

GLIBENCLAMIDE MICROSPHERES:- AN APPROACH TOWARDS THE CURE OF TYPE-II DIABETES MELLITUS

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ABSTRACT:

Microspheres are small spherical particles, with diameters in the Micrometer range (typically1µm to1000µm (1mm). microspheres are designed so as to enclose the drug molecule and thus produce a controlled drug release. Out of the several methods, normal polymerization is the process with benefits like less instrumentation and is less time consuming. Usage of ethyl cellulose imparts the water insoluble characteristics and provides a tough film while Sodium alginate helps in film formation by releasing alginate ions in the solution. The drug glibenclamide is an oral hypoglycaemic drug used in type 2 diabetes mellitus with a quick elimination rate. The aim of this work includes presenting a process that can produce a more sustained release by incorporating the drug into a microsphere drug delivery form.

KEYWORDS: Glibenclamide, Sodium alginate, Ethyl cellulose, Controlled Release, Microsphere.

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INTRODUCTION:¹

A spherical shell that is usually made of a biodegradable plastic polymer, that has a very small diameter usually in the micron or nanometer range that is often filled with a substance (as a drug or antibody) for release as the shell is degraded is called microsphere. Microspheres used usually made up of polymers which can be broadly classified into, Synthetic Polymers and Natural polymers. Here, the process of normal polymerization has been used which, is carried out using different techniques as bulk, suspension, precipitation, emulsion and micellar polymerization processes. In bulk, a monomer or a mixture of monomers along with the initiator or catalyst is usually heated to initiate polymerization. Polymer so obtained may be moulded as microspheres. Drug loading may be done during the process of polymerization. The polymers used during this process are sodium alginate and ethyl cellulose and the microspheres formed during this process enclose the 2nd generation oral hypoglycaemic drug, Glibenclamide. This drug serves to treat the patients

of type 2 diabetis mellitus. The apparent elimination half-life of Glibenclamide in oral dosage forms available ranges from 7 to 10 hours.^{1}

MATERIALS AND METHODS: ^{2,3,4}

POLYMERS USED:-

- 1. Sodium alginate.
- 2. Ethyl cellulose.

CHEMICALS USED:-

- 1. Calcium chloride.
- 2. Distilled water.

DRUG USED: - Glibenclamide. (Glyburide)

METHOD USED:- Normal polymerization (Bead or pearl polymerization)

The process has been described below:-

Table No.1

B SODIUM ALGINATE + SODIUM ALGINA						
B SODIUM ALGINATE + SODIUM ALGINA ETHYL CELLULOSE 0.5GM, ETH + DRUG. 0.5GM, ETH CELLULOSE-0.25, DRUG- 0.1GM IN 25	TRIAL NUMBER	SOLUTION	INGREDIENTS		QUANTITY	
ETHYL CELLULOSE 0.5GM, ETT + DRUG. 0.5GM, ETT CELLULOSE-0.25, DRUG- 0.1GM IN 25	TRAIL 1	Α	CALCIUM CHLORIDE		5MG IN 50 ML WATER	
+ DRUG. CELLULOSE-0.25, DRUG- 0.1GM IN 25		В	SODIUM	ALGINATE +	SODIUM	ALGINATE-
DRUG- 0.1GM IN 25			ETHYL	CELLULOSE	0.5GM,	ETHYL
			+ DRUG.		CELLULOS	SE-0.25,
WATER.					DRUG- 0.1	GM IN 25 ML
					WATER.	

Table No.2

1 abic 100.2		
TRIAL NUMBER	SOLUTION	INGREDIENTS QUANTITY
TRAIL 2	А	CALCIUM CHLORIDE 5MG IN 50 ML WATER
	В	SODIUM ALGINATE + SODIUM ALGINATE-
		ETHYL CELLULOSE 0.75GM, ETHYL
		+ DRUG. CELLULOSE-0.25,
		DRUG- 0.1GM IN 25 ML
		WATER.

Table No.3

TRIAL NUMBER	SOLUTION	INGREDIENTS	QUANTITY	
TRAIL 3	Α	CALCIUM CHLORIDE	5MG IN 50 ML WATER	
	В	SODIUM ALGINATE +	SODIUM ALGINATE-	
		ETHYL CELLULOSE	1GM, ETHYL	
		+ DRUG.	CELLULOSE-0.25,	
			DRUG- 0.1GM IN 25 ML	
			WATER.	

