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Original Article

FORMULATION AND EVALUATION OF SUSTAINED RELEASE MATRIX TABLETS OF LOSARTAN POTASSIUM

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ABSTRACT

Sustained release tablets of Losartan potassium (LP),an anti-hypertensive drug were prepared by direct compression method using different polymers such as Carbopol 934P, HPMC K100 M and Locust Bean Gum in different ratios. The compressed tablets were further evaluated for uniformity of weight, hardness, friability, thickness, content uniformity, in-vitro dissolution, swelling index study. In vitro release studies were conducted in phosphate buffer pH 6.8. To analyze the release mechanism Zero-order, First-order, Higuchi, and Korsmeyer-Peppas model were used. Similarity factor f2 was also calculated to compare the prepared matrices with the marketed product. All the formulations exhibited sustained drug release for 12 hrs. Majority of designed formulations followed Zero-order release kinetics and Korsmeyer- Peppas equation gave release pattern with n values greater than 1 indicating super case transport mechanism.The optimized formulation F5 was chosen based on acceptable physical properties, in vitro drug release profile and calculation of similarity factor. Among the three polymers used to formulate matrix tablets of LP, HPMC K100M was found to impart controlled release of drug with desired dissolution profile in 12hrs.

Keywords: *Losartan Potassium, anti-hypertensive, controlled release, zero order, HPMC K100*

INTRODUCTION

Oral controlled release delivery systems are programmed to deliver the drug in predictable time frame that will increase the efficacy, minimize the adverse effects and increase the bioavailability of drugs. Oral drug delivery is the most widely utilized route of administration among all alternatives that have been explored for systemic delivery of drug via various pharmaceutical products of different dosage form.

Availability of wide variety of polymers help the formulation scientist to develop sustained/controlled release products. Oral sustained release (SR)/Controlled release (CR) products provide an advantage over conventional dosage forms by optimizing bio-pharmaceutical, pharmacokinetic and pharmacodynamic properties of drugs.

Sustained release (S.R)/ Controlled release (C.R) pharmaceutical products have gradually gained medical acceptance and popularity. Regulatory approval for marketing and their pharmaceutics superiority and clinical benefits over immediate release pharmaceutical products have been increasingly recognized. Modified release oral dosage forms have brought new lease of life into drugs that have lost market potential due to requirement of frequent dosing, dose related toxic effects and gastrointestinal disturbances.

The term modified-release drug products used to describe products that alter the timing and/or the rate of release of the drug substance. A modified-release dosage form is defined "as one for which the drug-release characteristics of time course and/or location are chosen to accomplish therapeutic or convenience objectives not offered by conventional dosage forms such as solutions, ointments or promptly dissolving dosage forms as presently recognized"[1-3].

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Losartan is the first orally available Angiotensin II receptor antagonist that is used for the treatment of hypertension. The most preferred route for this drug is oral delivery in form of tablets. Losartan has good water solubility, low bioavaibility (approximately 33%), and shorter half-life (2 hours) [4].

The present work is aimed at preparing and evaluating sustained-release (SR) matrix tablets of Losartan potassium (LP) using different polymers to prolong the release of drug for extended period of time in order to improve patient compliance, reduces dosing frequency, increase bioavailability of the drug.

MATERIALS AND METHOD

Losartan Potassium was obtained as a gift sample from Aurobindo Pharma, Hyderabad. Polymers HPMC K100M, Cabopol934P, and Locust bean gum. Microcrystalline cellulose (MCC) (water-insoluble), Talc, Magnesium stearate, Sodium hydroxidewas purchased SD fine chemicals, India. All the chemicals were ether of pharmaceutical or analytical grade.

