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Research Article

Formulation Development And Analytical Development Of Glimepiride Polymeric Blend Matrices As Improved Release Medication System

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ABSTRACT

The blending of polymers is a method of reducing the overall cost of the material with improved physicochemical and mechanical properties. Blending provides a neat and smooth means of combining desirable properties of different polymers with synergistic effect. The development of two and three component blends using natural and biodegradable polymers represents an area of recent interest using materials with relatively low glass transition temperature. In the present work an attempt will be made to prepare polymeric blend matrices using natural and synthetic biodegradable polymers for modified release of glimepiride in the management of non insulin diabetes management. Polymeric blend matrices will be prepared with following objective. To prepare the drug incorporated polymeric blend matrices using miscible, biodegradable polymers of natural and synthetic origin by solution blending method.To characterize the polymeric blend matrices by fourier-transform infrared spectroscopy and scanning electron microscopy. To evaluate the polymeric blend matrices for drug encapsulation, swelling behavior and in vitro release study.To study the effect of two components, three components and the composition of polymers in the polymeric blend on the in vitro drug release behaviour.

INTRODUCTION

The development of controlled drug delivery system for the treatment of chronic disease is of great interest since this system act as a vector carrying the drug not only to the target but also adverse effect can be reduced. In the recent past, carbohydrate and biodegradable polymers have been extensively used to develop the controlled release formulation. Over the past decades, blends have been investigated to satisfy the need of specific sectors of polymer industry. Such polymer blend show superior performances over the conventional individual polymers and

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consequently, the range of application have grown rapidly for such class of materials.

Novel drug delivery system

Today a pharmaceutical scientist is well worsed with the fact that the overall action of the drug molecule is not merely dependent on its inherent therapeutic activity, rather on the efficiency of its delivery of the site of action. An increasing appreciation of the later has led to the evolution and development of several drug delivery systems (DDS) aimed at performance of the enhancement of the potential drug molecules. A review of the literature has revealed the recent several technical advancement have led to the development of various Novel Drug Delivery System(NDDS) that could revolutionize method of drug delivery and hence could provide definite therapeutic benefits. The new way of patenting the drug is to use "Novel Drug Delivery System"1 i.e. NDDS with improved bioavailability (BA). To formulate or to re formulate it in a form of NDDS is not a Herculean task if one goes methodically and skillfully this is where the formulation development study plays an important role.

Controlled drug delivery system

For most of civilized history, there was no clear difference in the way in which humans consumed food and medicine. To date, oral delivery is still the preferred route of drug administration, especially for chronic therapies where repeated administration is required. Oral administration offers patients less pain, greater convenience, higher likelihood of compliance, and reduced risk of cross-infection and needle stick injuries. physiological parameter inherent in a selected route of administration.

1. Reduction in fluctuation of drug blood levels about the mean.
2. Reduce the dosage frequency.
3. To improve patients compliance.
4. To ensure safety and improve efficacy of drugs.

MATERIALS AND METHODS

Analytical methods for the estimation of glimepiride

a. Determination of λ max for glimepiride71,72

Stock solution:

Glimepiride in pH 6.8 buffer solution (10 mg in 10 ml methanol)

Scanning:

From the stock solution 10µg/ml solution of glimepiride prepared in pH 6.8 buffer solution and scanned between 200-400 nm. The absorption maxima of 228 nm was selected and used for further studies.

b. Preparation of standard calibration curve of glimepiride

The standard calibration curve for glimepiride was prepared using pH 6.8 phosphate buffer.

Standard solution

10 mg of glimepiride was dissolved in 100 ml methanol to give a concentration of 1 mg/ml.

Stock solution

From standard solution take 10 ml of solution in 100 ml of phosphate buffer of pH 6.8 to produce the 100 mcg/ml concentration and take from the 100 mcg/ml of the solution aliquots of 0.2,0. 4, 0.6, 0.8, 1.2, 1.6 and 2.0 ml of stock solution was pipette out in 10ml volumetric flask. The volume was made up to mark with buffer of pH 6.8 to produce concentration as 2, 4, 6, 8, 12, 16 and 20 mcg/ml of glimepiride respectively. The absorbance of prepared solution of glimepiride was measured at 228 nm in Shimadzu UV/visible 1700 spectrophotometer against phosphate buffer pH 6.8 as blank. The absorbance data for standard calibration curve are given in table no-1 and plotted graphically as shown in the Fig - 2. The standard calibration curve yields a straight line, which shows that drug obeys Beer's law in the concentration range of 1 to 20 mcg/ml.

Method of preparation of blank polymer blends73

The blank polymer blendes were prepared using different concentration of agar, isabgol, aloevera and gelatin by solvent casting technique, the detailed composition is given in Table-2.

