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Formulation and Evaluation of Sustained Release Matrix Tablet of Quinapril by Using Natural Polymers

Apoorv Nitin Gholap[1], Dr. Pranav Parekh[2], Dr. Mrunal Shirsat[3], Vaibhav Narwade[4], Gokul Mali[5]
Kasturi Shikshan Sanstha College of Pharmacy

Abstract: ***In present investigation an attempt has been made to design and develop some Quinapril matrix tablets using KarayaGum, Guar gum, KollidonSRas release retarding polymers. Quinapril is Anti-hypertensive drug which lowers blood pressure level and has been selected to prepare sustained release dosage forms. Quinapril sustained release matrix tablets were prepared using KarayaGum, Guar gum, KollidonSR as base polymer by wet granulation method. FTIR spectral analysis showed that characteristic peak of Quinapril pure drug was retained in the spectra of all the formulations indicating the intactness of the drug in all the formulations. Quinapril matrix tablets formulated employing Kollidon SR and combination of Karaya Gum and Guar gum provided slow and controlled release of Quinapril up to 24 hr. All the tablet formulation showed compliance with pharmacopoeia standard as the time increases. The dissolution result shows that an increased amount of polymer resulted in reduced drug release. A concentration dependent drug release is evident in case of the polymer i.e., lower concentration of polymers, release is marginally retarded at higher concentration is considerable. Prepared sustained formulation containing KarayaGum, Guar gum, KollidonSR as release retarding polymers (F6) probably showing better release based up to 98% drug release within 24 hours.***

The development of sustained release (SR) oral dosage forms is a pivotal strategy in modern pharmaceutical technology, aiming to enhance therapeutic efficacy, reduce dosing frequency, and improve patient compliance, especially for chronic conditions such as hypertension. Quinapril, an angiotensin-converting enzyme (ACE) inhibitor, is widely prescribed for hypertension and heart failure but suffers from a short biological half-life and low oral bioavailability due to extensive first-pass metabolism. This study focuses on the formulation and evaluation of sustained release matrix tablets of quinapril using natural polymers as matrix formers. Natural polymers such as guar gum, xanthan gum, and sodium alginate were selected for their biocompatibility, biodegradability, and non-toxic nature, offering an eco-friendly alternative to synthetic polymers. The matrix tablets were prepared by direct compression method, optimizing the polymer concentration to achieve desired drug release kinetics. Pre-compression parameters (angle of repose, bulk density, compressibility index) and post-compression parameters (weight variation, hardness, friability, drug content, and in vitro dissolution) were systematically evaluated. The in vitro drug release studies were conducted in simulated gastric and intestinal fluids to mimic physiological conditions. The results demonstrated that the type and concentration of natural polymer significantly influenced the drug release profile, with optimized formulations achieving sustained release of quinapril over 12–24 hours, following non-Fickian (anomalous) diffusion kinetics. The optimized matrix tablets exhibited acceptable physicochemical properties and stability. This research underscores the potential of natural polymers in developing effective sustained release formulations of quinapril, which can enhance therapeutic outcomes and patient adherence in hypertension management.

Keywords: Sustained release, Quinapril, Karaya Gum,Kollidon SR Guar gum.

I. INTRODUCTION

Sustained drug delivery system was aimed to release the medication in a prolonged rate to maintain plasma drug levels. The drugs having shorter half-life are suitable for the sustained drug delivery system.[1] The main objective in designing sustained delivery system is to reduce dosing frequency and thereby increasing the action. The drug molecules show better sustained drug release profile in matrix systems by different mechanisms. The introduction of matrix tablet as a sustained release had made a new phase for the novel drug delivery system.[2]

The polymers aid in regulating or delaying the formulations' drug release kinetics. Because theyare readilyavailable, affordable, potentiallybiodegradable, and compatible, several naturally occurring gums and mucilage's are utilized as polymers to regulate and sustain the drug release.[3] Pharmaceutical researchers prefer employing natural biodegradable polymers over synthetic ones; therefore,this field of study is still active.

Future advancements in polymer synthesis and development will broaden the application of novel drug delivery systems.[4] Due to great need and demand in drug delivery systems the excipients are included in novel dosage forms to fulfill required functionsregarding the dosage form and these gumsdirectlyor indirectly influencesor affectstherateand extent ofdrug releaseaswell astheir absorption inthe GIT.[5]Thereforethe plant based and naturalproductsdemand the replacement of synthetic additives with these natural gums.

