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FORMULATION AND IN VITRO EVALUATION OF BILAYER TABLETS OF ANTIDIABETIC DRUG REPAGLINIDE

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ABSTRACT

Layered formulations have commenced new way of formulating formulations. These are used for same drug to modify its release and for different drug with the ration of using both the drug in to the same formulation. The most common layered formulation is multilayer tablet, They are used in the Pharmaceutical formulation due to their number of Advantages .In this research work an antidiabetic drug repaglinide is used for the preparation of the bilayer tablet, Two layers of the drug were formulated one for the immediate release of the drug and other one is for the sustained release of the drug, Then these prepared formulation having different amount polymer were subjected for the evaluation parameters like weight variation, thickness, hardness, friability and then in vitro drug release. Out of three different batched in which concentration of super disintegrants sodium starch Glycolate and polymer HPMC adjusted and best formulation was selected on the basis of the evaluation performed.

KEYWORDS: Super Disintegrants, HPMC, Bilayer.

INTODUCTION

BILAYER TABLET

From past few decade researchers has been constantly developing controlled drug delivery with major goal to reduce frequency of dosing. Even It has got acceptability now a days in most of the modern manufacturing. Multilayer tablet are bilayer, trilayer and even four layer tablets. Mainly bilayer tablet is the new era for the successful development of controlled release formulation. Bilayer tablet is unit dosage form with combination of two or more Active Pharmaceutical Ingredients (API) which promoting patient convenience compliance. (1) The goal of any drug delivery system is to provide therapeutic amount of the drug to proper site in the body to achieve promptly, and then maintain the desired drug concentration.

Usually conventional dosage form it has been observed that these produces fluctuations in drug concentration in the blood stream and tissues with consequent undesirable toxicity and poor efficiency. This lead to the problems of repetitive dosing and unpredictable absorption of the Drug led to us to the concept of sustained drug delivery system. The aim behind these sustained delivery systems is to reduce the frequency of dosing to increase effectiveness of the drug by localization of the drug at the site of action which in turn reduces the dose requirement and thus provides uniform drug delivery. The goal of sustained drug delivery is to ensure safety and to improve effectiveness of drug and thus improve patients compliance.2

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Diabetes Mellitus is a metabolic disorder resulting from defective insulin secretion, action or both [3]. Repaglinide is an effective ant hyperglycemic used for the management of Type 2 Diabetes Mellitus. It is a benzoic acid derivative belonging to meglitinide class of oral hypoglycemic. After oral administration it is rapidly & completely absorbed & peak plasma concentration is achieved in approximately 1hr. It is removed from the blood stream within a span of 1hr. The mean absolute bioavailability is 56% when given with food [4].That is why this drug is used in the formulation of bilayer tablet and then further invitro evaluation of drug entrapped formulation.

MATERIAL AND METHOD

Drug Repaglinide obtained as a gift sample and polymers like HPMC, MCC, Sodium starch Glycolate, magnesium sterate were purchased from CDH chemical new Delhi. Other solven used in the work were of Analutical grade.

WET GRANULATION METHOD

The main active ingredient, diluent, disintegrant are blended together, then it is allowed to pass through the sieve (sifting). Solutions of the binding agent are added in initial mixing with stirring. The amount of binding agent added should be sufficient, in order to avoid over wetting of the tablet. After drying the granules, they are allowed to pass through the screen, usually 60-100 mesh. After dry granulation, lubricant is added for the final compression of the Tablets.

Table 1.Ingredients of immediate Release layer

S NO	INGREDIENT	RF_1	RF_2	RF_3
1	REPAGLINIDE	1	1	1
2	SODIUM STARCH GLYCONATE	20	22	24
3	MCC	175	174	173
4	SODIUM CITRATE	4	4	4
5	MAGNESIUM STERATE	3	3	3

DRY GRANULATION METHOD

The active ingredient, diluent and lubricant are blended together, to form the slug. Thus, the compressed slug is passed through the mesh, and the remaining lubricant is added to the granulation, blended properly and compressed to form the tablets.

DIRECT COMPRESSION

Direct compression involves direct compressing the powdered material into tablets. Direct compression is adopted, if drug constitutes major portion of tablet total weight. Tablets containing 25% or less of drug substances can be formulated, with a suitable diluent which acts as a carrier or vehicle for the drug.

Tablets prepared by above method are subjected to compression machine which may be single station or multiple station.

