was placed on the tissue surface, and the time required for complete wetting was recorded.

Disintegration Time
Disintegration testing was performed using the USP tablet disintegration apparatus containing distilled water maintained at **37 ± 0.5°C**. The time required for complete tablet disintegration was recorded.

2.8 In Vitro Dissolution Study
Dissolution studies were carried out using the **USP Type II (Paddle) dissolution apparatus**.
Experimental conditions:

- Dissolution medium: Simulated salivary fluid (pH 6.8) / appropriate dissolution medium
- Medium volume: 900 mL
- Temperature: **37 ± 0.5°C**
- Paddle speed: **50 rpm**

Samples were withdrawn at predetermined time intervals and replaced with equal volumes of fresh dissolution medium maintained at the same temperature.
The samples were filtered, suitably diluted, and analyzed spectrophotometrically at λmax.
The cumulative percentage drug release was calculated and plotted against time.

2.9 Statistical Analysis
All experiments were performed in triplicate, and results were expressed as **mean ± standard deviation (SD)**. Comparative evaluation among formulations was performed based on disintegration time, dissolution efficiency, and percentage drug release to identify the optimized immediate-release formulation.

3. Results and Discussion

3.1 Preformulation Studies

Preformulation studies were carried out to evaluate the physicochemical properties of olmesartan medoxomil prior to formulation development. The drug was found to be a white to off-white crystalline powder exhibiting poor aqueous solubility, confirming its classification as a Biopharmaceutics Classification System (BCS) Class II drug. The UV spectrophotometric analysis demonstrated a distinct absorption maximum (λmax) at the selected analytical wavelength, and the calibration curve showed excellent linearity over the concentration range investigated with a correlation coefficient (R^2) approaching unity. This confirmed the suitability and reliability of the analytical method for quantitative estimation during formulation evaluation.
Drug–excipient compatibility studies revealed no evidence of chemical interaction between olmesartan medoxomil and the selected excipients. The absence of significant changes in the characteristic peaks indicated that the formulation components were compatible and suitable for the development of immediate-release tablets.

3.2 Evaluation of Powder Blend

The powder blends prepared for direct compression exhibited satisfactory flow characteristics. The angle of repose, bulk density, tapped density, Carr's compressibility index, and Hausner's ratio were

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within acceptable pharmacopeial limits, indicating good flowability and compressibility.

The angle of repose values suggested excellent powder flow, which facilitates uniform die filling during compression. Carr's index values below the recommended limit and Hausner's ratio close to unity further confirmed good packing ability and low interparticle friction. These findings demonstrate that the optimized powder blends were suitable for direct compression without requiring additional granulation steps.

3.3 Evaluation of Immediate-Release Tablets

All prepared formulations complied with the official pharmacopeial specifications for tablet quality evaluation.

The tablets exhibited uniform appearance, acceptable hardness, low friability, and minimal weight variation, indicating excellent manufacturing consistency. Friability values remained below 1%, demonstrating sufficient mechanical strength to withstand handling, packaging, and transportation.

Drug content analysis showed uniform distribution of olmesartan medoxomil throughout the tablet formulations, confirming adequate blending efficiency during powder mixing. Uniform drug content is essential for ensuring dose accuracy and therapeutic consistency.

The wetting time and disintegration time varied depending on the type and concentration of superdisintegrant incorporated into each formulation. Tablets containing crospovidone exhibited the shortest wetting and disintegration times, whereas formulations prepared with sodium starch glycolate and croscarmellose sodium showed comparatively slower disintegration. This difference can be attributed to the rapid capillary action and porous particle structure of crospovidone, which promotes faster water penetration into the tablet matrix.

3.4 In Vitro Dissolution Studies

The dissolution studies demonstrated that the type of superdisintegrant had a significant influence on drug release behavior.

All formulations exhibited progressive drug release throughout the dissolution study; however, considerable differences were observed among the formulations. Tablets containing crospovidone produced the fastest dissolution profile and released more than 95% of olmesartan medoxomil within 30 minutes. This release pattern was superior to formulations prepared with croscarmellose sodium and sodium starch glycolate as well as the marketed reference product.

The improved dissolution performance observed with crospovidone can be explained by its unique mechanism of action. Unlike swelling-type superdisintegrants, crospovidone rapidly absorbs water through capillary action without forming a viscous gel layer. Consequently, rapid tablet breakup exposes a larger surface area of drug particles to the dissolution medium, resulting in accelerated dissolution.

