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Formulation and Evaluation of Glipizide Fast Dissolving Tablets

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Abstract:

Glipizide is an oral drug that is used for treating type 2 diabetes. It belongs to the class of sulfonylurea acts by stimulating insulin secretion from beta cells of pancreatic islet tissue and is thus depend on functioning beta cells in the pancreatic islets.The present research work was aimed to develop the Fast dissolving tablet of Glipizide using Super disintegrats like Sodium starch glycolate and Croscarmellose sodium. Glipizide is a BCS II drug which is insoluble in water is complexed with different ratios of β cyclodextrin to enhance its solubility properties.The optimised drug : polymer (1:3)ratio was selected to formulate the fast dissolvimg tablets and were evaluated for physical appearance, weight variation, hardness, friability, content uniformity test, disintegration test and in vitro release studies. It was observed that formulation with 7.5 mg of sodium starch glycolate (F6) show faster drug release i.e; 98.5%in 30 min. The FTIR studies revealed that there was no interaction between the drug and excipients.

Keywords : Glipizide, β cyclodextrin, Super disintegrats, Fast dissolvimg tablets, FTIR studies.

INTRODUCTION:

Fast dissolving tablets are gaining importance in the recent past, as it is most conveniently administered with rapid dissolution and quicker absorption providing faster onset of action. The major advantage of this dosage form is that it can be administered without water. Fast dissolving tablets when placed in the oral cavity melts in it as the saliva quickly penetrates into the pores causing rapid disintegration [1]. To treat the condition of type-2 diabetes mellitus or non- insulin dependent diabetes mellitus (NIDDM) , Glipizide which comes under sulphonylurea class drug is most widely used and has the duration of action of up to 24 h. Glipizide is a poorly water soluble drug which comes under BCS class II . To increase it's solubility in gastrointestinal tract in this we are following solid dispersion method [2-3].

Solid dispersions are one the most successful strategic approach to improve drug release of poorly soluble drugs. Solid dispersion can be defined as a molecular mixture of poorly water soluble drugs in hydrophilic carriers, which present the drug release profile that is driven by the polymer properties. Polymer such as beta - cyclodextrin is used to increase the solubilty of Glipizide in solid dispersion [3].

METHODOLOGY:

Calibration curve of glipizide:

A spectrophotometric method based on the measurement of absorbance at 274 nm in pH 6.8 buffer was used in the present study for the estimation of Glipizide .10mg of Glipizide pure drug was dissolved in 1ml of 0.1N NaOH and shaken for 15 min then make up to 10ml with pH 6.8 buffer(stock solution - 1000µg/ml).The absorbance of the above dilutions was measured at 274nm by using the UV-Spectrophotometer using pH 6.8 buffer as the blank.Then a graph was plotted by taking concentration on X-axis and absorbance on Y-axis which gives a straight line[4].

Preparation of solid dispersion method:

The solid dispersion method was prepared by kneading method. Required amount of drug and the polymer were added in motor and to this add required amount of methanol and triturate thoroughly with the help of pestle until a clear solution is obtained. The solvent was evaporated in a hot air oven temperature at 50˚c[5].

Invitro dissolution of solid dispersion method:

10mg equivalent drug and polymer mixture added to 6.8 pH buffer and perform dissolution for 1hr at time intervals 5,10,20,30,45,60min[6].

Preparation of tablet formulation:

Tablets were formulated with super disintegrations like sodium starch glycolate and cross caramolose and formulated direct compression are given in table-1.

Table no-1: Tablet Formulation:

Ingredients	F1	F2	F3	F4	F5	F6
10mg equivalent of Glipizide in complex	40	40	40	40	40	40
Crosscaramellose sodium.	2.5	5	7.5	-	-	-
Sodium starch glycolate	-	-	-	2.5	5	7.5
Microcrystalline cellulose	55.5	53	50.5	55.5	53	50.5
Talc	1	1	1	1	1	1
Magnesium stearate	1	1	1	1	1	1
Total quantity.	100	100	100	100	100	1001

All ingredients were taken in mg.