The aim of this work is to preparesustainedrelease matrixtablet of Quinapril by using natural polymer. QuinaprilisanACE inhibitorprodrugusedtotreathypertension, congestiveheart failure, and slow rate of progression of renal disease.[6] Sustained release matrix tablet containing Quinapril strategies can be utilized to ensure targeted delivery for site-specific treatment as well as long-acting therapy, improving overall patient compliance.[7]

II. MATERIALS AND METHODS

A. Materials

Quinalapril obtained from GiftSamplefromCureMedicine(Pune), KarayaGum, Guar gum, KollidonSR, IPA, Microcrystallinecellulose, Magnesium stearate obtained from AnandAgencies,Pune. All materials used were of analytical grade procured from commercial sources.

B. Preparation of Matrix Tablets:

Matrix tablets were prepared by direct compression. The required quantities of quinapril, natural polymer(s), and excipients were accurately weighed and blended to ensure uniform distribution. The blend was evaluated for pre-compression parameters (angle of repose, bulk density, tapped density, Carr's index, Hausner's ratio) to assess flow propertiesThe powder blend was then compressed into tablets using a single-punch tablet machine.[8]

Materials and Methods (Expanded)

1) Materials

- Active Pharmaceutical Ingredient (API): Quinapril hydrochloride
- Natural Polymers: Guar gum, xanthan gum, sodium alginate (selected for their biocompatibility, swelling, and gel-forming properties)
- Excipients: Microcrystalline cellulose (binder), lactose (diluent), magnesium stearate (lubricant), talc (glidant)
- Other Chemicals: Analytical grade reagents for dissolution media preparation

2) Formulation of Matrix Tablets

a) Preformulation Studies

- *Drug-Polymer Compatibility:* FTIR spectroscopy was used to assess potential interactions between quinapril and selected polymers.
- *Powder Characterization:* The API and excipients were evaluated for bulk density, tapped density, angle of repose, Carr's index, and Hausner's ratio to ensure good flow and compressibility[9]

b) Preparation Method

- *Direct Compression Technique:* All ingredients were passed through a #44 mesh sieve to ensure uniform particle size. The required quantities of quinapril, natural polymer(s), and excipients were weighed accurately.
- *Blending:* The powders were mixed in a geometric dilution method for 10 minutes to ensure homogeneity.
- *Lubrication:* Magnesium stearate and talc were added and mixed gently for 2–3 minutes.
- *Compression:* The final blend was compressed into tablets using a rotary tablet press with appropriate tooling (e.g., 8 mm flat-faced punches).
- *Batch Variations:* Multiple formulations were prepared by varying the type and concentration of natural polymers to optimize sustained release characteristics.

3) Evaluation of Matrix Tablets

a) Pre-Compression Evaluation

- Angle of Repose: Measured to assess flow properties; values <30° indicate good flow.
- Bulk and Tapped Density: Used to calculate Carr's index and Hausner's ratio, which reflect compressibility and flowability
- Carr's Index: Calculated as Tapped Density−Bulk DensityTapped Density×100\frac{\text{Tapped Density} - \text{Bulk Density}}{\text{Tapped Density}} \times 100Tapped DensityTapped Density−Bulk Density×100; values <15% indicate good flow.
- Hausner's Ratio: Ratio of tapped to bulk density; values <1.25 are considered acceptable.[10,11,12]

b) Post-Compression Evaluation

- Physical Appearance: Tablets were visually inspected for color, shape, and surface defects.
- Weight Variation: Twenty tablets were weighed individually; the mean and standard deviation were calculated. Acceptable limits are ±5% for tablets >250 mg
- Thickness and Diameter: Measured using a digital vernier caliper to ensure uniformity.
- Hardness: Determined using a Monsanto or Pfizer hardness tester; values between 4–8 kg/cm² are generally acceptable for matrix tablets[9]
- Friability: Assessed using a Roche friabilator. Tablets were rotated at 25 rpm for 4 minutes, and the percentage weight loss was calculated. A value <1% indicates adequate mechanical strength
- Drug Content Uniformity: Ten tablets were powdered, and an amount equivalent to one tablet was dissolved in a suitable solvent. After filtration and appropriate dilution, quinapril content was determined spectrophotometrically at its λmax. Acceptable range: 95–105% of label claim

c) Swelling Index (Optional)

Tablets were weighed and placed in dissolution medium. At predetermined intervals, tablets were removed, blotted, and reweighed. Swelling index was calculated as:

Swelling Index=Weight at time t−Initial WeightInitial Weight×100\text{Swelling Index} = \frac{\text{Weight at time t} - \text{Initial Weight}}{\text{Initial Weight}} \times 100Swelling Index=Initial WeightWeight at time t−Initial Weight×100

This parameter helps assess the gel-forming ability of the natural polymers

d) In Vitro Dissolution Studies

- Apparatus: USP Type II (paddle) dissolution apparatus.
- Medium: 900 mL of 0.1N HCl (pH 1.2) for the first 2 hours, followed by phosphate buffer (pH 6.8) for up to 24 hours, maintained at 37±0.5°C.
- Procedure: Tablets were placed in the dissolution vessel, and samples (5 mL) were withdrawn at predetermined intervals, replaced with fresh medium to maintain sink conditions.
- Analysis: Samples were filtered and analyzed for quinapril content using UV-Visible spectrophotometry at the appropriate wavelength.
- Data Treatment: Cumulative percentage drug release was plotted against time. The release profiles of different formulations were compared to select the optimal batch.[13,14,15]

e) Drug Release Kinetics

- The dissolution data were fitted to various kinetic models:
  - Zero-order: Qt=Q0+k0tQ_t = Q_0 + k_0tQt=Q0+k0t
  - First-order:log Qt=log Q0−k1t/2.303\log Q_t = \log Q_0 - k_1t/2.303logQt=logQ0−k1t/2.303
  - Higuchi model: Qt=kHt1/2Q_t = k_H t^{1/2}Qt=kHt1/2
  - Korsmeyer-Peppas model: Qt/Q∞=ktnQ_t/Q_\infty = k t^nQt/Q∞=ktn
- The best-fit model was determined by the highest correlation coefficient (R^2). The release exponent (n) from the Peppas model indicated the mechanism (Fickian, non-Fickian, or case-II transport)

f) Stability Studies

- Conditions: Optimized formulations were stored at 40°C/75% RH for 3 months.
- Parameters Evaluated: Physical appearance, drug content, and in vitro release profile were assessed at 0, 1, 2, and 3 months to ensure stability

Summary Table: Evaluation Parameters

Parameter	Method/Instrument	Acceptance Criteria
Angle of Repose	Funnel method	<30° (good flow)
Bulk/Tapped Density	Graduated cylinder	-
Carr's Index	Calculated	<15% (good compressibility)
Hausner's Ratio	Calculated	<1.25 (good flow)
Weight Variation	Analytical balance	±5%
Thickness/Diameter	Vernier caliper	Uniform
Hardness	Monsanto/Pfizer tester	4–8 kg/cm²
Friability	Roche friabilator	<1%
Drug Content	UV-Vis spectrophotometer	95–105%
Swelling Index	Gravimetric	-
In Vitro Dissolution	USP II apparatus	As per design
Release Kinetics	Mathematical modeling	Highest R^2
Stability	ICH guidelines	No significant change

Evaluation of Tablets:

- Physical Parameters: Tablets were assessed for weight variation, thickness, diameter, hardness, and friability as per pharmacopeial standards.
- Drug Content Uniformity: Ten tablets were randomly selected, powdered, and analyzed spectrophotometrically for quinapril content.
- In Vitro Dissolution Studies: Drug release was studied using USP Type II (paddle) apparatus in 0.1N HCl (pH 1.2) for 2 hours followed by phosphate buffer (pH 6.8) for up to 24 hours. Samples were withdrawn at predetermined intervals and analyzed for quinapril content.
- Release Kinetics: The dissolution data were fitted to various kinetic models (zero-order, first-order, Higuchi, Korsmeyer-Peppas) to elucidate the drug release mechanism[16,17,18]

Results

Pre-compression, Evaluation:

The powder blends exhibited good flow properties, with angle of repose values below 35°, Carr's index below 15%, and Hausner's ratio below 1.25, indicating suitability for direct compression

Post-compression Evaluation:

- All formulations passed weight variation, hardness (4–6 kg/cm²), and friability (<1%) tests.
- Drug content ranged from 98% to 102%, indicating uniform distribution.

In Vitro Drug Release:

- The release profile was significantly influenced by the type and concentration of natural polymer.
- Formulations with higher polymer content showed slower drug release, achieving sustained release up to 24 hours.
- Guar gum and xanthan gum, due to their high swelling and gel-forming abilities, effectively retarded drug release, while sodium alginate provided additional mucoadhesive properties
- The optimized formulation (e.g., quinapril:guargum:xanthan gum in 1:2:1 ratio) released approximately 90% of the drug over 24 hours, following non-Fickian (anomalous) diffusion kinetics.

