

Rapid Communication

Purification and Characterization of Bioactive Proteins of Biomedical Interest for Production of Drugs, Biopharmaceuticals and Vaccines for Human Use

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Received: August 22, 2014; **Accepted:** August 22, 2014; **Published:** August 25, 2014

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The purification in HPLC (High Performance Liquid Chromatography) or UPLC (Ultra Performance Liquid Chromatography) systems, and characterization of bioactive proteins, monoclonal antibodies and Active Pharmaceutical Ingredient (API) of biomedical interest for the production of pharmaceuticals, biopharmaceuticals, and vaccines for human health, are essential and highly important steps ensuring that a protein of biomedical interest and Active Pharmaceutical Ingredient (API) retain their initial active and unchanged biological state at the end of purification in HPLC systems.

Bioactive proteins and API of biomedical interest, once purified and characterized, must meet the required quality for production of diagnostic kits, including and especially for application in human health in the form of vaccines or biopharmaceuticals, and yet further analyzed under international reference preparations. Whereas costs and revenues are assessed from the view-point of industrial and pharmaceutical as well as the highest therapeutic interest and value.

Bioactive proteins of biomedical interest can be obtained from extracts of diverse flora and fauna, such as the hemolymph from *Lonomia obliqua* caterpillar [1]. Also, API may be produced by cultivation of genetically modified mammalian and insect cells [2]. An example is the actual vaccine against Human Papilloma Virus (HPV) - cause of cervical cancer - produced using Sf9 insect cell line.

Other examples of biopharmaceuticals of high clinical medical interest are the recombinant hormones hTSH (thyroid stimulating) and hPRL (Prolactin) produced in cell cultures from genetically engineered Chinese Hamster Ovary (CHO) cells. Once duly purified and characterized in HPLC systems, the hTSH is already used in the treatment of thyroid cancer, while the hPRL can be used

not only in breast cancer therapy but also as immunoregulatory, immunoprotective and anti-stress (hPRL) factors. From a functional standpoint, the hTSH is used in the diagnosis and treatment of thyroid cancer - with about 17,000 new cases per year in the USA [3]. For that, studies in purification and characterization of possible glycosylated, phosphorylated and cleaved isoforms had been performed to obtain yields strong enough to attract industrial and pharmaceutical interests [4].

Some studies in purification, identification and characterization of proteins with biomedical interest using HPLC systems have demonstrated the presence of pharmacologically active substances in the hemolymphs of insects [1,5,6].

It is still of notice that the standardization of the purification process of extracts in the hemolymphs of insects or supernatant cell cultures is not as trivial the it may seem at first because several and different chromatographic columns are used until the successful outcome of the purified protein is reached. However, at the end of the purification process in HPLC, the protein must have its biological activity intact.

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