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Lyophilized Drug Product Cake Appearance: What Is Acceptable?

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Abstract

Cake appearance is an important attribute of freeze-dried products, which may or may not be critical with respect to product quality (i.e., safety and efficacy). Striving for "uniform and elegant" cake appearance may continue to remain an important goal during the design and development of a lyophilized drug product. However, "sometimes" a non-ideal cake appearance has no impact on product quality and is an inherent characteristic of the product (due to formulation, drug product presentation, and freeze-drying process). This commentary provides a summary of challenges related to visual appearance testing of freeze-dried products, particularly on how to judge the criticality of cake appearance. Furthermore, a harmonized nomenclature and description for variations in cake appearance from the ideal expectation of uniform and elegant is provided, including representative images. Finally, a science and risk-based approach is discussed on establishing acceptance criteria for cake appearance.

Keywords: amorphous; drying; formulation; freeze drying; glass transition; lyophilization; processing; protein formulation; stability.

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