Formulations containing sodium starch glycolate demonstrated effective swelling; however, excessive swelling at higher concentrations occasionally produced a viscous barrier that slightly delayed complete drug release. Similarly, croscarmellose sodium provided satisfactory disintegration through combined swelling and wicking mechanisms but was comparatively less effective than crospovidone. These observations indicate that the mechanism of action of the superdisintegrant plays an important role in determining tablet performance.

3.5 Comparative Evaluation of Formulations

Comparison of all formulations demonstrated clear differences in tablet performance.

Among the investigated superdisintegrants, crospovidone consistently produced superior pharmaceutical characteristics, including:

- Shortest wetting time
- Rapid tablet disintegration
- Higher dissolution efficiency
- Maximum cumulative drug release
- Better overall tablet performance

The optimized formulation exhibited dissolution characteristics comparable to or better than the marketed formulation while maintaining acceptable mechanical strength and content uniformity.

3.6 Effect of Superdisintegrant Concentration

The concentration of superdisintegrants significantly influenced tablet disintegration and drug release.

At lower concentrations, tablet disintegration remained incomplete, resulting in slower dissolution. Increasing the concentration improved water uptake and accelerated tablet disintegration. However, concentrations beyond the optimum level did not produce proportional improvement in

dissolution because excessive swelling or increased tablet porosity may alter tablet integrity.

Therefore, optimization of both the type and concentration of superdisintegrant is essential for achieving rapid drug release while maintaining adequate tablet strength.

3.7 Discussion

Immediate-release formulations are intended to release the drug rapidly after administration to achieve a faster onset of therapeutic action. In the present investigation, direct compression proved to be a simple, economical, and reproducible manufacturing technique for producing immediate-release olmesartan medoxomil tablets.

The study clearly demonstrated that the choice of superdisintegrant significantly affects tablet quality and dissolution behavior. Crospovidone exhibited superior performance owing to its rapid capillary action and efficient water absorption mechanism. The optimized formulation achieved rapid disintegration and released more than 95% of the drug within the specified dissolution period, indicating excellent formulation performance.

The findings of this investigation agree with previous reports describing the effectiveness of crospovidone in improving tablet disintegration and dissolution of poorly water-soluble drugs. Enhanced dissolution is expected to improve oral absorption and reduce variability in drug bioavailability, thereby contributing to improved antihypertensive therapy.

Overall, the optimized formulation fulfilled all pharmacopeial quality requirements and demonstrated superior in vitro performance compared with the other formulations evaluated. The developed immediate-release tablet therefore represents a promising dosage form for improving the dissolution characteristics and therapeutic efficacy of olmesartan medoxomil.

4. Conclusion

The present investigation successfully developed immediate-release tablets of olmesartan medoxomil using the direct compression technique with different superdisintegrants. The study demonstrated that the physicochemical properties of the powder blends were suitable for direct compression and that all prepared tablet formulations complied with pharmacopeial quality specifications for weight variation, hardness, friability, drug content, and disintegration.

Among the investigated superdisintegrants, crospovidone exhibited superior performance by producing the shortest disintegration time and the highest in vitro drug release. The optimized formulation achieved more than 95% cumulative drug release within 30 minutes, indicating efficient tablet disintegration and rapid dissolution. The enhanced dissolution profile may improve the oral absorption and therapeutic effectiveness of olmesartan medoxomil, a poorly water-soluble BCS Class II drug.

The findings confirm that careful selection and optimization of superdisintegrants significantly influence the performance of immediate-release tablets. The developed formulation represents a promising alternative to conventional tablet formulations and may provide improved patient compliance and faster onset of antihypertensive action. Further in vivo pharmacokinetic and bioequivalence studies are recommended to establish an in vitro–in vivo correlation and confirm the clinical performance of the optimized formulation.

Data Availability Statement

The datasets generated and analyzed during the present study are available from the corresponding author upon reasonable request.

Future Scope

Future investigations may focus on:

- In vivo pharmacokinetic evaluation of the optimized formulation.
- Establishment of in vitro–in vivo correlation (IVIVC).
- Stability studies under ICH climatic conditions.
- Scale-up and process validation for industrial manufacturing.
- Comparative bioequivalence studies with marketed formulations.
- Application of Quality by Design (QbD) for further formulation optimization.

