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Research Article

FORMULATION AND EVALUATION OF FLOATING AND MUCOADHESIVE TABLET OF ORAL HYPOGLYCEMIC DRUG OF METFORMIN

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ABSTRACT

In the present research work gastro retentive mucoadhesive floating formulation of Metformin by using various hydrophilic polymers. Metformin, marketed under the trade name Glucophage among others, is the first-line medication for the treatment of type 2 diabetes, particularly in people who are overweight. It is also used in the treatment of polycystic ovary syndrome. Limited evidence suggests metformin may prevent the cardiovascular disease and cancer complications of diabetes. Initially analytical method development was done for the drug molecule.

KEYWORDS: *Metformin, Hydrophilic polymers, Floating and Mucoadhesive tablet.*

INTRODUCTION

The oral route is increasingly being used for the delivery of therapeutic agents because the low cost of the therapy and ease of administration lead to high levels of patient compliance [1-3]. More than 50%of the drug delivery systems available in the market are oral drug delivery systems1. Controlled-release drug delivery systems (CRDDS) [4-6] provide drug release at a predetermined, predictable, and controlled rate. Controlled-release drug delivery system is capable of achieving the benefits like maintenance of optimum therapeutic drug concentration in blood with predictable and reproducible release rates for extended time period; enhancement of activity of duration for short half-life drugs [7, 8]; elimination of side effects; reducing frequency of dosing and wastage of drugs; optimized therapy and better patient compliances.

MATERIALS AND METHODS

Experimental Procedure:
Drug Profile:
Drug: Metformin

IUPAC name: 1-carbamimidamido-N,N-dimethylmethanimidamide

Synonyms: 1,1-Dimethylbiguanide, Dimethylbiguanid, Haurymellin, Metformin, Metformina, Metformine.

Description: Metformin is a biguanide antihyperglycemic agent used for treating non-insulin-dependent diabetes mellitus (NIDDM). It improves glycemic control by decreasing hepatic glucose production, decreasing glucose absorption and increasing insulin-mediated glucose uptake. Metformin is the only oral antihyperglycemic agent that is not associated with weight gain.

Solubility: Freely soluble in water, slightly soluble in alcohol, practically insoluble in acetone and in ethylene chloride.

Melting point: 222 °C to 226 °C

CAS No.: 1115-70-4

Molecular formula: $C_4H_{11}N_5.HCl$

Molecular Weight: Average:165.625,Monoisotopic: 165.078123116

Bioavailability: 50% to 60%

Half-life: 4-8.7 hours

Methodology:
Formulation development of Metformin Tablets:

All the formulations were prepared by direct compression(9-12). The compression of different formulations are given in Table.1.The tablets were prepared as per the procedure given below and aim is to prolong the release of Metformin. Total weight of the tablet was considered as 1150mg.

Procedure:

1) Metformin and all other ingredients were individually passed through sieve no ≠ 60.
2) All the ingredients were mixed thoroughly by triturating up to 15 min.
3) The powder mixture was lubricated with talc.
4) The tablets were prepared by using direct compression method.

RESULTS AND DISCUSSION

The present study was aimed to developing gastro retentive floating tablets of Metformin using various polymers. All the formulations

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were evaluated for physicochemical properties and invitro drug release studies.

Analytical Method:

Graphs of Metformin were taken in Simulated Gastric fluid (pH 1.2) at 244 nm.

Quality Control Parameters For tablets:

Tablet quality control tests such as weight variation, hardness, and friability, thickness, and drug release studies in different media were performed on the tablets.

Table No. 1: Formulation development of Metformin Tablets

S. No.	Excipient Name	EF1	EF2	EF3
1	Metformin	500	500	500
2	HPMCK 4M	180	180	180
4	CARBOPOL 934P	100	100	100
5	Accrual	60	120	180
5	Mg.Stearate	12	12	12

Table No. 2: Formulation composition for floating tablets

Formulation No.	Metformin	HPMC K4M	HPMC K15M	HPMC K100M	Accural	Carbopol 934P	Carbopol 971P	Mag. Stearate	Talc	MCC pH 102
F1	500	80	-----	-----	120	100	100	12	12	QS
F2	500	120	-----	-----	120	100	100	12	12	QS
F3	500	180	-----	-----	120	100	100	12	12	QS
F4	500	-----	80	-----	120	100	100	12	12	QS
F5	500	-----	120	-----	120	100	100	12	12	QS
F6	500	-----	180	-----	120	100	100	12	12	QS
F7	500	-----	-----	80	120	100	100	12	12	QS
F8	500	-----	-----	120	120	100	100	12	12	QS
F9	500	-----	-----	180	120	100	100	12	12	QS
F10	500	220	-----	-----	120	100	100	12	12	QS
F11	500	-----	220	-----	120	100	100	12	12	QS
F12	500	-----	-----	220	120	100	100	12	12	QS

All the quantities were in mg, Total weight is 1150 mg.