Calibration curve

Calibration curve of Losartan potassium was prepared using buffer pH 6.8 in the concentration range of 2 – 10µg/ml. The drug was analyzed spectrophotometrically at 205 nm (regression coefficient r2 = 0.9994 in buffer pH 6.8)

Preformulation Studies

Drug-excipient Compatibility studies

A Fourier Transform – Infra Red spectrophotometer was used to study the non-thermal analysis of drug-excipient (binary mixture of drug: excipient 1:1 ratio) compatibility. The spectrum of each sample was recorded over the 450-4000 cm-1.

Evaluation of Precompression Blend

Prior to compression, granules were evaluated for their characteristic parameter such as tapped density, Carr's Index and angle of repose. Carr's compressibility index was calculated from the bulk and tapped density using a digital tap density apparatus (Electrolab, India).

Preparation of Losartan Matrix Tablets

All the matrix tablets, each containing 50 mg of Losartan, were prepared by direct compression method. Accurately weighed amounts of drug, polymer and diluent were mixed geometrically in a mortar. This mixture was passed through No.40 sieve and thoroughly mixed in a polythene bag for 15 minutes. The powder blend was then lubricated with magnesium stearate and talc for 2 minutes and compressed into tablets on a 16 mm tabletting machine using 8-mm round, flat-faced punches.

The drug polymer ratio was developed to adjust drug release as per theoretical release profile and to keep total weight of tablet constant for all the fabricated batches under experimental conditions of preparations. The total weight of the matrix tablets was 250 mg with different drug polymer ratios like 1:0.25. 1:0.5, 1:0.75, and 1:1. The various polymers used were HPMC K100M, Cabopol934P, and Locust bean gum. MCC (water-insoluble) was used as a diluent for the preparation of matrix tablets. Magnesium stearate (MS) 1% and talc 2 % were used as lubricants. Compositions of different formulations (F1 to F12) are given in the Tables 1.

Formulation code	Losartan (mg)	HPMC K100M (mg)	Carbopol 934P (mg)	Locust bean gum(mg)	MCC (mg)	Talc (mg)	Mg. Stearate (mg)	Total weight (mg)
F1	50	-	25	-	167.5	5	2.5	250
F2	50	-	37.5	-	155	5	2.5	250
F3	50	-	50	-	142.5	5	2.5	250
F4	50	-	62.5	-	130	5	2.5	250
F5	50	25	-	-	167.5	5	2.5	250
F6	50	37.5	-	-	155	5	2.5	250
F7	50	50	-	-	142.5	5	2.5	250
F8	50	62.5	-	-	130	5	2.5	250
F9	50	-	-	25	167.5	5	2.5	250
F10	50	-	-	37.5	155	5	2.5	250
F11	50	-	-	50	142.5	5	2.5	250
F12	50	-	-	62.5	130	5	2.5	250

Table 1. Composition of Losartan potassium Matrix Tablets Containing

Evaluation of Matrix Tablets/ Post compression parameter

The formulated tablets were evaluated for thickness, hardness, friability, uniformity of weight and drug content.

Friability Test

Tablet strength was measured using Roche friabilator. A sample of pre weighed tablets was placed in Roche friabilator which was then operated for 100 revolutions. The tablets were then dedusted and reweighed and percent friability (% F) was calculated.

$$\text{Friability (\%)} = \frac{\text{Initial weightof 10 tablets} - \text{Final weight of 10 tablets}}{\text{Inital weight of 10 tablets}} x\ 100$$

F (%) = [W0-W/W0] X100

Where, W0 is the initial weight of the tablets before the test and

W is the final weight of the tablets after test.

Friability values below 0.8% are generally acceptable.

