

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	Generation	Specific Activity of Final Product (Units factor VIII/mg total protein after addition of stabilizer)	Viral Safety Studies in Humans with this Product?
Advate	Baxter	1. Immunoaffinity chromatography 2. Solvent/detergent (TNBP/polysorbate 80/Trixton X 100)	Trehalose	None	Third	4,000-10,000*	Yes
Helixate FS	Bayer (distributed by Aventis Behring)	1. Immunoaffinity chromatography 2. Solvent/detergent (TNBP/polysorbate 80)	Sucrose	Human plasma protein solution	Second	4000*	Yes
Kogenate FS	Bayer	1. Immunoaffinity chromatography 2. Solvent/detergent (TNBP/polysorbate 80)	Sucrose	Human plasma protein solution	Second	4000*	Yes
Recombinate	Baxter	1. Immunoaffinity chromatography	Human albumin	Bovine serum albumin	First	1.65-19	Yes
ReFacto	Wyeth	1. Immunoaffinity chromatography 2. Solvent/detergent (TNBP / Triton X100)	Sucrose	Human serum albumin (manufactured by Grifols, Spain, & Octa Pharma, Sweden**)	Second (B-domain deleted)	9,110-13,700***	Yes

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

** Note: This company has not received PPTA Certification.

*** Based on the new ReFacto standard.

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 (Units factor VIII/mg total protein after addition of stabilizer)	Viral Safety Studies in Humans with this Product	Viral Safety Studies in Humans with Another Product, but Similar Viral Inactivation Method
Hemofil M	Baxter	1. Immunoaffinity chromatography 2. Solvent/detergent (TNBP/Octoxynol 9)	2-20	Yes	No
Monarc-M	Manufactured by Baxter for American Red Cross (ARC) from ARC-collected plasma. (distributed by ARC)	1. Immunoaffinity chromatography 2. Solvent/detergent (TNBP/Octoxynol 9)	2-15	No	Yes
Monoclote-P	Aventis Behring	1. Immunoaffinity chromatography 2. Pasteurization (60°C, 10h)	5-10	Yes	Yes

TABLE I. FACTOR VIII PRODUCTS LICENSED IN THE U.S. (Continued)

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 (Units factor VIII/mg total protein after addition of stabilizer)	Viral Safety Studies in Humans with this Product	Viral 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/polysorbate 80) 3. Dry heat (80°C, 72h)	8-30	No	Yes	No (but application pending before FDA)
Humate-P	Aventis Behring GmbH (Marberg, Germany)	1. Pasteurization (60°C, 10 hrs)	1-2	Yes	No	Yes
Koate-DVI	Bayer	1. Solvent/detergent (TNBP/polysorbate 80) 2. Dry heat (80°C, 72h)	9-22	No	Yes	No

TABLE I. FACTOR VIII PRODUCTS LICENSED IN THE U.S. (Continued)

**D. PORCINE FACTOR VIII PRODUCTS
(FOR USE IN PATIENTS WITH INHIBITORS TO HUMAN FACTOR VIII)**

Product Name	Manufacturer	Method of Viral Inactivation	Specific Activity of Final Product (Units factor VIII/mg total protein)	Viral Safety Studies in Humans with this Product	Viral Safety Studies in Humans with Another Product, but Similar Method
Hyate:C	Ipsen, Inc. (Wales)	None (but no report of transmission of any viruses to humans)	>50	No	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	Generation	Specific Activity (Units factor IX/mg total protein after addition of stabilizer)	Viral Safety Studies in Humans with this Product
BeneFIX	Wyeth	1. Affinity chromatography 2. Ultrafiltration	Sucrose	None	Third	≥ 200	Yes

TABLE II. FACTOR IX PRODUCTS LICENSED IN THE U.S (Continued)