Table No. 3: Observations for graph of Metformin in 0.1N HCl (244 nm)

concentration	Absorbance
0	0
0.1	0.038
0.2	0.14
0.3	0.199
0.4	0.289
0.5	0.385
0.6	0.459

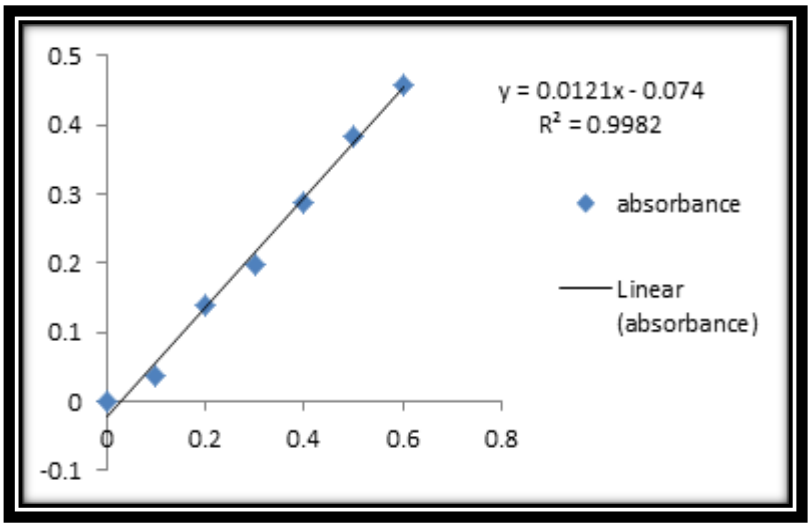

Fig. 1: Standard graph of Metformin in 0.1N HCl

Table No. 4: Preformulation parameters of powder blend

Formulation Code	Angle of Repose	Bulk density (gm/ml)	Tapped density (gm/ml)	Carr's index (%)	Hausner's Ratio
F1	26.01	0.49±0.07	0.57±0.01	16.21±0.06	0.86±0.06
F2	24.8	0.56±0.06	0.62±0.05	16.87±0.05	0.98±0.05
F3	22.74	0.52±0.03	0.68±0.07	17.11±0.01	0.64±0.03
F4	25.33	0.54±0.04	0.64±0.08	17.67±0.08	1.12±0.04
F5	26.24	0.53±0.06	0.67±0.03	16.92±0.04	1.2±0.08
F6	26.12	0.56±0.05	0.66±0.06	17.65±0.09	1.06±0.09
F7	27.08	0.58±0.06	0.69±0.04	16.43±0.05	0.76±0.03
F8	25.12	0.48±0.05	0.57±0.02	17.97±0.02	1.15±0.09
F9	25.45	0.54±0.08	0.62±0.03	17.54±0.09	1.17±0.02
F10	25.33	0.54±0.04	0.64±0.08	17.11±0.01	1.06±0.09
F11	26.24	0.53±0.06	0.66±0.06	16.92±0.04	0.64±0.03
F12	26.12	0.48±0.05	0.69±0.04	17.65±0.09	1.12±0.04

Table No. 5: quality control parameters for tablets *In-Vitro* Drug Release Studies

Formulation code	Weight variation (mg)	Hardness (kg/cm2)	Friability (%loss)	Thickness (mm)	Drug content (%)	Floating lag time (min)
F1	1155	3.5	0.52	4.8	99.76	4.0
F2	1143	3.2	0.54	4.9	99.45	4.2
F3	1149	3.4	0.51	4.9	99.34	4.5
F4	1152	3.5	0.55	4.9	99.87	4.1
F5	1150	3.4	0.56	4.7	99.14	4.0
F6	1148	3.2	0.45	4.5	98.56	4.4
F7	1147	3.1	0.51	4.4	98.42	4.5
F8	1151	3.3	0.49	4.7	99.65	4.6
F9	1153	3.5	0.55	4.6	99.12	4.7
F10	1145	3.5	0.45	4.5	98.42	4.5
F11	1146	3.4	0.51	4.4	99.65	4.6
F12	1149	3.2	0.49	4.7	99.12	4.7

Table No. 6: Dissolution Data of Metformin Tablets

Time (hrs)	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12
0	0	0	0	0	0	0	0	0	0	0	0	0
0.5	3.65	4.76	7.30	6.76	7.32	9.65	14.56	6.87	7.22	5.87	6.24	8.72
1	10.76	9.55	11.7	11.4	12.55	12.4	29.42	11.12	11.52	9.65	12.4	15.8
2	15.76	11.56	27.53	16.76	18.76	16.76	32.05	33.45	29.36	13.55	30.34	29.66
3	24.43	15.32	29.81	26.46	26.65	26.46	44.1	45.62	35.2	20.33	32.92	37.61
4	30.31	20.54	24.62	31.31	33.54	32.31	51.25	58.73	49.65	28.77	42.81	39.62
5	36.58	23.77	49.34	38.68	41.59	39.68	63.33	62.64	61.1	37.44	50.53	47.53
6	42.57	30.75	67.51	43.59	45.51	45.6	69.24	70.43	68.99	48.21	59.6	48.32
7	49.76	36.43	54.71	50.12	52.13	51.12	70.01	76.21	72.58	56.55	63.9	74.52
8	56.8	41.65	59.34	57.54	58.65	57.5	72.44	81.26	79.56	67.21	75.41	61.23
9	67.3	46.77	59.42	68.66	69.66	67.7	75.76	85.76	82.95	74.21	67.21	76.36
10	78.6	49.76	69.72	80.01	82.23	81	78.97	89.75	86.25	81.32	72.81	88.75

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