INFECTED BLOOD INQUIRY

BRENDON GRAY WITNESS STATEMENT

EXHIBIT WITN6984084

NATIONAL BIOLOGICAL STANDARDS BOARD

A W.H.O. International Laboratory for Biological Standards

NATIONAL INSTITUTE FOR BIOLOGICAL STANDARDS AND CONTROL
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MEDICINES ACT 1968

BATCH RELEASE CERTIFICATE No H 0089 A

PRODUCT LICENCE/ ~~CLINICAL TRIAL CERTIFICATE~~ No PL/0055/0107

PRODUCT Koate HT (Heat Treated Factor VIII)

In accordance with the provisions of the above Product Licence ~~Clinical Trial Certificate~~

held by Miles Laboratories Limited

THIS IS TO CERTIFY THAT protocols and samples of

Batch No/s	Filling Lot/s
50S062	

received from Miles Laboratories Limited

have been examined and that sale or supply is hereby authorised with the consent of the Licensing Authority of the Department of Health and Social Security.

Dated this 20th day of October 19 87

Signature.. GRO-C .....
NATIONAL BIOLOGICAL STANDARDS BOARD

6 October 1987

MWT/kp

Dr T Barrowcliffe
N.I.B.S.C.
Blanche Lane
South Mimms
Potters Bar
Herts
EN6 3QG

Dear Dr Barrowcliffe

BATCH RELEASE: KOATE HT

Please find enclosed the following samples of KOATE HT for batch release testing:

5 vials of KOATE HT batch 508062 (260 IU)

A protocol and 5 vials of Water for Injection batch 1858717V-F are also enclosed.

Yours sincerely

Maria W Tatt (Mrs)
Regulatory Affairs Manager

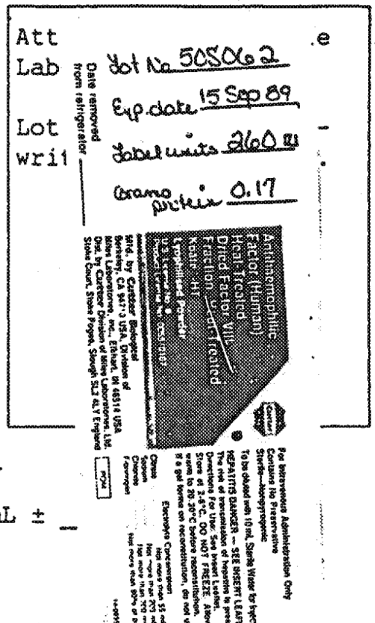
Encs:

CUTTER BIOLOGICAL

PROTOCOL FOR U.K RELEASE OF KOATE®

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 15 SEP 89
Final Product Lot Numer 50S062
Sterile Water for Injection, USP, Lot No. 1858717V-F



2. Sterilization and Filling

Sterilization: Membrane Filtration 0.22 MIcron Pore Size
Date 1 SEP 87, No. of Containers 8156
Filled container volume before freeze drying 9.82 mL ± _
[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 21 CFR and USP requirements)

Date Started 15 SEP 87
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 16 SEP 87
Mouse 16 SEP 87

Vials of filled final product tested: 2

Type of Animal	Sex	Strain	Dose	Route	Volumes	Diluent
Guinea Pigs	M	Charles River	26.48 IU*	ip	5.0 mL**	None
Mice	M	Charles River	26.48 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	342 g	386 g
2	335 g	371 g

Mouse Toxicity Tests

Range of wt. of animal used: 20 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.

Final Lot No. 50S062

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 18 SEP 87

Dose Injected 26.48 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	1900 g	YES	39.7 °C	39.3 °C 39.5 °C 39.3 °C	
2	2100 g	YES	39.8 °C	40.1 °C 39.6 °C 39.3 °C	0.3 °C
3	2100 g	YES	39.8 °C	40.1 °C 39.9 °C 40.0 °C	

Summed Response for each Group of Rabbits 0.6 °C.

6. Biological Potency

Assay Procedure: one stage

Standard Used

House Standard Lot No. MEGA I
Nature of House Standard: Freeze-Dried Concentrate
Temperature of Storage: -50°C
Standard against which it was calibrated:

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

3rd International Standard 80/556

Potency

Date of Assay 15 SEP 87

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 II*	Standard III*
1:100	49.9	50.7	
1:200	55.9	56.7	
1:400	62.3	63.1	
1:800	69.3	69.4	
1:1600	75.0	77.4	

Container 1

Dilution	a **	b **	c **
1:500	56.5	56.3	
1:1000	61.9	61.9	
1:2000	69.2	69.9	

Operator # 2

Dilution	Standard I*	Standard II*	Standard III*
1:100	50.5	50.4	
1:200	57.3	57.0	
1:400	63.0	62.8	
1:800	69.9	69.6	
1:1600	75.6	75.9	

Container 2

Dilution	a **	b **	c **
1:500	57.1	55.6	
1:1000	61.9	62.9	
1:2000	69.2	68.8	

Operator # 2

Dilution	Standard I*	Standard II*	Standard III*
1:100	51.3	51.1	
1:200	56.1	57.2	
1:400	62.4	63.2	
1:800	68.0	68.5	
1:1600	73.8	75.5	

Container 3

Dilution	a **	b **	c **
1:500	56.6	56.8	
1:1000	62.2	62.1	
1:2000	67.9	68.9	

Operator # 1

Dilution	Standard I*	Standard II*	Standard III*
1:100	50.6	50.4	
1:200	56.4	56.5	
1:400	63.4	63.9	
1:800	70.1	70.5	
1:1600	76.1	76.0	

Container 4

Dilution	a **	b **	c **
1:500	56.9	56.5	
1:1000	64.3	63.0	
1:2000	69.2	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. 50S062

Potency estimate for: Container 1 26.52 IU/mL
Range 25.24 - 28.58

Container 2 27.28 IU/mL
Range 26.99 - 27.83

Container 3 26.40 IU/mL
Range 25.98 - 27.24

Container 4 25.75 IU/mL
Range 24.80 - 26.42

Combined potency 4 containers 26.48 IU/mL
Range 24.80 - 28.58

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

Specific Activity 1.6 IU/mg Protein
Protein 0.17 g/container
Moisture Content 0.6 %
pH of Reconstituted Material 7.1

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

Na+ 156 mEq/liter

Cl^- 146 mEq/liter

Solution Time 1.8 minutes

HB_sAg non-reative

Aluminum not done

Anti-A (Saline) 1:16

Anti-B (Saline) 1:8

Glycine 0.8 %

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

30 SEP 87
Date of Signature

Each unit of plasma has been tested for antibody to HIV by ELISA-ENI Virgo and for Hepatitis B Surface Antigen by Radioimmunassay-ENI Riausure II and found nonreactive.

Signed GRO-C

Date 30 SEP 87