Solvent casting method

Accurately weighed quantity of agar was dissolved in distilled water. The solution was slowly heated to around 70oC to form a gel like consistency. Stirring was done in order to avoid bubbles in the final gel solutions. After stirring for about one hour, the optically clear solutions were obtained. The resultant solutions were poured into an upright placed glass syringe with a top cut off (machined perpendicularly to the cylinder axis), which was kept in an oven at 60 ◦C before use. The warm polymer solutions in the syringe were allowed to equilibrate at the ambient temperature (about 25 ◦C) to form a gel. After drying, solidified gel was cut in to 1 ml size. Similarly, isabgol, aloevera and gelatin polymer blends were also prepared by solvent casting technique at their gelation temperature 40, 60 and 90oC respectively

Table 1: Formulation details of blank polymer blends

FC	Ingredient weight ratio % (w/w)			
	Agar	Aloe vera	Gelatin	Isabgol
F1	67.6	33.4	---	---
F2	75.0	25.0	---	---
F3	50.0	50.0		---
F4	50.0	---	50.0	---
F5	67.6	---	33.4	---
F6	33.4	---	67.6	---
F7	67.6	---	---	33.4
F8	75.0	---	---	25.0
F9	50.0	---	---	50.0
F10	---	33.4	67.6	---
F11	---	25.0	75.0	---
F12	---	50.0	50.0	---
F13	---	---	67.6	33.4
F14	---	---	75.0	25.0
F15	---	---	50.0	50.0

Table 2: Formulation details of drug incorporated polymer blends

PBFC	Glimepiride mg	Ingredient weight % (w/w)			
		Agar	Aloe vera	Gelatin	Isabgol
PB1	40	67.6	33.4	---	---
PB 2	40	75.0	25.0	---	---
PB 3	40	50.0	---	50.0	---
PB 4	40	75.0	---	25.0	---
PB 5	40	25.0	---	75.0	---
PB 6	40	67.6	---	---	33.4
PB 7	40	75.0	---	---	25.0
PB 8	40	---	33.4	67.6	---
PB 9	40	---	25.0	75.0	---
PB 10	40	---	---	67.6	33.4
PB 11	40	---	---	75.0	25.0
PB 12	40	25.0	50.0	25.0	---
PB 13	40	16.6	50.0	33.4	---
PB 14	40	33.4	50.0	16.6	---
PB 15	40	25.0	---	25.0	50.0

PB 16	40	16.6	---	33.4	50.0
PB 17	40	33.4	---	16.6	50.0

FC= Formulation Code

Each 1 ml thick ring contains 4 mg of glimepiride.

.RESULT AND DISCUSSION

Figure 1: U.V scanning photograph of glimepiride

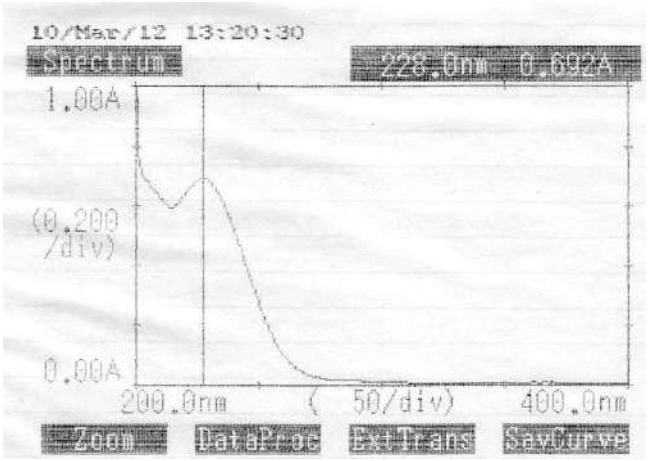


Table 3: Standard calibration curve data of glimepiride in phosphate buffer pH 6.8

Concentration	Absorbance
0	0
2	0.102
4	0.205
6	0.311
8	0.419
10	0.512
12	0.613
14	0.702
16	0.798
18	0.891
20	0.987

Figure 2: Standard calibration curve data of glimepiride in phosphate buffer pH 6.8