B. COAGULATION FACTOR IX PRODUCTS DERIVED FROM HUMAN PLASMA

Product Name	Manufacturer	Method of Viral Depletion or Inactivation	Specific Activity of Final Product (Units factor IX/mg total protein after addition of stabilizer)	Viral Safety Studies in Humans with this Product	Viral Safety Studies in Humans with Another Product, but Similar Viral Inactivation Method
AlphaNine SD	Grifols	1. Dual affinity chromatography 2. Solvent/detergent (TNBP/polysorbate 80) 3. Nanofiltration (viral filter)	229 ± 23	Yes	Yes
Mononine	Aventis Behring	1. Immunoaffinity chromatography 2. Sodium thiocyanate 3. Ultrafiltration	> 160	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, X. NOTE THAT CONTENT VARIES FROM LOT TO LOT AND
PRODUCT TO PRODUCT)**

Product Name	Manufacturer	Method of Viral Inactivation	Specific Activity of Final Product (Units factor IX/mg total protein after addition of stabilizer)	Viral Safety Studies in Humans with this Product	Viral Safety Studies in Humans with Another Product, but Similar Viral Inactivation Method
Bebulin VH	Baxter	1. Vapor heat (10h, 60°C, 190 mbar pressure plus 1 h, 80°C, 375 mbar)	1-4	Yes	Yes
Profilnine SD	Grifols	1. Solvent/detergent (TNBP/ polysorbate 80)	4.5	No	Yes
Proplex-T	Baxter	1. Dry heat (60°C, 144 h)	>0.8	No	Yes

TABLE II. FACTOR IX PRODUCTS LICENSED IN THE U.S. (Continued)

**D. ANTI-INHIBITOR COAGULATION COMPLEX (ACTIVATED PROTHROMBIN COMPLEX CONCENTRATES) DERIVED FROM HUMAN PLASMA
(FOR USE IN PATIENTS WITH INHIBITORS TO FACTOR VIII OR IX)**

Product Name	Manufacturer	Method of Viral Depletion or Inactivation	Specific Activity of Final Product (Units factor/mg total protein after addition of stabilizer)	Viral Safety Studies in Humans with this Product	Viral Safety Studies in Humans with Another Product, but Similar Viral Inactivation Method
Autoplex T	Baxter (distributed by Nabi)	1. Dry heat (60°C, 144h)	5	Yes	No
FEIBA VH	Baxter	1. Vapor heat (10h, 60°C, 190 mbar plus 1h, 80°C, 370 mbar)	≥ 0.8	Yes	Yes

TABLE III. FACTOR VIIa PRODUCTS LICENSED IN THE UNITED STATES

A. RECOMBINANT FACTOR VIIa

Product Name	Manufacturer	Method of Viral Depletion or Inactivation	Stabilizer	Human or Animal Protein Used in Culture Medium	Generation	Viral Safety Studies in Humans with this Product
NovoSeven	Novo Nordisk (Bagsvaerd, Denmark)	1. Affinity chromatography 2. Solvent/detergent (TNPB/polysorbate 80)	Mannitol	Bovine calf serum	Second	Yes

TABLE IV. DESMOPRESSIN FORMULATIONS USEFUL IN DISORDERS OF HEMOSTASIS

Product Name	Manufacturer	U.S. Distributor	Formulation	Recommended Dosage and Administration
DDAVP Injection	Ferring AB (Malmo, Sweden)	Aventis Pharma	For parenteral use (IV or SQ), 4 mcg/ml in a 10-ml vial	1) 0.3 mcg/kg, mixed in 30 ml normal saline solution, infused slowly over 30 minutes I.V. 2) 0.3 mcg/kg subcutaneous. Maximum dose 24 mcg. May repeat after 24 hours. Do not use in children under the age of 2 years or in pregnant women.
Stimate Nasal Spray for Bleeding	Ferring AB (Malmo, Sweden)	Aventis Behring	Nasal spray, 1.5 mg/ml. The metered dose pump delivers 0.1 ml (150 mcg) per actuation. The bottle contains 2.5 ml with spray pump capable of delivering 25 150-mcg doses or 12 300-mcg doses.	In patients weighing <50 kg, give one spray in one nostril (dose = 150 mcg). For those weighing >50 kg, give one spray in <u>each nostril</u> (dose = 300 mcg). May repeat after 24 hours. Do not use in children under the age of 2 years or in pregnant women.

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