Intermediate Purity Factor VIII Production Utilizing a Cold-Insoluble Globulin Technique

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An intermediate purity Factor VIII concentrate which can be made in the blood bank is obtained by combining the techniques of cryoprecipitation with the cold precipitation step for cold-insoluble globulin. Addition of 1 U/ml of heparin to fresh plasma prior to cryoprecipitation markedly enhances the yield of Factor VIII in the cryo-precipitate. Average Factor VIII recovery is 85% with 3 g/dl of protein. Following removal of the cryosupernatant, the cryo-precipitate was resuspended in a citrate-heparin buffer and subjected to cold precipitation at 0°C for 2 h. The resultant cold-insoluble globulin precipitate contained 66% of the Factor VIII and less than 1% of the starting protein, presenting a specific activity of $0.85 \text{ U} \pm 0.07/\text{mg}$ of protein. The final recovery for this process averages 660 U/l of plasma. Following lyophilization, the product is stable at 4 °C and when reconstituted, goes easily into solution and retains its activity for at least 2 h. Further, by using pools of plasma obtained from plas-mapheresis donors it is possible to produce this intermediate potency lyophilized product from a small number of donors thereby reducing the exposure of the haemophiliac to hepatitis virus.