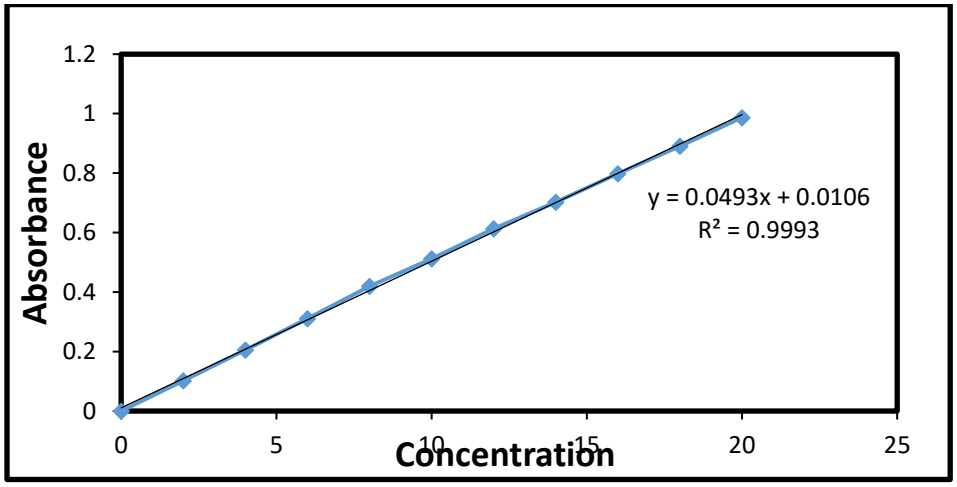


Figure 3: Photograph of the glimepiride polymer blend preparations containing (a) agar - aloevera PB1 (b) agar - gelatin PB3 (c) aloevera - gelatin PB9 (d) gelatin - isabgol PB11.

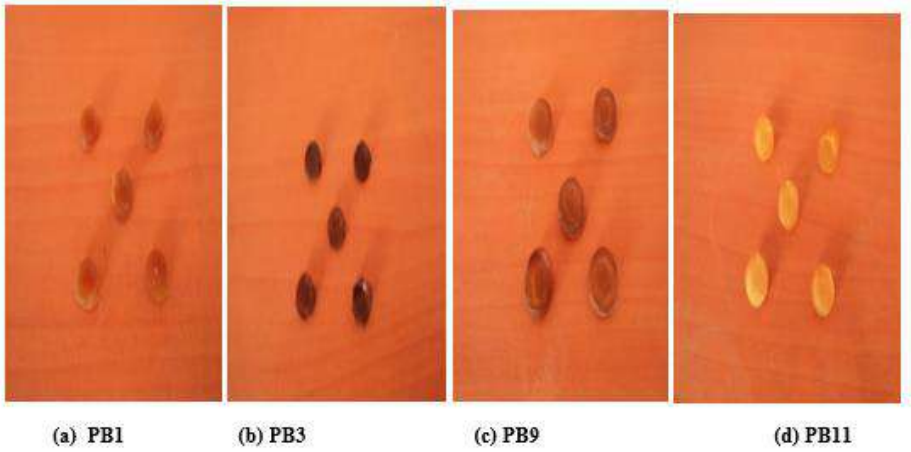


Figure 4: FTIR spectra of drug and polymer

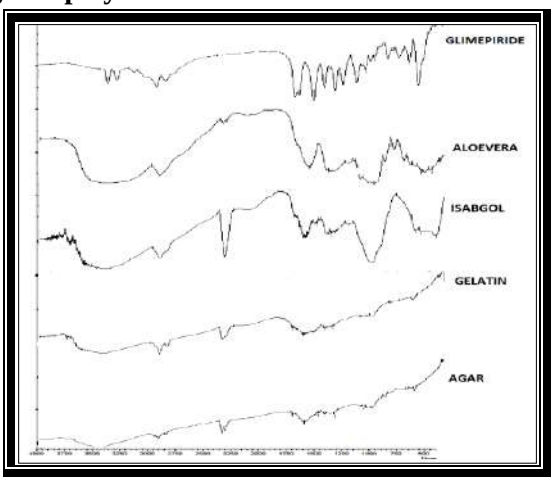


Figure 5: FTIR Spectra Of Drug Loaded Polymeric Blend Combination

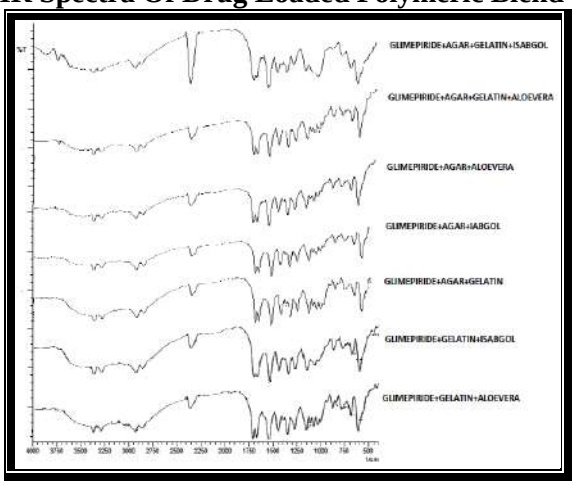


Figure 6: Scanning Electron Micrograph Of Glimepiride Loaded Polymeric Blend Containing Gelatin + Isabgol (PB11)

