

Measurement of final container residual moisture in freeze-dried biological products.

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The Center for Biologics Evaluation and Research has changed its regulations pertaining to residual moisture in freeze-dried biological products as published in Title 21 of the Code of Federal Regulations for Food and Drugs. The new regulation requires that each lot of dried product be tested for residual moisture and meet and not exceed established limits as specified by an approved method on file in the product license application. The gravimetric or loss-on-drying method is no longer listed as the required method; the 1.0% moisture limit is no longer specifically stated in the regulation. These revisions were made to bring the regulation into line with changes in residual moisture testing methods and the results obtained when new testing methods were applied to the determination of residual moisture. This is illustrated with data for Measles Virus Vaccine Live and Haemophilus b Polysaccharide Vaccine using final container residual moisture test results obtained by the gravimetric, coulometric Karl Fischer, thermogravimetric and thermogravimetric/mass spectrometric methods. Guidelines for the determination of residual moisture in dried biological products have been issued to describe residual moisture test methods and procedures used to set product residual moisture limits. For most products levels of residual moisture should be low, usually from less than 1.0% to 3.0%, so that the viability, immunologic potency and therefore the stability of the product is not compromised over time.