Weight Variation Test

The weight variation test is done by taking 20 tablets randomly and weighed accurately. The composite weight divided by 20 provides an average weight of tablet. Not more than two of the individual weight deviates from the average weight by 10 % and none should deviate by more than twice that percentage. The weight variation test would be a satisfactory method of

determining the drug content uniformity. The percent deviation calculated using the following formula:

$$\% \, Deviation = \frac{Individual\ weight - Average\ weight}{Average\ weight} \times 100$$

Estimation of Drug Content

Six tablets of each formulation were taken and powdered. Powder equivalent to one tablet was transferred to 100mL volumetric flask and volume was made up to 100 mL with phosphate buffer pH 6.8. The solution was filtered through a 0.45µ membrane filter, diluted suitably and the absorbance of resultant solution was measured by using UV-Visible spectrophotometer at 205 nm using pH 6.8 phosphate buffer as blank.

In - vitro Drug Release Characteristics

Drug release was assessed by dissolution test using USP type II dissolution apparatus, paddle method with the revolution speed of paddle at constantrate 50 rpm. Asdiffusion media/ dissolution medium 900 ml phosphate buffer pH 6.8 was usedand maintained attemperature 37˚C ± 0.5˚C. An aliquot (5mL) was withdrawn at specific time intervals up to 12 hrsand replaced with the same volume of fresh dissolution medium. Drug content in each sample was analyzed by UV-Visible spectrophotometer at 205 nm. N=3

Kinetic Analysis of Dissolution Data

To analyze the in vitro release data, various kinetic models, zero order, first order, Fickian diffusion, were used to describe.To find out the mechanism of drug release, first 60% drug release data was fitted in Korsmeyer–Peppas model 8 were applied to process in vitro data to find the equation with the best fit.

Similarity Factor (f2) Analysis

In vitro release profiles of all the batches of sustained release tablets were compared with the theoretical release profile which was calculated earlier. The data were analyzed by the following formula.

$f_2 = 50 \log [1 + 1/N \sum (R_i - T_i)^2]^{(-0.5)} \times 100$

where N = number of time points, Ri and Ti = dissolution of reference and test products at time i. If f2 is greater than 50 it is considered that 2 products share similar drug release behaviours[9].

Swelling Studies

The extent of swelling was measured in terms of percent weight gain by the tablets. The tablet was placed in a U.S.P type I Dissolution apparatus containing basket containing 900 ml of phosphate buffer pH 6.8. The tablets were taken out after completion of the respected stipulated time span0.5, 1, 2, 3, 4, 6, 8 and 12 hr and weighed after the excess of water has been blotted. The increase of the weight on the tablet reflects the weight of the liquid uptake. It was estimated according to following equation.

$$\text{Swelling index(S.I.)} = \frac{M_t - M_0}{M_0} \times 100$$

Where,

Mt = weight of tablet at time’t’

Mo = weight of tablet at time t = 0.

RESULTS AND DISCUSSION

3.1. Preformulation studies

Drug – Excipient compatibility studies by physical observation

Losartan potassium was mixed with various proportions of excipients showed no color change at the end of two months, proving nophysical drug-excipient interactions.

3.1.2. FTIR

The FTIR Spectra of physical mixturedrug and polymers (Carbopol934P, HPMC K100M and Locust bean gum) and (Fig. 2,3,4) was studied by comparing the with that of pure Losartan drug(Fig. 1).

There was no appearance or disappearance of any characteristics peak in the FTIR spectrum of drug and the polymers mixture. The presence of peaks at the expected range confirms that the materials taken for the study are genuine and there were no possible interactions.The comparison shows that there is no drug interaction between the drug and other ingredients of formulations.

The characteristic functional groups of the pure Losartan showed the peaks at the following wave number region. C-CH3stretching (Alkane) at 1358.25 cm-1, Hydroxyl stretching (bonded) at 1258.28 cm-1, C=N at 1458.14 cm-1, Aromatic groups (tetrazole and imidazole) and halogens at 672.21cm-1,788.32cm-1.

