Physico-Chemical Quality Control of Human Chorionic Gonadotropin Preparations

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Physico-chemical quality control, by reversed-phase high-performance liquid chromatography (RP-HPLC), was shown to be an important tool for ensuring the identity and efficacy of pharmaceutical preparations of human chorionic gonadotropin (hCG). An inter-comparison between different chemically purified preparations of hCG of urinary and recombinant origin was carried out in this study. Three homogeneous preparations were analyzed: the International Standard of urinary-hCG (WHO 75/589) and two commercial preparations, one urinary-derived and the other obtained by DNA recombinant techniques. The latter was the purest preparation under analysis (data also confirmed by high-performance size-exclusion chromatography), Concerning their RP-HPLC retention time (t_R), the hCG preparations of different origin presented t_R values practically coincident (0.08 min or 0.2% difference in 4 assays), a mean value of 36.7 ± 0.043 min being observed for these preparations. The hCG α- and β-subunits, prepared in our laboratory by acetic acid treatment, were also analyzed, the heterodimer and subunit forms migrating with significant different t_R ($p<0.001$), in the following order of increasing hydrophobicity: α-hCG < hCG < β-hCG. The hCG contents of these preparations were also determined using a dose-response curve previously set up: $Y_{au}= 959.4\ X_{\mu g} - 27.6$ ($r=0.9999$; $p<0.001$; $n=20$).

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