OBSERVATIONS:-

According to the dissolution study he following results were obtained:-

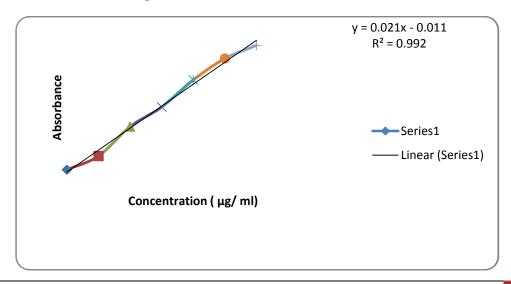
Table No.4:- Plot of Time Vs Percentage of drug release:-

TIME(MINS)	% OF DRUG RELEASE	% OF DRUG RELEASE	% OF DRUG
	IN TRIAL 1	IN TRIAL 2	RELEASE IN TRIAL 3
10	0.48	0.32	0.33
20	2.89	1.79	0.48
30	4.83	3.03	3.13
40	8.69	5.69	7.62
50	13.52	9.22	12.88
60	18.84	12.14	17.32
70	21.73	16.52	20.13
80	27.05	20.02	25.15
90	32.85	24.55	31.81
100	36.71	29.89	38.79
110	42.99	37.27	41.12
120	47.34	45.47	45.77

Table No.5:- A Plot of Time vs Concentration.

TIME(MINS)	CONCENTRATION(mcg/ml)
0	0
5	0.666
10	0.207
15	0.302
20	0.432
25	0.535
30	0.598

Figure 1:	Standard Curve	of Glibenclamide
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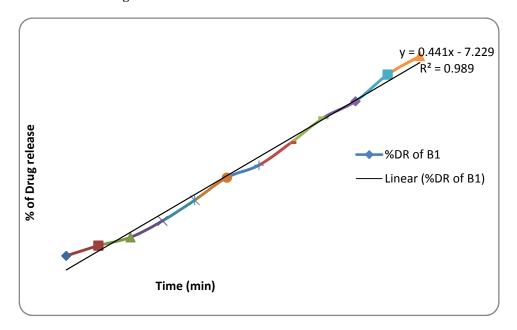
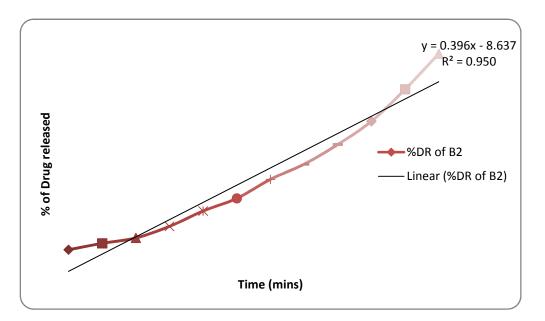


Figure 2: Zero order release kinetics of Batch B1





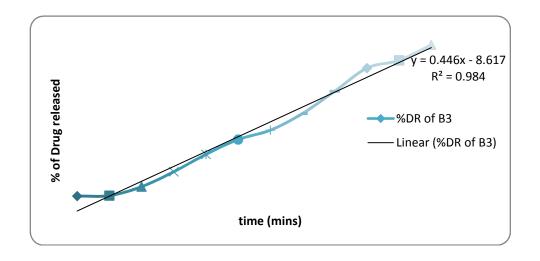


Figure 4: Zero order release kinetics of Batch B3

DISCUSSION:

This study on Glibenclamide microsphere drug delivery system claims that in place of Glibenclamide tablets that are available at a dose of 5mg, this newer form of drug delivery can be more beneficial as it's better dissolution characteristics. As obtained from different survey a vast majority of the population today suffers from diabetes and this drug delivery form may help to reduce the patient population of diabetes. Effective targeting and reduction in drug dosage that are the main targets of a microsphere drug delivery system were aimed

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 Patel N. R*, Patel D.A, Bharadia P. D, Pandya V, Modi D. Microsphere as a novel drug delivery. Int. J. Ph.and Life Sc., 2011, 2(8), 992-997. during this study. This study may thus be a better and more efficient form of drug delivery in place of the conventional methods.

CONCLUSION:

From this study it is concluded that amongst the three batches of microspheres formulated the first batch which contained the least amount of sodium alginate amongst all the batches showed the best dissolution profile. Thus, the microsphere form of drug delivery can be used to treat the diabetic patients who have been on Glibenclamide treatment.

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CONFLICT OF INTEREST REPORTED: NIL ;

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