



FIGURE 5 Mass flow rate versus condenser and chamber pressures for a typical valve/duct (DN 700) used in industrial freeze-dryers (*top*); contour plots of absolute pressure (Pa) and Mach number (dimensionless) under critical conditions (*bottom*). By permission of Telstar, Terrassa, Spain.

Great care must be paid to the possibility of choking flow in the duct connecting chamber and condenser, mainly due to the presence of the valve. In fact, due to the very low pressure values (and therefore very high water vapor velocities), critical sonic flow conditions may be encountered. The diameter and length of the duct, as well as the geometry of the isolating valve, must be properly designed to guarantee under a wide range of operating conditions that the desired sublimation rate is evacuated. Figure 5 reports the mass flow rate as a function of condenser and chamber pressures, for a specific case. As the pressure difference increases critical flow conditions are reached, resulting in a maximum flow rate, known as critical flow rate; it must be noted anyway that the flow rate in critical conditions increases with pressure in the chamber because this affects the static density of the fluid. This critical flow rate depends only on the chemical nature of the vapor and the length-to-diameter ratio of the duct or the equivalent length-to-diameter ratio of the isolating valve. Typical values for water vapor are reported in the figure.

RECIPE DEVELOPMENT

A freeze-drying cycle for a given formulation containing an API is generally specified as a sequence of values of shelf temperature and chamber pressure that allows obtaining the product with acceptable quality. The design of such recipe