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Stability Studies:
Tablets stored at accelerated conditions (40°C/75% RH) for 3 months showed no significant changes in physical appearance, drug content, or release profile.

III. DISCUSSION

The study demonstrates that natural polymers are effective matrix formers for sustained release tablets of quinapril. The swelling and gel-forming properties of guar gum and xanthan gum, combined with the mucoadhesive nature of sodium alginate, contributed to the modulation of drug release. The release mechanism was predominantly non-Fickian, indicating a combination of diffusion and polymer relaxation/erosion processes.
The use of natural polymers offers advantages such as biocompatibility, safety, and regulatory acceptance, making them suitable for chronic therapy formulations. The optimized matrix tablets maintained their integrity and sustained drug release over the desired period, which is crucial for improving patient compliance in hypertension management.[19,20,21]

IV. METHODS

A. FT-IRSpectroscopy

The identification of the drug was done by (FT-IR) spectroscopic method using Model350, Agilent FTIR spectrophotometer. The drug was placed for ATR scan at transmission mode in the region of 4000 to 400 cm^{-1}. Hence, the wave numbers of peaks in IR spectrum of the drug thus obtained was compared with the theoretical values of the wave number corresponding to the structure of drugs.

B. FormulationofQuinaprilMatrixtablets

PreparationofQuinapril Matrixtablets, eachcontaining 100 mg ofQuinaprilwere prepared by wet granulation method. Quinapril and MCC were sifted through sieve No. 40 manually and mixed well to form uniform premix blend. Drug and diluent premixes blend were then mixed with the selected ratio of Natural polymer(s) for 5to 10 minutes. Premix blend was then wet granulated with 5% w/v solution of Kollidon SR in a mortar. The wet mass was passed through No.18 sieve. The wet granules were dried at 55°C ± 5°C for 1 hour in a hot-air oven and the dried granules were sieved through No.22 sieve. These granules were lubricated with magnesium stearate and talc and compressed using 16 station rotary tableting machine, equipped with convex, round punches of12 mmdiameter.

TableNo.1:FormulationofQuinaprilMatrixTablets

Sr. No.	Ingredients	F1 (mg)	F2 (mg)	F3 (mg)	F4 (mg)	F5 (mg)	F6 (mg)
1	Quinapril	10	10	10	10	10	10
2	KarayaGum	80	50	-	-	40	25
3	Guar Gum	-	-	80	50	40	25
4	KollidonSR	50	50	50	50	50	50
5	IsopropylAlcohol	QS	QS	QS	QS	QS	QS
6	'ocrystalline cellulose	75	105	75	105	75	105
7	Magnesiumstearate	55	55	55	55	55	55
8	Talc	40	40	40	40	40	40
	Total(mg)	310	310	310	310	310	310

C. Micromeritic studies of QuinaprilMatrixTablets

Different Parameters like Angle of repose, Density (Tapped and Bulk), flow property, Carr's compressibility Index, Hausner's ratio, Percentage yield (i.e., recovery) of QuinaprilMatrixTabletsformed were studied.

D. PostcompressionEvaluationofQuinaprilMatrixTablets

Different Parameters like Thickness, WeightVariationTest, hardness, friability and drug content of QuinaprilMatrixTablets formed were studied.

E. In-Vitro Dissolution Studies

In -Vitro Drug Release Characteristics Drug release was assessed by dissolution test by using USP type II dissolution apparatus (paddle method) at 100 rpm in 900 ml of 0.1N HCl for first 2 hours and the phosphate buffer pH 3 from 3 to 12 hours, maintained at 37°C ± 0.5°C. An aliquot (10ml) was withdrawn at specific time intervals and replaced withthe same volume offreshdissolution medium. The sampleswithdrawnwere filtered throughWhatmanfilter paperanddrugcontent ineachsamplewasanalyzed byUV- visible spectrophotometer at 220 nm.

