**Title:** CONFORMATIONAL CHARACTERIZATION OF IL-2 MUTEIN BY CIRCULAR DICHROISM AND FLORESCENCE: ITS UTILITY FOR THE INDUSTRY.

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**Abstract**

Circular dichroism and fluorescence spectroscopy are used in the biopharmaceutical industry to study the effects of manufacturing, storage and comparability conditions on protein conformation and stability. These results are often included in the regulatory files. At the Center of Molecular Immunology, a Cuban biotechnology industry, these methodologies have allowed the characterization of the conformational features of products under development, such as mIL2, a mutant of interleukin-2 for the treatment of melanoma and renal cancer. This product has 165 amino acids and a molecular weight of 18.3 kDa. Different batches of mIL2 were included to assess the consistency of the productive process. All lots showed similar features of secondary structure as determined by far-ultraviolet circular dichroism spectroscopy. The bands in the near ultraviolet circular dichroism spectra, which reflect the aromatic residues absorption suggest different three-dimensional folding. Besides, these lots showed different position of the emission maxima and spectral profile by fluorescence, upon selective excitation of Trp residues and Trp/Tyr. For this reason, the differences observed for batches of final product and active pharmaceutical ingredient in this process have an impact on their biological activity. Here we discuss the relationship between the spectroscopic response in different situations and biological activity. The evaluation of the conformational characteristics of proteins by orthogonal methodologies widely described in the state of the art: circular dichroism and fluorescence, and their possible impact on biological function is very useful for the biotechnology industry.

**Keywords:** circular dichroism, fluorescence, mIL2 and conformational characterization.