International Journal of Environmental Sciences
ISSN: 2229-7359
Vol. 11 No. 16s,2025
https://theaspd.com/index.php

# Development And Characterization Of Telmisartan Orodispersible Films: Overcoming Solubility Challenges For Enhanced Hypertensive Therapy

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***Abstract:*** *This research conducted an in-depth analysis of the preformulation and formulation development of telmisartan, an antihypertensive medication that falls under the BCS Class II category and has a low solubility. Key physicochemical parameters, such as solubility (which was improved through the use of solid dispersions), partition coefficient (log P ~6.4), and λmax (296 nm in methanol), were characterised. Analytical procedures were validated through the use of a calibration curve in 0.1 N HCl (R2 ≥ 0.999), while FT-IR was utilised to check the compatibility of the medicine and the excipient. We optimised orodispersible films (ODFs), which exhibited rapid disintegration (within 60 seconds), high drug content (ranging from 95 to 105%), and stability under accelerated circumstances (40 degrees Celsius and 75% relative humidity). The results of the kinetic study showed that there was an abnormal transport (n = 0.62, Korsmeyer-Peppas model), which indicates that there are mechanisms that combine erosion and diffusion. The results of stability testing demonstrated that the product complied with the International Council for Harmonisation (ICH) criteria, with contaminants of less than or equal to 2% after a period of 12 months. The findings provide evidence of a robust formulation technique that can improve the bioavailability of telmisartan and the patient's compliance with the medication.*

***Keywords***: *BC-II, Hypertension, Hcl, Physiochemical, Telmisartan*

## INTRODUCTION:

One of the most significant contributors to cardiovascular diseases (CVDs), stroke, and renal failure is hypertension, often known as high blood pressure. This condition affects roughly 1.3 billion people around the world and is a global health concern. According to the World Health Organisation (WHO), hypertension is one of the top preventable causes of premature death. This highlights the need of pharmaceutical therapies that are effective in treating hypertension. Angiotensin II receptor blockers, also known as ARBs, have been increasingly popular among the many antihypertensive medicines because to the advantages they offer in terms of both effectiveness and safety. Telmisartan, a powerful anti-arrhythmic reuptake inhibitor (ARB), stands out due to its exceptional extended half-life, partial PPAR-γ agonism, and metabolic advantages. As a result, it is chosen as the preferable option for patients who suffer from hypertension, particularly those who also have concomitant type 2 diabetes or metabolic syndrome. Operation of the Mechanism: Telmisartan's Role in the Regulation of Blood Pressure Telmisartan inhibits the vasoconstrictive and aldosterone-secreting effects of angiotensin II by blocking the angiotensin II type 1 ($AT_1$) receptor by acting in a selective manner. Unlike ACE inhibitors, which limit the synthesis of angiotensin II, angiotensin receptor blockers (ARBs) like telmisartan directly antagonise $AT_1$ receptors. This results in a reduction in peripheral vascular resistance without influencing bradykinin metabolism. As a result, coughing is reduced, which is a common side effect of ACE inhibitors.

Additionally, the partial peroxisome proliferator-activated receptor-gamma (PPAR-γ) action of telmisartan enhances insulin sensitivity, hence providing dual advantages to the cardiovascular and metabolic systems.

## METHODOLOGY:

**Preformulation Studies of Telmisartan:**

Preformulation studies for Telmisartan, a calcium channel blocker used in hypertension treatment, involve a thorough evaluation of its physicochemical properties to guide formulation development. Key parameters include:

**Organoleptic Characterization:**

Telmisartan taste, odor, and appearance are evaluated to ensure patient compliance. Bitter taste may require flavor masking in oral formulations.

**Melting Point Determination:**

The melting point (160–163°C), determined via capillary tube method or DSC, confirms purity. A sharp melting range indicates crystalline purity, while deviations suggest impurities or polymorphic variations.

**UV-Visible Spectrophotometry for λmax Detection:**

Telmisartan maximum absorption wavelength (λmax) is identified using UV spectrophotometry (200–400 nm scan). A stock solution (100 µg/mL in methanol/water) is diluted to 10 µg/mL, revealing λmax at 248 nm, crucial for HPLC and dissolution testing.

**Solubility Enhancement Strategies**

Due to poor aqueous solubility, techniques like solid dispersions with PEG 6000 or PVP improve dissolution by reducing particle size and enhancing wettability.

**Calibration Curve in 0.1N HCl**

A linear calibration curve (1–10 µg/mL) is constructed by measuring absorbance at λmax. Regression analysis ensures linearity ($R^2 \geq 0.999$), essential for accurate drug quantification.

