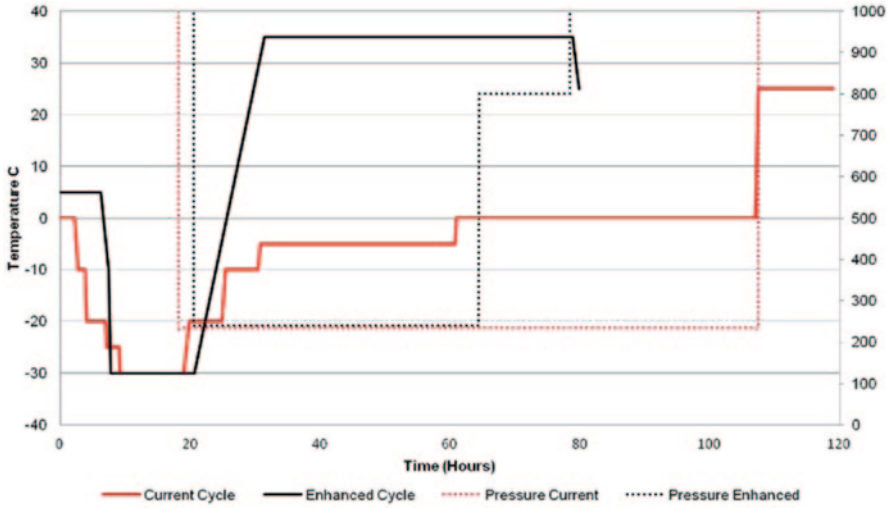

Fig. 9 Vancomycin HCl 10 g/vial cycle comparison

proposed to determine if controlled nucleation could mitigate the factors causing breakage allowing a more aggressive, shorter freeze-drying cycle. Figure 9 outlines the cycle parameters. As in the earlier trials, identical numbers of units were used and filled under the class B conditions. Table 4 summarizes the findings.

Human Serum Albumin (HSA) Used as a surrogate for a protein formulation, a nucleation evaluation was conducted along with an evaluation of tubing versus molded glass vials. This particular product cycle included an annealing step, which is designed to accomplish much the same phenomenon as controlled nucleation, which is to create large ice crystals to allow faster mass flow of water vapor through the product matrix during drying. In this study, both molded and tubing vials were processed in one of two cycles. The first cycle with natural nucleation and annealing, and the second cycle with controlled nucleation and annealing.

Figure 10 displays the average thermocouple traces during drying. The data imply that for tubing vials, annealing combined with controlled nucleation has no perceived benefit from annealing following natural nucleation. Of course, the time spent on the annealing step could be saved by using controlled nucleation only. For the tubing vials, the data indicate that due to more inefficient vial heat transfer, annealing is not as effective, and controlled nucleation provides a significant benefit in cycle time reduction.

Monoclonal Antibody Monoclonal antibodies (mAbs) therapies are a being developed by a large number of firms and appear to be one of the leading growth product segments for years to come [3]. A study was proposed to see if a model mAbs product could benefit from ice-fog nucleation. Factors tested were cycle time reduction, surface area reduction, and reconstitution.