

Scottish National Blood Transfusion Service

Protein Fractionation Centre



SCOTTISH NATIONAL BLOOD TRANSFUSION SERVICE
STABLE PLASMA PROTEIN SOLUTION

400 ml. of 45g/l protein of human venous plasma origin
Contains 5mmol/l caprylic acid, 140-150 mmol/l sodium
2-10 mmol/l citrate and 40-50 mmol potassium per litre of solution.
The contents should be used or discarded within 4 hours of opening.

STORE AT A TEMPERATURE BELOW 8°C, PREFERABLY
IN A COOL DARK PLACE.
DO NOT FREEZE.

DO NOT USE UNLESS SOLUTION IS CLEAR
AND FREE FROM DEPOSIT.

PLEASE ENTER BATCH NUMBER IN PATIENT'S NOTES.

Protein Fractionation Centre,
Ellen's Glen Road, Edinburgh EH17 7QT.

STABLE PLASMA PROTEIN SOLUTION

FROM: BLD 50M

Batch No 1194

Expiry Date MAY 1988

FROM

Ellen's Glen Edinburgh EH17 7QT

34

Product Clearance SheetProduct Name: SAMIBatch: 1176Date Formulated: 9/78

Production Parameters



Preliminary Inspection



Volume Reconciliations



GRO-C

4/2/83

Sterility Tests

(Append)



Pyrogen Tests

(Append)



Toxicity Tests

(Append)



Analysis

(Append)

GRO-C

9/6/8330/6/83

Passed for inspection and packing

20/6/83

Inspection area cleared and ready for use

580

Inspection

29.7.83

Labelling and Machine free from labels and cleared for use

29.7.83

Labelled and Packed. Satisfactory

29.7.83

For Identity Tests. (Append) Satisfactory

29.7.83

For Product Library

29.7.83

Passed for Issue

10/8/83

Inventoried

11.8.83

GRO-C

37

PPPS ANALYSIS SUMMARYBATCH: 9194

		<u>PFC LIMIT</u>	<u>BATCH RESULT</u>
Total Protein	g/l	45 - 50	<u>46.1</u>
Albumin by Cellulose			
Acetate Electrophoresis	%	< 88	<u>87</u>
Aggregated Protein	% >800,000 daltons	> 15	<u>1.2</u>
Sodium	mmol/l	130-150	<u>143</u>
Potassium	mmol/l	>0.05 mmol/g protein	<u>0.4</u>
Chloride	mmol/l	No Limit	<u>91.95</u>
pH		6.7-7.3	<u>6.88</u> (20°C)
Haem	absorbance 403nm	0.850	<u>0.114</u>
Ethanol	ml/l		<u>0.37</u>
	mg/g protein	> 10	<u>6.3</u>
Prokallikrein Activator	% BSB Ref I	> 20	<u>0.9</u>
Alkaline Phosphatase	IU/l	> 8	<u>0</u>
Immunoelectrophoresis		Certified	<u>> 1000</u>
Polyacrylamide Gel Electrophoresis		As Normal	

ADDITIONAL INFORMATION

PASSES*/DOES NOT PASS CURRENT ANALYTICAL LIMITS

ACCEPTABLE*/NOT-ACCEPTABLE FOR INSPECTION AND LABELLING

* Delete As Appropriate

GRO-C

LABORATORY MANAGER

DATE

RESULTS FOR MICROBIOLOGICAL RELEASEPRODUCT TYPE SPRBATCH No. 81194

- | | | |
|----|---------------------------------------|-----------|
| 1. | Toxicity Test Status | PASS/FAIL |
| 2. | HB Ag Status | PASS/FAIL |
| 3. | Rabbit Pyrogen Status | PASS/FAIL |
| 4. | Sterility Test Status | PASS/FAIL |
| 5. | DETAILS OF ANY ABNORMAL OBSERVATIONS: | |

THIS BATCH COMPLIES/~~DOES NOT COMPLY~~ WITH RELEASE CRITERIA

SIGNED:

GRO-C

(MICROBIOLOGIST)

DATE: 9/6/87

109

ALBUMIN ANALYSIS REQUEST 1

BATCH NO. P1194

Requested By: J.S

Date: 20.5.83

Return To: T.M.O.