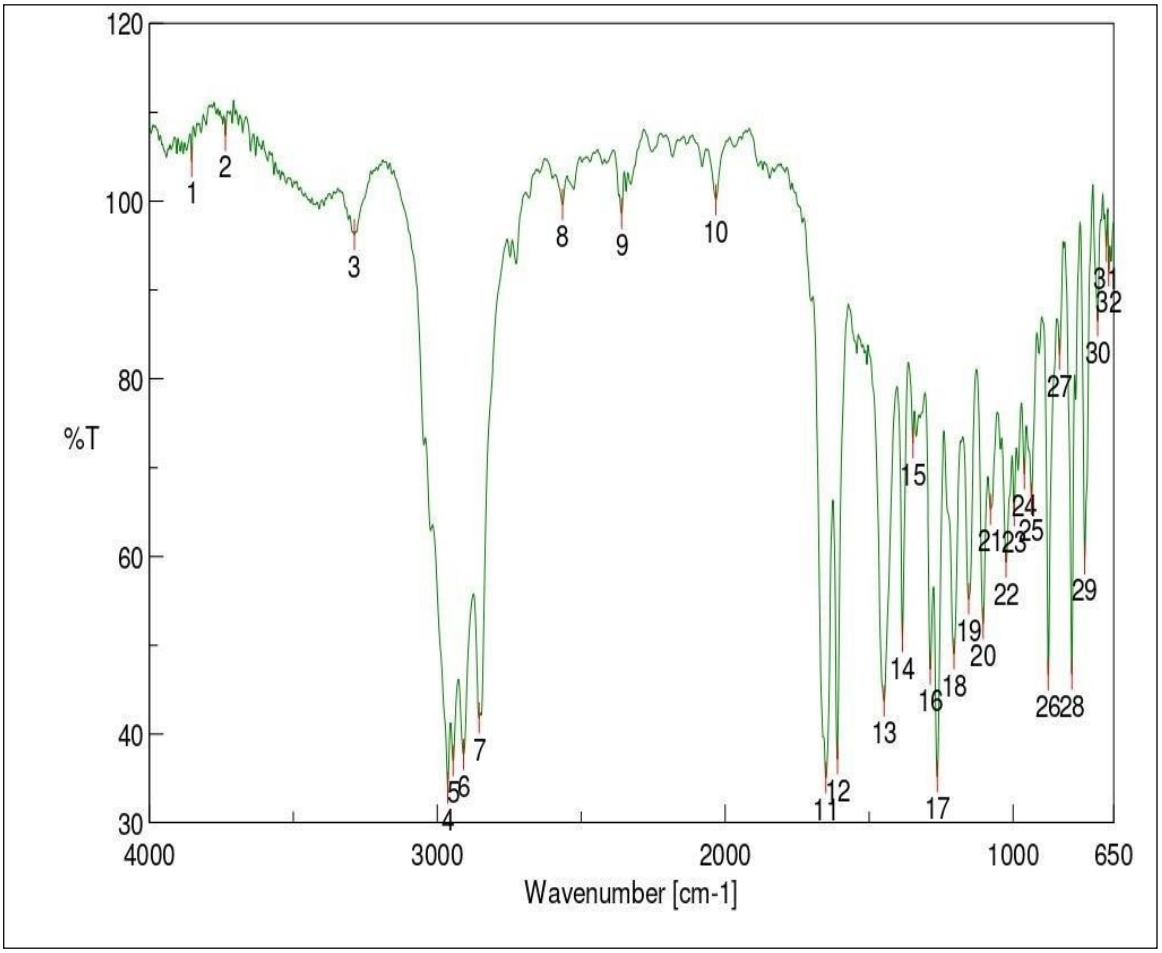
F. Stability Studies

The optimized formulation was subjected for three month stability study according to standard guidelines. The selected formulations were packed in aluminium foils, which were in wide mouth bottles closed tightly. They were stored at 40^0C / 75% RH for 3 months and evaluated periodically.[22,23,24]