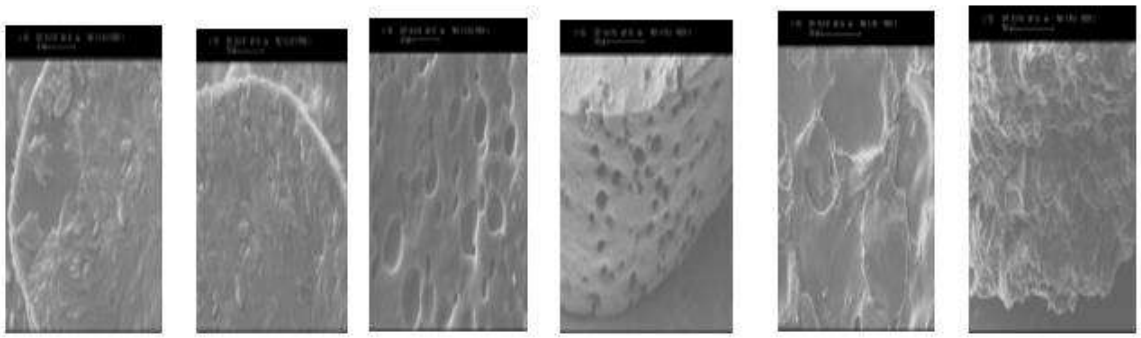


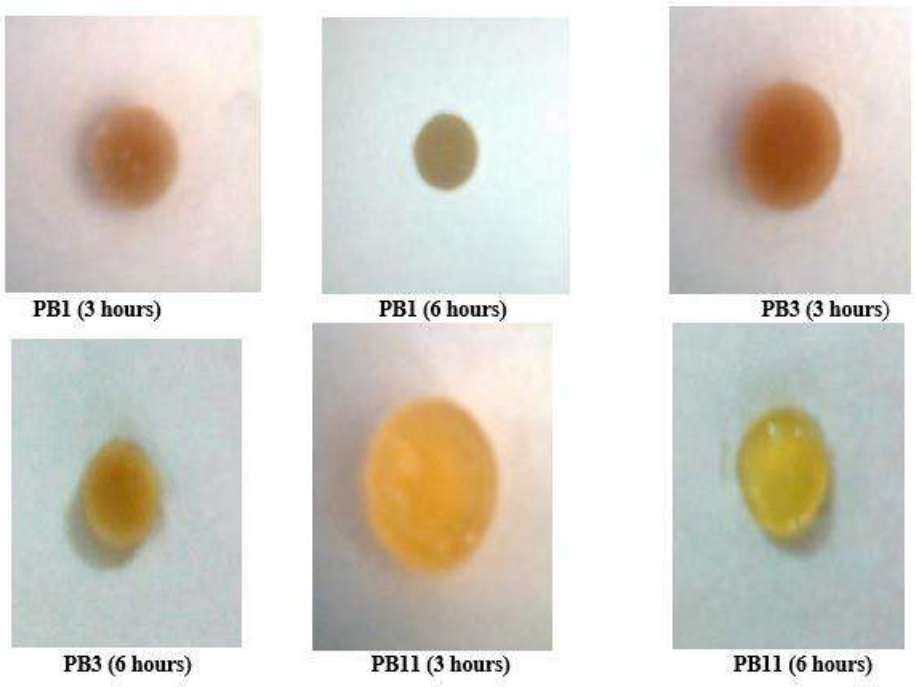
Figure 7: Scanning electron micrograph of glimepiride loaded polymeric blend containing agar + gelatin (PB3

Figure 8: Scanning electron micrograph of glimepiride loaded polymeric blend containing agar + aloevera (PB2)

Table 4 : Evaluation parameter of glimepiride polymer blend (mean I.S.D, n=3)

PBFC	Avg. Weight (mg) ± SD, n=3	Avg. Thickness (mm) ± SD, n=3	Hardness (kg/cm^2)	Drug content (%)
PB1	96.91 ± 1.155	3.650 ± 0.098	6.21 ± 0.114	96.41 ± 0.491
PB2	95.66 ± 1.528	3.720 ± 0.140	6.64 ± 0.141	97.88 ± 0.676
PB3	97.66 ± 0.577	3.690 ± 0.043	7.31 ± 0.080	96.11 ± 0.845
PB4	101.00 ± 1.732	3.610 ± 0.080	6.96 ± 0.141	98.61 ± 0.511
PB5	98.66 ± 0.577	3.703 ± 0.185	6.98 ± 0.090	97.47 ± 1.496
PB6	95.66 ± 1.528	3.723 ± 0.117	7.45 ± 0.096	98.51 ± 0.320
PB7	97.33 ± 1.528	3.710 ± 0.111	7.33 ± 0.125	97.31 ± 0.341
PB8	99.33 ± 1.528	3.667 ± 0.102	7.11 ± 0.125	97.11 ± 0.367
PB9	100.00 ± 1.155	3.727 ± 0.092	7.45 ± 0.095	97.27 ± 0.347
PB10	97.66 ± 1.528	3.617 ± 0.129	6.85 ± 0.135	98.15 ± 0.392
PB11	96.00 ± 1.732	3.643 ± 0.123	8.33 ± 0.056	96.67 ± 0.472
PB12	97.89 ± 1.528	3.617 ± 0.155	8.26 ± 0.131	98.02 ± 0.496
PB13	96.66 ± 0.577	3.747 ± 0.113	7.48 ± 0.050	98.08 ± 0.581
PB14	99.00 ± 1.000	3.733 ± 0.126	6.40 ± 0.147	96.59 ± 0.547
PB15	100.33 ± 0.577	3.623 ± 0.115	7.75 ± 0.118	97.98 ± 0.838
PB16	99.38 ± 1.528	3.747 ± 0.100	7.70 ± 0.117	98.76 ± 0.374
PB17	97.33 ± 1.528	3.657 ± 0.068	7.50 ± 0.078	97.52 ± 0.904

