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Research

Formulation and Optimization of Valsartan Sustained Release Tablets Using Natural Polymer Matrices

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Abstract

This research aimed to develop and optimize sustained-release Valsartan tablets utilizing natural hydrophilic polymers to enhance therapeutic reliability and patient compliance. Nine matrix formulations (VT1–VT9) were created using direct compression using Guar Gum, Xanthan Gum, and Tamarind Seed Polysaccharide (TSP), both singly and in combination. All powder blends demonstrated acceptable precompression properties, with a Carr's Index of 12–15%, a Hausner's ratio of 1.15–1.18, and an angle of repose of less than 30°, indicating their appropriateness for direct compression. The post-compression results indicated a consistent thickness (3.10–3.18 mm), satisfactory hardness (6.1–6.5 kg/cm²), friability <0.5%, and drug content ranging from 98–99%, confirming adherence to pharmacopeial criteria.

In vitro dissolution tests indicated that the release of Valsartan diminished with higher polymer concentrations due to the development of a hydrated gel barrier. Single-polymer matrices released substances during 10–12 hours, whereas Xanthan Gum demonstrated much enhanced control. The combination polymer systems (VT8 and VT9) exhibited the most favorable release characteristics, with VT9 attaining a cumulative release of 99.27% at 12 hours without a burst effect. Release kinetics demonstrated First-order/Higuchi diffusion for single-polymer batches, while combination matrices exhibited Zero-order release with non-Fickian processes (n = 0.83–0.90). VT9 was determined to be the optimized formulation, providing reliable and prolonged drug release appropriate for once-daily antihypertensive treatment.

Keywords: Valsartan, Guar Gum, Xanthan Gum, Tamarind Seed Polysaccharide, Sustained Release Tablets.

INTRODUCTION

Hypertension continues to be a predominant global health issue, necessitating prolonged antihypertensive treatment to sustain blood pressure within therapeutic parameters. Valsartan, a selective antagonist of the angiotensin II type-1 (AT_1) receptor, is widely utilized in the treatment of hypertension. Nonetheless, its brief half-life and BCS class II properties frequently need repeated daily administrations, thus diminishing patient adherence and causing variability in plasma drug levels.[1]

Sustained-release (SR) matrix tablets provide a logical solution: by regulating drug release over a specified duration, SR formulations can sustain more stable plasma concentrations, diminish peak-trough variations, decrease dose frequency, and potentially improve therapeutic efficacy and safety.[2] Natural polymers have garnered heightened interest as matrix-forming agents in sustained-release tablets owing to their biodegradability, biocompatibility, non-toxicity, and regulatory compliance.[3]

Hydroxypropyl methylcellulose (HPMC), a semi-synthetic yet biocompatible hydrophilic polymer, is extensively utilized in controlled-release matrices due to its ability to swell in aqueous environments, creating a viscous gel barrier that regulates drug diffusion over time. Elevating HPMC concentration generally results in a more compact gel layer and a concomitant reduction in drug release rate – a recognized mechanism for attaining extended and consistent release profiles.[4] Natural polymers, such as sodium alginate a polysaccharide sourced from brown seaweed have been efficiently utilized in matrix tablets, leveraging their gel-forming and bioadhesive characteristics to prolong drug release.[5]

Research indicates that the amalgamation of natural polymers, such as alginate, with hydrophilic or synthetic polymers, such as HPMC, can synergistically enhance matrix integrity, release kinetics, and the overall efficacy of sustained-release tablets.

Recent studies on Valsartan SR tablets have shown that formulations utilizing natural polymers (e.g., guar gum, pectin, alginate), either individually or in combination, can markedly extend drug release, with some attaining controlled release over 23 to 24 hours. These findings highlight the practicality and therapeutic significance of natural polymer-based sustained release systems for antihypertensive medications.[6]

This study seeks to develop and optimize sustained-release matrix tablets of Valsartan utilizing combinations of natural polymer matrices (sodium alginate) and hydrophilic polymers (HPMC) to facilitate once-daily dosing, enhance patient compliance, and maintain stable therapeutic plasma concentrations. We assessed the impact of different polymer concentrations on tablet physicochemical qualities, in vitro release kinetics, and stability to determine the optimum formulation for long-term hypertension therapy.

MATERIALS AND METHODS

Chemicals

Valsartan was obtained as a gift sample from UniChem laboratories Ltd., Mumbai. Gaur gum and xanthan gum were purchased from Shilex Chemicals Pvt. Ltd., Delhi, India. Tamarind Seed Polysaccharide (TSP) and Talc were purchased from S.D. Fine-Chemical Ltd, Mumbai. Microcrystalline Cellulose and Magnesium Stearate from Crest Cellulose Pvt. Ltd., Hyderabad, India. All the used reagents and chemicals were of analytical grade.