TEST	S.O.P. NO.	UNIT	A SAMPLE	B SAMPLE
			SAMPLE NO. 76502	SAMPLE NO. 76503
Total Protein	81 156 0057 01	g/l	46.2	46.1
CAE	81 156 0016 01		✓	✓
% Albumin		%	88	87
Sodium	81 156 0008 01	m mol/l	140	143
Potassium	81 156 0008 01	m mol/l	0.41	0.40
Chloride	81 156 0005 01	m mol/l	90.0	91.75
pH	81 156 0007 01	20 °C	6.86	6.88
Bithanol	81 156 0020 01	ml/l	0.37	0.37
Ethanol		mg/g Protein	6.3	6.3
P.K.A.	81 156 0053 01	% U.S. Ref. 1	0.1	0.9
Citrate	81 156 0058 01	m mol/l		

CCB

Report Complete: ✓

Date: 1.6.83

Signature: GRO-C

PROTEIN FRACTIONATION CENTRE

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ALBUMIN ANALYSIS 2

SAMPLE RECEIVED - DATE 11.5.83BATCH No. P1194
8624 9142

1. GEL FILTRATION S.O.P. No. 81 156 0030 01

Gel Type - S200-T Run Number/Date
Flow Rate - 20.1 ml/hr
% Area Under Peak A (Monomer)
A
B
C
D

A SAMPLE	B SAMPLE
1307. 24.6 83	1310. 29.6 83
<u>89.8</u>	<u>85.2</u>
<u>5.6</u>	<u>3.4</u>
<u>1.6</u>	<u>1.2</u>
<u>2.5</u>	<u>11.2</u>

2. OSMOLALITY S.O.P. No. 81 156 0031 01

A SAMPLE	B SAMPLE
<u>255</u> mOsm/kg	<u>255</u> mOsm/kg

3. ALKALINE PHOSPHATASE S.O.P. No. 81 156 0063 01

A SAMPLE	B SAMPLE
<u>44.0</u> IU/l	<u>0</u> IU/l

4. IMMUNOELECTROPHORESIS S.O.P. No. 81 156 0025 01

Aras present for:

Albumin	Haptoglobins	Transferrin	Immunoglobulin
<u>++</u>	<u>++</u>	<u>++</u>	<u>++</u>
<u>+</u>	<u>+</u>	<u>+</u>	<u>+</u>
<u>+</u>	<u>+</u>	<u>+</u>	<u>+</u>
<u>+</u>	<u>+</u>	<u>+</u>	<u>+</u>

Comments:

Date of Run

A SAMPLE	B SAMPLE
<u>17.6.83</u>	<u>17.6.83</u>
<u>8-6-83</u>	<u>8-6-83</u>

5. POLYACRYLAMIDE GEL ELECTROPHORESIS S.O.P. No. 81 156 0026 01

Gel Photo No./Date

A SAMPLE	B SAMPLE
<u>342-B, 9.6.83</u>	<u>342-B, 9.6.83</u>

Band present for:

Albumin	Transferrin	Albumin Dimer	Haptoglobin	Series	Polymer
<u>++</u>	<u>++</u>	<u>++</u>	<u>++</u>	<u>++</u>	<u>++</u>
<u>+</u>	<u>+</u>	<u>+</u>	<u>+</u>	<u>+</u>	<u>+</u>
<u>+</u>	<u>+</u>	<u>+</u>	<u>+</u>	<u>+</u>	<u>+</u>
<u>+</u>	<u>+</u>	<u>+</u>	<u>+</u>	<u>+</u>	<u>+</u>
<u>+</u>	<u>+</u>	<u>+</u>	<u>+</u>	<u>+</u>	<u>+</u>

Comments:

6. HAEM S.O.P. No. 81 156 0024 01

10 g/l solution of albumin. OD at 403nm

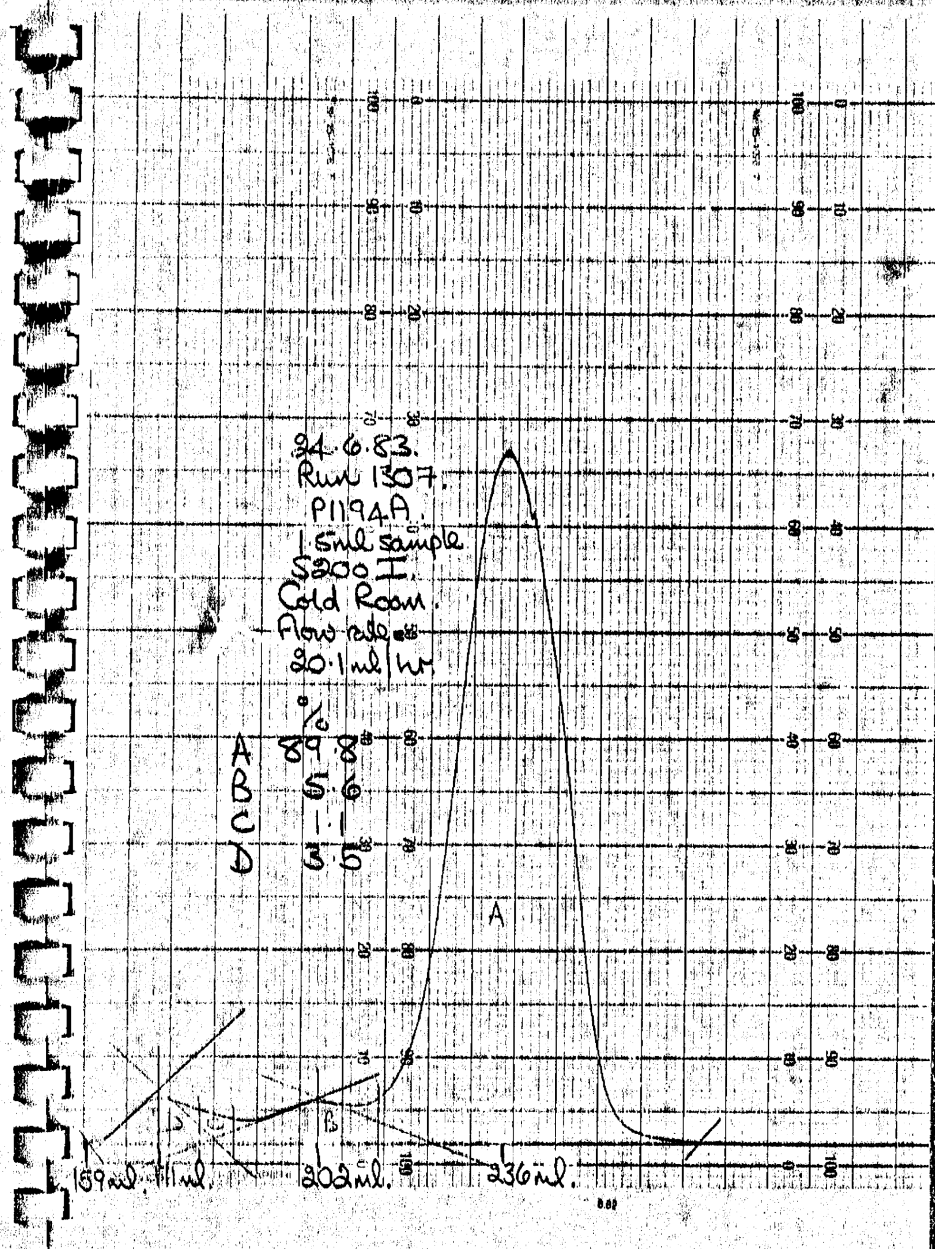
A SAMPLE	B SAMPLE
<u>0.117</u>	<u>0.114</u>

