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DEVELOPMENT AND INVESTIGATION OF TELMISARTAN MATRIX TABLET USING NATURAL POLYMER

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ABSTRACT

In order to develop a controlled delivery of poorly water-soluble Telmisartan using hydrophilic natural gums like xanthan gum [X] and modified guar gum[MGG] as cost-effective, nontoxic, easily available. The granules of Telmisartan were prepared by wet granulation method using a different ratios drug: gum ratios of X, MGG and XMGG. Magnesium stearate and talc were added to the granules before punching because of to improve the flow ability and compressibility of the granules, and to avoid its adhesion to punch and die. The tablets was analysed to determine hardness, friability, % drug content and *invitro* release study was carried out. The release of Telmisartan from a gelatinous swollen mass, which controls the diffusion of drug molecules through the polymeric material into aqueous medium. The XMGG matrices show precise controlled release than the X and MGG matrices because of burst effect and fast release in case of X and MGG matrices respectively. Matrices with XMGG show zero-order release via swelling and diffusion mechanism. The XMGG matrices lead to more precise result than X and MGG alone by the utilization of synergistic interaction between two biopolymers and uniformity in the hydration layer in dissolution media.

KEYWORDS

Telmisartan, Matrix tablet, Xanthum gum, Modified guar gum and Controlled release.

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INTRODUCTON

Oral drug delivery system has been the most widely utilized route of administration among the all route because of certain advantages because it has a low cost, cheapest for packaging unit dosage form etc[1]. Matrix systems are widely used for the purpose of controlled release. It is the release system which prolongs and controls the release of the drug that is dissolved or dispersed. Numbers of polymers have been investigated to develop in situ gel-forming systems, due to the capability of this gelling system

to release an entrapped drug in aqueous medium and to control the release of such drug by control of swelling and cross-linking[2].

The natural materials have advantages over synthetic ones since they are chemically inert, less expensive, nontoxic, biodegradable and widely available. They can also be modified in different ways to obtain desirable materials for drug-delivery systems[3]. The hydrophilic natural gums hydrate and swell on contact with water and these have been used for the preparation of single unit dosage forms[4]. The use of hydrophilic polymers like xanthan gum (X) and modified guar gum (MGG) alone and combination was used in this study for oral controlled release dosage forms.

Both guar and xanthan gums are natural polysaccharide that is used as excipients in many pharmaceutical formulations and food products. The treatment of guar gum is reported to produce a treated gum with superior properties for pharmaceutical purpose[5,6]. Based on the nature of their molecular structure, xanthan (anionic), guar gum (nonionic), thermally treated guar gum (nonionic with low molecular weight) are expected to improve different effects on physical performance of fabricated oral controlled drug delivery matrices as a consequence of their different hydration, swelling, gel strength and erosion characteristics[7].

Xanthan gum is a naturally occurring polysaccharide, secreted by the non-pathogenic organism Xanthomonas campestris. It consists of a β-(1–4)-linked glucose backbone with orderly distributed trisaccharide side chains and completely soluble in cold and hot water. Due to the high molecular weight this gum exhibited high viscosity in solution. Xanthan gum improves the flow and viscosity of formulation this characterization facilitates the mixing, handling, pouring and swallowing of the formulation. Due to having low shear rate, the viscosity is comparatively high and provides a superior stability for the system. Xanthan gum show highly resistant to enzymatic degradation due to the nature of the sugar linkages and the structure of the side chains on the polysaccharide backbone[8].

Guar gum (GG) is galactomannan, derived from guar (cyamopsistetragonolobus) kernels which belong to family Leguminosae[9]. Guar gum has the ability to produce highly viscous, pseudo plastic aqueous solutions even at low concentrations due to the high molecular weight Chemically guar gum has a linear chain of (1→4)-linked β-Dmannopyranosyl units with (1→6)-linked α-D-galactopyranosyl residues as side chains with mannose[10].

