

A plethora of terms are used by manufacturers, such as Sustained release, Extended release, Controlled release, Timed release, Delayed Release, Prolonged release, long acting, etc. Sustained release is again an overexploited term used to describe dosage forms that provide prolonged therapeutic action by slowly releasing the drug. Sustained-release systems are sometimes more precisely referred to as the systems in which one portion of the drug offers a bolus dose, whereas another portion of it provides a constant maintenance dose (zero-order release).

To provide some clarity in this regard, various definitions are presented as follows:

3.1. Conventional Release Dosage Form

Any dosage form of delivery system that is not modified with any of the composition or process and drug-release represents the intrinsic dissolution properties of the API. This is also known as conventional immediate-release dosage form. Such dosage form facilitates the API to release without any rate control. For example, solution, emulsion, immediate-release tablets, capsules, etc.

3.2. Modified Drug-Release Dosage Form

It is defined as the preparation in which the drug release is deliberately modified with the use of polymer, manufacturing method, coating, or encapsulation of API when compared with conventional dosage form. Modified-release formulations can be further classified as controlled release, prolonged release, and delayed release.

3.3. Prolonged-Release Dosage Form

This is one kind of modified release preparation that demonstrates the slow release of active substances for a prolonged time when compared with conventional dosage form of the same active substance. This prolonged release can be achieved by use of suitable rate-controlling polymer or specific manufacturing method. This is also known as extended or sustained drug release dosage form.

3.4. Controlled-Drug Release Dosage Form

This term is widely used as synonym of prolonged release or sustained release or extended release dosage form. However, in some cases, it was discussed very specifically with respect to the release rate of the drug from delivery systems. When the drug release is predetermined as zero order or first order with the polymeric modification or manufacturing method, then such sustained release or extended-release preparations are considered as controlled-release dosage forms.

3.5. Delayed-Drug Release Dosage Form

This is a type of modified drug release dosage form in which the preparation is deliberately modified to delay the release of active substance after oral administration or release at the specific site of the gastrointestinal tract. The objective of such preparation is to protect the active substance from the external physiological environment such as pH, enzyme, or chemical reaction. Additionally, delayed-release system can be utilized to prevent adverse event such as gastric mucosal irritation or food-drug interaction. Sometimes, such delivery system can provide effective site-specific delivery of the drug. Enteric-coated formulation and colon-targeting delivery systems are examples of delayed-drug release dosage forms. This is also known, some times, as Targeted drug release dosage form [24, 25].

Further in this chapter, an attempt is made to distinguish these systems and to have a basic idea of each mechanism. Various controlled-drug delivery systems were developed and classified based on their mechanism of drug release or site-specific delivery or their unique stimuli-responsive drug release as shown in Table 1.

4. POLYMERS USED IN CONTROLLED-RELEASE SYSTEMS

The drug release is dependent on the polymer concentrations and their properties. Polymers are now being used in almost all drug delivery systems in the pharmaceutical industry. They can be used as viscosity modifiers, binders, masking agents, stability enhancers, and of course, as the rate-controlling agents in controlled-release systems [16]. A delivery system is termed controlled when a natural or a synthetic polymer is combined with a drug in a judicious manner such that the drug is released from the system at a predetermined rate [27].

Polymers are applied in various strategies of oral drug delivery systems such as hydrophilic or erodible polymers for matrix systems, water-insoluble, or enteric polymers for membrane or reservoir systems. Also, floating and bioadhesive systems can be formulated to increase the retention time of the delivery systems in the stomach for prolonged release. Synthetic polymers are preferred over natural polymers because of their consistent quality, stability, availability, and cheaper cost [27]. The drug release from controlled-release systems can be influenced by physiological conditions, such as pH, enzymes, motility, and ions. Release rate-controlling polymers can be broadly classified into hydrophilic polymers and hydrophobic polymers based on their chemical structure and functional groups (Table 2) [28].