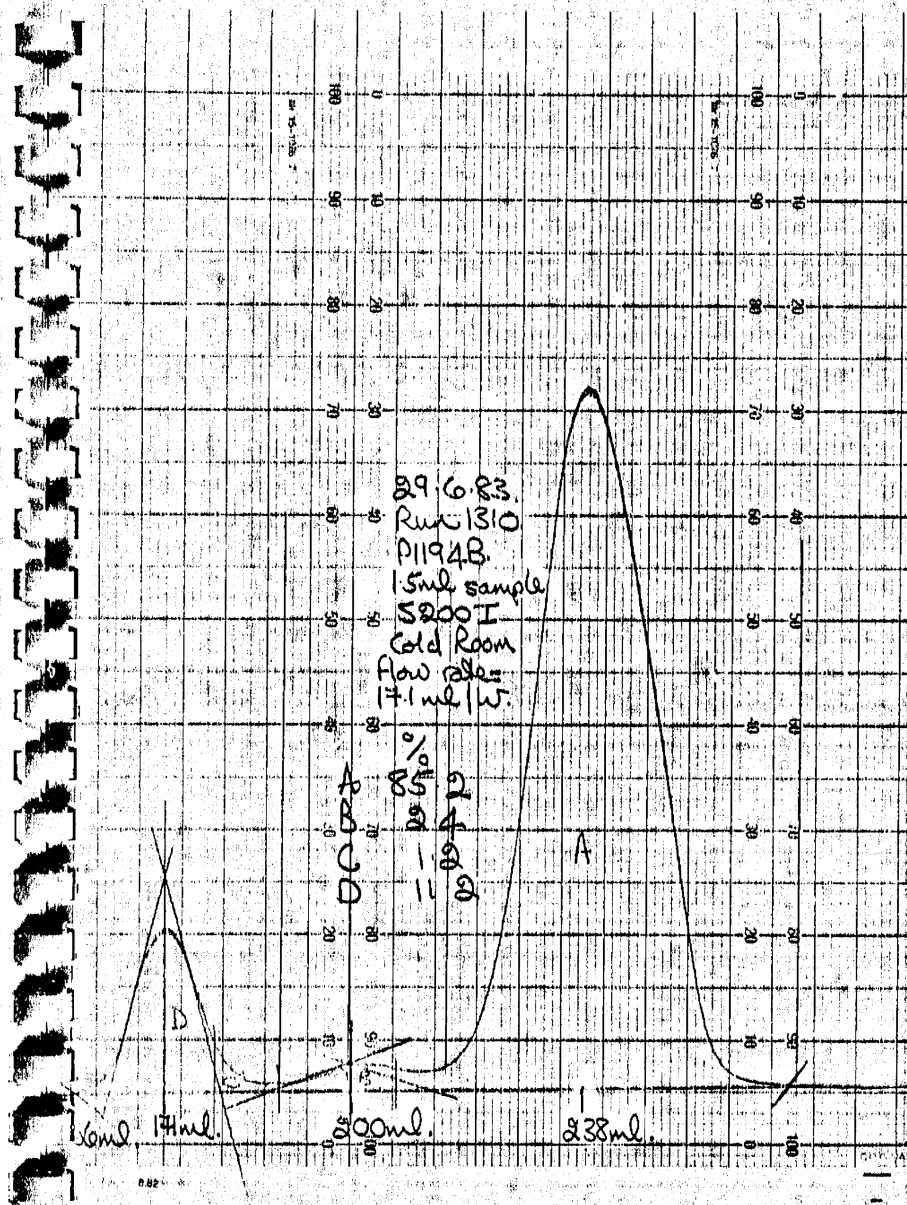
REPORT COMPLETE:

DATE: 30.6.83

SIGN:

GRO-C





Batch: P. 1196Date: 10/5/83

Autoclave load and date	Filter change	Bubble point, etc.
Autoclave 31" 8/5/83		BATCH 1/31
Autoclave 0.31" 8/5/83		BATCH 3/11/83 NO. 1008/22/10/8011
		52 psi.

Autoclave sterilization and filling protocol data and modifications.

File and cap Autoclaving: 2966, 2967, 2968 - 9/5/83
 Caps - DB/274, DB/275

A good bottle filled, No. 5916

Filled volume _____ Filter wash volume _____

Filling completed by _____ GRO-C

Autoclave Load:

Crates	mm./p.m.	A.M./p.m.	Date	Remarks
1-60	3.15	1.15	10/5/83	Cabinet No. 1. Run Satisfactory. C.L. G.