Valsartan calibration curve:

A primary stock solution of Valsartan (1000 µg/mL) was produced by dissolving 10 mg of the medication in pH 6.8 phosphate buffer and adjusting the total volume to 10 mL. The solution was further diluted to achieve a secondary stock concentration of 100 µg/mL. Aliquots were extracted to formulate working

standard solutions within the 2–10 µg/mL concentration range utilizing the same buffer. The absorbance of each solution was assessed at λmax ≈ 250 nm utilizing a UV–Visible spectrophotometer, with the buffer serving as the blank reference. A calibration curve was constructed relating absorbance to concentration, and the regression equation together with the correlation coefficient (R^2) was computed to verify linearity within the specified range.

Fourier Transform Infrared (FT-IR) Spectroscopy:

Using the ATR FTIR spectrometer (Shimadzu FTIR-8400S, Japan) drug's FT-IR spectra were recorded. When using the diffuse reflectance technique, the mid-IR 4000-400 cm-1 spectral region was covered. The sample was placed in sample holder made from Zinc Selenide. The position and relative strength of the absorption maximums in the spectrum produced with the substance under examination match those in the reference spectrum. To create a transparent Jellies, the mixture was taken and compressed in a hydraulic press at a pressure of 10 tons. The particle was scanned in an infrared spectrophotometer between 4000-400 cm-1. Following the light route, the Jellies was placed, the spectrum was recorded twice, and the characteristic peaks associated with the functional groups were determined.

Preparation of tablets:

Valsartan sustained-release matrix tablets were manufactured using direct compression. The necessary amounts of Valsartan, natural polymers (Guar gum, Xanthan gum, Tamarind Seed Polysaccharide), and microcrystalline cellulose (MCC) were precisely measured and subjected to a #40 sieve to eliminate agglomerates and guarantee consistent particle size. The sifted components were placed in a clean mortar and mixed systematically to achieve a homogeneous mixture. Talc and magnesium stearate, previously sieved through a #60 mesh, were thereafter used as glidant and lubricant, respectively, and blended gently for 2 to 3 minutes to prevent excessive lubrication. The final lubricated mixture was compressed into tablets with an 8-station rotary tablet punching machine with suitable flat-faced punches to achieve tablets with a target weight of 200 mg for each formulation (F1–F9).

Table 1: Composition of various tablet formulations

Ingredients (mg/tablet)	**F1**	**F2**	**F3**	**F4**	**F5**	**F6**	**F7**	**F8**	**F9**
Valsartan	80	80	80	80	80	80	80	80	80
Guar Gum	20	40	80	–	–	–	–	40	40
Xanthan Gum	–	–	–	40	80	–	–	–	40
Tamarind Seed Polysaccharide (TSP)	–	–	–	–	–	40	80	40	–
Microcrystalline Cellulose (MCC)	96	78	38	78	38	78	38	36	36
Magnesium Stearate	2	2	2	2	2	2	2	2	2
Talc	2	2	2	2	2	2	2	2	2
Total Weight (mg)	200	200	200	200	200	200	200	200	200

Evaluation Parameters

Precompression parameters:

Twelve different formulations were tested using blend characterization metrics, including bulk and tapped density, compression index, Hausner's ratio and angle of repose.

Post Compression Parameters[7]:

Evaluation of tablets:

The pharmacopeial standards were followed to assess each batch of tablet's physical attributes, including the thickness, mass variability, drug content, hardness, friability, and in vitro disintegration.

In -vitro dissolution studies[8]:

An apparatus (EI -1916, Electronics India, Pune, India) was used for in-vitro release investigations. For every experiment, at a pH of 6.8 of phosphate buffer 500 milliliters was mixed with 50 revolutions per minute of hot water at 37°c. At predetermined intervals, 5 ml samples were withdrawn and the absorbance was measured at 250 nm to determine the concentration of Valsartan. At predetermined intervals, 5 ml of each test medium was taken out and swapped out for an equivalent volume of a buffered phosphate solution with a pH of 6.8.

Release Kinetics[9]

The results of the in-vitro diffusion study were utilised to look at the drug release kinetics of Valsartan SRT, including their order and mechanism. The zero order, first order, and Higuchi equations were among the kinetic models that were plotted; the Korsmeyer-Peppas equations were employed to determine the release.

Stability Studies:[10]

The stability testing of the optimized Valsartan sustained release tablet formulation was conducted in compliance with ICH Q1A(R2) requirements. Tablets were enclosed in aluminium–PVC blisters, sealed, and preserved in a stability chamber regulated at 40 °C ± 2 °C / 75% RH ± 5% (accelerated conditions) for a duration of 60 days. Samples were collected at 0, 30, and 60 days and assessed for appearance, hardness, friability, surface pH, drug content, and in vitro drug release to identify any physical or chemical alterations. All analyses were conducted in triplicate, and the mean values were documented.

RESULTS AND DISCUSSION

Valsartan's standard calibration curve:

In Figure 1, we can see the Valsartan curve of calibration in phosphate buffer at pH 6.8, provides the absorbance values together with their matching concentrations. Within a concentration ranged from 0 to 10 µg/ml, it was determined that it was linear at 250 nm, with an R^2 value of 0.9936.