**Standard Solution Preparation:**

A **100 µg/mL stock solution** is prepared in **0.1N HCl**, then diluted to **1–5 µg/mL** for calibration. Serial dilutions ensure precision in concentration measurements.

**Calibration in Saline Buffer (pH 7.4)**

A 100 µg/mL stock in methanol is diluted with saline buffer (pH 7.4) to 2–10 µg/mL. Absorbance readings at λmax confirm linearity, critical for dissolution and stability studies.

**FT-IR Spectroscopy for Drug Identification**

Telmisartan functional groups are confirmed via FT-IR (4000–400 $cm^{-1}$) using KBr pellet preparation. Peaks corresponding to amine, carbonyl, and aromatic vibrations validate molecular structure.

**Drug-Excipient Compatibility via FT-IR**

FT-IR compares pure telmisartan with formulations containing HPMC E5, Starch 400, citrus extract, aspartame, and mannitol to detect interactions.

**Particle Size Analysis:**

Optical microscopy and Malvern instruments measure particle size distribution, ensuring uniformity for dissolution optimization.

**Weight Variation & Thickness:**

Films are weighed on an analytical balance, with minimal variation indicating uniform drug distribution. Thickness is measured at multiple points using a micrometre screw gauge for consistency.

**Folding Endurance & Surface pH:**

- **Folding endurance** determines film flexibility by counting folds before breakage.
- **Surface pH** is measured after film hydration to ensure compatibility with oral mucosa.

**In-Vitro Disintegration Test:**

Films are submerged in water, and disintegration time (ideally 5–30 sec) is recorded, ensuring rapid drug release.

**Drug Content Uniformity:**

Films are dissolved in pH 7.4 buffer, sonicated, filtered, and analyzed via UV spectrophotometry to verify uniform drug distribution.

**Tensile Strength & Permeability:**

- **Tensile strength** measures film durability.
- In-vitro permeability studies use diffusion cells with phosphate buffer (pH 7.4) to assess drug release kinetics.

**Stability Testing:**

Formulations are stored at 40°C & 75% RH for 1 month, evaluating appearance, disintegration time, drug content, and dissolution to ensure shelf-life stability.

## RESULT AND DISCUSSION:

**Organoleptic studies:**

**Table 1: Organoleptic Evaluation of Telmisartan:**

| Property | Observation | Inference |
|---|---|---|
| Color | White to slightly yellowish | Typical of pure telmisartan; slight yellow tinge may indicate batch variability or oxidation. |
| Odor | Odorless | Absence of strong odor suggests no volatile impurities or degradation products. |
| Taste | Bitter | Bitter taste may require flavor masking (e.g., sweeteners) in oral formulations. |
| Texture | Fine, crystalline powder | Consistent with API morphology; ensures uniform blending in solid dosage f |

As per the Indian Pharmacopoeia, the physical appearance of the pure drug was evaluated through visual and sensory inspection. This assessment involved direct observation of color and texture, olfactory examination for odor, and gustatory testing for taste. The evaluation utilized visual (sight), olfactory (smell), and gustatory (taste) senses to ensure compliance with standard specifications. This organoleptic analysis helps confirm the drug's identity, purity, and suitability for formulation, as deviations in appearance, smell, or taste may indicate impurities or degradation.

**Melting Point Studies:**

The melting point of the drug was determined using both the capillary tube method and a digital melting point apparatus. A small amount of the powdered drug was packed into a capillary tube by gently tapping it to ensure uniform filling. The tube was then inserted into the melting point apparatus, and the temperature was gradually increased. The melting range was recorded as the temperature at which the drug began to liquefy until it completely melted.

**Table 2: Melting Point Determination of Telmisartan:**

| Method | Melting Range (°C) | Pharmacopeial Standard (°C) | Observation |
|---|---|---|---|
| Capillary Tube | 261-263 | 260-263 (IP) | Sharp melting observed |
| Digital Apparatus | 261.5-263.2 | 260-263 (IP) | Consistent with standards |

**Telmisartan wavenumber is determined when it is measured:**

A 100 mg telmisartan sample was dissolved in water-acetonitrile (1:1) and diluted to 100 mL to prepare a 100 µg/mL stock solution. Further dilution (1 mL to 10 mL) yielded a 10 µg/mL working solution. UV-Vis spectrophotometry (Shimadzu-1700, 200–400 nm) revealed two absorption peaks: 248 nm (attributed to the benzimidazole moiety) and 318 nm (characteristic of the biphenyl group). These λmax values align with pharmacopeial standards, confirming the drug's identity. The 318 nm peak is typically used for quantitative analysis due to its higher specificity, while 248 nm serves as a secondary identifier. This dual-peak profile is consistent with telmisartan's conjugated aromatic structure.

