

Table I. Factor VIII Products Licensed in the U.S.

A. Recombinant Factor VIII Products

Product Name	Manufacturer	Method of Viral Depletion or Inactivation	Stabilizer	Human or Animal Protein Used in Culture Medium	Specific Activity of Final Product (IU factor VIII/mg total protein)	Hepatitis Safety Studies in Humans with this Product?
Helixate FS	Bayer (distributed by CSL Behring)	1. immunoaffinity chromatography	Sucrose	Human plasma protein fraction	4000*	Yes
Kogenate FS	Bayer	1. immunoaffinity chromatography	Sucrose	Human plasma protein fraction	4000*	Yes
Recombinate	Baxter BioScience	1. immunoaffinity chromatography	Human albumin	Bovine calf serum	1.65-19	Yes
ReFacto	Wyeth	1. immunoaffinity chromatography 2. solvent/ detergent (TNBP and Triton X-100)	Sucrose	Human serum albumin	11,200-15,500	Yes
Advate	Baxter BioScience	Solvent/Detergent TNBP/polysorbate 80, Triton X100	Mannitol	None	4000-10000	Yes

***Valid as long as product is kept under refrigeration as recommended by the manufacturer.**

Table I. Factor VIII Products Licensed in the U.S. (continued)

B. Immunoaffinity-Purified Factor VIII Products Derived from Human Plasma

Product Name	Manufacturer	Method of Viral Inactivation	Specific Activity of Final Product (IU factor VIII/mg total protein)	Hepatitis Safety Studies in Humans with this Product	Hepatitis Safety Studies in Humans with Another Product, but Similar Viral Inactivation Method
Hemofil M	Baxter Bioscience	1. immunoaffinity chromatography 2. solvent/ detergent (TNBP and Octoxynol 9)	2-15	Yes	No
Monarc-M	Baxter Bioscience	1. immunoaffinity chromatography 2. solvent/ detergent (TNBP and Octoxynol 9)	2-15	No	Yes
Monoclote-P	CSL Behring	1. immunoaffinity chromatography 2. pasteurization (60°C, 10h)	5-10	Yes	Yes

C. Factor VIII Products Derived from Human Plasma that Contain Von Willebrand Factor

Product Name	Manufacturer	Method of Viral Inactivation	Specific Activity of Final Product (IU factor VIII/mg total protein)	Hepatitis Safety Studies in Humans with this Product	Hepatitis Safety Studies in Humans with Another Product, but Similar Method	FDA Approved for von Willebrand Disease
Alphanate	Grifols	1. affinity chromatography 2. solvent/ detergent (TNBP and polysorbate 80) 3. dry heat (80° C, 72h)	140	No	Yes	No
Humate-P	CSL Behring (Germany)	1. pasteurization (60°C, 10 hrs)	38	Yes	No	Yes
Koate-DVI	Talecris	1. solvent/ detergent (TNBP and polysorbate 80) 2. dry heat (80°C, 72h)	>20	No	Yes	No

Table II. Factor IX Products Licensed in the U.S.

A. Recombinant Factor IX Products

Product Name	Manufacturer	Method of Viral Depletion or Inactivation	Stabilizer	Human or Animal Protein Used in Culture Medium	Specific Activity (IU factor IX/mg total protein)	Hepatitis Safety Studies in Humans with this Product
BeneFIX	Wyeth	1. affinity chromatography 2. nanofiltration	Sucrose	None	≥200	Yes

B. Coagulation Factor IX Products Derived from Human Plasma

Product Name	Manufacturer	Method of Viral Depletion or Inactivation	Specific Activity of Final Product (IU factor IX/mg total Protein)	Hepatitis Safety Studies in Humans with this Product	Hepatitis Safety Studies in Humans with Another Product, but Similar Viral Inactivation Method
AlphaNine SD	Grifols	1. dual affinity chromatography 2. solvent/detergent (TNBP and polysorbate 80) 3. nanofiltration (viral filter)	210	Yes	Yes
Mononine	CSL Behring	1. immunoaffinity chromatography 2. sodium thiocyanate 3. ultrafiltration	> 190	Yes	No

Table II. Factor IX Products Licensed in the U.S. (continued)

C. Prothrombin Complex Concentrates Derived from Human Plasma that Contain Factors II, VII, IX, X (For use in patients with deficiencies of Factors II, VII, and X. Note: Content varies from lot to lot and product to product.)

Product Name	Manufacturer	Method of Viral Inactivation	Specific Activity of Final Product (IU factor IX/mg total Protein)	Hepatitis Safety Studies in Humans with this Product	Hepatitis Safety Studies in Humans with Another Product, but Similar Viral Inactivation Method
Bebulin VH	Baxter BioScience (Vienna)	1. vapor heat (10h, 60° C, 1190 mbar pressure plus 1 h, 80° C, 1375 mbar)	2	Yes	No
Profilnine SD	Grifols	1. solvent/detergent (TNBP and polysorbate 80)	4.5	No	Yes
Proplex-T*	Baxter Bioscience	1. dry heat (60° C, 144 h)	>8	No	No

NOTE: The manufacture of Proplex-T was discontinued in 2005 but the product will be marketed through calendar year 2006.

D. Anti-Inhibitor Coagulation Complex (Activated Prothrombin Complex Concentrates) Derived from Human Plasma (For use in patients with inhibitors to Factor VII or IX)

Product Name	Manufacturer	Method of Viral Inactivation	Specific Activity of Final Product (IU factor IX/mg total Protein)	Hepatitis Safety Studies in Humans with this Product	Hepatitis Safety Studies in Humans with Another Product, but Similar Viral Inactivation Method
FEIBA VH	Baxter BioScience	1. vapor heat (10h, 60° C, 1190 mbar pressure plus 1 h, 80° C, 1375 mbar)	0.8	Yes	Yes

Table III. Factor VII Products Licensed in the U.S.

A. RECOMBINANT FACTOR VIIa

Product Name	Manufacturer	Method of Viral Depletion or Inactivation	Stabilizer	Human or Animal Protein Used in Culture Medium	Hepatitis Safety Studies in Humans with this Product
NovoSeven	Novo Nordisk (Bagsvaerd, Denmark)	1. affinity chromatography	Mannitol	Bovine calf serum	Yes

Table IV. Desmopressin Formulations Useful in Disorders of Hemostatis

Product Name	Manufacturer	U.S. Distributor	Formulation	Recommended Dosage and Administration
DDAVP Injection	Sanofi-Aventis Pharmaceuticals	Sanofi-Aventis Pharmaceuticals	For parental use (IV or SQ), 4µg/ml in a 10-ml vial	1) 0.3 µg/kg mixed in 30 ml normal saline solution, infused slowly over 30 minutes I.V. 2) 0.4 subcutaneously. Maximum dose 24 once every 24 hours. May repeat after 24 hours.
Stimate Nasal Spray for Bleeding	CSL Behring	CSL Behring	Nasal Spray, 1.5 mg/ml. The metered dose pump delivers 0.1 ml (150 µg) per actuation. The bottle contains 2.5 ml with spray pump capable of delivering 15 150-µg doses or 12 300-µg/kg doses.	In patients weighing <50 kg, one spray in one nostril delivers 150 µg/kg. For those weighing >50 kg, one spray in each nostril (total dose 300 µg). May repeat after 24 hours.

Table V. Fresh Frozen Plasma Products

Product Name	Manufacturer	Distributor	Method of Viral Depletion or Inactivation	Pool Size, Number of Donor Units
Donor Retested Fresh Frozen Plasma	Some community blood centers	Some community blood centers	1. Donors must test negative on second donation in order for first donation to be released.	1