Study of Recombinant Human Interferon-a Presents in Therapeutics Formulations

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Interferons (INFs) were the first cytokines' family discovery, with at least 23 species of structurally similar proteins. Since 1980, have been produced by genetic engineering, and their products have been isolated in a very pure form with specific activity about 1 to 2 x 10^8 international units per miligram. Today, IFNs are used for the treatment of a variety of malignancies and viral diseases like hepatitis, some kinds of tumors, and autoimmune diseases. The aim of this study is to develop a methodology to isolate the INF-α (MW 19,000) from the excipients presents in the formulation, thereafter, the molecular characterization structure will be performed. One of these excipients, is Human serum albumin (HSA) (MW 66,000). HSA is present in the proportion of tenfold to INF. This is a problem for INF-α characterization of the in the final product. The two proteins were isolated employed molecular exclusion chromatography, due to difference on the molecular mass. Different columns and mobile phases were experimented, to make possible the best chromatographic separation. High homogeneity got in the INF-α fraction was verified by SDS-PAGE, became possible the analysis by mass spectrometry. Three-dimensional INF-α structure was accomplished by fluorescence and no degradation was observed, during the chromatography process. This suggests that no artifacts were formed during separation.

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