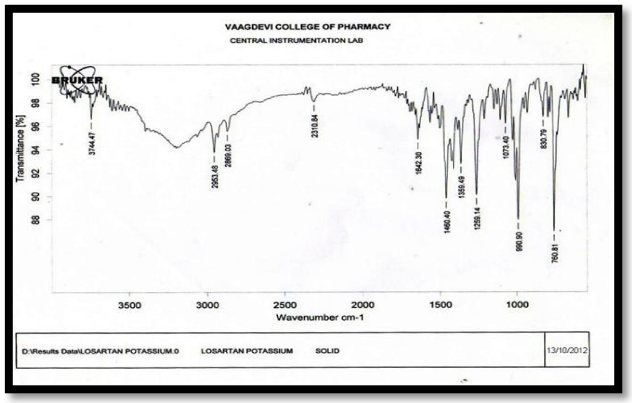

Fig: 1. FTIR Spectrum of pure Losartan potassium

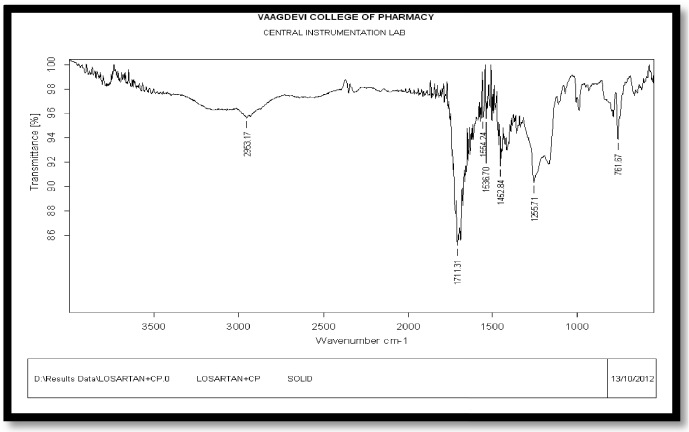

Fig: 2. FTIR Spectrum of Losartan potassium+ Carbopol 934P

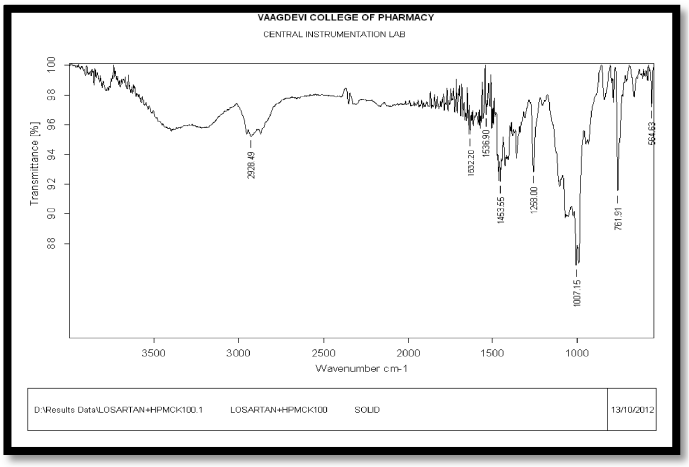

Fig: 3. FTIR Spectrum of Losartan potassium+HPMC K100M

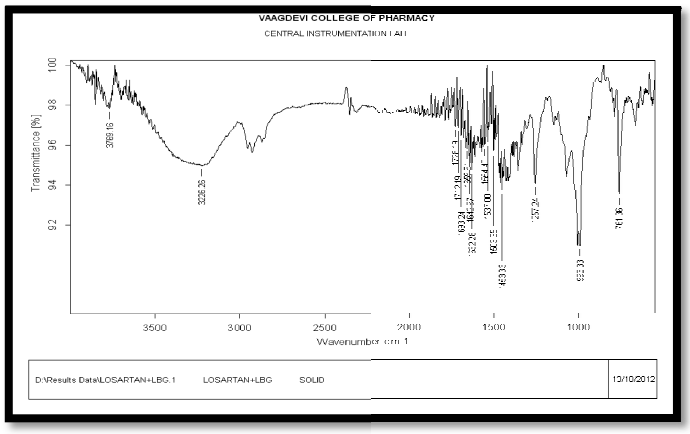

Fig: 4. FTIR Spectrum of Losartan potassium+ LBG

Table 4.FT IR studies of Drug and polymer mixture

BOND	LOSARTAN	LOSARTAN + C 934P	LOSARTAN+HPMC K100M	LOSARTAN+LBG
Alcoholic OH	1258.28	1255.71	1007.15	1257.24
Aliphatic C-CH_3	1358.25	1536.70	1453.55	1503.36
Aromatic C-Cl	788.32	761.67	564.63	761.36
Nitrile C=N	1458.14	1554.24	1536.90	1642.97

Determination of absorption maxima λmax

The maximum absorbance of Losartanin phosphate buffer pH 6.8 was found to be at wavelength 205nm, hence analysis of dissolution studysampleswasperformed at this particular wavelength.

3.3. 1. Characterization of Pre compression Blend

The quality of tablet, once formulated, by rule is generally dictated by the quality of physicochemical properties of blends. There are many formulations and process variables involved in mixing and all these can affect the characterization of blends produced.