Figure 9: Photograph of In vitro swellable polymeric blend (a) agar - aloevera PB1 (b) agar - gelatin PB3 (c) gelatine - isabgol PB11 after 3 hour and 6 hour



In vitro swelling data of glimepiride polymeric blend containing agar - aloevera (2:1) PB1, agar aloevera (3:1) PB2, agar - gelatin (1:1) PB3, agar - gelatin (3:1) PB4

Percent swelling index of PB1 to PB4 Figure 10:

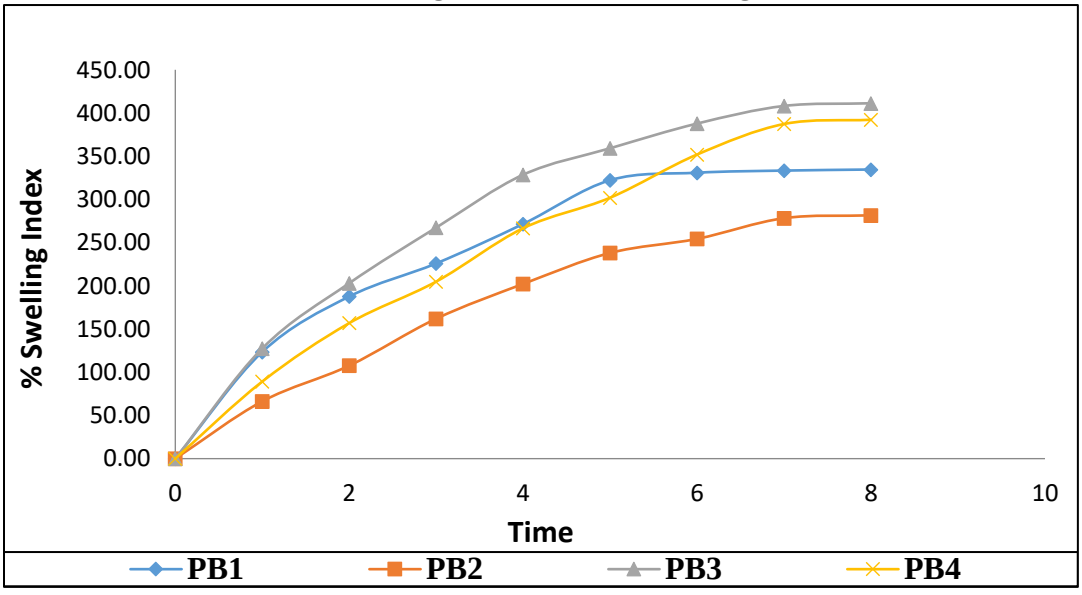


Table 6: In vitro swelling data of glimepiride polymeric blend containing agar - gelatin (1:3) PB5, agar - isabgol (2:1) PB6, agar - isabgol (3:1) PB7, aloevera - gelatin (1:2) PB8

Time hrs.	% Swelling index			
	PB5	PB6	PB7	PB8
1	72.34	117.05	86.96	89.90
2	114.89	175.00	136.96	137.37

3	172.34	228.41	170.65	165.66
4	205.32	264.77	209.78	195.96
5	231.91	287.50	254.35	224.24
6	262.77	300.00	276.09	248.48
7	281.91	307.95	284.78	260.61
8	287.23	318.18	293.48	262.63

