

**Table 17-2B** *D* Values for *Bacillus subtilis* var. *niger* Exposed to Different Sterilization Treatments

Process	Parameters	<i>D</i> value (min)
Steam	121°C	0.5
	118°C	5.0
Dry heat	250°C	5.0
Ethylene oxide	600 mg/L gas; 54°C, 60% RH	3.9
Gamma radiation	NA	0.6 kG

Original source unknown. Information obtained from Kenneth E. Avis course notes, University of Tennessee, 1980. *D* Values may no longer be accurate, but purpose of the table is to point out relative differences among sterilization treatments to the same bacterial spore destruction.

### F Value

The *F* value is the equivalent time at a given temperature that a lethal amount of sterilization is delivered to a unit of product. The *F* value is the sterilization process equivalent time and applies to steam sterilization primarily. It has been applied to dry heat sterilization kinetics, but the main emphasis of *F* value in the pharmaceutical industry has been to determine minimum and overkill cycles for terminal sterilization processes used steam.

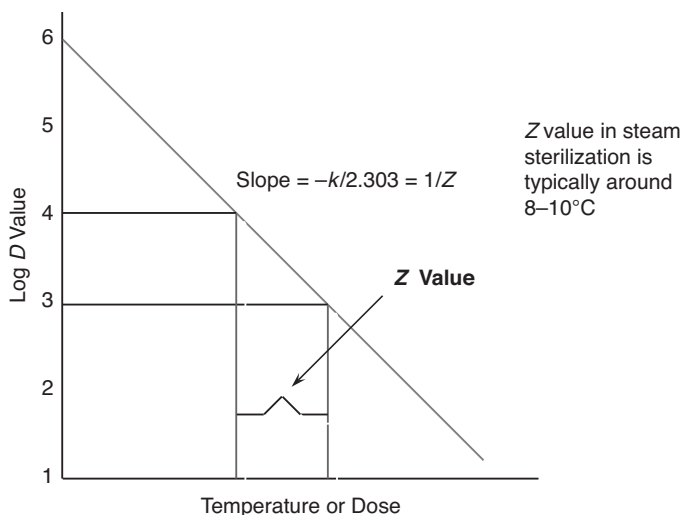
The *F* value is a convenient measure of the lethality delivered per unit time. Unlike *D* value, the *F* value term is not clock time, but "equivalent time." *F* value is a single quantitative value that relates the microbial death efficiency of a given temperature to a standard temperature known to produce microbial kill. For example, an *F* value of eight minutes means that the item being sterilized was exposed to the equivalent of eight minutes at the reference temperature (e.g., 121°C) regardless of actual temperatures attained.

*F* values are calculated according to the following thermal algorithm:

$$F = \Delta t \sum 10^{(T-T_0)/Z} \quad (\text{Equation 1})$$

where *T* is the measured temperature, *T*<sub>0</sub> is the reference temperature (e.g., 121°C), *Z* is the thermal resistance value calculated from *D* values at different temperatures, and  $\Delta t$  is the time interval between temperature determinations.

Table 17-3 and Figure 17-4 exemplify the calculation of the *F* value. Table 17-3 gives real time and temperature data with the last column being the calculation of the exponential



**Figure 17-3** Microbial resistance value (*Z* value). The *Z* value is the change in sterilization condition that affects a 10-fold (1 log) reduction in the *D* value.