



**Fig. 12** Extrapolated decomposition curve of a solution obtained (e.g., in January 1993 after three months accelerated data) compared with the actual data accumulated in time and plotted 33 months later (i.e., in October 1995).

**Table 2.8** Data from Table 6 Plotted by the  $t_{90}$  Method

Temperature	$1000/T$	$k_1$ ( $\text{mo}^{-1}$ )	$t_{90}$ (months) <sup>a</sup>	$\ln[t_{90}]$
55°C	3.049	0.031	3.40	1.233
45°C	3.145	0.0118	8.93	2.189
37°C	3.224	0.0052	20.26	3.009

<sup>a</sup> Calculated from  $k_1$  values from the equation  $kt_{90} = -0.1054$ .

Table 8 shows the data from Tables 6 and 7 plotted by the  $t_{90}$  method. The data are shown in Fig. 13. The least squares fit equation in Fig. 13 is  $\ln[t_{90}] = -29.695 + (10.142/T)$ , and it is noted that the slope (activation energy) is the same as in Fig. 11 (where the slope is 10.153). The small difference lies in rounding off errors in calculating  $t_{90}$  from the  $k_1$  values.

The  $t_{90}$  value at room temperature is determined to be 4.072 [Eq. (2.53)]. If plotted on semilogarithmic paper, the value will emerge directly, and this type of plotting is more easily understood by those not familiar with kinetics than plots of the type in Fig. 11.

## 7.1. Cyclic Testing

One advantage of testing at higher temperatures is that it is possible to construct decomposition profiles at nonconstant temperature. It should be pointed out that extended room temperature is defined in the USP, 1990, as between 15 and 30°C but is now 15–25°C. Stability studies are usually carried out isothermally, e.g., as mentioned, at 25°C. The rationale for testing temperatures will be discussed at a later point in the book; suffice it to say at this point that a product in the marketplace will never experience an isothermal shelf history.