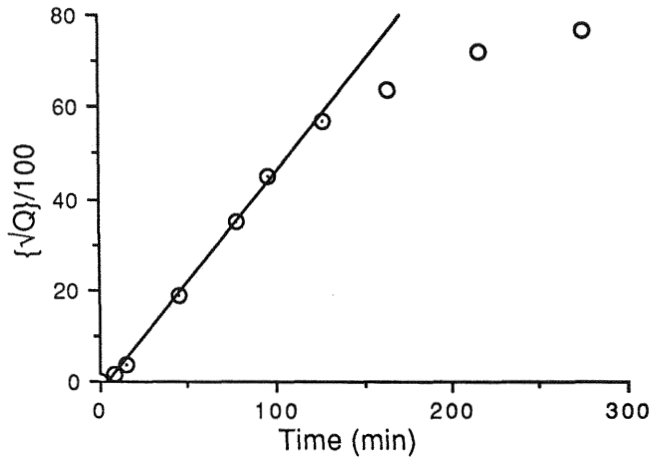

Fig. 34 Dissolution pattern in matrix dissolution. (Graph constructed from data published by Fessi et al., 1982.)

the tablets is neatly square root of time dependent as predicted by the Higuchi equation (Higuchi, 1962) shown in Eq. (10.58).

9.4. Osmotic Pump

The osmotic pump is a tablet coated with an impervious film, into which is (laser-)drilled a hole of exacting dimensions. Dissolution liquid will penetrate into the interior of the tablet, and a saturated solution will form. The excipients are chosen so that they have a given solubility and hence produce a given osmotic pressure. (The drug itself contributes to this as well.) This will be larger than the osmotic pressure in the outside liquid, and the difference between the osmotic pressure inside and outside will be the driving force by which liquid is being forced out through the hole. This gives rise to zero-order kinetics (which biopharmaceutically is an advantage), and the osmotic pump in many experimental situations, as well as in marketed situations, seems to be the dosage form that gives the most desirable release pattern, and also the one most likely to give in-vivo results that are predictable from in-vitro data. Dissolution data will therefore plot linearly, when amount released is plotted as a function of time. There may be a small nonzero (negative y-) intercept, i.e., a lag time. There will also be a point in time when there is no more solid drug inside the tablet, and deviations from linearity will occur from this point on.

There is no literature published on the stability pattern of this type of dosage form, but it is to be expected that it would be no more (and probably less) prone to change on storage than the other types mentioned.

9.5. Gel Forms

There are sustained release tablets that rely on gel-forming substances to accomplish the sustained release. In these cases the dissolution liquid will form a gel when it