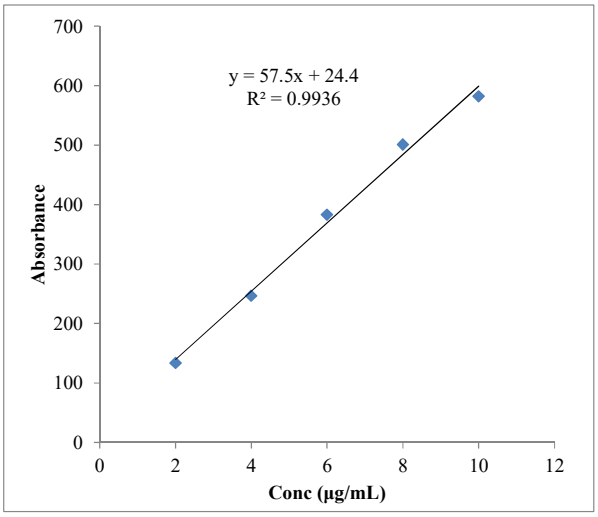

Figure 1: Calibration graph of Valsartan

Studies on drug-excipient compatibility by FT-IR:

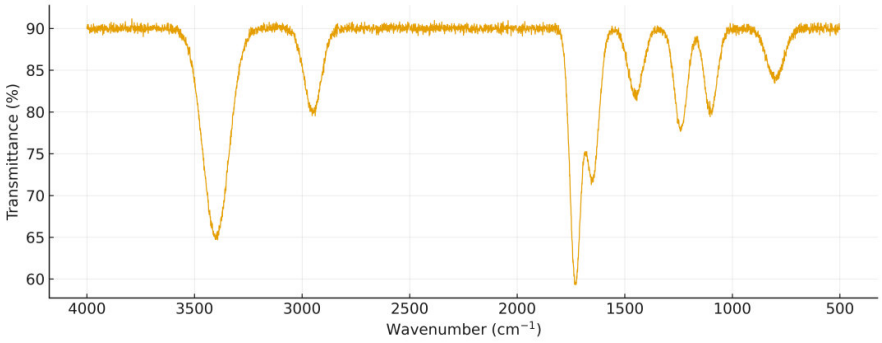

Figure 2: FTIR graph of Pure drug (Valsartan)

