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Characterization of mechanical properties of freeze-dried cake in vial: application for Pharmaceutical formulation development

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Freeze-drying (FD), or lyophilisation, is a standard commonly used method for the production of long-term stable solid products. The most frequently used containers for freeze-drying are glass vials and blister packs. The aim of this study was to develop and optimize a Texture Analysis (TA) technique to study the compressive mechanical properties of FD cakes directly in glass vials using a standard commercially available texture analyser. Examining the cakes in glass vials has many advantages as it allows studying the intact FD cakes minimizing the bias from texture distortion during samples preparation, and reducing the moisture uptake. The mechanical properties of the FD cakes can provide valuable information on the strength and susceptibility to breakage of the FD cakes, in particular, when developing the formulation for the orally disintegrating tablets. Besides, analysis of the mechanical properties and the texture of the FD cakes can help improve the freeze-drying protocols as the properties of FD cakes (in particular, the pore size and the wall thickness of FD solids) depend on the FD cycle parameters. The application of a standard texture analysis (TA) technique to study the mechanical properties of the freeze-dried cakes directly in glass vials used for freeze-drying has been demonstrated. A procedure allowing quantitative assessment of the strength, fracturability, and elastic properties of the FD cakes using TA has been developed. The results show that the TA method is sensitive to the variations in cake materials, storage conditions (temperature, excessive moisture), and cake quality. The results also show that TA can also be applied for optimization and improvement of the freeze-drying protocols and rapid disintegrating tablet formulation development.

Biography

Irina Ermolina obtained her PhD degree in molecular physics and after 15 years of work in biophysics she expanded her interests into the pharmaceutical science. After post-doc positions at University of Jerusalem and University of Glasgow she got a senior lectureship at De Montfort University, UK. Irina Ermolina has her expertise in Pharmaceutical and Biological Materials Science (especially, amorphous materials); Drug Delivery Systems (hydrogels); Process Analytical Technologies for Pharmaceutical Manufacture (esp. Freeze-Drying and Roller Compaction); and different analytical techniques (Dielectric Relaxation Spectroscopy, Terahertz Imaging and Terahertz Spectroscopy, Thermoanalytical methods). She has published 48 articles and book chapters.

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