Stand at 100 Prior to Pasteurizing:

Crates	mm./p.m.	A.M./p.m.	Date	Remarks

Step	mm./p.m.	Initial	Remarks
(1) Wash			
(2) Wash			
Final Inspection			

FILLING ROOM RECORD

Product Batch Number

F113/194

Date Of Filling

10-5-83

Type Of Vial/Bottle

BIN

Filling Machine

Piston

Setting

US 276

Volume Of Fill

400ml

Batch Of Vial/Bottle

2969, 2970, 2971

2969, 2970, 2971

Batch Of Bung/Stopper

276, 275, 278, 277

Batch Of Cap

51 + 52

Batch Number Of Jar/Churn

A-79

Batch Of Piston/Syringe

AP-76

INCIDENTS DURING FILLING

FILLING TEAM

C. J. B. K. D. E. M.

P. B. C. D. A. L.

micronclean

REGIONAL TRANSFUSION SERVICE
ROYAL INFIRMARY, EDINBURGH

HBs Ag/HBs Ab TESTING

NAME Philip Cuneo

SERIAL No. (if applicable) _____

DEPARTMENT SPCREPORT TO BE RETURNED TO MISSIONARY

TE 12/5702

FOR LABORATORY REPORT ONLY

DATE TESTED 16/5/53 Ref: H0308

STB Ad ☐ ☒

HA8 Ab ☐ ☐

NL

HBs Ab-1.0 U./ml.

As a result, the Ca^{2+} concentration in the cytosol of the cell is maintained at a low level, and the Ca^{2+} concentration in the ER is maintained at a high level.

marks

Pub ☐ ☐ ☐

No ☒ ☐ ☐

GRO-C

Signed

REQUEST FOR TOXICITY TEST

(E.P. Vol. II, 1971, p. 81)

(Manufacturer's Licence No. 9.69)

SCOTTISH NATIONAL BLOOD TRANSFUSION SERVICE

Protein Fractionation Centre, 21 Ellen's Glen Road, Edinburgh EH17 7QT

Telephone: 031-664 2317

Telex: 72428

REQUEST FOR PYROGEN TESTTest Centre LAWProduct 511Batch No. 81194Date 17/5/83Quantity Dispatched Container(s) totalling 4.22 millilitresContainer Distinguishing Marks 81194 1.2.4.8Dispatcher P. G. G. G. G.Advance
Notification

Letter	Phone	Telex

3 ml / kg

Test date 17/5/83

Rebbit No.	Weight	Vol. injected	Peak or Maximum Temperature Rise	Mean peak or mean Temperature Rise
K173	2.1 Kg	6.3 mls	NIL	
K372	2.1 Kg	6.3 mls	0.1°C	
K373	2.2 Kg	6.6 mls	0.1°C	

Result checked by: GRO-C

Remarks on conduct and result of test: Animal response, etc.

REQUEST FOR TOXICITY TEST

(E.P. Vol. II, 1971, p. 01)

(Manufacturer's Licence No. 9.09)

PRODUCT: 588BATCH NO: 91194REQUESTED BY: B. CullenDATE: 13/5/83SPECIAL INSTRUCTIONS:DATE TESTED:

16/5/83

TESTED BY:

GRO-C

ANIMAL EXPERIMENT BOOK NO:

GUINEA PIGS: 9353 - 9354

MICE: 9355 - 9359

DOSAGE: GUINEA PIGS: 5 ml

MICE: 0.5 ml

ANIMAL	MARKING	DAILY WEIGHING					
		0	1	2	3	4	7
GUINEA PIG	1 BRINDLE	249	258	257	263	263	285
	2 TRICOLOUR	243	254	255	267	273	298
MICE	1 H&B L/S	20.64	23.79	24.70	25.55	26.08	28.00
	2 " R/S	21.31	25.15	26.00	26.61	28.11	30.55
	3 " TAIL	21.47	23.73	24.65	25.15	26.00	28.37
	4 " HEAD	19.63	21.77	22.54	23.07	23.73	25.59
	5 " N/A	19.26	21.92	22.84	23.30	24.55	26.51

RESULT: (in)SIGNATURE:

GRO-C

DATE: 21/5/83

LIMULUS TEST RESULTS

Ref: S.O.P. No. 81 157 0003 01

PRODUCT BATCH NUMBER: P1196

SAMPLE	END-POINT TITRE	ENDOTOXIN EQUIVALENT
Unbark	2 1/10	20.25 mg/ml
Park	2 1/10	20.25 mg/ml