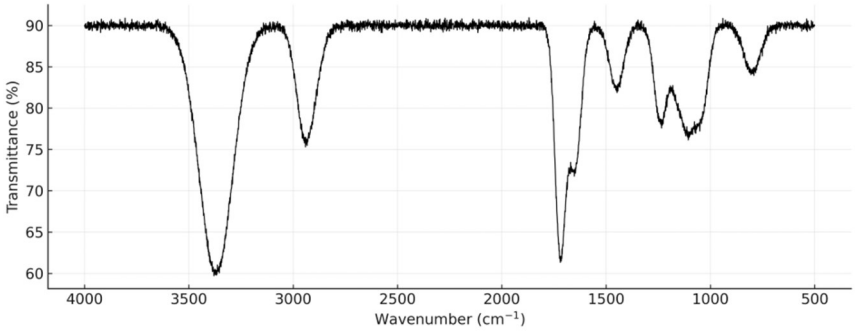

Figure 3: FTIR graph of Guar gum formulation

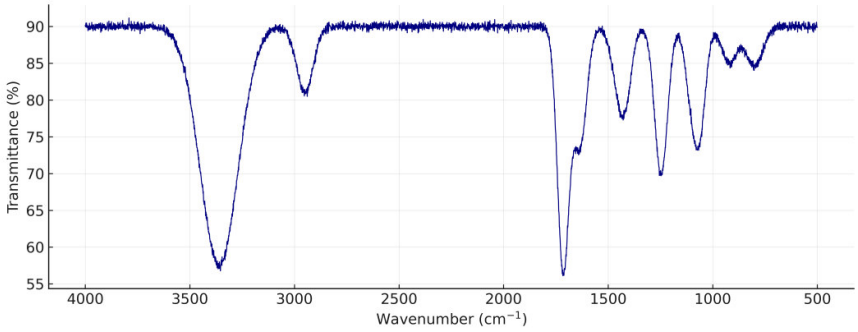

Figure 4: FTIR graph of xanthan gum formulation

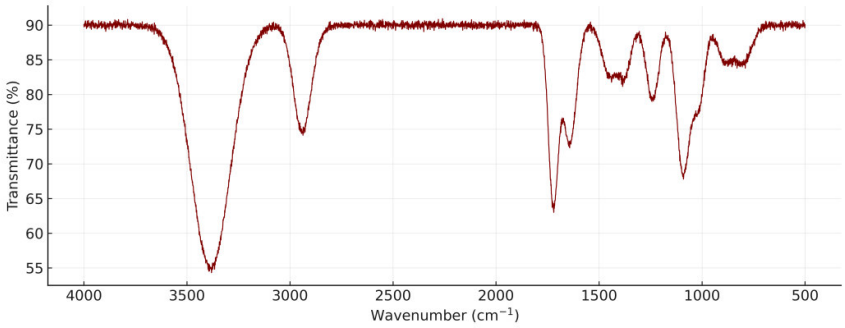

Figure 5: FTIR graph of TSP gum formulation

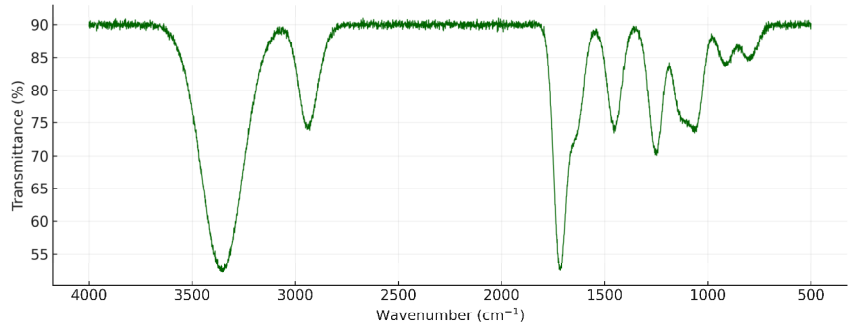

Figure 6: FTIR graph of Guar gum+xanthan gum formulation

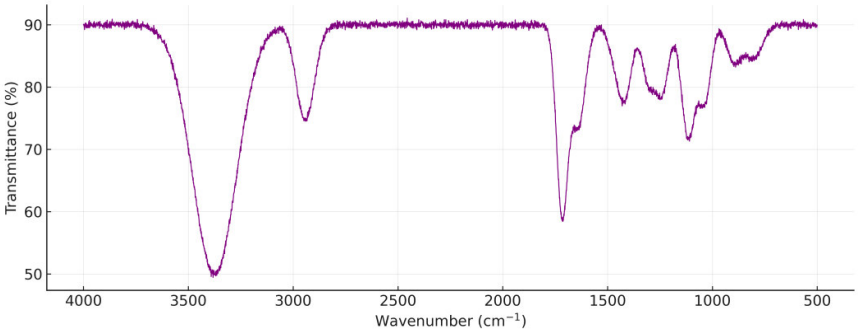

Figure 7: FTIR graph of Guar gum+TSP gum formulation

The FTIR spectrum of pure Valsartan displayed distinctive absorption bands at approximately 3400 cm^{-1} (O–H/N–H stretching), 2950 cm^{-1} (aliphatic C–H stretching), 1730 cm^{-1} (C=O stretching of the carboxyl group), 1650 cm^{-1} (amide/alkene stretching), 1450–1100 cm^{-1} (C–H bending and C–N/C–O stretching), and a prominent band at approximately 800 cm^{-1}. These peaks used as reference marks for observing drug–polymer interactions in later formulations.

The addition of Guar gum resulted in a small broadening of the Valsartan O–H stretching band, accompanied by a minor shift from 3400 to around 3370 cm^{-1}, signifying improved hydrogen bonding. The supplementary bands at approximately 1150 and 1040 cm^{-1} are indicative of the glycosidic C–O–C stretching of galactomannan, so affirming the successful integration of the polymer without modifying the principal functional groups of Valsartan. No elimination of drug-specific peaks was noted, indicating compatibility.

The Valsartan–Xanthan gum spectrum exhibited a more pronounced and widened O–H band (3360 cm^{-1}), accompanied by a significant shift of the C=O peak from 1730 to 1715 cm^{-1}. Distinct absorptions peculiar to polysaccharides at approximately 1415, 1255, and 1060 cm^{-1} were evident, indicating the existence of acetyl and pyruvate substituents in Xanthan. Peak shifts without removal signify physical interactions (hydrogen bonding) rather than chemical alteration of Valsartan.

Moderate peak changes were noted in the O–H (3385 cm^{-1}) and C=O (1722 cm^{-1}) areas for Tamarind Seed Polysaccharide. Additional peaks at 1085 and 1015 cm^{-1}, corresponding to C–O and β-D-glucopyranose units, were observed. The preservation of all significant drug peaks indicates excellent compatibility and the lack of drug degradation.

The combined spectra of Valsartan–Guar–Xanthan

and Valsartan–Guar–Tamarind exhibited significant expansion of the O–H band (3355–3375 cm^{-1}) and slight cumulative shifts in the carbonyl and amide areas (1717–1718 cm^{-1}; 1635–1640 cm^{-1}). The presence of several overlapping polymer-specific C–O and glycosidic peaks (1140–1050 cm^{-1}) validates polymer synergy within the matrix. The lack of additional peaks or the loss of core Valsartan indicators suggests that the interaction is predominantly physical, characterised by hydrogen bonding and entanglement within the polysaccharide matrix.