Upon dispersion in water the galactose side chains attached to mannose back bone interact with water molecule leading to an inter-molecular chain entanglement of guar gum molecule present in the aqueous phase, which leads to enlargement of viscosity in the solution it causes gelling or thickening property. When the guar gum concentration is enhanced the entanglement of degree of inter-molecular chain interaction enhanced causing an increase in viscosity and gelling[11]. The main disadvantage of guar gum shows uncontrolled rate of viscosity, uncontrollable rate of hydration so guar gum finds limited use in original forms. As a result of thermal treatment of guar gum show the loss of viscosity due to decreasing of molecular weight caused by thermal degradation. Temperature causes the water molecules to lose their ordering around the guar molecules, thus affecting the conformation and resulting in reduced-viscosity behaviour[12]. The present study addresses modifications of GG by heat the GG at the 120˚c for 1 hour.

Telmisartan is 4’-[1, 4’-dimethyl-2-propyl [2, 6’-bi-benzimidazole]-1’-yl] methyl 1, 1’- biphenyl 2-carboxylic acid. Telmisartan is a nonpeptide Angiotensin Receptor II(Type- ATI) Antagonist, That Cause Inhibition of the action of Angiotensin II on Vascular Smooth Muscle thereby, relaxing blood vessels, causing them to widen in the Symptomatic Treatment of Hypertension[13]. High blood pressure reduction helps prevent strokes, heart attacks, and kidney problems[14]. Telmisartan that are easily absorbed from the gastrointestinal tract (GIT) and shows more fluctuation in the basic pH to avoid this drawback, the oral controlled release formulations have been developed to release the drug slowly into the GIT and maintain an

effective drug concentration in the serum for longer period of time as a matrix tablet[15]. This work was an attempt to determine the relative contribution of the different drug release mechanisms exhibited by Telmisartan matrix tablets with commercial xanthan and modified Guar gum. Different concentrations of gums, alone (X or MGG) and in physical mixture (XMGG) of X and MGG is prepared to evaluate their performance as release-controlling agents.

MATERIAL AND METHODS

Materials

Telmisartan gift sample obtained from Apotex research PVT. LTD, Guar gum (GG) and xanthan gum(X) was purchased from Shreeji chemicals, Mumbai. Dicalcium phosphate (DCP), polyvinyl pyrolidine K- 90(PVPK-90), alcohol, Talc and Magnesium stearate (Mg. st) were analytical reagent grade and used without further purification.

Preparation of thermally treated guar gum

Take 50 gm of guar gum in a china dish and heat at 120˚c and maintain for 1 hr with constant stirring. After 1 hr remove and cool for sometimes.

Preparation of matrix tablets

Matrices were prepared by wet granulation method by using the PVPK-90 as binding agent, alcohol as wetting agent and dicalcium phosphate as diluent, granules were prepared, talc and magnesium stearate was used as a lubricant in 2:1 ratio. 400 mg of the prepared granules were compressed using a rotary punch tablet machine. All the formulations of Telmisartan tablets containing X, MGG and XMGG were prepared and the formulation chart is as shown in Table No.1.

CHARACTERIZATION OF TELMISARTAN MATRICES[16]

Weight variation

Weigh 20 tablets individually and calculate the average weight and comparing the individual weights to the average. The weight variation calculated by fallowing formula

[(Average weight - Individual weight)/Average weight] × 100

Hardness

Hardness of the tablets was determined using a hardness testing apparatus (Monseto Type). A tablet hardness of about 5-6 kg/cm2 is considered adequate for mechanical stability.

Friability

6 tablets were weighted in a weighing balance. These tablets were transformed into a friabilator set 100 revolutions. After the completion of revolution dust was removed completely, weighted again in the same balance and percentage loss was calculated by following formula

$$\% \text{ Friability} = (W0\text{-}W)/W0 \text{ X } 100$$

Drug content uniformity

Five tablets were weighed and crushed in mortar & powder equivalent to 80 mg of Telmisartan was weighed and dissolved in 100 ml of phosphate buffer PH (6.8). This was the stock solution from which 1ml withdrawn and diluted to 10 ml with phosphate buffer. The absorbance was measured at wavelength 296 nm using UV-Visible spectrophotometer. The drug content in each tablet was calculated using the standard calibration curve of Telmisartan in phosphate buffer pH 6.8 solution.

