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Lyophilization of pharmaceuticals using a rack system

Fiora Artusio[1], Marco Adami[2], Antonello A. Barresi[1], Davide Fissore[1], Maria Chiara Frare[3], Francesco Zanetti[3], Claudia Iuliana Udrescu[1], Gabriele Zunino[1], Roberto Pisano[1]

[1]Department of Applied Science and Technology, Politecnico di Torino, 24 corso Duca degli Abruzzi, IT-10129, Torino, Italy
[2]Independent Consultant, IT-20100, Milano, Italy
[3]Stevanato Group, 17 via Molinella, Piombino Dese, IT-35017, Italy

Corresponding authors: fiora.artusio@polito.it; roberto.pisano@polito.it

PURPOSE

The minimization of downtime is a common practice to increase the productivity of pharmaceutical manufacturing processes. At the same time, guaranteeing aseptic conditions during handling and filling of vials is crucial[1]. For this purpose, vials can be used as shipped from the manufacturer, i.e., in their sterile secondary packaging. The present study addresses how a rack system can impact the lyophilization process.

METHODS

The experiments were conducted using a 5 wt% sucrose solution and a lab-scale freeze-dryer (Revo, Millrock Technology, Kingston, New York, USA). Tubing vials (2R ISO, Stevanato Group, Piombino Dese, Italy) were either loaded directly on the shelf or nested in a rack system packaging (SG EZ-fill® Nest, Stevanato Group, Piombino Dese, Italy).

RESULTS

The loading configuration had a strong impact on the freezing conditions[2]. In the case of the rack system, vials tended to nucleate at higher temperatures because of the slower cooling experienced by vials nested in the rack system, compared to vials in direct contact with the shelf. Consequently, the product morphology displays larger pores and surface area. During primary drying, the loading configuration also affects the heat transfer efficiency, especially at high pressures, e.g., 20 or 30 Pa. This result is a consequence of the reduced contribution of gas conduction in the rack system configuration as vials are slightly raised above the shelf.

CONCLUSION

When developing a freeze-drying cycle using a rack system, the different freezing and drying behavior of vials have to be taken into account as they affect product morphology and primary drying time. The formation of larger pores in the case of vials nested in the rack system is interesting for all active molecules that are sensitive to denaturation at the ice-water interface.

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