Figure 11: Percent swelling index of PB5 to PB8

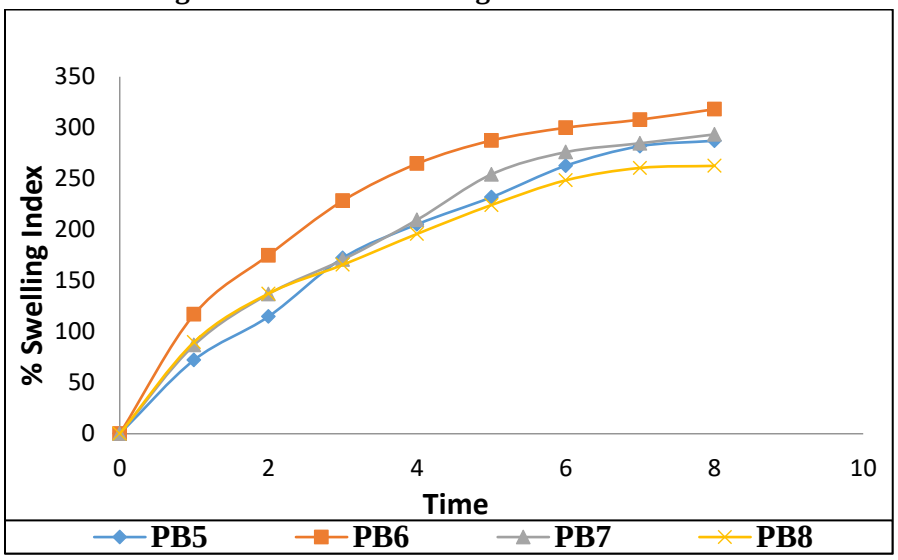


Table 7: In vitro swelling data of glimepiride polymeric blend containing aloevera - gelatin (1:3) PB9, gelatine - isabgol (2:1) PB10, gelatin - isabgol (3:1) PB11, agar – aloevera - gelatin [(1:1):1] PB12

Time hrs.	% Swelling index			
	PB9	**PB10**	**PB11**	**PB12**
1	79.21	96.94	106.74	59.38
2	130.69	167.35	164.04	105.21
3	161.39	217.35	238.20	145.83
4	198.02	281.63	305.62	189.58
5	227.72	318.37	359.55	237.50
6	244.55	370.41	391.01	255.21

Figure 12: Percent swelling index of PB9 to PB12

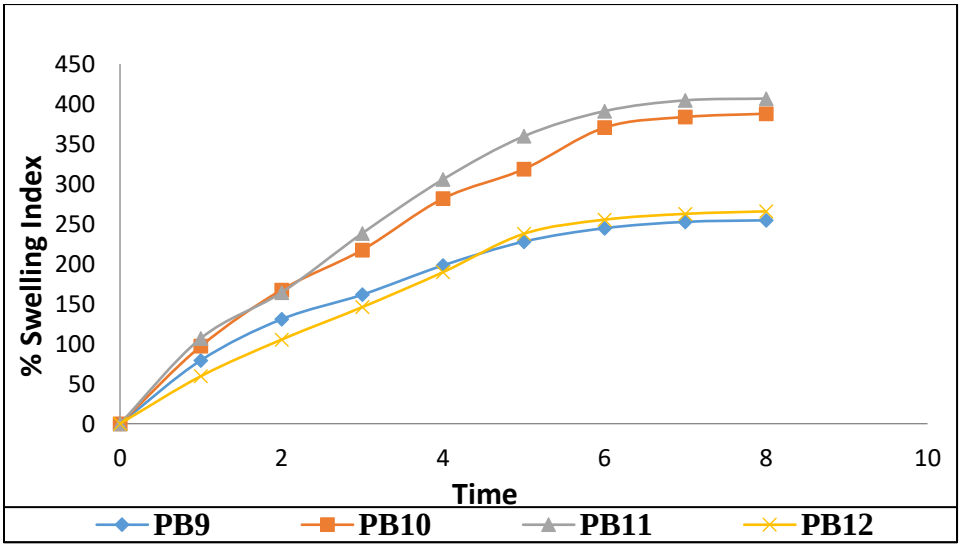


Table 8: In vitro swelling data of glimepiride polymeric blend containing agar-gelatin - aloevera [(1:2):1] PB13, agar – gelatine - aloevera [(2:1):1] PB14, agar – gelatine - isabgol [(1:1):1] PB15, agar – gelatine –i sabgol [(1:2):1] PB16, agar – gelatine - isabgol [(2:1):1] PB1

Time hrs.	% Swelling index				
	PB13	PB14	PB15	PB16	PB17
1	55.67	82.83	77.45	51.49	84.95
2	142.27	135.35	128.43	89.11	134.41
3	186.60	166.67	158.82	138.61	167.74
4	211.34	204.04	195.10	175.25	206.45
5	258.76	245.45	235.29	207.92	250.54
6	270.10	254.55	244.12	222.77	272.04
7	282.47	265.66	244.12	244.55	280.65
8	293.81	273.74	244.12	247.52	289.25

