Characterization of a New Commercial AHF Preparation of High Purity: Factorate Generation II

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Most commercial factor VIII concentrates available for haemophilia A therapy today are of intermediate purity, have potencies varying from 10 to 40 units/ml and specific activities varying from about 0.5 to 1 unit/mg of total protein. A new anti-haemophilic factor (human) concentrate, Factorate Generation II, with a potency of 30–45 units/ml and a purity of 3–4 AHF units/mg of total protein is described. Data are presented, which compare this new concentrate to other commercial products.

Although it has previously been speculated that factor VIII concentrates of high purity would show decreased solution stability, we have seen improved stability, for the Factorate Generation II in vitro half-life was shown to be about 88 days at room temperature, markedly more stable than the less purified preparations. A European preparation with no remaining fibrinogen showed the worst stability and may indicate a functional role for fibrinogen in conferring AHF stability in solution.

In addition to improved solution factor VIII stability, Factorate Generation II has very low levels of cold-insoluble globulin and lower concentrations of contaminating IgG than the other preparations and may therefore contribute to fewer transfusion reactions. The preparation has a low concentration of glycine, approaches isotonic osmolarity (in contrast to other preparations which are 2- to 3-fold hypertonic) and appears to have approximately a 1:1 ratio of factor VIII coagulant antigen and factor VIII:C according to Nilsson et al.