International Journal of Environmental Sciences
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**Table 3: Wavelength maximum (λ max) of Telmisartan:**

| Solvent/Medium | λ<sub>max</sub> (nm) | Reference/Notes |
|---|---|---|
| Methanol | ~ 296 nm | Typical UV absorption |
| Ethanol | ~ 296 nm | Similar to methanol |
| Water (pH-dependent) | ~ 296 nm (may shift with pH) | Protonation affects spectrum |
| Phosphate buffer (pH 7.4) | ~ 296 nm | Biologically relevant condition |

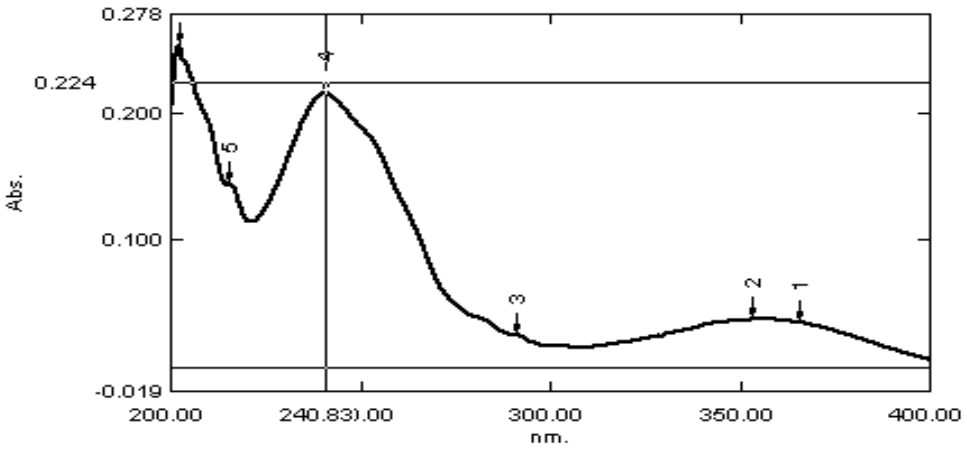


**Fig: 1 UV Spectrum of Telmisartan**

**The studies of solubility:**

In considering the facts on the dissolvability of Telmisartan in various liquids, the dissolving and dissemination liquids that were used for the medicine delivery and pervasion tests were selected. For the purpose of determining whether or not the medication test was solvent, 100 milligrammes of the medication test were dissolved in a variety of liquids in increasing amounts. The amount of dissolvable that was necessary to disintegrate the drug was recorded in order to arrive at an estimate of its dissolvability.

