CHAPTER 18

Solid Oral Controlled-Release Formulations

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1. INTRODUCTION

Pharmacotherapy is defined as the treatment and prevention of illness and disease by means of drugs of chemical or biological origin [1]. But it must be realized that the therapeutic agent is only a part of the therapy, and it is the dosage form or formulation or delivery system that assists to provide the desired therapeutic efficacy and plays an important role in clinical outcomes. Drug delivery system exhibits a vital role as it controls the pharmacological effect, pharmacokinetic profile, release rate, delivery at the site of action, duration of action, and also the side effects of the drug [2].

Dosage forms can be classified based on their physical state into:

- Gaseous—anesthetics, and aerosols.
- Liquids—solution, emulsion, and suspensions.
- Semisolids—cream, ointment, gel, and paste.
- Solids—powder, granules, tablets, and capsules.

Dosage forms can also be differentiated based on the route through which they are administered, such as oral, parenteral, transdermal, sublingual, nasal, vaginal, and rectal. One of the routes is through injections or infusions (also known as parenteral). Again based on site, it can be divided into an intravenous (IV), intramuscular, subcutaneous, intradermal, and intraperitoneal. Transdermal route is another route of drug administration through the skin. However, the most important one is through the mucosal membranes. Out of all the mucosal membranes available for drug administration, the most important one is gastrointestinal that allows oral drug delivery. Hence, the solid dosage forms when administered orally are considered as "Solid Oral Drug Delivery Systems" [3].

These most commonly used pharmaceuticals, solid oral dosage forms, are cheaper and easier to manufacture than most other dosage forms. These dosage forms offer a plethora of advantages to both the manufacturer and the patients. The manufacturer avails benefits such as easy packaging, hassle-free transport, and excellent physical and chemical stability. On the other hand, solid oral dosage forms are preferred by the patients as well for their advantages in dosage administration, single-unit dose measurement, availability of different flavors, palatibility, and many more [4].

Patient convenience is one of the most important advantages of the oral route [5]. The convenience comes from the ability of self-administration that is offered by the oral dosage forms. The oral route can be utilized for the design and administration of a large variety of dosage forms suitable for all ages. Various solid oral dosage forms that have been developed include tablets, capsules, pellets, oral films, mini tablets, powders, granules, lozenges, and many more. More recently to overcome the problems, such as pill swallowing, faced by a particular group of patients, new technologies such as orally disintegrating tablets (Zydis®) and fast melting tablets (Advantol™ 300) have been introduced [6–8].

Novel technologies in solid oral dosage form have enabled the pharmaceutical researchers and manufacturers to achieve better bioavailability. Targeted drug delivery, controlled-drug delivery, and other advances have enhanced bioavailability and reduced the frequency of dosing, giving a boost to the growth of their market. The global market is predicted to grow from US$ 493.2 billion in 2017 to US$ 926.3 billion by the end of 2027, according to a report from The Express Wire [9].

A major portion of pharmaceutical research over the history was contributed to oral controlled-release formulations as the conventional dosage forms could not satisfy patient's and physician's needs completely. In many cases, conventional solid oral dosage forms are associated with some limitations such as frequent administration, dose-related side effects, shorter duration of action, high pill count, degradation of drug molecule in extreme environments of GIT, and unacceptability by pediatrics and older patients [10]. Hence, these clinical

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