INFECTED BLOOD INQUIRY

BRENDON GRAY WITNESS STATEMENT

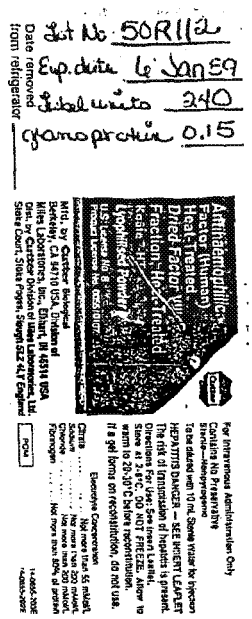
EXHIBIT WITN6984079

PROTOCOL FOR U.K RELEASE OF KOĀTE®

1. Information Identifying Lot of Filled Final Product

Manufacturer's Name - Cutter Laboratories
Manufacturer's address at which all processing and testing are performed Clayton, N.C., USA
Product License Number-0055/0107
Product Name-Koate®-HT Antihemophilic Factor (Human)
Expiration Date 6JAN89
Final Product Lot Numer 50R112
Sterile Water for Injection, USP, Lot No. 1858617R-F
1858631S-F

Attach c
Label he
Lot data
written



2. Sterilization and Filling

Sterilization: Membrane Filtration 0.22 MIcron Pore Size
Date 8DEC86, No. of Containers 8545
Filled container volume before freeze drying 9.77 mL ± 0.38
[X] Under Vacuum
[X] Dry Heat-Treated at 68°C for 72 hrs.

3. Sterility Test of Final Filled Product (Test carried out in accordance with CFR and USP requirements)

Date Started 9JAN87

No. of tubes showing growth in medium:
Fluid Thioglycollate Medium None out of 20
Soybean Casein Digest Medium None out of 20

4. Tests for Freedom from Abnormal Toxicity Testing

Kind of Test: Guinea Pig and Mouse Toxicity Test Both
Date of Test: Guinea Pig 14JAN87, Mouse 6JAN87

Vials of filled final product tested: 2

Type of Animal	Sex	Strain	Dose	Route	Volumes	Diluent
Guinea Pigs	M	Charles River	24.24 IU*	ip	5.0 mL**	None
Mice	M	Charles River	24.24 IU*	ip	0.5 mL**	None

*IU Factor VIII/mL **Undiluted Solution

Number of Animals used: 2 guinea Pigs; 2 Mice

Guinea Pig Toxicity Test

Two Guinea Pigs	Weight at Beginning of Test	Weight at End of Test
1	387 g	508 g
2	391 g	483 g

Mouse Toxicity Tests

Range of wt. of animal used: 21 g
Route of injection 0.5 mL intraperitoneally
Period of Observation 7 days

No loss of weight, no symptoms of sickness, no death. Period of observation: 7 days.

5. Tests for Freedom from Pyrogenic Substances

The pysrogen test is caried out in accordance with the U.S. Code of Federal Regulations

Vials of Filled Final Product 2
Date of Test 9JAN87

Dose Injected 24.24 IU Factor VIII/kg
Method of preparation of the solution injected: Product reconstituted in recommended volume of Water for Injection.

For Each Rabbit

Rabbit Number	Rabbit Weight	Whether Rabbit Previously Used	Temperatures Recorded Before Injection (0) Minutes)	Temperatures Recorded After Injection	Maximal Temperature Rise After Injection
				+60 +120 +180 Min	
1	2600 g	No	39.8 °C	39.7 °C 39.4 °C 39.3 °C	
2	2500 g	No	39.6 °C	39.7 °C 39.7 °C 39.7 °C	0.1 °C
3	2500 g	No	39.7 °C	39.5 °C 39.4 °C 39.7 °C	

Summed Response for each Group of Rabbits 0.1 °C.

6. Biological Potency

Assay Procedure: one stage

Standard Used

House Standard Lot No. MEGAI
Nature of House Standard: Freeze-Dried Concentrate
Temperature of Storage: -50°C
Standard against which it was calibrated: 3rd International Standard 80/556

Date of calibration: Dec. 1983
Potency Assigned to House Standard: 10.2 IU/mL
Date of Recalibration: Dec. 1984

Potency

Date of Assay 6JAN87

After reconstitution
Initial dilution of: Standard 1-10
Test 1-10

Diluent used Imidazole with 0.5% Albumin, pH 7.3

Results: One assay for each of 4 containers:

Operator # 1

Dilution	Standard I*	Standard ~~IIII*~~ II*	Standard III*
1:100	51.0	51.0	
1:200	56.7	57.6	
1:400	63.2	64.0	
1:800	70.0	70.0	
1:1600	76.3	78.6	77.7

Container 1

Dilution	a **	b **	c **
1:500	57.5	58.4	
1:1000	64.4	64.6	
1:2000	70.6	70.8	

Operator # 2

Dilution	Standard I*	Standard ~~IIII*~~ II*	Standard III*
1:100	51.9	52.6	
1:200	58.6	59.7	
1:400	65.0	66.1	
1:800	72.5	72.9	
1:1600	79.5	80.2	

Container 2

Dilution	a **	b **	c **
1:500	59.6	59.4	
1:1000	66.5	66.3	
1:2000	73.9	73.7	

Operator # 3

Dilution	Standard I*	Standard ~~IIII*~~ II*	Standard III*
1:100	51.0	52.0	
1:200	57.9	58.1	
1:400	64.3	64.3	
1:800	69.8	70.4	
1:1600	76.8	76.6	

Container 3

Dilution	a **	b **	c **
1:500	56.9	59.9	58.4
1:1000	64.2	65.1	
1:2000	70.7	71.2	

Operator # 1 II*

Dilution	Standard I*	Standard ~~IIII*~~	Standard III*
1:100	50.1	50.2	
1:200	55.9	57.0	
1:400	62.3	63.1	
1:800	69.1	69.5	
1:1600	76.7	74.8	74.9

Container 4

Dilution	a **	b **	c **
1:500	57.4	55.7	58.5
1:1000	63.0	61.5	
1:2000	69.3	69.9	

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* Independent sets of dilutions made up from the same ampule of reconstituted standard.

** Independent sets of dilutions derived from separate 1-10 dilutions of sample.

Final Lot No. 50R112

Potency estimate for: Container 1 24.13 IU/mL
Range 23.72 - 24.83

Container 2 23.85 IU/mL
Range 22.99 - 24.30

Container 3 24.00 IU/mL
Range 23.91 - 24.04

Container 4 24.98 IU/mL
Range 23.53 - 27.11

Combined potency 4 containers 24.24 IU/Ml
Range 22.99 - 27.11

7. Test on Product Reconstituted in the Recommended Volume of Water for Injection

Specific Activity 1.6 IU/mg Protein
Protein 0.15 g/container
Moisture Content 1.0 %
pH of Reconstituted Material 7.3

Ouchterlong Precipitin Test
Anti-Human Positive
Anti-Bovine Negative
Anti-Equine Negative

Na+ 143 mEq/liter

Cl^- 138 mEq/liter

HB_sAg non-reative

Aluminum not done

Solution Time 1.8 - 2.5 minutes

Anti-A (Saline) 1:8

Anti-B (Saline) 1:8

Glycine 0.9 %

Product prepared from fractionated pooled plasma obtained from donors tested for Hepatitis B Surface Antigen, HTLV III Antibody, ALT, and found negative.

Responsible GRO-C
Quality Assurance Release Coordinator

2 Feb 87
Date of Signature

Each individual unit of plasma has been tested for antibody to HTLV III by an FDA approved method and found non-reactive.

Signed GRO-C

2 Feb 87