Immediate-Release Tablets

Immediate-release tablets are designed to disintegrate and release their medication with no special rate-controlling features, such as special coatings and other techniques.

Rapidly Disintegrating or Dissolving Tablets

Rapid-release tablets (rapidly dissolving tablets or RDTs) are characterized by disintegrating or dissolving in the mouth within 1 minute, some within 10 seconds (e.g., Clarinex Reditabs [loratadine], Schering). Tablets of this type are designed for children and the elderly or for any patient who has difficulty in swallowing tablets. They liquefy on the tongue, and the patient swallows the liquid. A number of techniques are used to prepare these tablets, including lyophilization (e.g., Zydis, R.P. Scherer), soft direct compression (e.g., Wow-Tab, Yamanouchi Shaklee Pharma), and other methods (e.g., Quicksolv, Janssen). These tablets are prepared using very water-soluble excipients designed to wick water into the tablet for rapid disintegration or dissolution. They have the stability characteristics of other solid dosage forms.

The original fast-dissolving tablets were molded tablets for sublingual use. They generally consisted of active drug and lactose moistened with an alcohol–water mixture to form a paste. The tablets were then molded, dried, and packaged. For use, they were simply placed under the tongue to provide a rapid onset of action for drugs such as NTG. Also, they have been used for drugs that are destroyed in the gastrointestinal tract, such as testosterone, administered sublingually for absorption to minimize the first-pass effect.

These RDTs are more convenient to carry and administer than an oral liquid. They are generally packaged in cards or bubble-type packaging with each individual tablet in its own cavity. As these tablets are often soft, the backing is peeled back to reveal the tablet where it is then removed, as opposed to attempting to press the tablet through the backing material as is common with standard compressed tablets. There are no standards that define an RDT, but one possibility is dissolution in the mouth within approximately 15 seconds; anything slower would not be categorized as rapidly dissolving.

Notwithstanding these advantages, there are a number of disadvantages and difficulties associated with formulating RDTs, including drug loading, taste masking, friability, manufacturing costs, and stability of the product.

Drug loading is incorporation of the drug into the dosage form. Some RDTs are made as blanks to which a drug is postloaded, or added after the blank is made. Generally, the drug is in solution, often in an organic solvent (alcohol), and is added to the tablet, after which the solvent evaporates. It is also possible for the drug to be added as a dry powder electrostatically at this stage. Most drugs, however, are incorporated into the tablets during manufacturing.

Taste masking poses numerous challenges for RDTs. Since the drug product dissolves in the mouth, any taste of the drug must be covered, either by a flavoring technique or by microencapsulation or nanoencapsulation. The product also should not be gritty, which necessitates very small particle sizes if microencapsulation is used.

Friability is an inherent problem in RDTs. For a product to dissolve instantly, it may be quite friable. Making it more firm and less friable may increase dissolution time. A balance generally must be achieved between friability and the speed of dissolution.

Lyophilized Foam

The first entry into the RDT field was the Zydis delivery system. The tablets are prepared by foaming a mixture of gelatin, sugar or sugars, drug, and any other components and by pouring the foam into a mold. The mold also serves as the unit dose-dispensing package. The foam is lyophilized (Fig. 8.5), and the tablets in the mold are packaged. This system is the fastest disintegrating system on the market, as the tablets will dissolve on the tongue in a matter of a few seconds. One disadvantage of this method is that taste masking can be a problem, since the drug is incorporated during the formation of the tablet itself. Another difficulty is that these