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A CRITICAL REVIEW ON THE MODIFIED RELEASE FORMULATION

PRIYA CHAHAL*, ASHWANI MISHRA**

ABSTRACT

In this review work an effort is made to explain the importance of modified release formulation along with the limitation of this sort of formulation in pharmaceutical manufacturing formulations. It was also tried to explain the properties of suitable drug properties which could be used to formulation modified release formulations Different classes of Modified release formulations were also explained in order to understand that these types of formulation would be formulated to get desired drug release profile to get better bioavailability of the formulation and to reduce the side effect of the formulation, it also reduce dosing frequency of the formulation which leads to the feasibility of administration and patient compliance

INTRODUCTION

Modified release formulation is characterized as the time course and location of drug release characteristics are finished therapeutic or suitability objectives. A few formulations like ointments, solutions, or fast dissolving dosage forms are not offered by customary dosage forms. [1] Modified release formulations, where the rate and site of release of the active materials are disparate since that of the prompt release administered by the same route. This thoughtful change is performed by superior formulation design and manufacturing methods dosage form. Modified release products are administered by different routes like orally, intramuscularly, subcutaneously, intravaginal and transversal dosage forms. The bioavailability, blood concentration and time profile of drug are increased in modified release formulations method. [2] Modified release formulation if used aptly in research increases the bioavailability of the formulation. [3]

The development of modified release formulation is more useful when selected agent possess different mechanism of action, It also decreases the required doses of drug as compare to the dose available in the marketed conventional drug delivery system. [4]

Modified release formulations have been created to appropriate drug to the part of the body where it will be absorbed, it additionally shorten dosing plans and guarantee that concentration of drug is maintaining. [5] Modified release formulations are intended to release drug in a controlled way to achieve security profile and desired efficacy. [6]

The modified release delivery system may be separated conveniently in to different groups:

- Prolonged release
- Delayed release
- Multiphasic release

*Department of Pharmacy, Barkatullah University, Bhopal.
Correspondence E-mail Id: editor@eurekajournals.com

- Biphasic release
- Pulsatile release
- Multiple unit
- Single unit [7]

ADVANTAGES OF MODIFIED RELEASE FORMULATION

1. Shows kinetics similarity to I.V infusion, with respect of a tablet.
2. Dosing frequency is reduced. [5]
3. High capability in treatment, more uniform blood concentration, optimized therapy.
4. Systemic and local side effects is reduced. [2]
5. Better bioavailability
6. Advanced technology is used. [8]

DISADVANTAGES OF MODIFIED RELEASE FORMULATION

1. It will take long time to treat patient.
2. The first pass effect is strong by staying below the metabolizing enzymes saturation point. [5]
3. In vitro-in vivo correlation is very poor.
4. Systemic availability is reduced in comparison to immediate release conventional dosage form.
5. For dose adjustment of drug potential is reduced normally administered in varying strengths. [2]
6. If a toxic dose is given, it will stay toxic for a long time.

Table 1.Example of Marketed Modified Release Formulations9

S. no	Active ingredients	Brand name	Dosage form	Application
1	Ortho Evra	Ortho-Mcneil	Trans Dermal Patch	Hypertension
2	Viadour	Ortho biotech bayer	Subcutaneous Implants	Advance prostate cancer
3	Carbotrol	Shri Us	Oral capsule	Epilepsy
4	Glucotrol XR	Pfizer	Oral tablet	Hyperglycemia
5	Doxil	TAP	Intravenous infusion	Ovarian cancer

DRUG SELECTION CRITERIA FOR THE MODIFIED RELEASE FORMULATION

1. pK a of nonionized should be moiety > 0.1% at pH 1 to pH 7.8.
2. Solubility should be greater than 0.1 ug/ml for pH 1 to pH 7.8.
3. Molecular size and weight should be less than 1000.
4. The apparent partition coefficient should be diffusion.
5. The release should not be partial by enzyme and pH.
6. General absorbability should be from all GI segments.

FACTOR AFFECTING MODIFIED RELEASE FORMULATIONS

EFFECT OF ALCOHOL

Some modified release formulations contains dynamic fixings and excipients that shows created dissolvability in ethanolic solutions contrasted with water.

GASTROINTESTINAL FUNCTION

The modified release formulation affecting gastrointestinal physiology used by co-administered with active substances.

FOOD

In oral modified release formulation the effect of food on bioavailability must be investigated in a single dose study.

UNEXPECTED RELEASE CHARACTERISTICS (E.G. DOSE DUMPING)

The active ingredient is not released suddenly from the test formulation. Due to safety issues or reduced efficacy the dose dumping can poses important risk to patients on the depending of

therapeutic indication and therapeutic index of an active ingredients.

OTHER FACTORS

In different physiological condition like pH, transit time, intake of food and food type in pediatric, vegetarian and elderly patients or in patients those taking antacids daily should be taken in to thinking especially when designing of oral once daily modified release formulations. [6]

CONCLUSION

The pharmaceutical researchers are focusing on such sort of delivery systems which provide the best therapeutic effect and reduce the associated side effects. The Modified release drug dosage forms are anatomical to release a drug at a prefix rate in order to keep a stable drug concentration for a distinct period of time with minimum side effects. At present formulations available in the market do have problems Therefore, change in the works is a convenient and improve way to make some drug more effective by small change in the drug delivery. Sustain Release is also providing hopeful way to reduce the side effect of drug by inhibit the fluctuation of the therapeutic concentration of the drug in the body. There are various causes for gracefulness of these dosage forms: supply enhanced bioavailability of drug product, lack in the reprint of administration to prolong duration of effective blood levels, reduced the instability of peak through concentration and side effects and reduction in overall healthcare costs also.

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