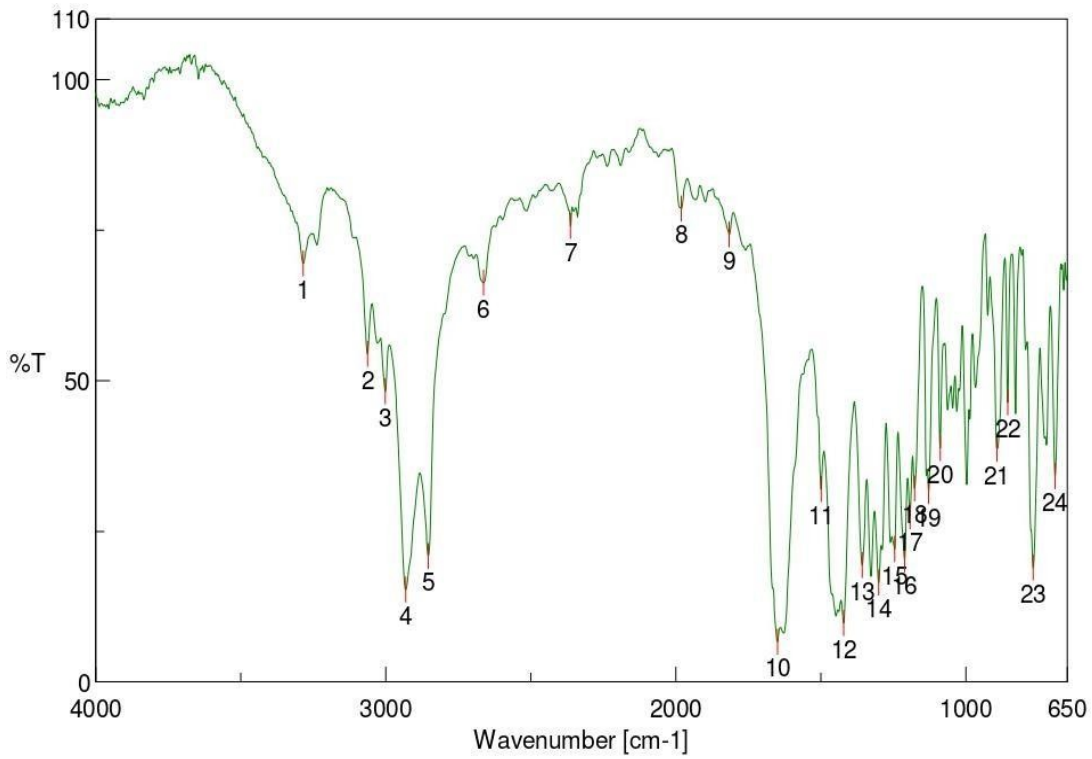
V. RESULT AND DISCUSSION

A. FT-IRSpectroscopy

FT-IRspectroscopywascarriedouttocheckthecompatibilitybetweendrugand excipients.Theinteractionbetweendrug-excipientswas observed fromIR- spectralstudiesbyobservinganyshiftinpeaksofdruginthespectrumofphysical mixture of drug excipients.



FigureNo.1:FTIRspectraofQuinapril



FigureNo.2:FTIRSpectraofcompatibility

B. EvaluationofGranules

TableNo2:PhysicalParametersforPrecompressionBlend

atch No.	Repose (º)	Bulk Density (g/ml)	Tapped Density(g/ml)	sIndex (%)	usner's Ratio
F1	28.33±1.74	0.53±0.001	0.64±0.016	8.07±1.39	1.03
F2	27.71±1.14	0.56±0.006	0.63±0.011	11.20±1.44	1.05
F3	28.33±1.15	0.57±0.003	0.64±0.013	11.42±1.36	1.06
F4	28.20±1.18	0.56±0.004	0.61±0.016	10.74±1.40	1.08
F5	27.12±1.42	0.54±0.005	0.63±0.010	10.38±1.32	1.19
F6	25.30±1.44	0.58±0.004	0.64±0.017	13.42±1.43	1.15

TheangleofreposefortheformulationsF1-F6wasfoundtobeintherange25.30to28.33 shows good flow property Compressibility index for the formulations F1-F6 found within 8.07 % to 13.42 % indicating the good flow property. Hausner's Ratio for the formulationsF1-F6foundwithin 1.03to 1.19indicatingthegoodflowproperty.