Water uptake and erosion determination[17]

Measurement of hydration and erosion rates of XMGG4 were carried out, after the immersion of the tablets in the test medium to relate the observed phenomena of drug release with the rates of polymer hydration. Weighed tablets were placed in the baskets of the dissolution apparatus rotating at 50 rpm, with the dissolution medium of phosphate buffer pH 6.8 at 37±0.5ºC. After 0.5, 1, 2, 3, 4, 5, 6, 7 and 8 hrs, each dissolution basket containing the sample was withdrawn, blotted to remove excess water and weighed on an analytical balance. The wet samples (basket + sample) were then dried in an oven at 110–120ºC for 24 h time period, allowed to cool in a desicator and finally weighed until constant weight was achieved (final dry weight). The experiment was performed in 3 times for each time point fresh samples were used for each individual time point. The increase in weight is due to the absorbed liquid (Q) and it was estimated at each time point from the following equation.

$$Q = \frac{100\ (Ww - Wf)}{Wf}$$

where Ww is the mass of the hydrated sample before drying and Wf the final weight of the same dried and partially eroded sample. The percentage erosion (E) was estimated from the following equation

$$E = \frac{100\ (Wi - Wf)}{Wf}$$

Where Wi is the initial dry sample weight.

***In vitro* studies**[18]

The dissolution test was carried out using apparatus II USP at 100 rpm. In order to reproduce digestive physiological phases 900mL of dissolution medium with different pH environment sat 37±0.5ºC was performed. The dissolution state with the pH of 1.2 was changed to 7.2 after 2h and continued for up to 24 hrs. At suitable intervals, samples were withdrawn, filtered, diluted when necessary with suitable buffer and analyzed spectro photometrically at 296nm and It plot by cumulative percentage dug release against time studies were performed. During the drug release studies, all the formulations were observed for physical integrity at different time.

Release Kinetic[19]

The dissolution profile of all the formulations was fitted in to zero-order, first-order, and Higuchi and Korsmeyer - peppas models to ascertain the kinetic modeling of drug release

Zero Order Kinetic

It describes the system in which the drug release rate is independent of its concentration.

$$Qt = Qo + Ko\ t \quad (1)$$

Where

Qt= Amount of drug dissolved in time t and the

Qo = Initial amount of drug in the solution, which is often zero

Ko = zero order release constant.

If the zero order drug release kinetic is obeyed, then a plot of Qt versus t will give a straight line with a slope of Ko and an intercept at zero.

First Order Kinetic

It describes the drug release from the systems in which the release rate is concentration dependent.

$$\mathbf{\log Qt = \log Qo + kt/\ 2.303 \quad (2)}$$

Where

Qt = the amount of drug released in time t.

Qo = the initial amount of drug in the solution

k = first order release constant

If the first order drug release kinetic is obeyed, then a plot of log (Qo- Qt) versus t will be straight line with a slope of kt/ 2.303 and an intercept at t=0 of log Qo.

Higuchi Model

It describes the fraction of drug release from a matrix is proportional to square root of time.

$$\mathbf{Mt / M_{\infty} = kHt1/2}$$

Where

Mt and M_{∞} = cumulative amounts of drug release at time t and infinite time,

kH = Higuchi dissolution constant reflection formulation characteristics.

If the Higuchi model of drug release (i.e. Fickian diffusion) is obeyed, then a plot of Mt / M_{∞} versus t1/2 will be straight line with slope of kH.

Korsmeyer-Peppas model (Power Law)

The power law describes the drug release from the polymeric system in which release deviates from Fickian diffusion, as expressed in following equation.

Mt / M= ktn

$$\log [Mt / M_{\infty}] = \log k + n \log t$$

Where

Mt and M_{∞} = cumulative amounts of drug release at time t and infinite time

k = constant incorporating structural and geometrical characteristics of CR

n = diffusional release exponent indicative of the mechanism of drug release for drug dissolution.

RESULTS AND DISCUSSION

Characterization of Telmisartan matrices

The tablets with weight of 400mg, a diameter of 9.5mm and height of 4.8mm were obtained and subjected to quality control tests such as weight variation, Hardness, friability and drug content (Table No.2). All formulation products lied within the pharmacopoeial requirement within ±5 for weight variation. The drug contents of the formulations were found to be uniform, since the amount of the active ingredient in each of the

formulation tested was within the range of 96.0-99.5% and the relative standard deviations were less than 2.0%, indicating uniform mixing of gums, dicalcium phosphate end drug. The mean values for hardness was within 5.5-6 kg/cm^2 and all formulations exhibits friability within the 0.1-0.55% during the friability determination.