The FTIR data unequivocally demonstrated that Valsartan is compatible with all utilised polymers, including Guar gum, Xanthan gum, Tamarind Seed Polysaccharide, and their mixtures. The noted changes and band broadening are ascribed to hydrogen bonding and physical interactions, with no indication of chemical instability or degradation of the medication in any formulation.

Pre-compression parameters:

The precompression analysis of formulations VT1–VT9 (Table 2) indicated that all blends exhibited appropriate micromeritic characteristics for direct compression. Bulk density (0.44–0.48 g/cm^3) and tapped density (0.51–0.55 g/cm^3) demonstrated effective packing, whilst Carr's index values (12.73–15.09%) and Hausner ratios (1.15–1.18) validated satisfactory compressibility and flow characteristics. The angle of repose values (25.9–28.5°) corroborated favourable to exceptional flow characteristics. The addition of natural polymers (guar gum, xanthan gum, TSP) did not negatively impact flow, indicating that all blends were homogeneous, free-flowing, and appropriate for compression into sustained-release matrix tablets.

Table 2: Pre-compression parameters of Sustained release Valsartan tablets

Formulations	Bulk Density (g/cm^2)	Tap Density (g/cm^2)	Carr's Index (%)	Hausner ratio	Angle Of Repose(Ɵ)
VT1	0.46 ± 0.02	0.53 ± 0.03	13.21 ± 0.61	1.15 ± 0.04	27.3 ± 1.1
VT2	0.45 ± 0.03	0.52 ± 0.02	13.46 ± 0.68	1.16 ± 0.03	26.9 ± 1.0
VT3	0.44 ± 0.05	0.51 ± 0.04	13.73 ± 0.65	1.16 ± 0.04	27.8 ± 1.2
VT4	0.47 ± 0.02	0.54 ± 0.02	12.96 ± 0.59	1.15 ± 0.03	26.5 ± 1.1
VT5	0.48 ± 0.04	0.55 ± 0.05	12.73 ± 0.63	1.15 ± 0.03	25.9 ± 1.0
VT6	0.46 ± 0.02	0.54 ± 0.03	14.81 ± 0.70	1.17 ± 0.04	28.1 ± 1.2
VT7	0.45 ± 0.03	0.53 ± 0.04	15.09 ± 0.75	1.18 ± 0.04	28.5 ± 1.1
VT8	0.47 ± 0.02	0.55 ± 0.05	14.55 ± 0.68	1.17 ± 0.04	27.2 ± 1.0
VT9	0.46 ± 0.04	0.54 ± 0.02	14.81 ± 0.65	1.17 ± 0.03	27.6 ± 1.1

Parameters after compression:

Weight variation test:

Every tablet in each batch underwent the weight variation test. The results, including the percentage deviation and difference in weight, are displayed in Table 3. The tablet's weight is around 199.7±3.1 to 200.6±3.1 mg. All of the dosage weights were found to be within the acceptable range according to the pharmacopoeia.

Hardness test:

Results are displayed in Table 3. The results indicated that the tablet's hardness fell within the accepted IP limits, ranging from 6.1 ± 0.19 to 6.5 ± 0.22 kg/cm^2.

Thickness:

In order to determine the thickness of each batch, three tablets were measured with a vernier calliper, and the results are displayed in Table 3. The tablet's thickness ranged from 3.10 ± 0.07 to 3.18 ± 0.09, according to the results.

Table 3: Post-Compression parameters of Sustained release Valsartan tablets

F code	Weight variation (mg)	Hardness (kg/cm^2)	Thickness (mm)	Friability (%)	Drug Content (%)
VT1	200.4 ± 3.2	6.2 ± 0.18	3.12 ± 0.06	0.46 ± 0.03	98.8 ± 1.9
VT2	199.8 ± 3.0	6.1 ± 0.19	3.10 ± 0.07	0.44 ± 0.05	99.1 ± 2.0
VT3	200.6 ± 3.1	6.3 ± 0.20	3.14 ± 0.08	0.43 ± 0.02	98.5 ± 1.9
VT4	200.1 ± 3.0	6.4 ± 0.19	3.11 ± 0.06	0.42 ± 0.04	99.3 ± 2.0
VT5	199.9 ± 3.2	6.5 ± 0.21	3.16 ± 0.08	0.40 ± 0.03	99.6 ± 2.0
VT6	200.2 ± 3.1	6.2 ± 0.19	3.13 ± 0.07	0.47 ± 0.05	98.9 ± 1.9
VT7	200.5 ± 3.2	6.3 ± 0.20	3.18 ± 0.09	0.48 ± 0.04	98.7 ± 2.0
VT8	199.7 ± 3.1	6.4 ± 0.21	3.15 ± 0.07	0.45 ± 0.06	99.4 ± 1.9
VT9	200.3 ± 3.2	6.5 ± 0.22	3.17 ± 0.08	0.42 ± 0.02	99.8 ± 2.0

Friability:

Table 3 shows the results of the evaluation of the percentage of friability for every tablet batch. All the formulations had an average friability ranging from 0.40 ± 0.03 to 0.48 ± 0.04%, which is below the statutory limit of 1% for IP and suggests that the tablets have acceptable mechanical resilience.