C. EvaluationofQuinaprilTablets

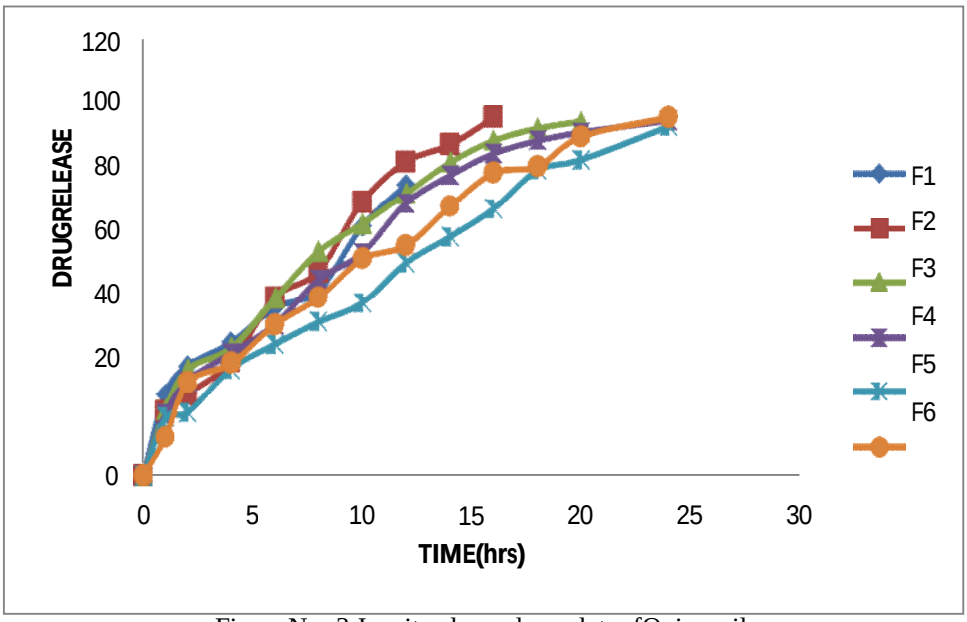
TableNo.3:PhysicalEvaluationofMatrixTablet

Batch.No	WeightVariation (%)	Friability(%)	Thickness(mm)	Hardness (Kg/cm^2)
F1	311±1.54	0.23±0.19	3.68±0.06	5.6±0.11
F2	310±2.38	0.22±0.24	3.75±0.02	6.4±0.08
F3	309±1.46	0.21±0.10	3.79±0.07	6.7±0.06
F4	311±1.86	0.25±0.31	3.83±0.05	6.2±0.15
F5	312±2.14	0.28±0.12	3.89±0.06	6.3±0.20
F6	310±2.57	0.27±0.31	3.82±0.02	5.8±0.08

The weight variation of the tablet in the range of ± 1.46 % to ± 2.57 % (below 7.5 %) complying with pharmacopoeia specification. The friability of the tablet in the range of 0.21 % to 0.28 % **(**below 1%) complying with pharmacopoeia specifications. ThethicknessoftheformulationsfromF1-F6wasfoundtobeintherangeof3.68±0.06 to 3.89 ± 0.06 and hardness of the formulated tablets was found to 5.6 ± 0.11 to 6.7 ± 0.06 indicatingasatisfactorymechanicalstrengthforthesustainedrelease.[25,26]

D. In-vitroEvaluationofmatrixtablet

Matrix tablets were prepared successfully after selecting the optimized formulations ofsustainreleasethepreparedmatrixtabletswereevaluatedforpostcompressionparametersandresultswerefoundtobewithin thelimitsmentione din theabovesection andwereshowninTable7.9.Invitrodrugreleasestudiesofmatrixtabletswerecarried out using USP dissolution apparatus type II in 900 mL Potassium Phosphate buffer of pH solutionsupto24hours. Fromtheresults,drugreleaseofQuinaprilmatrixtabletwas foundtobe98%of24hoursdrugreleaseofmatrixtablet.



FigureNo. 3:In-vitrodrugreleasedataofQuinapril

E. StabilityStudies

TableNo.4:StabilityStudyData

ability period	40^0C/75%RH			
	Hardness Mean±SD	%Friability Mean±SD	% Drug content Mean±SD	Drugrelease
Initial	5.8±0.08	0.27±0.31	99.6±0.3	98.75±0.11
1 month	4.9±0.12	0.30±0.3	98.7±0.2	98.0±0.3
2month	4.8±0.46	0.35±0.2	97.4±0.3	98.3±0.2
3month	4.6±0.13	0.62±0.1	97.1±0.3	97.8±0.2

The matrix tablets were subjected to short term stability study, storing the formulation at40^0C / 75% RH for 3 months. The data for stability studies revealed that no considerable differencesinphysicalparameters,drugcontentand*invitro*drugreleaseratewere observed.

VI. CONCLUSION

In the present work sustained release matrix tablet of Quinapril were prepared by using natural polymer namely Karaya gum, Guar gum, Kollidon SR, Magnesium stearate, Microcrystalline cellulose, Talc was used.

