



**FIGURE 17** Scanning electron micrograph of each of the freeze-dried cakes, noncollapsed (NC), micro-collapsed (MC), and collapsed (C). Magnification is 760 $\times$ .

protein activity is calculated as the percentage of the  $T_0$  activity. As expected, the activity decreases most rapidly at the higher storage temperatures. However, this loss of activity at 40°C appears to be slightly greater for the NC and MC samples than for the C samples. At the lower storage temperatures, the loss of activity appears to be slightly greater in the C samples than in the MC or NC samples after the 18 month storage time point.

The results of this study suggest that collapse is not necessarily detrimental to either the activity or stability of freeze-dried protein. Particularly, data support the hypothesis that the more aggressive, shorter primary drying cycle permitted by the MC cycle does not compromise the stability of the protein product. The similarity between the results of the stabilities of the samples lyophilized by the NC and MC cycles indicates that using the more aggressive cycle is not harmful to the protein. This is important because it permits a more efficient freeze-drying cycle to be used, without decreasing the stability of the protein. However, it is important to point out that such a conclusion may only