Drug content:

The produced formulations were subjected to assay investigations. The assay investigations indicated that the medication content percentages in each formulation ranged from 98.5 ± 1.9 % to 99.8 ± 2.0 %.

Studies on in vitro dissolution: Utilising a USP dissolving device and the paddle method, 500 ml of pH 6.8 phosphate buffer was utilised for in vitro dissolution tests. The duration of the dissolution experiments was approximately twelve hour.

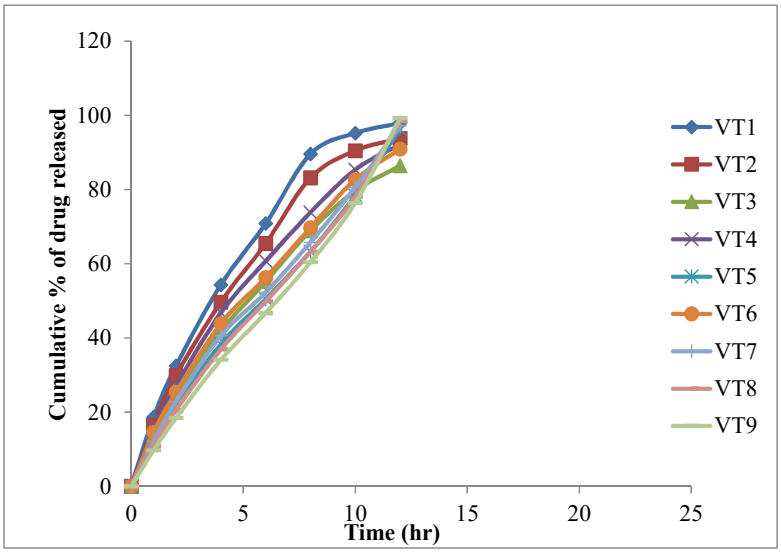

Figure 8: Dissolution profile of VST sustained release tablets all formulations.

An in-vitro dissolution analysis of Valsartan sustained release tablets (VT1–VT9) was performed in pH 6.8 phosphate buffer over 12 hours, with all formulations demonstrating a progressive and controlled release profile. The release of the medication was negatively correlated with polymer concentration; an increase in Guar gum, Xanthan gum, and Tamarind Seed Polysaccharide (TSP) led to a deceleration in release due to the establishment of a more robust gel matrix that impeded drug diffusion. Xanthan gum (VT5) exhibited superior sustained release among single-polymer formulations when compared to Guar gum and TSP. Combination formulations with mixed natural polymers (VT8 and VT9) exhibited more uniform and prolonged release for up to 12 hours, sustaining virtually zero-order kinetics. The optimised formulation VT9 demonstrated the most favourable profile, achieving 99.27% cumulative drug release at 12 hours, signifying effective matrix integrity and regulated drug diffusion appropriate for once-daily sustained release dose.

Utilizing Kinetics of Release Rate for Dissolution:

Various models were utilized to examine the drug release kinetics. A number of release of drug models, including first-order, zero-order, Higuchi, and Korsmeyer-Peppas, were fitted to the collected data to examine the mechanism underlying the rate kinetics of the dose form.

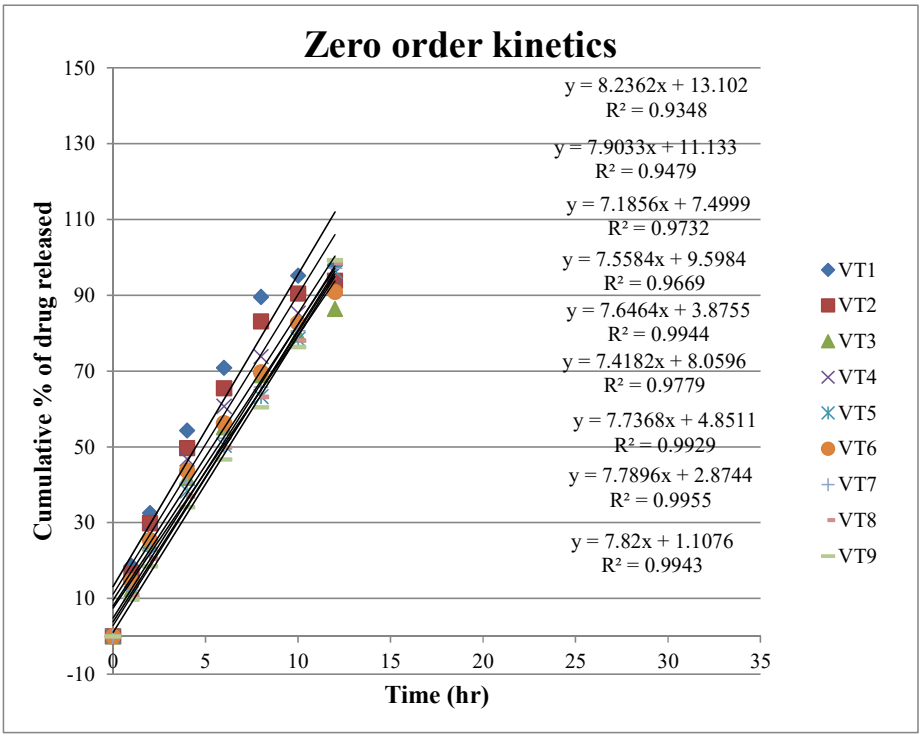

Figure 9: Zero order release kinetics graph of Valsartan formulations.