The Precompression blend for matrix tablets were characterized with respect to angle of repose, bulk density, tapped density, Carr's index, and drug content Table5 Angle of repose was less than 30° and Carr's index values were less than 18 for the precompression blend of all the batches indicating good to fair flowability and compressibility. Hausner's ratio was less than 1.25 for all the batches indicating good flow properties11-15.

Table 5. Physical Properties of Precompression Blend

Formulation Code	Angle of repose (˚)	Bulk Density (g/mL)	Tapped Density (g/mL)	Carr's Index (%)	Hausner's ratio
F1	25.46 ± 1.2	0.483 ± 1.8	0.574 ± 1.6	15.85 ± 0.02	1.18 ± 0.1
F2	26.12 ± 2.5	0.480 ± 1.2	0.569 ± 1.3	15.64 ± 0.1	1.18 ± 0.05
F3	28.91 ± 2.5	0.532 ± 1.5	0.612 ± 0.8	13.07 ± 0.08	1.15 ± 0.1
F4	25.63 ± 1.2	0.356 ± 0.5	0.403 ± 1.2	16.10 ± 0.15	1.19 ± 0.08
F5	24.26 ± 0.8	0.216 ± 2.5	0.253 ±1.6	14.38 ± 0.12	1.17 ± 0.5
F6	26.52 ± 1.2	0.232 ± 2.8	0.284 ± 0.8	18.30 ± 1.8	1.22 ± 0.06
F7	28.92 ± 0.4	0.422 ± 1.6	0.506 ± 1.4	16.60 ± 2.0	1.19 ± 0.2
F8	26.42 ± 1.2	0.308 ± 0.9	0.364 ± 2.8	15.30 ± 1.8	1.18 ± 0.1
F9	23.45 ± 0.1	0.523 ± 1.6	0.603 ± 1.2	13.26 ± 2.4	1.15 ± 0.08
F10	25.49 ± 1.2	0.526 ± 0.5	0.634 ± 1.8	15.45 ± 1.6	1.20 ± 0.05
F11	26.05 ± 0.9	0.336 ± 1.2	0.398 ± 1.4	15.57 ± 2.5	1.18 ± 1.8
F12	27.34 ± 0.8	0.280 ± 1.8	0.328 ± 2.0	14.63 ± 1.8	1.17 ± 1.2