***Invitro* drug release**

The aqueous medium on contact with hydrophilic polymer matrix gradually begins to hydrate from the peripheral towards the centre, and it forming a gelatinous swollen mass, this process which leads to controls the diffusion of drug molecules through the polymeric material into aqueous medium. The hydrated gel layer thickness determines the diffusional path length of drug. The *invitro* drug release profiles of Telmisartan from tablets containing X, MGG and X MGG in different gum proportions are shown in Figure No.1 respectively. After 2h, the initial pH 1.2 was changed to 7.2 continue the dissolution up to 24h. It was shown that as the amount of gum in the matrix increased, there would be a greate degree of gum hydration with simultaneous swelling. This resulted in corresponding lengthening of the drug diffusion pathway and drug release rate. Drug release was generally linear for most of the formulations, especially XMGG matrices. Such linear release was from hydrophilic matrices has been recognized to management between swell ling and erosion of the polymer in maintaining a constant gel layer. MGG in all the formulation swelled and the outer layer of most of tablets appeared to be hydrated after being placed in dissolution medium, shows a controlled hydrated layer size than original gum, specially visualized for matrices containing xanthan, followed by a gradual loss of integrity, resulting from the hydrodynamic stress induced by the dissolution apparatus. Thereafter, it remained more or less unchanged until the final stages of dissolution test, when the inner dry core became wetted.

The profiles of the formulation of X, MGG, XMGG, and the erosion and drug release at different drug: gum ratios of 1:1, 1:1.5, 1:2and1:2.5 are shown in Figure No.1. In each case of X there was an initial burst of xanthan gum erosion from the matrices during the acidic pH thereafter, the erosion of xanthan gum slowed considerably. It follows, therefore, that the hydrated xanthan gum network maintains its tight integrity with drug release by erosion. Furthermore, there is a burst of xanthan gum erosion in the formulation containing the lower proportion of xanthan gum in 1:1 and 1:1.5 drug: gum ratios. MGG tablets formulations showed a medium tend encytoloss of integrity. In case of MGG matrix shows fast drug release for 12 hrs but not for 24 hrs like xanthan gum but it has a synergistic action along with the xanthan gum and shows precise controlled release effect. In all the formulations, it has been observed that by increase the concentration of hydrophilic polymers in the formulations there by respectively retard the drug release form the matrices. The drug release was slower from the matrices with XMGG compared to X and MGG. The release of X and XMGG was similar but in case of X the release of Telmisartan at low concentration of xanthan gum a starting burst effect of release was seen in acidic pH. In case of X MGG this type of burst effect was not seen in acidic pH. The XMGG formulations exhibits good controlled release effect by the utilization of synergisticinter action between two biopolymers to produce a strong and elastic gel around the core of the matrices in the presence of a ternary component there by control the drug release form the matrices containing XMGG formulation. There by XMGG formulations show precise control release.

Water uptake and erosion studies

The swelling behaviour and erosion studies were carried out with XMGG4 formulation of drug: gum ratio of 1:2.5, which resulted in the better dissolution profile. The results of swelling and erosion tests were shown in Figure No.2. The swelling behaviour indicates the rate at which this formulation absorbs water from dissolution media and swells. The change in weight is characteristic of water uptake and swelling, started from the beginning and continued until 8 h of experiment (Figure No.2a). This matrix showed a high ability to swell. From the beginning of the test, matrices

appeared swollen almost and viscous gel mass was created when they came into contact with the liquid. The matrix erosion measured the weight loss from matrix tablets immersed in dissolution media as a function of time. The weight loss of the tablets was in constant progression until the end of 8 h (Figure No.2b) and was about 70% observed.

Drug Release Kinetics

The release data of all the formulations were fitted into four different mathematical models namely zero order, first order, Higuchi model and Peppas model. The rate constants and R^2 values for zero order, first order, Higuchi and "n" value for power law of all the formulated matrix tablets are given in Table No.3.

Considering the correlation coefficient (R^2) values as obtained from the different kinetic equations, the drug release from matrix tablets were found to follow zero order for combination formulation (XMGG) and korsmeyer-peppas kinetics for (X and MGG alone). The release exponent "n" value for the different formulation ranged from 0.709 to 1.00. However, all the formulations showed the diffusional exponent; "n" in between 0.5 and 1.0 which indicate the anomalous transport kinetics that means the drug is released by the combined mechanism of pure diffusion controlled and swelling controlled drug release.

