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FORMULATION AND EVALUATION OF MODIFIED RELEASE TABLETS OF GLICLAZIDE

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ABSTRACT

Gliclazide Modified from once daily administration to 24hrs blood glucose control. Employing an innovative pharmaceutical form based on a hydrophilic matrix to deliver this short-acting sulfonylurea, gliclazide modified release is associated with an unsurpassed efficacy: acceptability ratio, with the potential additional advantages inherent in reduced dosage and once-daily administration. The Formulation of Gliclazide Modified Release tablets using polymers namely hydroxy propyl methyl cellulose and in different grades. All 6 formulations were evaluated for invitro drug release using HPLC up to 16hrs. The drug release pattern was compared with that of marketed formulation. Hence it was the optimized formulation for sustaining the release of Gliclazide. The present works concludes with Gliclazide Modified Release six as the best formulation for the sustained release of Gliclazide.

KEYWORDS: Gliclazide Modified, Hydroxy propyl methyl cellulose.

1. INTRODUCTION

1. Sustained drug action at a predetermined rate by maintaining a relatively constant, effecting drug level in the body with concomitant minimization of undesirable side effects that may be associated with a saw tooth kinetic pattern of controlled release.
2. Localized drug action by spatial placement of a controlled release system (usually rate controlled) adjacent to or in the diseased tissue or organ.
3. Targeted drug action by using carriers or chemical derivatives to deliver drug to a particular target cell type.

4. Provide physiologically or therapeutically basic drug release system. In other words, the amount and the rate of the drug release are determined by physiological or therapeutic needs of the body.

Potential Advantages of modified Drug Therapy[5]

1. Avoid patient compliance problems.
2. Employ less total drug.

a. Minimize or eliminate local side effects.
b. Minimize or eliminate systemic side effects.
c. Obtain less potentiation or reduction in drug activity with chronic use.
d. Minimize drug accumulation with chronic dosing.

3. Improve efficiency in treatment

a. Cure of control condition more promptly.
b. Improve control of condition, i.e. reduce fluctuation in drug level.
c. Improve bioavailability of some drugs.
d. Make use of special effects, e.g. delayed– release aspirin for morning relief of arthritis by dosing before bedtime.

4. Economy.

1. MATERIALS AND METHODS

MATERIALS

Gliclazide (99.96% purity), were gift samples from Dr. Reddy's Labs Ltd, Hyderabad, hpmc k4m and HPMC 15 cps were gift samples from Dr. Reddy's Labs Ltd, Hyderabad,. All other reagents and chemicals used were of analytical reagent grade.

MANUFACTURING PROCEDURE OF MODIFIED RELEASE TABLETS OF GLICLAZIDE

(1) Gliclazide, povidone IP were weighed accurately and sifted through sieve no: 60
(2) The materials were subjected to dry mixing.
(3) Purified water was added slowly to the above materials and blending is performed.
(4) The blended material was passed through mesh 60 after which drying is performed in a hot air oven at 60 c for 1hour.
(5) The dried granules were passed through sieve no:30.

(6) To the dried granules (except Magnesium stearate) the other excipients like Methocel, HPMC, co-povidone were added and blended.

(7) Now sifted Magnesium stearate was added to the blend.

(8) Now the sieved product is compressed to round, flat tablets.

Table 1: Master formula for the preparation of Gliclazide Modified Release tablets.

S.NO	INGREDIENTS (mg/tab)	GMR I	GMR II	GMR III	GMR IV	GMR V	GMR VI
1	GLICLAZIDE	30	30	30	30	30	30
2	POVIDONE	10	10	10	10	10	10
3	MICROCRYSTALLINE CELLULOSE	95.67	95.67	95.67	95.67	95.67	95.67
4	METHOCEL K4M (4000cps)	----	40	25	15	20	21
5	HYDROXYPROPYL METHYL CELLULOSE 15CPS	40	-----	15	25	20	19
6	CO-POVIDONE	4	4	4	4	4	4
7	MAGNESIUM STEARATE	2	2	2	2	2	2
8	PURIFIED WATER	3.33	3.33	3.33	3.33	3.33	3.33

2. RESULTS

Table 2: Evaluation of pre compression parameters of modified release tablets of Gliclazide.

Property	GMR I	GMR II	GMR III	GMR IV	GMR V	GMR VI
Angle of repose (^{0})	29.2±0.03	29.6±0.04	28±0.02	28.85±0.02	30.5±0.01	27±0.07
Bulk density (gm/cm^3)	0.58	0.60	0.57	0.57	0.58	0.56
Tapped density (gm/cm^3)	0.69	0.68	0.67	0.66	0.68	0.65
Carr's compressibility index (%)	14.7	13.6	14.9	13.63	14.7	13.9
Hausner's compressibility Ratiox	1.18	0.88	1.3	1.15	1.17	1.16
Flow property	Good	Good	Good	Good	Good	Good

Table 3: Evaluation of Post Compression Parameters of modified release tablets of Gliclazide.

Formulation code	Weight variation (mg) **	Thickness (mm) *	Hardness (kg/cm^3) *	Friability (%) ***	Drug content uniformity (%) **
GMR I	182	**3.04**	4.3	0.011%	99.1
GMR II	183	3.04	4.2	0.027%	98.4
GMR III	181	3.01	4.1	0.054%	101.7
GMR IV	182	3.07	4.3	0.0217%	102
GMR V	183	3.13	4.24	0.0325%	99.8
GMR VI	185	3.14	4.3	0.032%	99.2

Table 4: Invitro Dissolution Profile of Gliclazide Modified Release Tablets (Gmr I).

S.No	Time in hours	GMR I % DRUG RELEASE	GMR I I % DRUG RELEASE	GMR III % DRUG RELEASE	GMR IV % DRUG RELEASE	GMR V % DRUG RELEASE	GMR VI % DRUG RELEASE
1	0	0.00	0.00	0.00	0.00	0.00	0.00
2	1	4.50	5.30	9.60	10.60	9.90	12.90
3	2	7.80	8.10	15.60	18.10	17.90	22.80
4	3	12.10	13.00	29.00	27.00	26.00	32.10
5	4	15.35	19.70	38.10	35.70	38.20	40.30
6	6	22.80	25.00	44.10	42.20	47.00	59.80
7	8	37.10	40.00	56.70	51.00	59.40	69.00
8	10	48.70	53.20	66.30	69.30	69.80	77.10
9	12	64.10	69.20	73.30	75.60	82.90	88.00
10	16	80.20	83.50	88.30	89.90	98.20	99.30

4. CONCLUSION

All 6 formulations were evaluated for invitro drug release using HPLC up to 16hrs. The drug release pattern was compared with that of marketed formulation. Hence it was the optimized formulation for sustaining the release of Gliclazide.

The present works concludes with (Gliclazide Modified Release) GMR six as the best formulation for the sustained release of Gliclazide. Further more Invivo studies might confirm the formulation to have lower dose frequency and thus improve the patient compliance.

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