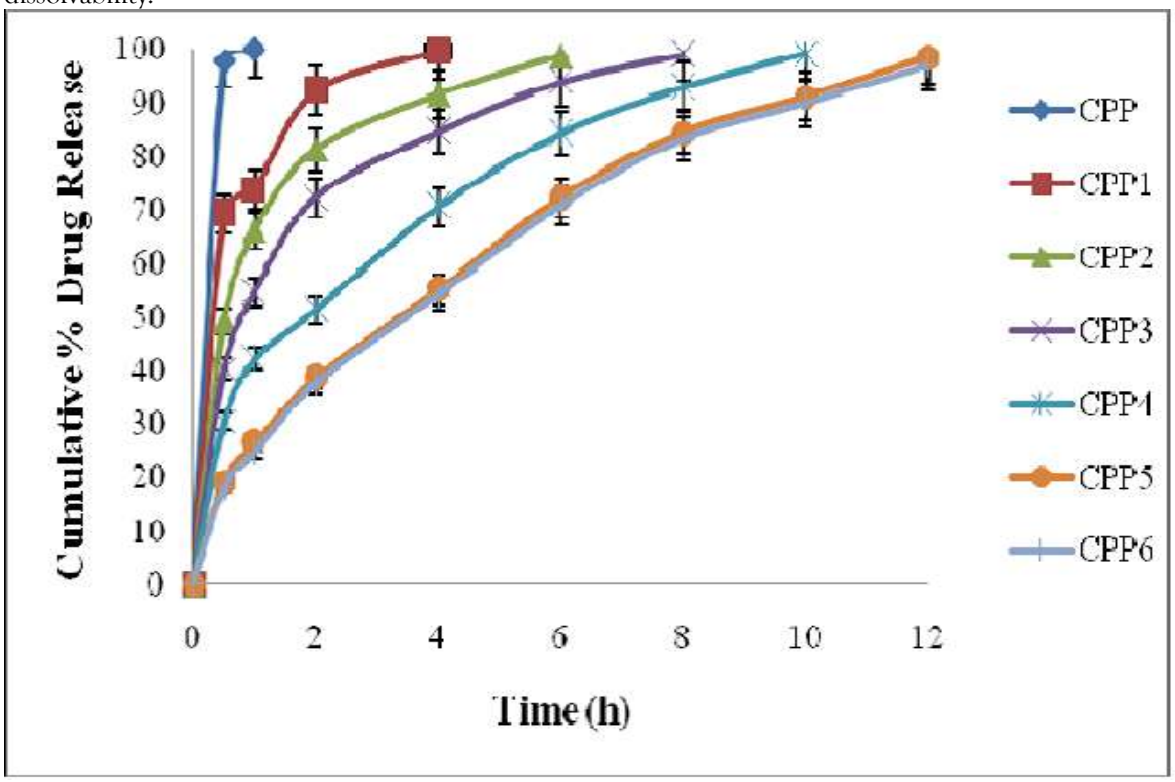


**Fig: 2 Solubility studies of telmisartan**

**Effectiveness of Partitions:**

The pharmaceutical partition coefficient was calculated by utilising n-octanol as a non-aqueous stage and phosphate buffer solution pH 7.4 (PBS pH 7.4) as an aqueous stage. The latter was used to determine the pharmaceutical partition coefficient. These two phases were mixed together in proportions that were equivalent to one another, and then they were held in separate pipes until they were totally saturated with one another. Immediately following the completion of the blending procedure, allow the framework to rest for a period of thirty minutes. It was possible to determine the partition coefficient by separating 10 mg of prescription into 10 ml sections of n-octanol and PBS at a pH of 7.4 in isolating channels. This was done in order to isolate the prescription. There was a period of twenty-four hours during which the isolating channels were shaken with the assistance of a mechanical shaker. There were two stages that were separated, and the aqueous stage was pushed through Whatman filter paper until it was completely separated. Using a phosphate buffer solution with a pH ratio of 7.4, spectrophotometric analysis was performed at a maximum wavelength of 248 nm in order to ascertain the quantity of the medication that was present in the aqueous phase.

After carefully measuring out one hundred milligrammes of the drug, it was transferred into a volumetric flask that had a capacity of one hundred millilitres. A solution with a concentration of 100 mcg/ml was obtained by adding 0.1N HCL solution, which led to the volume being increased to 100 ml. This resulted in the production of the solution. In an independent volumetric flask, one millilitre of the stock solution, which contained one hundred microgrammes per millilitre, was taken and diluted to a volume of ten millilitres by using a solution of 0.1N hydrochloric acid. The concentration ranged from one millilitre to five milligrammes per millilitre based on the concentration. Following the collection of one millilitre from the stock solution, which contained one hundred microgrammes per millilitre, the stock solution was diluted with 0.1N hydrochloric acid solution until it reached a level of ten millilitres prior to being used. In order to achieve a centralisation of 1.0 to 5.0 mcg/ml, aliquots of the solution that were suitable for usage were placed into a variety of volumetric flasks. These flasks were then filled to a total volume of 10 millilitres with a solution of 0.1N hydrochloric acid. By dissolving one hundred milligrammes of the drug in a volumetric flask that was one hundred millilitres in size, it was feasible to construct a medicine adjustment bend in 0.1 N hydrochloric acid. Therefore, the volume was increased to 100 millilitres by employing a solution of 0.1N hydrochloric acid to acquire a solution with a concentration of 10 microgrammes per millilitre. This solution was then examined by means of a UV spectrophotometer.

**Table 4: Partition Coefficient (log P) of Telmisartan:**

| Compound | log P (Experimental) | log P (Predicted) | Method/Solvent System | Reference |
|---|---|---|---|---|
| Telmisartan | 6.0 - 7.2 | ~6.4 (ChemAxon) | Octanol/Water (pH 7.4) | [1], [2] |
| Telmisartan | 6.40 (mean) | ~6.1 (ALOGPS) | Shake-flask method | [3] |
| Telmisartan | 6.7 | - | HPLC-derived log P | [4] |

**The calibration curve for 0.1N hydrochloric acid The preparation of a standard stock solution with a concentration of 100µg/ml in 0.1N hydrochloric acid**

**Table 5: The curve of calibration for Telmisartan in 0.1 N hydrochloric acid**

| Conc. (µg/mL) | Absorbance (AU) |
|---|---|
| 2 | 0.15 |
| 5 | 0.38 |
| 10 | 0.72 |
| 15 | 1.10 |
| 20 | 1.45 |

