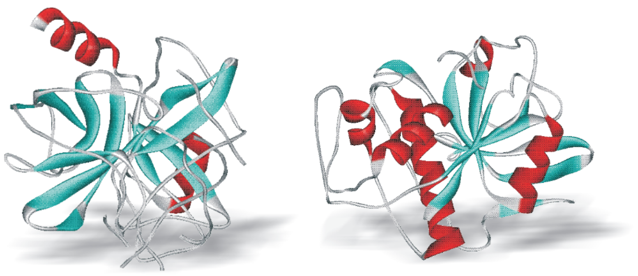
BioPharmaceutical Formulation

Spring 2011

ACCELERATE YOUR DEVELOPMENT OF STABLE PROTEIN FORMULATION WITH PROTA

THE PROBLEM

Formulation of protein-based drugs often requires processes such as lyophilization or spray-drying. However, it has been shown that the freezing and drying steps involved in lyophilization could lead to protein unfolding. This unfolding of the native structure leads to an incomplete recovery of activity and results in aggregation and poor storage stability. These problems are often discerned through tedious and time-consuming measurements of activity or through detailed structure analysis. New and faster analytical techniques are needed in order to accelerate the development of protein formulation.



THE TECHNOLOGY

Infrared (IR) spectroscopy has widely proven to be a fast, cost-effective, accurate and reliable technique to determine secondary structure of a protein or to follow structural changes with perturbations like formulation. Amide I IR bands are a direct probe of the protein structure. Sample preparation is minimal and results can be obtained in less than half an hour with concentrations as low as 0.1-3mg/ml.

IR spectroscopy is the only spectroscopic technique that can be used for analysis of solids, such as lyophilized powders. Powder, fibrils, KBr disks, mulls or any other formulation can be used for study with FTIR. The use of the same technique provides a direct comparison between the native and the formulated protein.

THE SOLUTION

The PROTA Analyzer features dedicated software for protein analysis. Its data analysis function provides the necessary tools to quickly evaluate the structural differences between native and formulated proteins. This can be accomplished using the integrated formulation algorithm developed by Prof. John Carpenter, of the University of Colorado, or through the quantitative determination of structure using the built-in spectral database. This database includes the FT-IR spectra of 50 proteins with known secondary structure, and was acquired under strictly controlled conditions that match the crystallographic conditions. PROTA's database is the largest commercial protein IR database available.

LEADERS CHOOSE PROTA... LET US SHOW YOU WHY!

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- Pfizer
- Regeneron
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