

DEVELOPMENTS AND APPLICATIONS OF CHEMICAL CHARACTERIZATION OF BIOPHARMACEUTICALS

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Abstract

I. The aim of the study: Understanding the behaviour and function of biomolecules at the molecular level is the key to the discovery and development of new drugs, as well as diagnostic techniques. The characterization of biological drugs, where therapeutic monoclonal antibodies (mAbs) are placed, poses many challenges compared to those of low-molecular mass drugs because of their inherent complexity due to their protein nature. Achievements in this field of science have changed the way that drugs are being designed and developed nowadays.

II. Materials and methods: Vibrational spectroscopy techniques, like Fourier Transform Infrared (FTIR) Spectroscopy and Raman Spectroscopy (RS) have been applied and helped to determine the secondary structure and possible interactions and modifications of complex protein molecules, as well as protein-ligand complexes.

III. Results: Our investigation has demonstrated the use of these tools to understand protein-ligand interactions in important immune-complexes with previously no available structural information.

IV. Conclusion: The approach presented here has significant potential for analyzing the structure, stability and possible toxicity of biotherapeutics as well as any other biological molecules which are used as therapeutic/diagnostic agents.