Table No.1: **Composition of Temisartan (80 mg) matrix tablets (400 mg)**

S.No	Formulation (drug: gum)	Xanthan (mg)	MG (mg)	DCP (mg)	PVPK-90 (mg)	Talc (mg)	Mg. Stearate (mg)
1	X1(1:1)	80	-	216	15	6	3
2	X2(1:1.5)	120	-	176	15	6	3
3	X3(1:2)	160	-	136	15	6	3
4	X4(1:2.5)	200	-	96	15	6	3
5	MGG1(1:1)	-	80	216	15	6	3
6	MGG2(1:1.5)	-	120	176	15	6	3
7	MGG3(1:2)	-	160	136	15	6	3
8	MGG4(1:2.5)	-	200	96	15	6	3
9	XMGG1(1:1)	40	40	216	15	6	3
10	XMGG2(1:1.5)	60	60	176	15	6	3
11	XMGG3(1:2)	80	80	136	15	6	3
12	XMGG4(1:2.5)	100	100	96	15	6	3

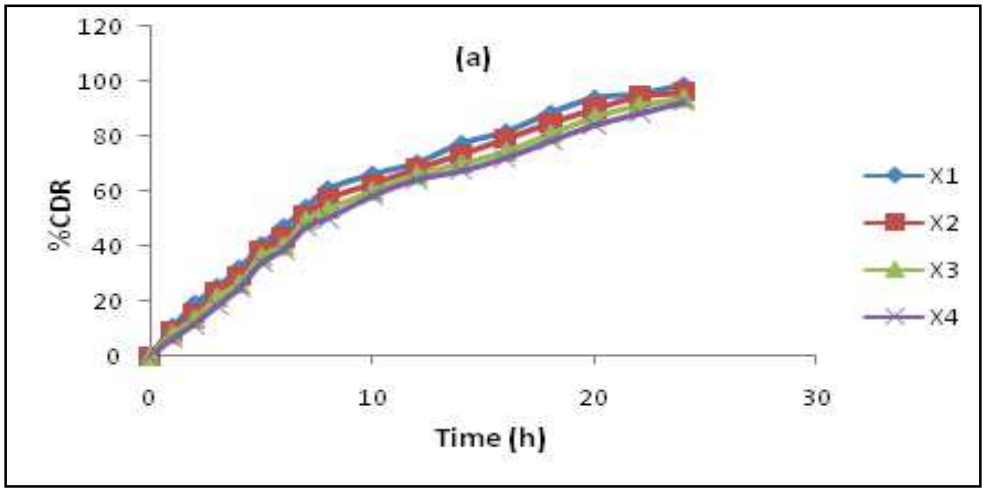
X (xanthan gum), MGG (Modified guar gum), XMGG (xanthan gum and Modified gum mixture), DCP (Dicalcium phosphate), PVPK-90(polyvinylpyrolidineK-90)

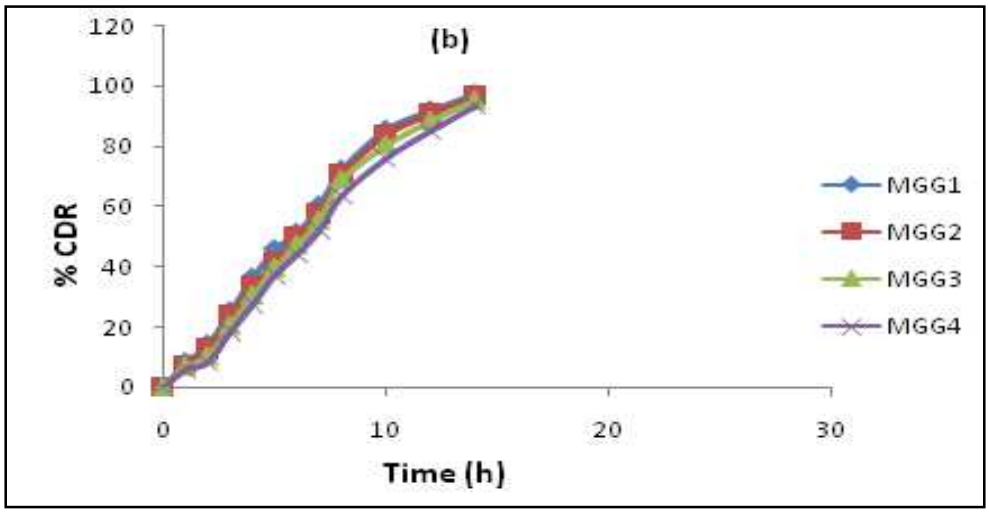
Table No.2: Results of Post-compression studies of Telmisartan controlled release matrix tablet

