Research and Reviews: Drug Delivery

Drug Delivery System and its Development in 20th Century

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Opinion Article

Received: 27-Sep-2022, Manuscript No. 80821;
Editor assigned: 30-Sep2022, PreQC No. DD-22-80821(PQ);
Reviewed:14-Oct-2022, QC No. DD-22-80821;
Revised: 21-Oct-2022, Manuscript No. DD-22-80821(R);
Published: 31-Oct-2022, DOI : 10.4172/resrevdrugdeliv.6.4.003
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ABOUT THE STUDY

A rational drug therapy for most chronic disorders demands prolonged treatment regimens during which maintenance of optimal plasma concentration is a prime necessity in order to achieve a satisfactory therapeutic effect. Considering this need, continuous efforts have been made during the drug discovery to identify New Chemical Entities (NCEs) that would elicit reproducible and prolonged effective plasma levels. However, a good number of therapeutic agents and NCEs discovered is inherently short acting requiring multiple doses in a day to maintain a constant blood level, when administered as conventional or immediate release dosage forms. Such dosage forms need frequent dosing in order to maintain the plasma concentration of the drug in the therapeutic range. However, frequent dosing poses compliance issues in chronic diseases where most often the treatment would be lifelong. Considering these limitations of conventional dosage forms a number of extended release drug delivery systems have come into existence. As per the food and drug administration extended release products are those that release the drug over an extended or prolonged period of time and therefore allow reduction in the dosing frequency. These products are known to maintain a constant plasma concentration throughout a 24 hr period thereby minimizing the blood level fluctuations that are commonly encountered during the repeated administration of dosage forms. Extended release drug delivery systems are further classified into sustained release and controlled release drug delivery systems based on the pattern of drug release.

Sustained release drug delivery systems refer to any dosage forms that release the medications over an extended time period. The drug release from these systems is often concentration dependent and therefore in a slow first order way. A first order release usually refers to the release kinetics that is usually dictated by the amount of the

drug in the dosage form. These systems synonymously termed as prolonged release or time release by different manufacturers may not be able to precisely maintain a constant plasma concentration though they are able to prolong the drug release. Sustained release is the terminology that is generally confined to oral dosage forms. Representative examples of sustained release products include Isoptin, trental, Cardizem, Dilatrate and Ritalin.

Controlled release drug delivery systems are those formulations that are designed to maintain predictably constant plasma concentration that would be independent of the biological environment of application site. These systems actually maintain a steady plasma concentration over an extended time period, rather than merely extending the drug release from the dosage forms. To accomplish this, the drug release from CDD systems must invariably follow a zero order pathway. A zero order release refers to the release kinetics that is usually not affected by any physiological variable or the amount of drug in the delivery system. In such case, the in *vitro* release can be precisely used to predict the rate of release in *vivo* as the two rates typically would be the same. Oral osmotic delivery systems are CDDS containing therapeutic agents that release the drug by zero order kinetics. Contrary to SDDS, CDDS systems are designed to be administered by various routes such as perioral, transdermal ocular, intrauterine. Representative examples of controlled release systems include osmotic therapeutic systems of nifedipine, Norplant, Coreg CR, Ditropan XL, etc. The oral and transdermal systems for regulated medication delivery are first-generation technologies that were created.