Figure 13: Percent swelling index of PB13 to PB17

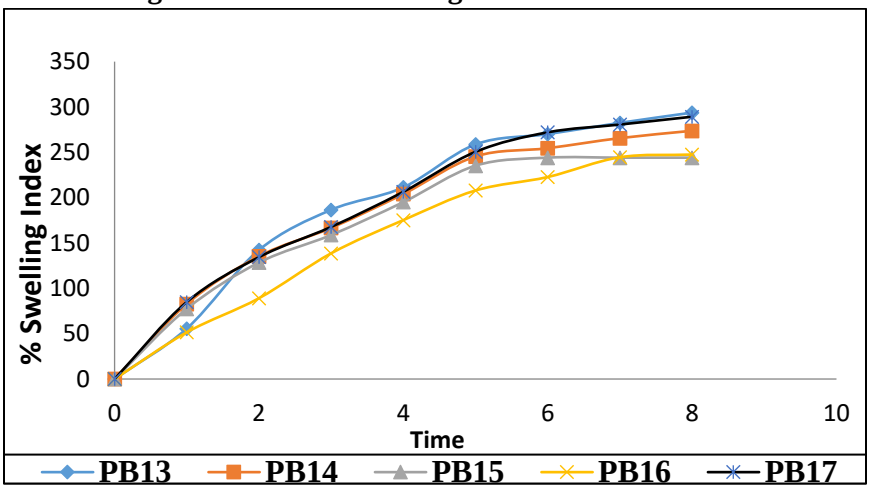


Table 9: In vitro release data of glimepiride polymeric blend containing agar - aloevera (2:1) PB1, agar - aloevera (3:1) PB 2, agar - gelatin (1:1) PB 3, agar - gelatin (3:1) PB 4

Time hrs	% Drug release			
	PB1	PB2	PB3	PB4
1	20.20	19.29	14.69	22.50
2	32.71	29.75	26.26	37.32
3	45.75	42.06	38.34	49.92
4	62.08	59.74	50.03	67.19
5	72.06	72.01	57.65	75.36
6	80.72	79.75	70.83	81.75
7	86.21	88.45	84.53	91.84
8	87.60	89.85	90.96	93.71

Figure 14: Release plots of glimepiride polymer blends from PB1 to PB4

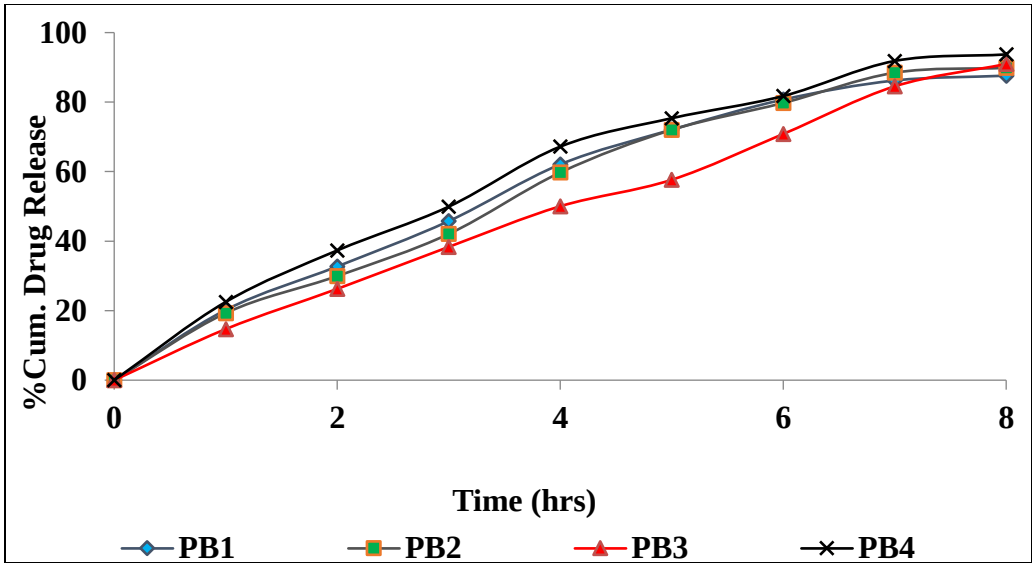


Table 10: In vitro release data of glimepiride polymeric blend containing agar - gelatin (1:3) PB5, agar - isabgol (2:1) PB6, agar - isabgol (3:1) PB7, aloevera - gelatin (1:2) PB8

Time hrs.	% Drug release			
	PB5	PB6	PB7	PB8
1	18.83	14.69	17.45	15.82
2	24.90	30.39	23.97	24.74
3	41.11	45.71	32.83	35.63
4	55.57	63.41	47.71	58.71
5	70.57	77.99	59.91	68.97
6	77.39	83.47	65.75	79.60
7	82.86	87.60	75.75	88.87
8	89.74	88.08	92.69	92.78

