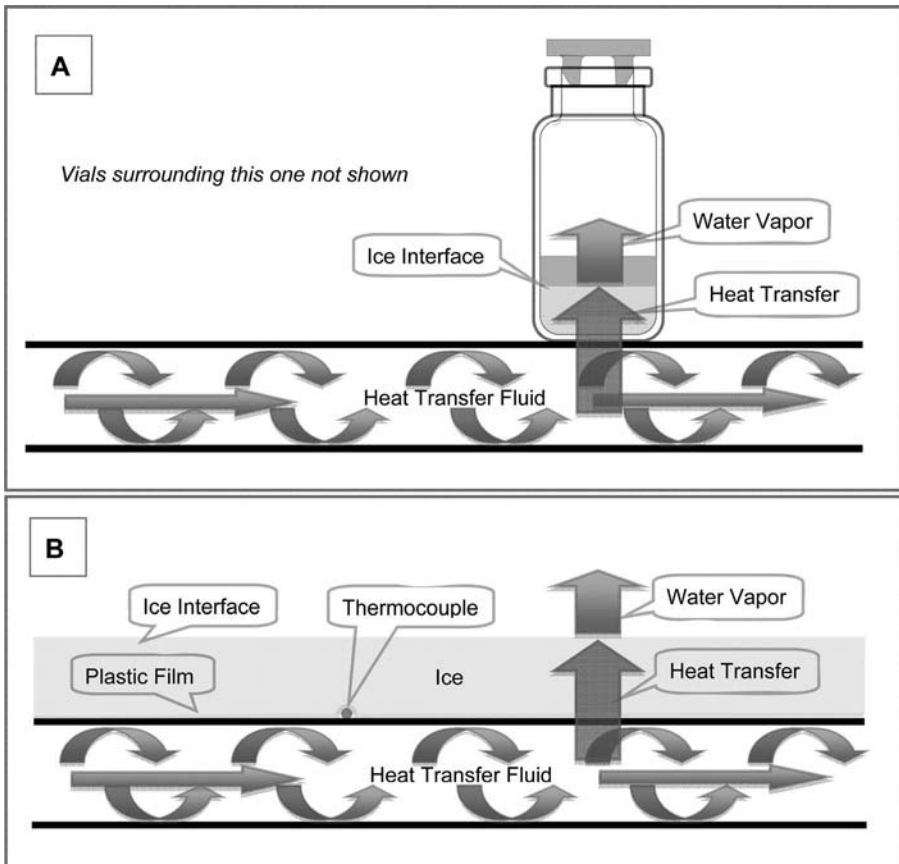


individual shelf results represents the maximum supportable sublimation rate at that chamber pressure (the average chamber pressure over the six-hour hold).

Run part B over the desired chamber pressure range—usually 100, 200, and 300 mTorr. Plot each freeze-dryer's results as a different series, with the measured sublimation rate on the  $y$ -axis, and average chamber pressure for the six-hour hold on the  $x$ -axis. This will enable comparison of the capabilities of all freeze-dryers tested.

### CALCULATING SHELF HEAT TRANSFER COEFFICIENTS

In the freeze-drying of pharmaceutical and biological products, an aqueous solution is filled into vials, or sometimes trays, for drying. For freeze-dryer capacity testing discussed above, tray rings lined with plastic film are used to create a 2.5-cm deep ice slab on the top of each shelf. The heat and mass transfer paths for these are shown in Figure 3. Comparing panels A and B of the figure,



**FIGURE 3** Heat transfer pathways from the bulk heat transfer fluid in a shelf to the ice interface (A) for product loaded in vials and (B) for ice slab studies. The heat transfer pathway from the bulk heat transfer fluid in a shelf to the top of the shelf surface is the same for both cases, therefore the heat transfer coefficient calculated from ice slab studies using data from a thermocouple under the plastic film applies regardless of trays or vials or ice slabs.