LYSATE BATCH No.: 962227

LYSATE SENSITIVITY: 0.025

DATE OF ASSAY: 20.5.93

SIGNATURE:

GRO-C

P1194

REQUEST FOR COLONY COUNT (Manufacturer's Licence No. 9.83) P1194/1195													7
Sample Provided	By	Date	Time	Kept	Diln	Poured			Examined			20 ⁰	Comment
						By	Date	Time	By	Date			
SMALL					N	S.S.	1.5.83	1.15	T.M.	12.5	12		
PRE-EKS	AK	9/5/83		+40C.									
LARGE					N							11	
PRE-EKS													
POST-EKS					N							<1	
Pool		12/3/83	9.15		N							<1	
Piston Tissue			12.00		N							<1	
Cartridge Tissue					N							<1	

CENTRITHERM P1194/1195

REQUEST FOR COLONY COUNT (Manufacturer's License No. 9.63)						Poured			Examined			Comment
Sample Provided	By	Date	Time	Kept	Diln	By	Date	Time	By	Date	20"	
C1 (I)	Cu	9/5/83	0940	+5°C	N		9/5		T.M.	11/5	<1	
C1 (II)	J.M.	--	1105	--	N						37	
C2	AJ	--	0930	--	N						6	
C3	J.M.	--	1305	--	N						6	
C4	Cu	--	1425	--	N						30	
C5 (I)	J.M.	--	1405	--	N						<1	
C5 (II)	Cu	--	1445	--	N						12	

P1194

T. S. A. SETTLE PLATES

MAN. LICENCE REF: 9.65

PRODUCT BATCH NO: P.1194/1195

DATE FILLED: 10/5/53

SITE OF EXPOSURE	COLONY COUNT	ORGANISM IDENTIFICATION
Angioma 1 inset	0	
Angioma 2	0	
Pisier Trolley	1	Sc. 60.01.01.01.01.01
Bottle Trolley	1	Sc. 84.01.01.01.01.01

EXAMINED BY:

GRO-C

DATE:

12/5/53

BIOLOGICAL INDICATORSAutoclave No.Load No.DateCycleIndicator Type

Aust. P. 1174/1195

Load Contents DIM BUNAS

DB/875

Submitted by

GRO-C

Date Received 10/5Date Due Off 12/5Inoculation 48 hrs @ 57°CControl

Positive at 24 hours

Indicator
IdentificationPosition in AutoclaveResult

N

Negative at 48
hours.Examined by

GRO-C

Date

12/5/83

BIOLOGICAL INDICATORSAutoclave No.Load No.DateCycleIndicator Type Casual P-1194/1198Load Contents DIN BUNGS

DB/274

Submitted by

GRO-C

Date Received 10/5Date Due Off 12/1Incubation 4 hrs @ 58°CControl Positive at 24 hoursIndicator
IdentificationPosition in AutoclaveResult

M

Negative at 48
hoursExamined by

GRO-C

Date 12/2/83

BIOLOGICAL INDICATORSAutoclave No. 1Load No. 5Date 9-5-83CycleIndicator Type ATTESLoad Contents

210 Bil approx Borne 2968

P1214

Submitted by

GRO-C

Date Received 9/5Date Due Off 11/5Incubation 48 hrs @ 57°CControl Positive at 24 hoursIndicator
IdentificationPosition in AutoclaveResult
 4 BC
 X TZ
 Y BBR
 2 TFL

 Negative at
 48 hours
Examined by

GRO-C

Date

11/5/83

BIOLOGICAL INDICATORS

Autoclave No. 1

Load No. 4

Date 9-5-83

Cycle

Indicator Type Arrest

Load Contents

210 fal capped Bottles 2967

1414

Submitted by

GRO-C

Date Received 9/5

Date Due Off 11/5

Incubation 48 hrs @ 55°C

Control Positive at 24 hours

<u>Indicator Identification</u>	<u>Position in Autoclave</u>	<u>Result</u>
BC		Negative at 48 hours
TC		
BBR		
TRC		