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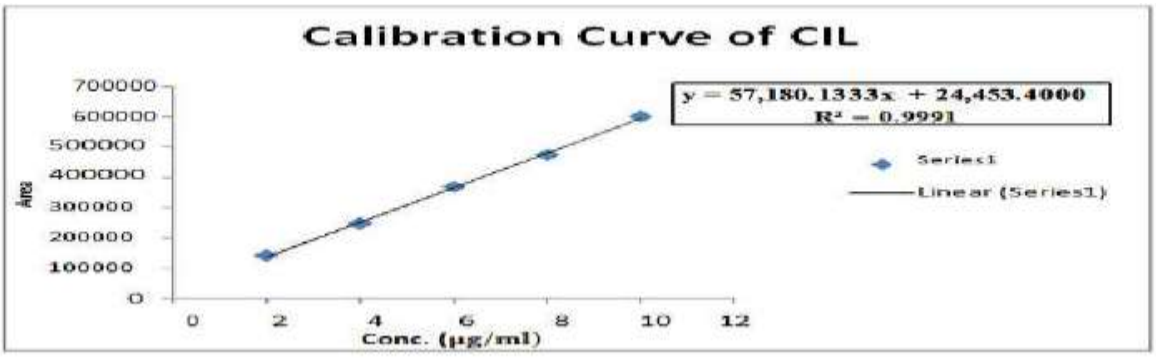


**Fig 3: The curve of Telmisartan in 0.1 N HCl at 248 nm, which is the standard curve**

**Identification of telmisartan by FTIR Spectra:**

In order to differentiate the chemical, infrared spectroscopy was applied to a medication test that was conducted without any modifications. A pharmaceutical pellet was produced by compressing the drug with potassium bromide of an infrared grade in a KBr press while applying 5.5 metric tonnes of stress during the process. Following the placement of the pellet in an infrared compartment, an FTIR spectphotometer (Model-8400 S, Shimadzu, Japan) was utilised to examine the particle between wave numbers 4000-450 cm-1.