S.No	Formulation	Weight variation±SD	Hardness (kg/cm2)±SD	Friability (%)	% Drug content ±SD
1	X1	0.399±0.38	5.75±0.27	0.400	98.76±0.7
2	X2	0.406±0.25	6.00±0.31	0.432	99.41±0.8
3	X3	0.396±0.12	5.91±0.20	0.513	98.7±1.4
4	X4	0.390±0.22	6.00±0.31	0.550	98.3±1.3
5	MGG1	0.380±0.32	5.08±0.37	0.425	97.1±1.1
6	MGG2	0.402±0.56	6.00±0.31	0.387	97.4±0.6
7	MGG3	0.405±0.85	5.9± 0.25	0.492	96±0.7
8	MGG4	0.391±0.25	6.1±0.24	0.35	98±0.58
9	XMGG1	0.398±0.56	5.5±0.03	0.458	98±0.05
10	XMGG2	0.394±0.21	5.7±0.95	0.100	98±0.71
11	XMGG3	0.390±0.65	5.9±0.34	0.109	99.5±0.26
12	XMGG4	0.400±0.02	5.6±0.02	0.306	99±0.45

Table No.3: Results of *in vitro* kinetic data

S.No	Formula code	Zero order	First order	Higuchi	Korsmeyer-Peppas	
		r	r	r	r	N
1	X1	0.927	0.9326	0.9771	0.9807	0.709
2	X2	0.936	0.9653	0.9717	0.9722	0.786
3	X3	0.941	0.9759	0.9726	0.9780	0.819
4	X4	0.9455	0.9736	0.9685	0.9834	0.900
5	MGG1	0.9555	0.9305	0.9595	0.9893	0.794
6	MGG2	0.9596	0.9506	0.9508	0..9897	0.832
7	MGG3	0.9608	0.9621	0.9453	0.9887	0.896
8	MGG4	0.9622	0.9766	0.9318	0.9857	0.998
9	XMGG11	0.9742	0.8968	0.9585	0.9727	0.893
10	XMGG2	0.9745	0.9438	0.9514	0.9672	0.954
11	XMGG3	0.9747	0.9565	0.9461	0.9499	0.99
12	XMGG4	0.9761	0.9609	0.9412	0.9511	1.00





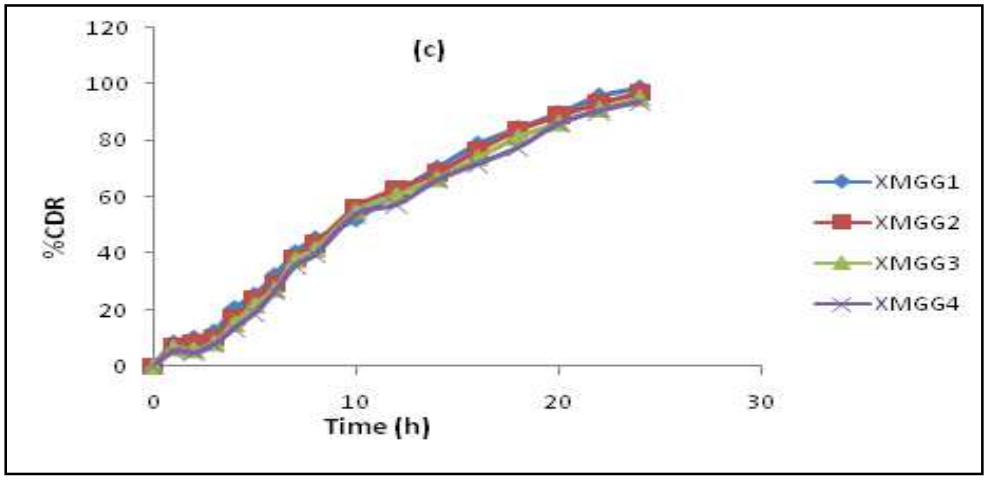
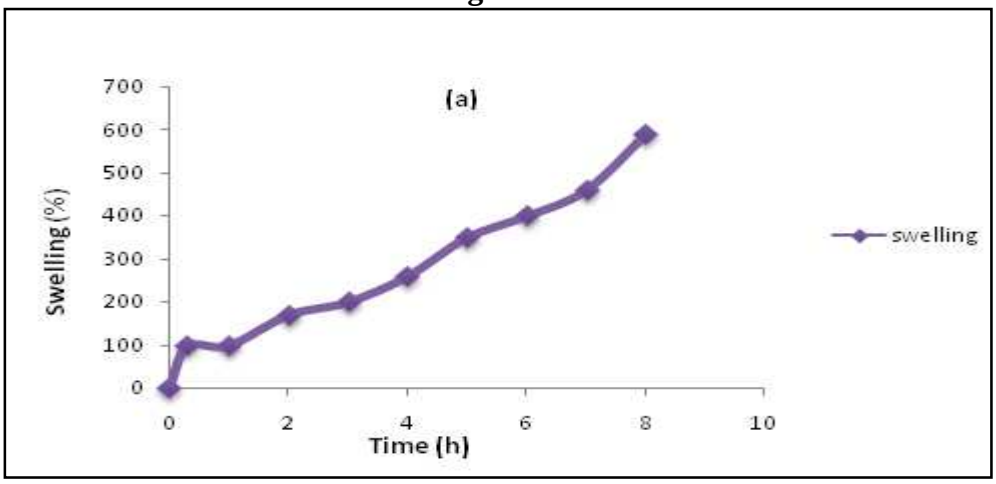