Figure 15: Release plots of glimepiride polymer blends from PB5 to PB8

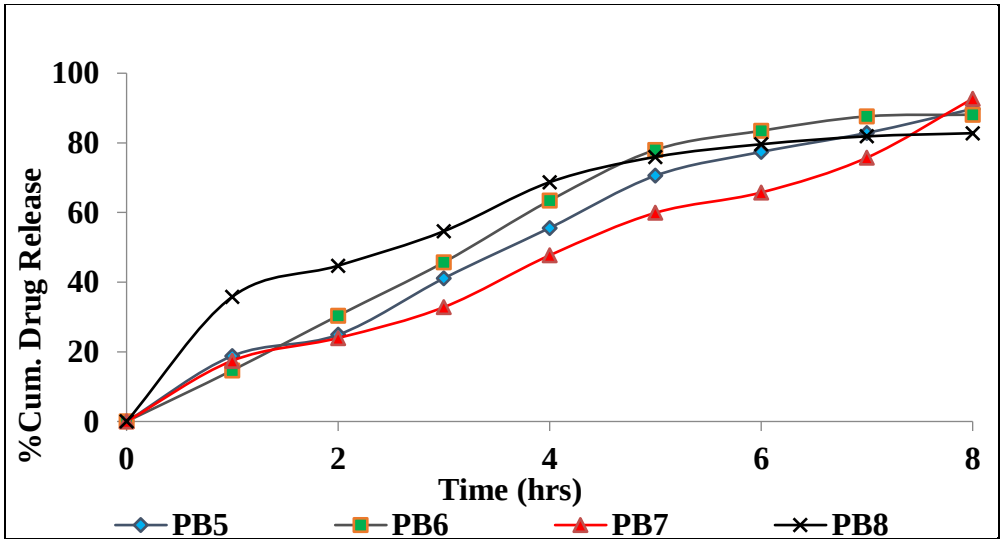


Table 11: In vitro release data of glimepiride polymeric blend containing aloevera - gelatin (1:3) PB9, gelatine - isabgol (2:1) PB10, gelatine - isabgol (3:1) PB11, agar – aloevera - gelatin [(1:1):1] PB12

Time	% Drug release

hrs	PB9	PB10	PB11	PB12
1	15.61	22.96	19.29	16.53
2	23.51	36.40	33.63	28.10
3	34.20	48.08	45.75	41.57
4	50.00	65.34	54.73	53.28
5	62.67	77.18	65.59	68.27
6	75.92	82.65	76.97	76.45

Figure 16: Release plots of glimepiride polymer blends from PB9 to PB12

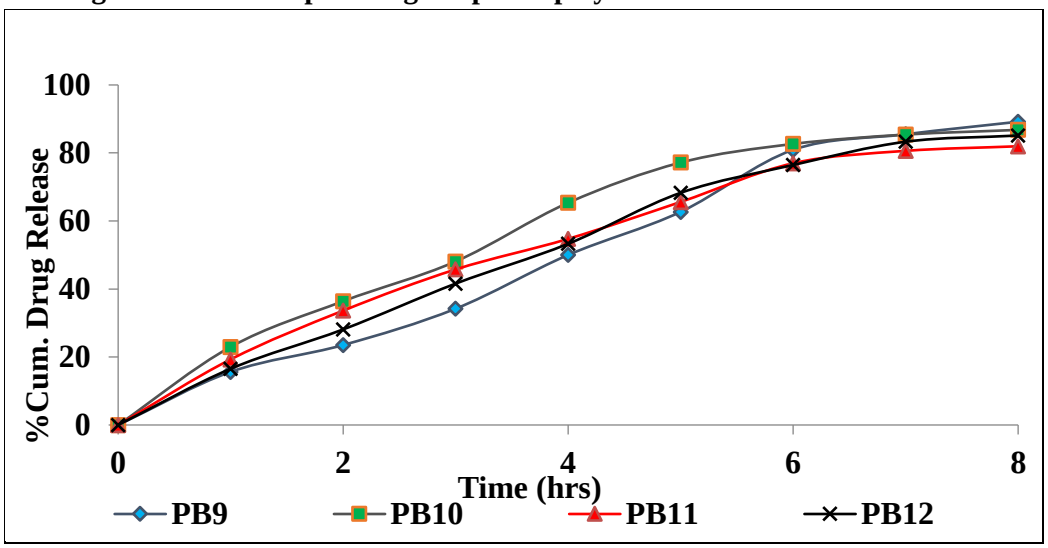


Table 12: In vitro release data of glimepiride polymeric blend containing agar – gelatin - aloevera [(1:2):1] PB13, agar – gelatin - aloevera [(2:1):1] PB14, agar – gelatin - isabgol [(1:1):1] PB15, agar – gelatin - isabgol [(1:2):1] PB16, agar – gelatin - isabgol [(2:1):1] PB17

Time hrs.	%Drug release				
	PB13	PB14	PB15	PB16	PB17
1	14.69	19.74	18.83	14.23	23.88
2	29.01	37.30	29.03	22.58	42.38
3	42.49	50.37	41.13	37.40	53.63
4	61.09	66.72	46.87	52.76	69.08
5	77.04	79.94	58.15	66.36	78.65
6	82.97	83.59	66.27	79.59	84.14
7	84.80	86.81	79.95	84.61	89.64
8	88.94	90.95	84.06	85.54	91.04

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