

Fig. 10 GORE® LYOGUARD® trays as loaded for a freeze-drying cycle. (Courtesy W. L. Gore & Associates, Inc., Elkton, MD, USA; GORE, LYOGUARD and designs are trademarks of W.L. Gore & Associates)



can be effectively used for product containment and prevent product loss post the drying cycle. Gassler and Rey describe some of the unique design features of the GORE® LYOGUARD® trays, present a detailed performance evaluation of the GORE® LYOGUARD® trays and also highlight the advantages of using GORE® LYOGUARD® trays in bulk freeze-drying processes [13].

The GORE® LYOGUARD® trays (Figs. 9 and 10) consist of a polypropylene frame, the bottom of the tray is a thin, flexible film with the product contact layer (inner side) made of polypropylene. The top surface of the tray comprises a GORE-TEX® expanded polytetrafluoroethylene (ePTFE) membrane permeable to water vapor. The tray is also provided with a filling port which can be secured by a screw cap. This filling port permits easy filling and unloading of the tray.

Gassler and Rey describe the evaluation of GORE® LYOGUARD® trays with regards to three aspects: (i) freezing and heating temperature profiles of the tray (heat transfer); (ii) mass transfer resistance for the upper membrane barrier (effect on primary drying); and (ii) effectiveness of the upper membrane barrier [13]. The findings suggest that GORE® LYOGUARD® trays permit better heat transfer compared to the stainless steel open trays. Furthermore, the GORE-TEX® membrane exerted negligible resistance for drying of 5% mannitol solution. Their findings also suggested that the primary drying time for a typical product could be reduced when using GORE® LYOGUARD® tray compared to stainless steel trays. Finally, the authors recommend a thorough evaluation of the product-specific heat and mass transfer characteristics of the GORE® LYOGUARD® tray before any process modifications or transfers.

Mayeresse et al. describe the successful transfer of a bulk freeze-drying process from a glass container to a GORE® LYOGUARD® tray utilizing a robust process validation approach. The investigators designed two optimized lyophilization cycles (namely A and B) using the GORE® LYOGUARD® trays. The transferred process was deemed feasible and profitable with regards to freeze-drying capacity; however, detailed evaluation of container compatibility and estimation of the heat and mass transfer properties for both container types (glass vial and GORE®