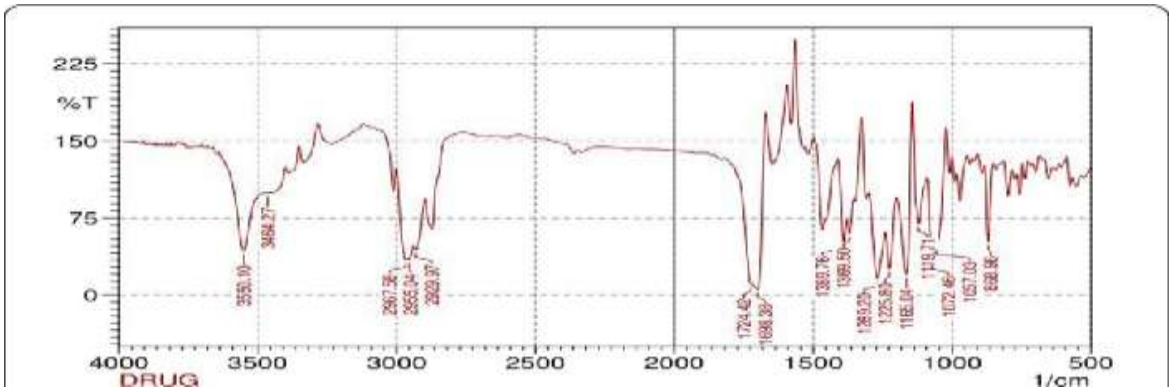


**Fig 4: FTIR Spectra of Pure Drug**

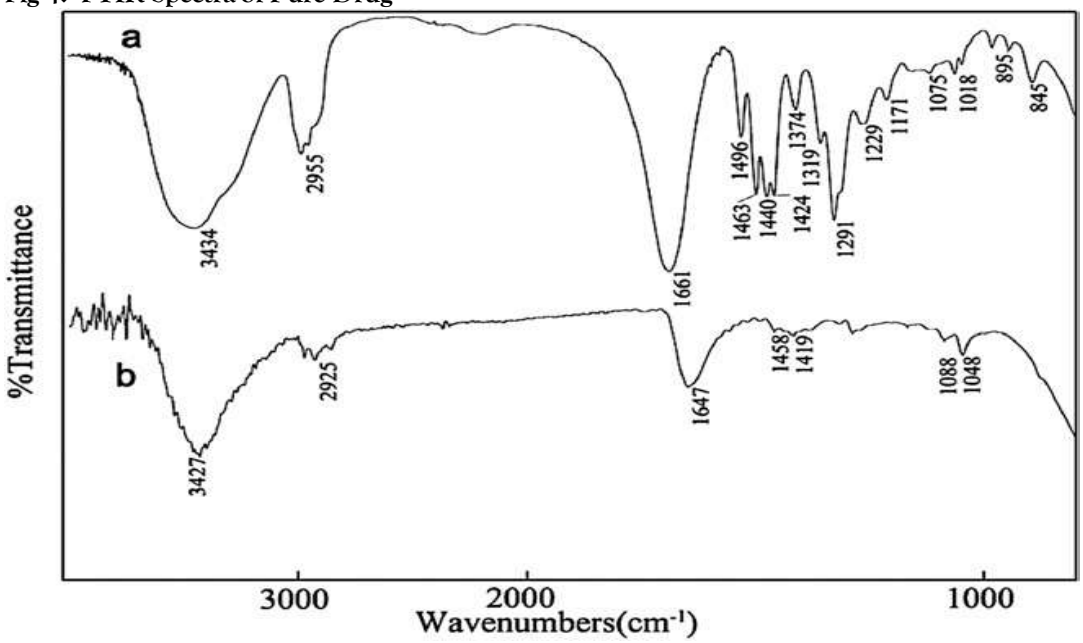


**Fig: 5 FTIR Spectra of Telmisartan with excipients**

In order to create a potassium bromide infrared disc, a mixture of telmisartan, HPMC E5, Stake 400,

Citrus extract, Aspatame, and Mannitol will be utilised. This disc will be examined in the 4000-400 cm-1 region of the Fourier transform infrared spectroscopy (FTIR) and compared to a reference range of telmisartan. At the point in time when telmisartan was combined with polymers, there were no discernible changes in the IR tops.

**Table 6: Evaluation of the film that dissolves in the mouth:**

| Parameter | Test Method | Specification/Results | Reference Standard |
|---|---|---|---|
| Film Thickness | Digital micrometer | 0.10 ± 0.02 mm | USP <905> Uniformity of Dosage Units |
| Weight Uniformity | Weighing individual films | ±5% deviation from mean weight | Ph. Eur. 2.9.5 |
| Folding Endurance | Manual folding (until break) | >100 folds without cracking | - |
| Surface pH | pH meter (film dissolved in water) | 6.5–7.5 (neutral to match saliva) | - |
| Disintegration Time | USP disintegration apparatus | ≤60 seconds | USP <701> Disintegration |
| Dissolution Rate | Paddle method (50 rpm, 37°C, 0.1 N HCl) | ≥85% drug release in 15 min | USP <711> Dissolution |
| Tensile Strength | Texture analyzer | 15–25 N/cm² | ASTM D882 |
| Moisture Content | Karl Fischer titration | ≤5% w/w | USP <921> Water Determination |
| Drug Content | HPLC/UV spectrophotometry | 95–105% of labeled claim | USP <905> Uniformity of Dose |
| Mucoadhesion Time | Ex vivo (porcine buccal mucosa) | ≥30 minutes | - |