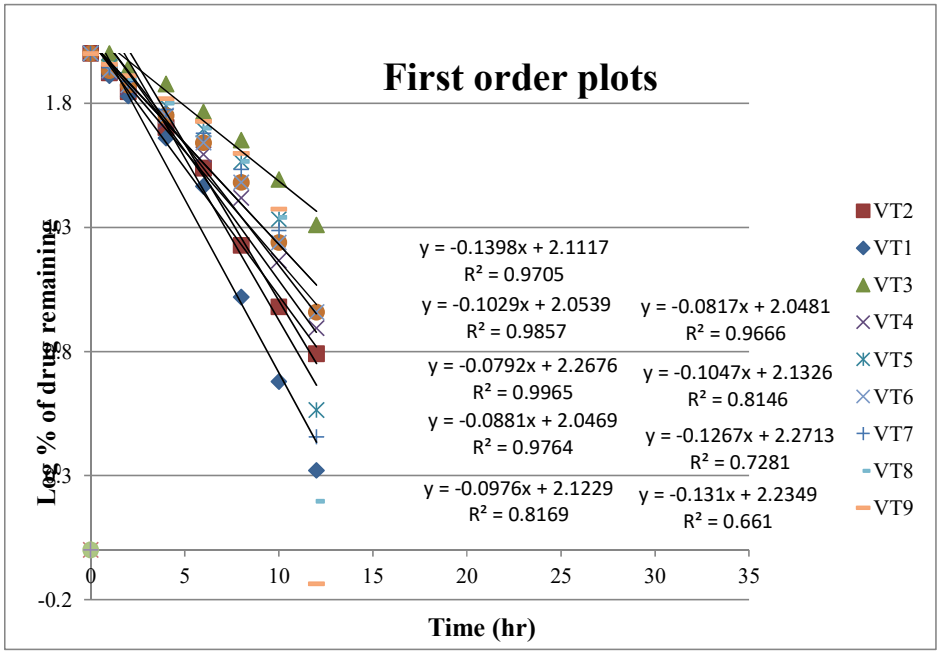

Figure 10: First order release kinetics graph of Valsartan formulations

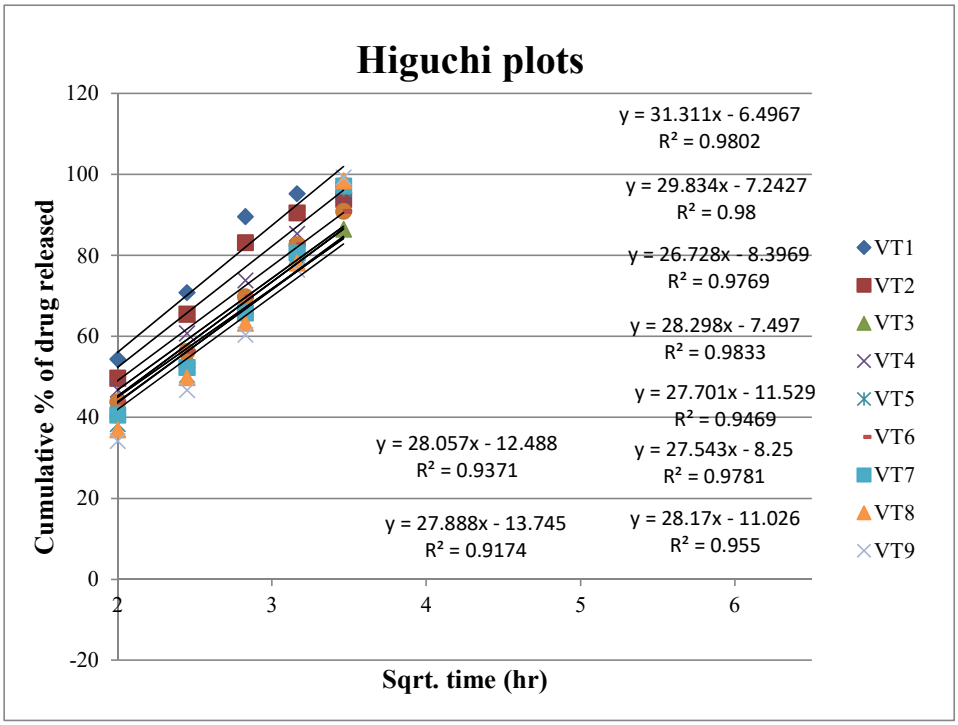

Figure 11: Higuchi release kinetics graph of Valsartan formulations

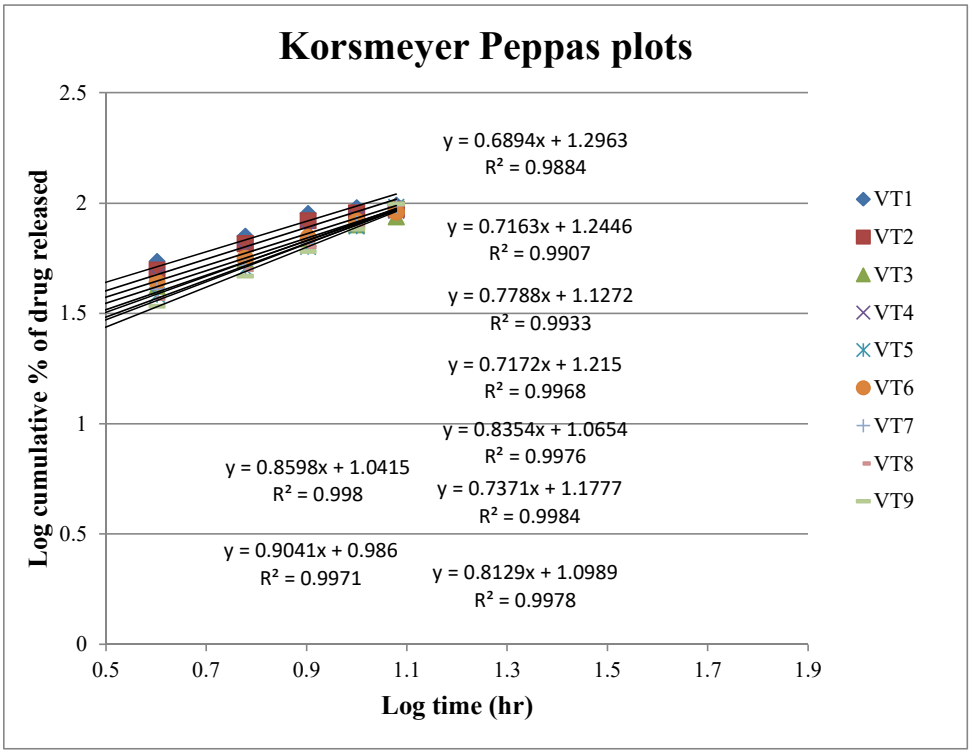

Figure 12: Korsmeyer-Peppas kinetics graph of Valsartan formulations.

The kinetic analysis of Valsartan sustained release tablets (VT1–VT9) revealed that formulations with reduced polymer content (VT1–VT4) conformed well to First-order and Higuchi models (R^2=0.97–0.98), indicating a diffusion-controlled, concentration-dependent release with non-Fickian behaviour (n=0.68–0.77). In contrast, formulations with increased polymer and combination matrices (VT5–VT9) demonstrated excellent linearity with Zero-order and Korsmeyer–Peppas models (R^2>0.99) and elevated n values (0.83–0.90), confirming anomalous transport influenced by both diffusion and polymer relaxation. Notably, VT8 and particularly VT9 exhibited near Zero-order release with a strong Peppa's fit, designating VT9 as the optimised formulation for reliable, controlled Valsartan delivery over a 12-hour period.

Selection of Best Formulation

Following the evaluation of dissolution characteristics and post-compression parameters, VT9 was identified as the optimised sustained-release formulation. It demonstrated a regulated, incremental release profile devoid of an initial surge, attaining nearly whole drug release (99%) at 12 hours while preserving favourable mechanical qualities, minimal friability, satisfactory hardness, and consistent drug content. The prolonged release efficacy of VT9 is due to the synergistic effect of the natural polymer matrix, which established an efficient gel barrier and ensured a consistent diffusion-controlled release appropriate for once-daily Valsartan therapy.

Stability Studies

A three-month stability investigation was carried out on the VT9 refined compounds in a controlled environment with a 40°C temperature and a 75% relative humidity. Every thirty days, the tablets were tested for a variety of properties, including thickness, diameter, hardness, consistency of content, friability, weight change and disintegration time. All of the metrics were within the predetermined range, and there was no discernible change from the original data. Measurements were taken every 30 days throughout the three-month in-vitro dissolving research. Exposure to elevated temperatures and controlled humidity levels had no effect on the release patterns.

CONCLUSION

The research effectively shown that natural polymers, including Guar Gum, Xanthan Gum, and TSP, may proficiently regulate Valsartan release in sustained-release tablet formulations. The combination matrix VT9 demonstrated superior mechanical strength, consistent drug content, and regulated Zero-order release over a duration of 12 hours. These data indicate that VT9 is a promising once-daily sustained-release formulation that can enhance antihypertensive therapy and patient adherence. Additional stability, pharmacokinetic, and scale-up investigations are advised to bolster its prospects for commercial advancement.

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