

Properties of a new fibrin glue stable in liquid state.

Authors: Chabbat J., Tellier M., Porte P., Steinbuch M.

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Abstract:

A pasteurized preparation of fibrin glue composed of two separate stable, liquid components: highly purified human thrombin and fibrinogen concentrate is described. The components are mixed extemporaneously during application. Thrombin was prepared using a prothrombin complex concentrate as starting material which was activated by calcification and then heated in solution during 10 hours at 60degreeC in the presence of stabilizers. The isolation of thrombin was carried out using a column of benzamidine-Sepharose 6B. The eluate contained thrombin with a high degree of purity (more than 95% assessed by SDS-PAGE) with a specific activity > 2,500 IU/mg protein. The purified liquid thrombin preparation remained stable for at least 6 months. The fibrinogen concentrate was prepared from cryoprecipitate after removal of factor VIII and then virally inactivated by pasteurization in the presence of glucose and sorbitol. After purification the concentrate containing a high level of fibrinogen was formulated with urea 0.5 M or arginine 5% before conditioning. Both components of the fibrin glue kept its biological properties for more than 6 months at +4degreeC.