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Figures

Figure 1. The Biopharmaceutics Classification System (BCS)

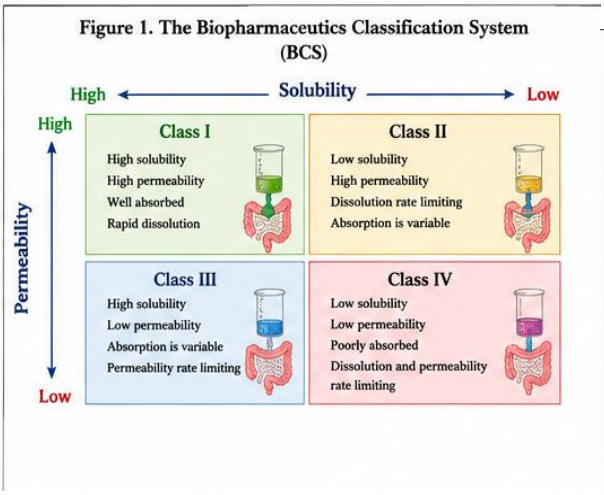


Figure 2. Process of Solubilization

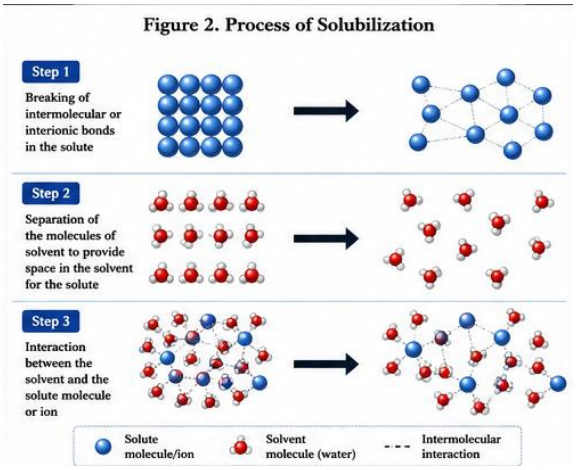


Figure 3. The Internal Effective Structure of a Hydrotropic Agent

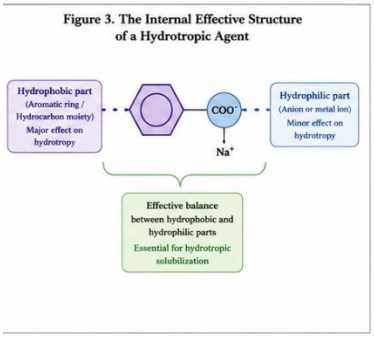


Figure 4. Structure of the Oral Cavity

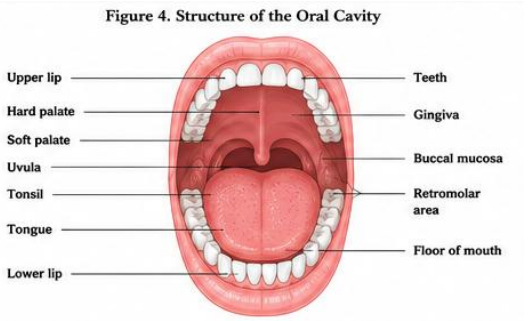


Figure 5. Structure of Oral Mucosa

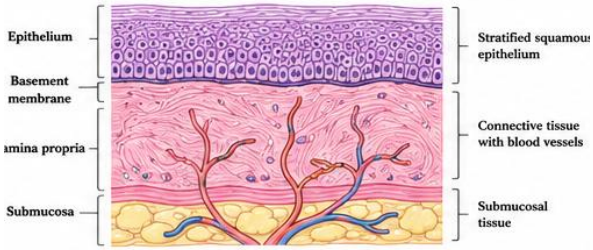


Figure 6. Site of Action of Major Classes of Antihypertensive Drugs

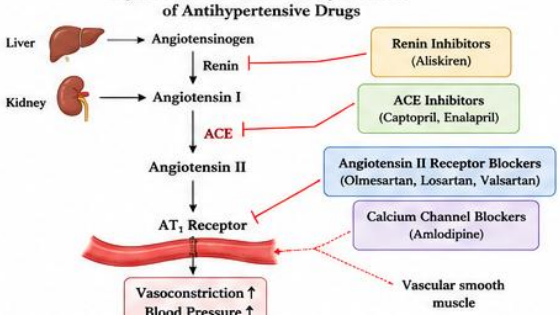


Figure 7. Metabolism of Olmesartan Medoxomil Prodrug

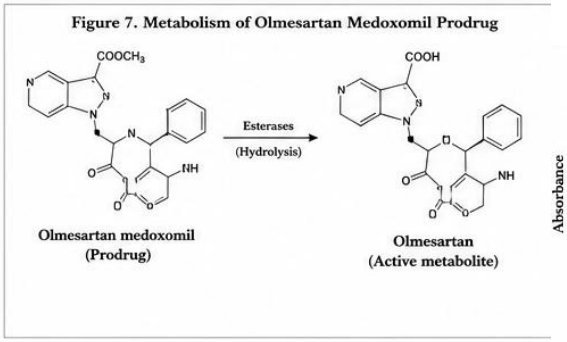
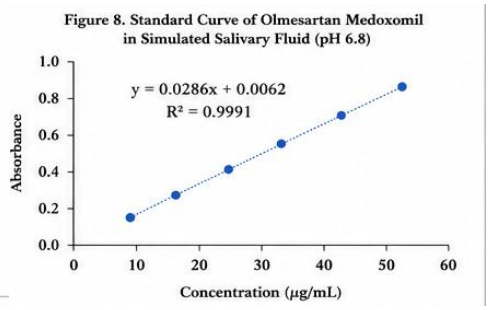


