

**ONE-STEP PURIFICATION OF RECOMBINANT HUMAN GROWTH HORMONE (REC-HGH) DIRECTLY FROM BACTERIAL OSMOTIC SHOCK FLUIDS FOR THE PURPOSE OF RADIOIMMUNOASSAY (RIA) TRACER PREPARATION**

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A good quality tracer, to be used in the RIA of human growth hormone, was prepared applying the classical chloramine T iodination technique to the product of a single step purification, by high performance size exclusion chromatography (HPSEC), of bacterial osmotic shock fluids. Preparative osmotic shock-HPSEC was carried out as previously described (Dalmora et al. J. Chromatogr. A 1997; 782:199) on bacterial fluids that contain approximately 250 µg/ml of rec-hGH.

A labelling yield of 60% and an antibody binding of 40% (antiserum dilution 1:300,000) were obtained. When applied to RIA determinations the new type of tracer presented a perfectly acceptable precision and accuracy, the assay being validated by the use of National Institute of Health (NIH, Bethesda, MD, USA) standard reagents and of well known commercial quality control samples (Dade Tri-levels, Baxter Diagnostic, Deerfield, IL, USA). A control tracer, derived from the same osmotic shock which was submitted to the regular purification process, showed a similar RIA performance but a higher labelling yield (88%) and antibody binding (61%). The performance of both tracer was followed for up to two months, a lower stability having unfortunately been detected for the new type of tracer. Studies are in progress in order to identify and eliminate the cause of this instability, thus being able to utilize this new source of freshly prepared, radioiodination grade hGH.

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