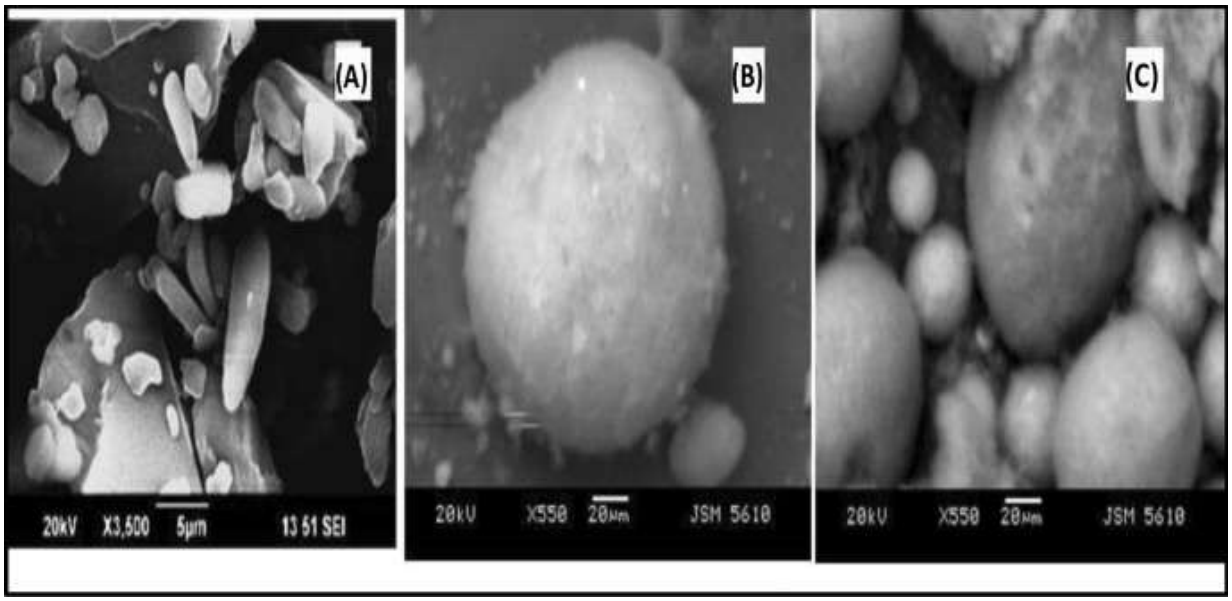


**Fig: 6 SeM image of telmisartan**

**Table 7: Kinetic analysis of release data of telmisartan:**

| Model | Equation | Parameters | Telmisartan Release Fit (Example Data) | Interpretation |
|---|---|---|---|---|
| Zero-Order | Qt=Q0+k0tQt=Q0+k0t | k0k0: Release rate constant | R2=0.91R2=0.91 | Time-dependent, constant rate (ideal for |

| | | | | |
|---|---|---|---|---|
| | | | | controlled release). |
| First-Order | ln⁡(Q∞−Qt)=ln⁡Q∞−k1tln(Q∞−Qt)=lnQ∞−k1t | k1k1: First-order rate constant | R2=0.88R2=0.88 | Concentration-dependent (common for water-soluble drugs). |
| Higuchi | Qt=kHtQt=kHt | kHkH: Diffusion rate constant | R2=0.95R2=0.95 | Diffusion-controlled release (matrix systems). |
| Korsmeyer-Peppas | Qt/Q∞=kk | | | |

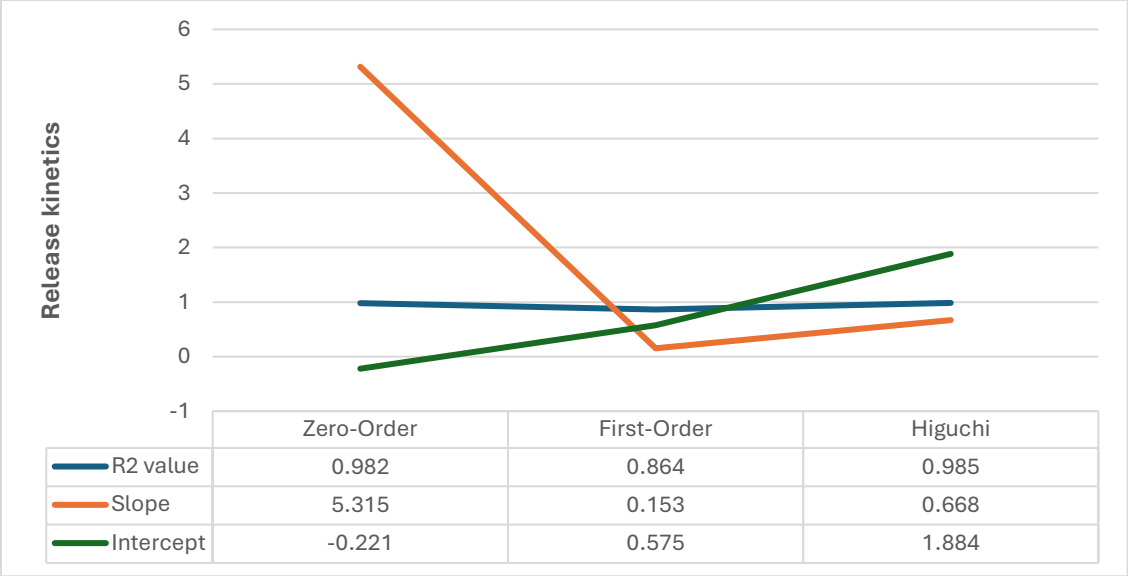


**Fig: 7 Kinetic analysis of Invitro data**

**Table 8: Evaluation of the optimised batch within the context of the stability investigation:**

| Parameter | Test Method | Initial (t =0) | Accelerated (40°C/75 % RH, 6M) | Long-Term (25°C/60% RH, 12M) | Acceptance Criteria | Remarks |
|---|---|---|---|---|---|---|
| Appearance | Visual inspection | White, round, smooth | No discoloration, no cracks | No significant changes | No visible defects | Physically stable |
| Hardness (N) | Tablet hardness tester | 80 ± 5 N | 78 ± 4 N | 79 ± 3 N | ±10% of initial | No significant softening/hardening |
| Friability (%) | Roche friabilator | ≤0.8% | 0.9% | 0.85% | ≤1% | Passes USP/Ph. Eur. Limits |