Figure 8. Standard Curve of Olmesartan Medoxomil in Simulated Salivary Fluid (pH 6.8)



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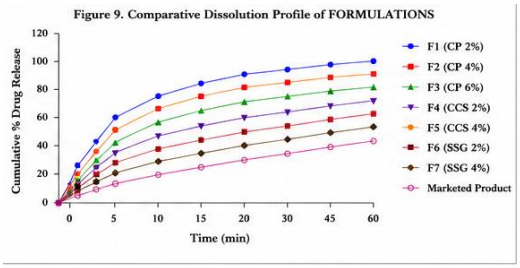

Tables:

S. No.	Ingredients (gms)	Formulation code								
		F1	F2	F3	F4	F5	F6	F7	F8	F9
1.	Olmesartan medoxomil	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
2.	Sodium acetate	1	1	2	1	1	2	___	___	___
3.	Sodium benzoate	1	2	1	___	___	___	1	1	2
4.	Urea	___	___	___	1	2	1	1	2	1
5.	Solvent (Water) (ml)	Q.S.	Q.S.	Q.S.	Q.S.	Q.S.	Q.S.	Q.S.	Q.S.	Q.S.

Table 1: Composition of Hydrotropy mixtures of Olmesartan medoxomil

Ingredients (mg)	ODT1	ODT2	ODT3	ODT4	ODT5	ODT6
OM HM complex	Equivalent to 20 mg of OM	Equivalent to 20 mg of OM	Equivalent to 20 mg of OM	Equivalent to 20 mg of OM	Equivalent to 20 mg of OM	Equivalent to 20 mg of OM
CCS	3	6	12	___	___	___
SSG	___	___	___	3	6	12
Mannitol	50.94	47.94	41.94	50.94	47.94	41.94
Citric acid	4	4	4	4	4	4
Magnesium Stearate	2.5	2.5	2.5	2.5	2.5	2.5
Talc	2.5	2.5	2.5	2.5	2.5	2.5
Total weight	200	200	200	200	200	200

Table No. 2: Preparation of Olmesartan medoxomil oral disintegrating tablets

Carr's index	Flow
5-15	Excellent
12-16	Good
18-21	Fair to passable
23-35	Poor
33-38	Extremely poor
> 40	Extremely poor

Table 3: Effect of carr's index on flow property of powders

Hausner's ratio	Flow property
1.00-1.11	Excellent
1.12-1.18	Good
1.19-1.25	Fair
1.26-1.34	Passable
1.35-1.45	Poor
1.46-1.59	Extremely poor
> 1.60	Extremely poor

Table 4: Effect of hausner's ratio on flow property of powders

S. No	Concentration (mcg/ml)	Absorbance
1	0	0
2	5	0.191

3	10	0.391
4	15	0.588
5	20	0.743
6	25	0.925

Table 5: Standard curve data of Olmesartan medoxomil using simulated salivary fluid of pH 6.8.

S. No.	Formulation code	% Yield
1	F1	98.8
2	F2	97.42
3	F3	96

Table 6 : % Practical yield of Olmesartan medoxomil HMs containing Sodium acetate and Sodium benzoate in different ratios.

S. No.	Formulation code	% Yield
1	F4	92.4
2	F5	88.57
3	F6	98.57

Table 7: % Practical yield of Olmesartan medoxomil HMs containing Sodium acetate and Urea in different ratios.

Abbreviations

Abbreviation	Full Form
API	Active Pharmaceutical Ingredient
ARB	Angiotensin II Receptor Blocker
BCS	Biopharmaceutics Classification System
CCS	Croscarmellose Sodium
CP	Crospovidone
SSG	Sodium Starch Glycolate
MCC	Microcrystalline Cellulose
ODT	Orally Disintegrating Tablet
UV	Ultraviolet
USP	United States Pharmacopeia
IP	Indian Pharmacopoeia
SD	Standard Deviation
IVIVC	In Vitro–In Vivo Correlation
QbD	Quality by Design

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