Figure No.1: *In vitro* release profile of Telmisartan from tablets containing drug: gum, 1:1, 1:1.5, 1:2 and 1:2.5 ratios of (a) Xanthan gum (b) Modified guar gum and (c) Mixture of Xanthan and Modified guar gum



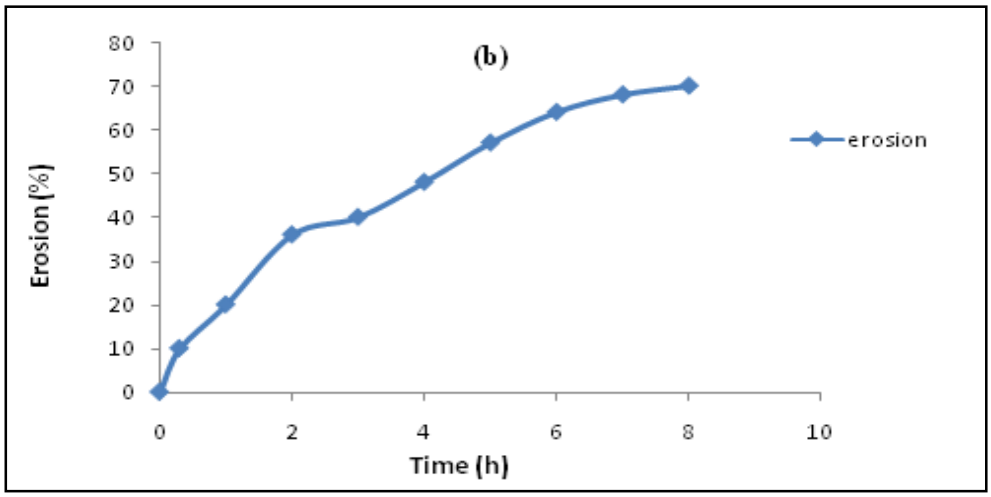


Figure No.2: Analysis of XMGG in drug: gum ratio of 1:2.5 at pH 7.2: (a) Swelling behaviour; (b) Erosion behaviour. Each point represents the mean value of three samples

CONCLUSION

The tablets with XMGG resulted in more uniform controlled drug release matrices than X and MGG, due to the employment of the synergistic interaction of two biopolymers to generate a strong and elastic gel in the presence of a ternary component this process shows the control drug release. The XMGG formulation was found to provide the required release rate, with zero-order release kinetics. The synergistic action with the xanthan and modified guar gum shows precise controlled release effect till 24 hrs. The predominant release mechanism varied with matrices composition and drug release was with the combined mechanism of pure diffusion controlled and swelling controlled drug release.

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CONFLICT OF INTEREST

We declare that we have no conflict of interest.

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