All values represent mean ± Standard Deviation (SD), n=3

Table 6.Physical Evaluation of Matrix Tablets of Losartan potassium

Formulation Code	Weight Variation (mg)	Hardness (Kg/cm2)	Thickness (mm)	Friability (%)	Content uniformity (%)
F1	249.8±1.48	5.20±0.4	3.80±0.17	0.74	100.28±1.37
F2	250.4±0.54	5.84±0.31	3.65±0.27	0.72	99.12±2.46
F3	248.6±0.41	4.98±0.37	3.91±0.71	0.68	99.53±1.84
F4	248.8±1.64	5.53±0.76	4.12±0.88	0.53	98.25±1.36
F5	250.6±1.14	5.68±0.67	3.85±0.36	0.78	99.12±1.58
F6	249.2±0.83	5.75±0.57	3.64±0.89	0.64	96.34±2.18
F7	249.9±0.67	5.56±0.69	3.87±0.25	0.58	94.57±1.22
F8	249.0±0.43	5.84±0.70	4.26±0.58	0.77	93.28±1.98
F9	246.5±0.80	5.82±0.56	3.71±0.86	0.59	99.54±2.15
F10	251.6±0.83	5.91±0.80	3.67±0.45	0.68	97.63±1.58
F11	252.3±0.93	5.80±0.18	3.18±0.89	0.64	98.86±1.23
F12	251.2±0.97	5.48±0.57	3.95±0.15	0.53	98.86±1.18

All values represent mean ± Standard Deviation (SD), n=3

Physical Evaluation of Matrix Tablets of Losartan potassium

The results of the weight variation, hardness, thickness, friability, and drug content of the tablets are given in Table 6. All the tablets of different batches complied with the official requirements of weight variation as their weight variation passes the limits. The ftablets F1 to F12 have average weight varying between 246.5±0.80 to 252.3±0.93. The hardness of the tablets ranged from 4.98 to 5.91 kg/cm2 and the percentage friability values varying between 0.53 to 0.78 indicating that the matrix tablets were compact and hard. The thickness of the tablets ranged from 3.18to 4.26 mm and the percentage drug content varying between93.28±1.98 to 100.28±1.37 of Losartan.

Good uniformity in drug content was observed. Thus, all the physical attributes of the prepared tablets were found to be practically within control.

In-vitro Drug Release Studies

The results of release studies of formulations F1 to F4 are shown in Fig 5. The release of drug depends not only on the nature of matrix but also upon the drug polymer ratio. As the percentage of polymer increased, the kinetics of release decreased. Formulation F1 to F4 with drug polymer ratios 1:0.5, 1:0.75, 1:1, and 1:0.25, respectively have extended-release rate for 12 hrs.

Formulation F1 showed 93.09% release of drug at the end of 12hrs and this may be due to swelling of matrices followed by erosion. The viscosity of the gel layer around the tablet increases with the increase in the hydrogel concentration, thus limiting the release of the active ingredient. As the carboxyl groups of Carbopol dissociate highly at pH above the pKa (6 ± 0.5) electrostatic repulsions between the negatively charged carboxyl groups cause uncoiling and expansion of molecules, resulting in polymer swelling and consequent gel formation reported. The drug release at the end of 12hrs was found to be93.09%, 88.97%, 85.0%, and 82.53%17-18.

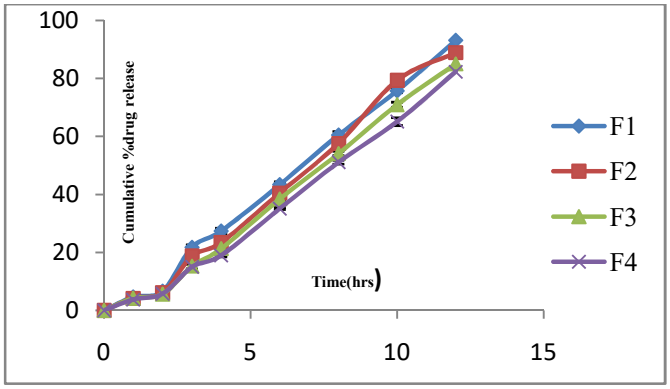

Fig: 5 In- vitroRelease Profiles of Losartan potassium matrix tablets containing Carbopol 934P matrices

The results of release studies of formulations F5 to F8 are shown in Fig. 6. The release of drug depends not only on the nature of matrix but also upon the drug polymer ratio. As the percentage of polymer increased, the kinetics of release decreased. Formulations F5composed of drug polymer ratios of 1:0.5 showed burst release in the first 3 hours. This phenomenon may be attributed to formation gel layer around the tablet core. Remaining all formulations showed extended release for 12 hrs.The drug releases at the end of 12 hrs were found to be 96.25%, 90.30%, 86.83%, 81.206% respectively.