Table 2.Ingredients used in sustain release layer

S NO	INGREDIENT	RF_1	RF_2	RF_3
1	REPAGLINIDE	1	1	1
2	MCC	173	176	174
3	HPMC	49	48	50
4	MAGNESIUM STEARATE	3	4	4

EVALUTION OFREPAGLINIDE BI LAYER TABLET

WEIGHT VARIATION

Twenty tablets were randomly selected from each batch and individually weighed. The average weight and standard deviation of 20 tablets was calculated. The batch passes the test for weight variation test if not more than two of the individual tablet weight deviates by more than the percentage shown.

FRIABILITY

Ten tablets were weight and placed in the ROCHE friability apparatus and apparatus ws rotated at 25 rpm for 4 minute .After revolutions the tablets were dedusted and weighed Again. The observed value should not be more than 1% The percentage friability was measured using the formula.

%f={1-(wt/w)*100

Where, %f=friability in percentage, w=Initial weight of tablet, wt=weight of tablets after revolution.

HARDNESS

The tablet was placed between two anvils of hardness tester (Monsanto) and increasing amount of force (kg) was applied . The reading at the marked scale was recorded for the pressure which is required to break the tablet.

IN VITRO DISSOLUTION STUDY

Comply with the dissolution test for tablets By using apparatus as the medium 900 ml of 0.1M hydrochloric acid and rotating the basket at 50 rpm .maintaining the temperature of 37±0.5°c .one tablet was placed the basket of dissolution apparatus. The apparatus was allowed to run for 6 hour sample measuring 5 ml were withdraw after 1 hour 2 hour 3 hour 4hour 5hour 6hour.the fresh dissolution medium was replaced every time with the same quantity of the sample.

Table 3.Observation table of Evaluations of three batch prepared

S.NO	Trial batch	Weight variation %	Hardness (kg/cm$^{2)}$	Thickness(mm)
1	RF_1	Pass	10	5.32
2	RF_2	Pass	9	5.40
3	RF_3	Pass	9.5	5.38

Fraibility =Fraibility of the tablets was found to be 1.6%

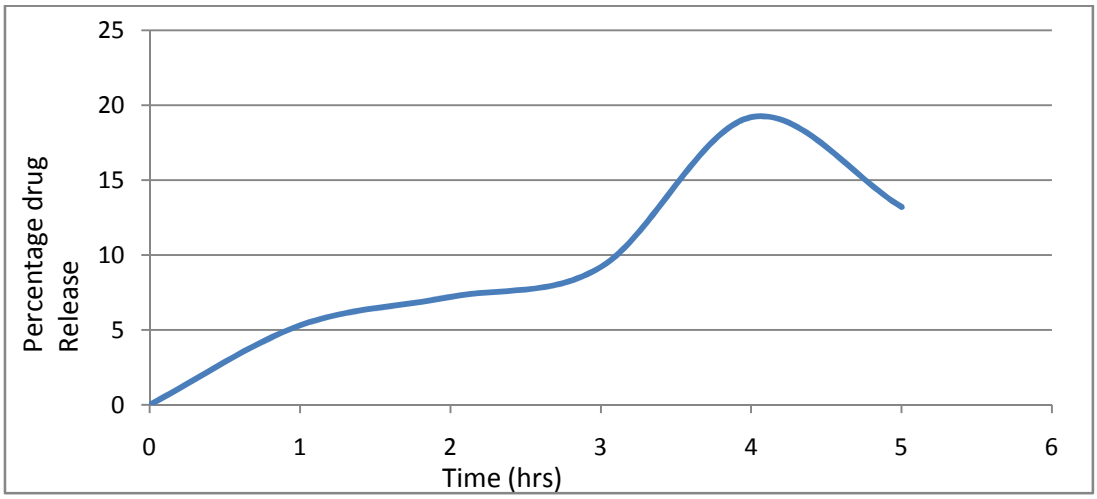

Figure 1.Percentage of drug release of Batch RF3

RESULT AND DISCUSSION

Form the above result it can be concluded that formulation of sustained release tablet of REPAGLINIDE batch RF_3has shown better drug and It could be taken as an optimized formulation of bi layer tablets, from the present research it can be concluded that a successful bilayer tablet of Repaglinide can be formulated using MCC HPMC magnesium stearate sodium starch glyconateetc in different concentration.

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