In the presentstudy,theformulation and production technology of Quinapril sustained release matrixtablet have beendeveloped withgood physicalcharacteristics, predictable andreproducibledrugreleaseprofiles.QuinaprilisanACEinhibitorprodrugusedto treat hypertension, congestive heart failure, and slow rateofprogressionofrenaldisease.

ThisstudydemonstratedthatNaturalpolymerprovidesareliable sustainedrelease matrix formulation BCS I class drugs such as Quinaprilwhich is an antihypertensive agent.

Based onthe above evaluation studies, it could be concluded that naturalpolymers could be used as a suitable matrix forming agent by wet granulation method for sustained release of Quinapril over 24 hr byproviding reduced side effects.[27,28,29,30]

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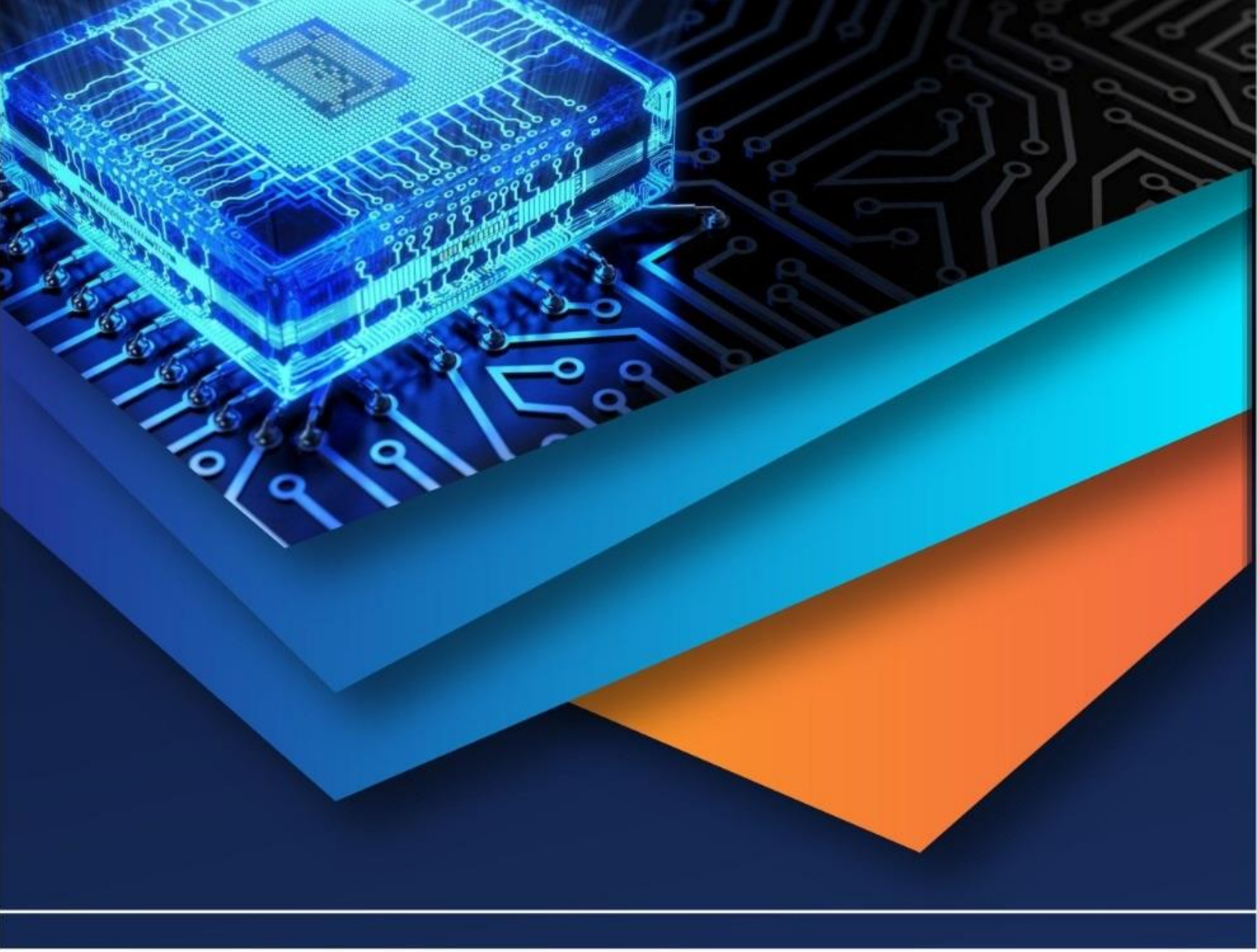

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