

Recombinant Human Antihemophilic Factor VIIa

Certificate of Analysis and Data Sheet

➤ Source: BHK cells	➤ Catalog No. PRO-331
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➤ **Background :**

Human coagulation factor VII is a single chain protease that circulates in the blood as a weakly active zymogen at concentrations of approximately 10 nmol/L. When converted to the active 2 chain form (VIIa), it is a powerful initiator of hemostasis. Recombinant Factor VIIa is a unique hemostatic agent with potential for broad-spectrum applications in bleeding patients with congenital and acquired bleeding abnormalities. At present, recombinant Factor VIIa is only approved for the treatment of hemophilia A and B patients who have acquired antibodies to Factors VIII and IX.

➤ **Description :**

Recombinant Human Factor VIIa produced in BHK is a glycosylated polypeptide two-chain dimer consisting of 406 amino acids with a molecular weight of 50kD. Factor-VIIa is purified by proprietary chromatographic techniques

➤ **Physical Appearance:**

Sterile Filtered White lyophilized (freeze-dried) powder.

➤ **Formulation:**

Recombinant Factor-VIIa, at a concentration of 1 mg/ml, was lyophilized from a sterile solution containing 4.86mg/ml sodium chloride, 2.45mg/ml calcium chloride dihydrate, 50mg/ml mannitol and 116µg/ml Tween 80.

➤ **Solubility:**

It is recommended to reconstitute the lyophilized Factor-VIIa in sterile 18MO-cm H₂O not less than 100µg/ml, which can then be further diluted to other aqueous solutions.

➤ **Stability:**

Lyophilized Factor-VIIa although stable at room temperature for 3 weeks, should be stored desiccated below -18 C. For long term storage it is recommended to add a carrier protein (0.1% HSA or BSA).

Please avoid freeze-thaw cycles.

➤ **Purity:**

Greater than 98.0% as determined by:

(a) Analysis by RP-HPLC.

(b) Anion-exchange FPLC.

(c) Analysis by reducing and non-reducing SDS-PAGE Silver Stained gel.

➤ **Dimers and aggregates:**

Less than 1% as determined by silver-stained SDS-PAGE gel analysis.

➤ **Biological Activity:**

This Recombinant Factor-VIIa was per mg was tested and found to have 50,000 IU/mg.

➤ **Endotoxin:**

Less than 0.1 ng/μg (IEU/μg) of Factor-8.

➤ **Usage:**

This material is offered for research, laboratory or further evaluation purposes.