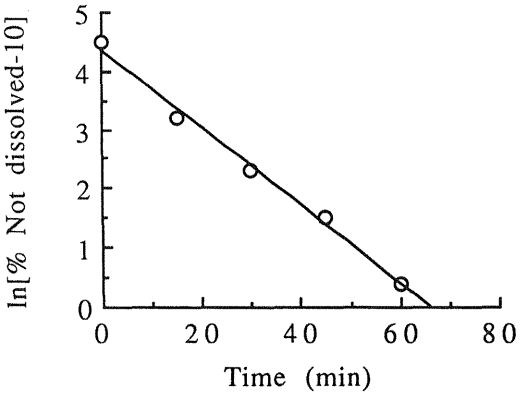

Fig. 6 The least squares fit equation is $y = 4.69 - 0.066x$ with $R^2 = 0.99$. (Graph constructed from data published by Cárdenas et al., 1994.)

antacids have high pH values, and hence hydrolysis of the esters occurs. The rationale for using several in combination is, exactly, to allow a certain amount to remain to retain preservative qualities of the suspension. An assay of the four esters and the parent acid (one of the decomposition products) in products where all occur has been described by Schieffer et al. (1984).

3.5. Dissolution of Suspensions

The 1987 Guidelines require testing of suspensions for dissolution. Cárdenas et al. (1994) have described the dissolution profiles from suspensions of benzoyl metronidazole, and a graph constructed from their published data is shown in Fig. 6. The curves should, by all rights, follow a cube root law without lag time, but they do not do so. If adjusted for amount not dissolved at the end (in the figure, 10%) they will adhere to a sigma minus plot.

3.6. Temperature Testing of Disperse Systems

A suspension is, as the name implies, a two-component system consisting of a solid and a liquid phase. (Gas phases are considered nonessential in this connection). Obviously, the solubility of the compound is a function of the temperature, and at a given temperature above 25°C this solubility will be reached. Testing about this temperature obviously has no meaning as far as suspension stability (neither physical nor chemical) is concerned. Prior to starting a program, this temperature should be established, so that unnecessary sampling stations can be avoided.

3.7. Semisolid Suspension Systems (Ointments, Suppositories)

Some semisolid systems (ointments and suppositories) are suspensions. Their testing is not different, in general philosophy, from what is described above, except that the rheology is checked differently. Davis (1987) has reviewed sophisticated means of checking the stability of such systems.