encounters the surface of the tablet. Drug must dissolve and diffuse out through this gel layer. As time goes on, the gel layer gets thicker, and the diffusion path becomes longer. The data can be represented by Eq. (14.49) (Bamba et al., 1979). There is also the possibility of some "sloughing off" (i.e., erosion) of gel, and in this case the release becomes a hybrid between erosion and diffusion through increasing thickness of gel.

10. COATED TABLETS

Tablets are often film coated and, less frequently, they are sugar coated. Sugar coating, when properly applied, provides an excellent moisture and quite an adequate oxygen barrier. Film coating does the same, but not quite as effectively. For instance, vitamin A beadlets are more stable in a (properly made) coated tablet, less so (but yet quite stable) in a film coated tablet, of course provided there are no drastic incompatibilities in the core.

Film coating offers many advantages and often is the coat of preference, because (a) its application is much less labor intensive (cycle times being in hours for film coated tablets, in days for sugar coated tablets); (b) they also provide the advantage of allowing an engraving to "show through," i.e., identification requires no extra operation. On the contrary, sugar coated tablets, for identification, require a separate printing step; and (c) there is an inherent advantage in film coating in that it allows the appearance of a deep color without the use of much dye. If an uncoated tablet is colored, the dye is present throughout the tablet, whereas in a film coated tablet it is only present in the outer layer (the film itself).

Enteric coated tablets belong in the category of coated tablets and will be treated below as well.

10.1. Film Coated Tablets

Film coated tablets are produced either in a coating pan or by column coating (Wurster coating). Most coatings, nowadays, are aqueous film coats (hydroxymethyl cellulose, hydroxypropyl methylcellulose). There are several types of defects that can occur originally (orange peel effect for instance). All coatings, essentially, are such that each applied coat is not complete, so that there are overlaps, and in essence there is always an orange peel effect, except in a "good" tablet this cannot be seen. It is simply assumed in this writing, that the tablets placed on stability are not defective.

From a stability point of view there may be changes in appearance, mostly due to dislodging or rupture of the film. Sometimes these changes are first seen in the engraving. To properly record changes in appearance of the film, descriptive means can be used, but it is often a good idea to take a photomicrograph originally of all coated tablets (be they sugar or film coated). If defects show up in the coating as a function of time, then the question arises whether this is due to the formula (film and uncoated tablet) or to the way in which it was made (initial defective procedure, possibly not noticeable). Most often, these problems result in efforts in the formulation area, and recording (visually or photographically) at many intervals (3, 6, 9, 12 months) is therefore advisable. In this manner reformulation can be carried out as soon as the problem is identified.