A conjugate proteomic approach for the structural and functional analysis of erythropoietin alpha and its biosimilars

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Biotechnology products constitute an increasing part of medicines available for patients today. The patents for many of these biotechnologies have expired or are about to expire, creating the difficulty of analyzing new non-innovator drugs with fast and economic techniques.
We propose a useful quality control system for a rapid primary screening of potential biosimilar drugs. For this purpose, the comparison of three commercially available epoetins have been discussed.
In particular, the HPLC has been used to perform qualitative and quantitative analyses. MALDI-TOF-MS and 2D-PAGE has been employed for the identification of proteins and the separation of isoforms, respectively.
Furthermore, the biological activity of these drugs has been studied both in vitro, evaluating the TF-1 cell proliferation rate; and in vivo, using the innovative experimental animal model of the zebrafish embryos.
In our research, we firstly developed an economic and reliable approach for a direct comparison of biotechnology drugs with their respective biosimilars (Figure 1).

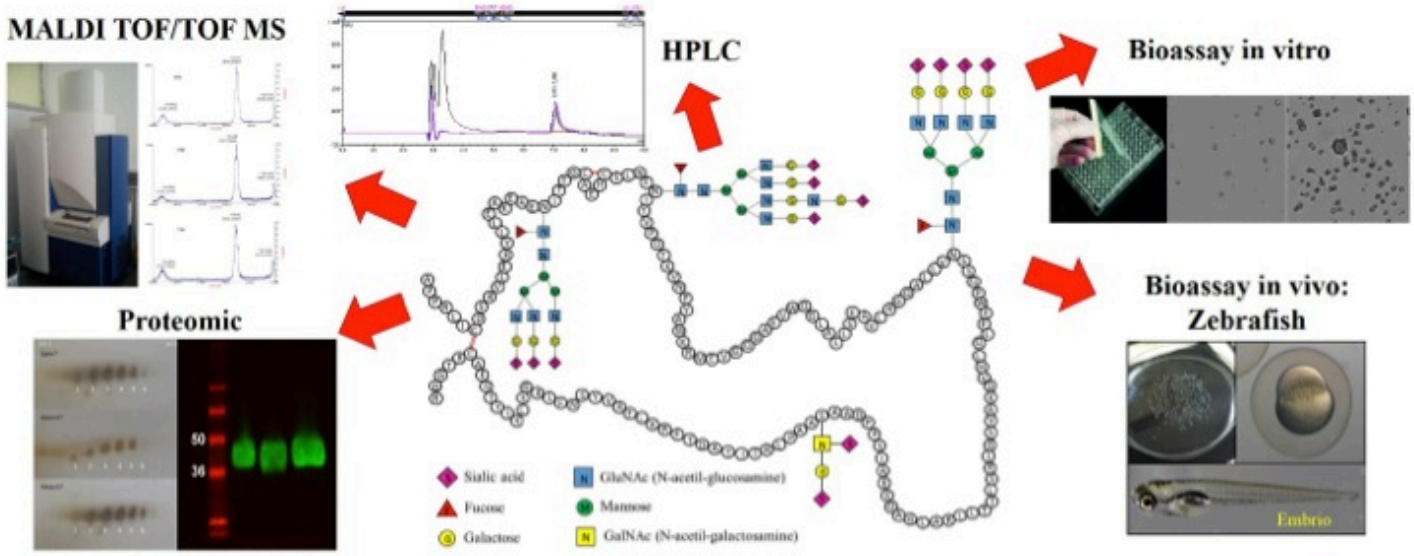

Figure 1:Workflow