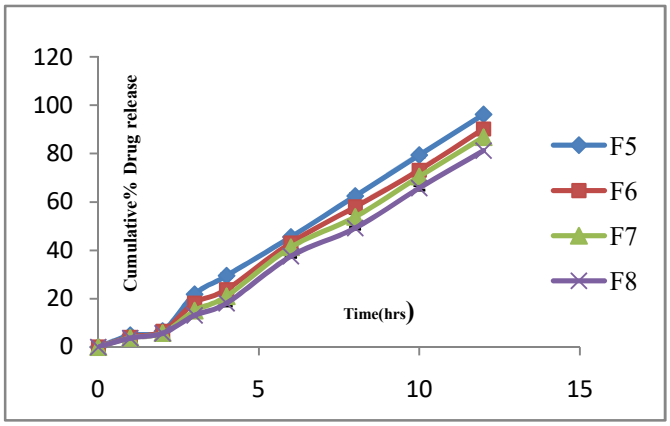

Fig: 6 In-vitro Release Profiles of Losartan potassium matrix tablets containing HPMC K100M

Locust bean gum was used as a natural polymer for controlling drug release. The results of release studies for formulations F9 to F12 was shown in the Fig. 7. The release of drug has been extended for 12 hrs. It has been observed that the cumulative percent drug release decreases with increasing concentration of gum and swelling index. The reason attributed to this fact is hydration of individual locust bean gum particles results in extensive swelling. As a result of rheology of hydrated product, the swollen particles coalesce. This results in a continuous viscoelastic matrix that fills the interstices, maintaining the integrity of the tablet, and retarding further penetration of the dissolution medium.The drug release at the end of 12 hrs was found to be92.84%, 88.052%, 82.33%, 80.23% respectively.

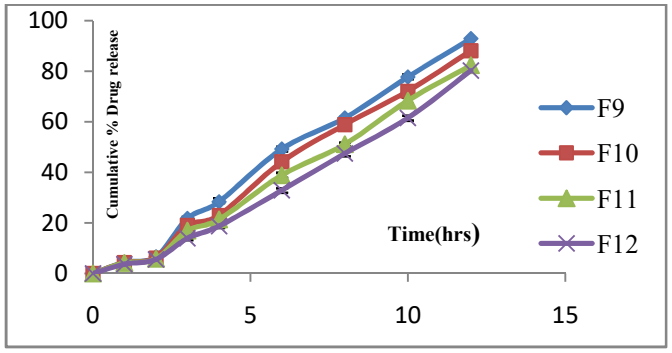

Fig: 7.In-vitroRelease Profiles of Losartan potassium matrix tablets containingLocust bean gum

Out of total 12 batches, the drug releases the initial burst release was found to be for the formulations F5 and release profile was similar to marketed drug release. So, formulation F5 was selected for further studies like kinetic data analysis and similarity factor analysis.

Kinetic Analysis of Dissolution Data

Among all the formulations formulation F5showed more linearity by Zero order equation, as the plots showed the highest linearity (R2 = 0.994), followed by Korsmeyer - Peppeas(R2= 0.965) so it was chosen as the optimized formulation. As indicated by the value of R2 the release kinetics was best explained by zero order kinetics and to determine the drug release pattern the in vitro dissolution data was fitted into the Korsmeyer-Peppas equation and the value of release exponent (n) for the optimized formulation was 1.286 (R2 = 0.965) indicating the drug release follows Super case II transport8-10.

