

PHYSICO-CHEMICAL STUDY ON THE FIRST INTERNATIONAL STANDARD OF RECOMBINANT HUMAN PROLACTIN, CARRIED OUT AT IPEN-CNEN/SP IN COLLABORATION WITH WHO

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Our laboratory is carrying out an International Collaborative Study with the World Health Organization (WHO), for the definition of the First International Standard of Recombinant Human Prolactin (*rec-hPRL*), having offered to give particular emphasis to physico-chemical characterization of the lyophilized preparations. These are the Recombinant-hPRL International Standard (WHO 97/714), Glycosylated (WHO 98/580) and Non-Glycosylated (WHO 98/582) hPRL and a Chemical Reference Standard (hPRL-CRS) more specifically prepared for physico-chemical studies, which was first provided in solution.

A novel reversed-phase high performance liquid chromatography (RP-HPLC) methodology, already set up in our laboratory, has been used for the qualitative and quantitative analysis of the different samples, with basis on their different hydrophobic properties. Isoforms with different hydrophobicity have been detected in all samples and especially in hPRL-CRS, which had been sent from London (UK) in solution and at room temperature. These data, which have been compared to the classical high performance size exclusion chromatography (HPSEC) and SDS-PAGE analysis, indicate good stability and reproducibility of the three lyophilized samples, that can thus be properly used as International Reference Preparations for qualitative and quantitative purposes, not only for immunoassays and bioassays but also for physico-chemical assays.

Supported by FAPESP (São Paulo), IAEA (Vienna) and CNPq (Brasília) and WHO.