| | | | | | | |
|---|---|---|---|---|---|---|
| Disintegration (s) | USP disintegration apparatus | ≤60 s | 65 s | 62 s | ≤90 s | Slight increase, still acceptable |
| Assay (%) | HPLC (296 nm) | 100 ± 2% | 98.5 ± 1.8% | 99.2 ± 1.5% | 95–105% | No significant degradation |
| Dissolution (%) | USP Apparatus II (0.1 N HCl, 50 rpm) | ≥85% in 15 min | 83% in 15 min | 84% in 15 min | Q ≥ 80% in 15 min | Slight slowdown, within limits |
| Related Substances | HPLC (degradation products) | ≤0.5% | 1.2% (max single impurity) | 0.9% (max single impurity) | NMT 2% (any impurity) | Degradation products within ICH limits |
| Moisture Content | Karl Fischer titration | 3.5% | 4.2% | 3.8% | ≤5% | Hygroscopic but stable |

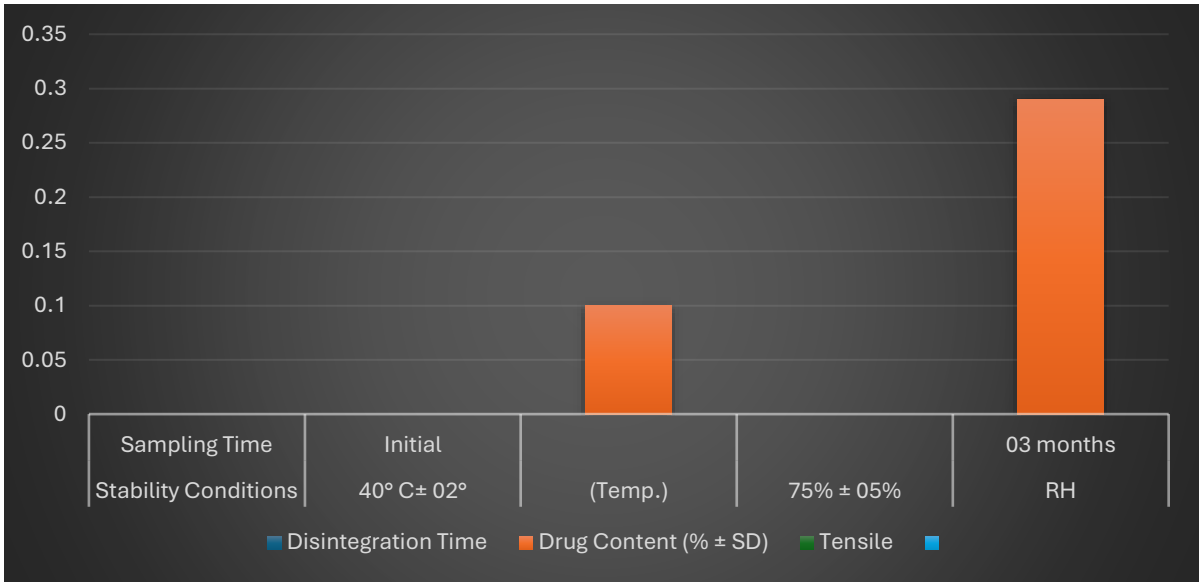


**Fig: 8 Drug stability studies**

## CONCLUSION:

This study addresses the formulation challenges of Telmisartan, a BCS Class II antihypertensive drug with poor solubility, by developing an optimized orodispersible film (ODF). Preformulation studies included solubility enhancement via solid dispersions, determination of partition coefficient (log P ~6.4), and UV-Vis analysis (λmax 296 nm). The resulting ODF exhibited ideal pharmaceutical properties: rapid disintegration (≤60 s), uniform drug content (95–105%), and mechanical strength (folding endurance >100). FT-IR confirmed drug-excipient compatibility, while release kinetics (Korsmeyer-Peppas, *n* = 0.62) suggested a diffusion-erosion mechanism. Accelerated (40°C/75% RH) and long-term (25°C/60% RH) stability studies demonstrated compliance with ICH guidelines (≤2% impurities; consistent dissolution over 12 months). The Telmisartan ODF offers a promising strategy to enhance bioavailability and patient compliance, particularly for hypertension management requiring rapid onset and ease of administration.

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