Similarity Factor Analysis

Similarity factor analysis between F5 tablets and theoretical release has shown an f2 factor greater than 50 with a value of f2 factor 64.649.The In-vitro release behaviour of all the 12 formulations tablets were compared with the theoretical release profile and showed in the Table 11.

A close relationship was observed between F5formulation and theoretical release patterns. So, F5 was considered as optimized formulation, as these tablets showed initial burst release and extended the release beyond 12 hours with similar release pattern to that of theoretical release profile.

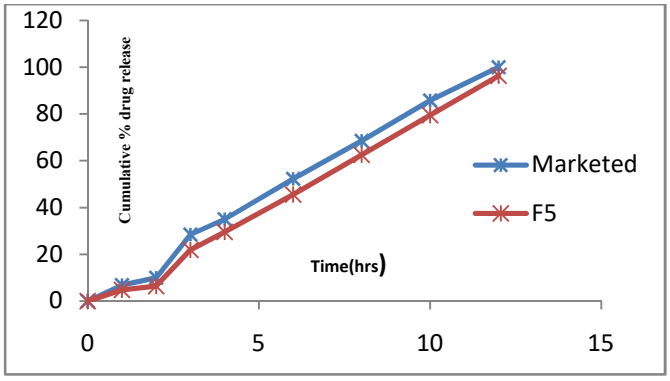

Fig: 8. Comparison of in-vitroCumulative % drug release of OptimizedFormulation(F5) With Marketed matrix tablet of Losartan potassium

Swelling Index

The percentage swelling of optimized tablet is shown in Fig.9.Maximum swelling was observed in first 3-4hrs.The swelling behaviour indicates the rate at which tablets absorb the water from dissolution media and swells. Swelling of matrix tablets increases with respect to time because weight gain by tablets was increased proportionally with rate of hydration up to 4 hrs and matrix appeared swollen almost from the beginning and a viscous gel mass was created after contact with water. Later on,swelling was decreased due to dissolution of outermost gelled layer of tablets. As swelling increases drug release will be more diffusion controlled or erosion controlled for water soluble and water insoluble drugs.

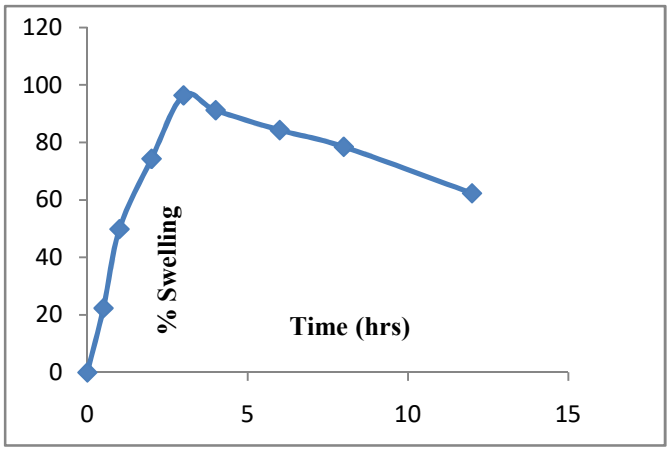

Fig.9. Swelling Study of Optimized Formulation (F5) of Losartan potassium

CONCLUSION

The aim of the present study was to design and evaluate matrix tablets of losartan potassium using Carbopol 934P, HPMC K100M, and Locust bean gum for controlled delivery and to assess the kinetics of drug release mechanism. The study revealed that the release followed zero order kinetics with super case II transport diffusion mechanism. The formulation prepared by direct compression technique containing drug and polymer in the ratio 1:0.5 using HPMC K100M showed drug release similar to that of marketed formulation. Results of the drug release profile demonstrate that all three polymers i.e., Carbopol 934P, HPMC K100M and Locust bean gum could be suitable candidates for formulating controlled release matrix tablets of Losartan potassium.

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