



Methods for Evaluating Lyophilized Product in a Laboratory Setting

ABSTRACT:

Physical appearance of a lyophilized product can provide significant insight into the attributes of a product and relative effects of processing. Developing a detailed cake description during the development of a lyophilized product is important in order to discern subtle differences with regards to formulation variations, product designs, processing variables, and the impact of scale-up activities on product appearance. Cake descriptions also present an opportunity to compare physical characteristics, which can provide determination of vial to vial and batch to batch uniformity during the product development process.

A thorough cake description should include, at minimum, color, macroscopic and microscopic structure, and texture of the lyophilized product. Developing a standard method for evaluating lyophilized product in a laboratory setting allows for uniformity in cake descriptions. Photographs are used in conjunction with, and not as a substitute for, a detailed written description thereby providing continuity throughout the development process. It will be from the development cake description that a manufacturing inspection standard may eventually be developed.