Evaluation Tests:

Pre-compression methods[7]:

FTIR study discussion:

Fourier transform infrared (FT– IR) spectral measurements were performed using Thermo-IR 200 FT–IR spectrophotometer. Potassium bromide pellet method

was employed. The pure drug and the pure drug along with the polymer mixture used for the preparation of films was finely grounded with KBr to prepare pellets under a hydraulic pressure of 600psi and a background spectrum was collected under identical conditions. Each spectrum was derived from 16 single average scans collected in the range of 4000- 400 cm-1.

Post Compression methods:

Disintegration test:

The time taken by the dosage form to complete and break into fragments is called as disintegration test and no of cycles permin is 28 cycles /minute.

Invitro dissolution studies:

The dissolution studies of solid dispersions were done in 6.8 pH buffer which were prepared with cyclodextrin complexes in the ratios 1:0.5,1:1,1:2,1:3 .out of which 1:3 of drug :polymer ratio was optimised and it was formulated as fast dissolving tablet with sodium starch glycolate and crosscaramellose sodium in different proportions like 2.5mg ,5mg and 7.5 mg ,the formulation with 7.5mg of sodium starch glycolate proved as best optimised formula[8].

Drug content

An accurately weighed quantity of solid dispersion equivalent to 10mg of drug was taken into 100ml volumetric flask and dissolved in minimum amount of methanol and volume was made upto the mark with pH 6.8 buffer and measure at 274 nm using U.V spectrophotometer[9].

RESULTS AND DISCUSSION:

Evaluation of Precompression parameters:

From the results obtained (table.no.2), the angle of repose, bulk density, tapped density, carr's index, hausner ratio values indicate good flow property for formulations F1 to F7.

FTIR Study

FTIR has been used to assess the no interaction between drug and polymer.IR analysis revealed that the frequencies of functional groups of pure drug remained un effected in physical mixture containing polymers, hence there was no chemical interaction occurred between the drug and polymers and the results were shown in the FTIR graphs of fig no.1,2.

In-vitro dissolution profile Of Solid Dispersion:

The dissolution studies of solid dispersions were done in 6.8 pH buffer which were prepared with β-cyclodextrin complexes in the ratios 1:0.5,1:1,1:2,1:3 .The results were shown in the table 3.

Post Compression Evaluation Factors

These were shown in table:5.

In-vitro dissolution testing of tablets:

The dissolution studies of solid dispersions were done in 6.8 pH buffer which were prepared with β-cyclodextrin complexes in the ratios 1:0.5,1:1,1:2,1:3 .The results were shown in the table.no.3,4.

Drug content

Drug content of all formulations were in the range of 90% - 105% it complies with official specifications.

Table no 02: Precompression parameters

S.no	Formulation code	Angle of repose	Bulk density	Tapped density	Carr's index(%)	Hausner's ratio
1	F1	22.34	0.58	0.71	30.12	1.40
2	F2	28.54	0.45	0.65	26.38	1.25
3	F3	23.69	0.49	0.60	20.56	1.38
4	F4	24.32	0.54	0.75	25.65	1.45
5	F5	27.98	0.48	0.68	28.36	1.26
6	F6	23.59	0.59	0.68	24.78	1.24
7	F7	24.26	0.57	0.75	23.65	1.42

Table no-3: Invitro dissolution profile of solid dispersion

S.no	Time in min	Amount of drug dissolved			
		1:0.5	1:1	1:2	1:3
1	0	0	0	0	0
2	5	13.0	14.8	20.9	23.3
3	10	15.4	23.6	27.7	35.1
4	20	22.5	31.7	36.7	38.0
5	30	29.5	39.9	43.5	42.3
6	45	36.7	42.1	52.3	50.2
7	60	42.1	49.5	56.9	59.3

Table.no-4: Invitro dissolution profile of physical mixtures

S.no	Time in min	Amount of drug dissolved			
		1:0.5	1:1	1:2	1:3
1	0	0	0	0	0
2	5	13.0	14.8	20.9	23.3
3	10	15.4	23.6	27.7	35.1
4	20	22.5	31.7	36.7	38.0
5	30	29.5	39.9	43.5	42.3
6	45	36.7	42.1	52.3	50.2
7	60	41.7	47.7	54.9	56.3

Table no-5:Physicochemical properties of fast dissolving tablets

Formulation	Thickness(mm)	Hardness(kg/cm2)	%Friability	Weight variation(mg)	Drug content (%)
F1	4.26±0.01	4.56±0.325	0.52±0.01	2.5±0.5	95.3
F2	4.32±0.02	4.30±0.256	0.64±0.03	2.8±7.8	96.5
F3	4.39±0.03	4.08±0.406	0.58±0.02	3.0±0.6	98.4
F4	4.58±0.12	3.84±0.989	0.65±0.04	3.5±0.5	97.6
F5	4.56±0.02	3.95±0.426	0.45±0.03	2.7±0.6	97.6
F6	4.35±0.13	4.45±0.356	0.59±0.02	3.4±0.7	95.7

Table.no-6:Dissolution rate test profile of cross caramallose sodium by using solid dispersion method(2.5mg,5mg,7.5mg)

S.no	Time in min	Amount of drug dissolved		
		2.5	5	7.5
1	0	0	0	0
2	5	13.9	24.8	25.3
3	10	36.2	39.9	35.8
4	15	45.6	47.7	51.3
5	20	49.8	62.1	68.6
6	25	51.6	70.1	91.6
7	30	61.0	80.6	95.3

Table.no-7:Dissolution rate profile of sodium starch glycolate by using solid dispersion method(2.5mg,5mg,7.5 mg)

S.no	Time in min	Amount of drug dissolved		
		2.5	5	7.5
1	0	0	0	0
2	5	15.2	20.9	26.2
3	10	25.0	29.1	39.5
4	15	28.7	41.7	52.1
5	20	34.0	52.1	68.5
6	25	40.3	61.4	78.5
7	30	52.1	77.5	98.5

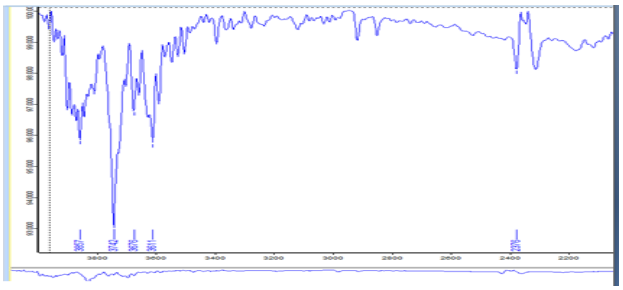

Fig no:01 FTIR graph of glipizide

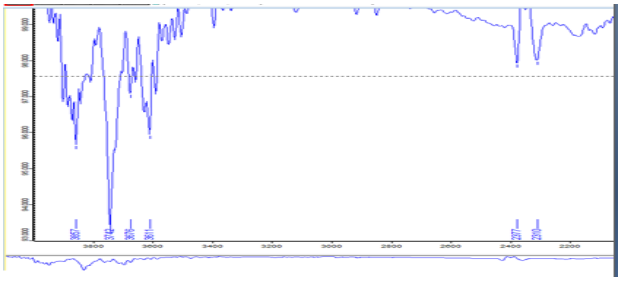

Fig no: 02 FTIR graph of solid dispersion (1:3)

CONCLUSION:

The purpose of fast dissolving formulations possesses individual and reproducible characteristics of disintegration time and enhanced dissolution rate. This study shows that the disintegration and dissolution rate of Glipizide FDT enhanced to a greater extent by different superdisintegrants with different ratios. Hence drug-sodium starch glycolate was taken for the preparation of glipizide FDTs by dry granulation method. IR analysis reveals that the frequencies of functional groups of pure drug remained un effected in tablets containing super disintegrants hence there was no chemical interaction occurred between the drug and super disintegrants.Sodium starch glycolate and cross caramellose sodium and were used as super disintegrants in alone and with different ratios for the preparation of glipizide FDTs. It was found that all formulations show better physico chemical properties. Among all formulations it was found that sodium starch glycolate (F6) to be with good disintegration time and faster in releasing the drugi.e; 98.5% in 30 min, so it may be optimized as a best formula.

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