Examined by

GRO-C

Date 11/2/83

BIOLOGICAL INDICATORS

Autoclave No. 1

Load No. 2

Date 9-5-83

Cycle

Indicator Type A-125

Load Contents

210 Foil capped Bottles 2966

81214

Submitted by

GRO-C

Date Received 9/5

Date Due Off 11/5

Incubation 48 hrs @ 50°C

Control Positive at 48 hours

<u>Indicator Identification</u>	<u>Position in Autoclave</u>	<u>Result</u>
BC		} Negative at 48 hours
TZ		
BBR		
TFL		

Examined by

GRO-C

Date 11/8/83

210

2966

2 P1194
Temp check on no. 5/11
probe of Honeywell

GRO-C

60	59	58	57	56	55	54	53	52	51
41	42	43	44	45	46	47	48	49	50
30	39	38	37	36	35	34	33	32	31
21	22	23	24	25	26	27	28	29	30
20	19	18	17	16	15	14	13	12	11
1	2	3	4	5	6	7	8	9	10

BATCH NO P1194

Run Started 3.15pm

Position of temperature probes in batch

Run Finished 1.15a.m

Temperature checked during

run and found to be 60.00c

- 1 1
- 2 171
- 3 740
- 4 331
- 5 450
- 6 510

PASTEURISATION CABINET NO 2

DATE

BATCH NO

Run Started

Position of temperature probes in batch

Run Finished

Temperature checked during

run and found to be

- 1
- 2
- 3
- 4
- 5
- 6

SIGNED

GRO-C

0000

LARGE

41

Formulation of albumin concentrate

Batch: P1194/1195

Operator: GRO-C

Date: 9/5/83

1st Dilution

50 ~~25~~ l Concentrate @ 322 g/l = $\frac{50 \times 322}{52}$ l @ 62 g/l
= 309 l

Washes to be added:

	Batch	Type	Volume	Conc. g/l	Total g
1	P1142	EKSWASH	32		
2					
3					
4					
Total			32		

∴ Water to be added = $309 - 32 = 50 = 227$ l
less 10% = 1

(5A) Volume 300 l; Na⁺ 72 mmol/l (Total Na⁺ 21.6 mol) T.P. 49.9 g/l

2nd Dilution

300 l solution @ 49.9 g/l = $\frac{300 \times 49.9}{47.5}$ l @ 47.5 g/l
= 315 l

∴ Water to be added = $315 - 300 = 15$ l

315 l @ 140 mmol/l = 44.1 mol

Na⁺ present at 5A = 21.6 mol

∴ Na⁺ to be added as NaCl = 22.5 mol = 1315 g NaCl (58.44 g/mol)

* (5B) Volume 315 l; Na⁺ 138 mmol/l PH 6.84 T.P. 46.8 g/l

Filtered through 34 x 40 cm BKS pads @ 1/hr.

(5D) Volume 423 l; Na⁺ 142 mmol/l PH 7.10 T.P. 46.6 g/l

Appearance of filtrate 24 hrs * 36 g NaCl, 50 g NaOH

Volume of filter wash 1

Handed to filling team at hr.

Remarks & Variations from Standard Procedure

SMALL

41.

Formulation of albumin concentrate

Batch: P1194/1195

Operator: GRO-C

Date: 9/5/83

1st Dilution

23 l Concentrate @ 322 g/l = $\frac{23 \times 322}{52}$ l @ 52 g/l
 = 142 l

Washes to be added:

	Batch	Type	Volume	Conc. g/l	Total g
1					
2					
3					
4					
Total					

∴ Water to be added = $142 - 23 = 119$ l
 less 10% = 112 l

(5A) Volume 135 l, Na⁺ 64 mmol/l (Total Na⁺ 64 mol) T.P. 47.7 g/l

2nd Dilution

135 l solution @ 47.7 g/l = $\frac{135 \times 47.7}{47.5}$ l @ 47.5 g/l
 = 135.5 l

∴ Water to be added = $135.5 - 135 = 0.5$ l

135.5 l @ 140 mmol/l = 18.97 mol

Na⁺ present at 5A = 6.64 mol

∴ Na⁺ to be added as NaCl = 10.73 mol = 603.4 mmol g. (58.44 g/mol)

*(5B) Volume 135.5 l, Na⁺ 138 mmol/l pH 6.86 T.P. 47.2 g/l

Filtered through 34 x 40 cm WKS pads @ 1/hr.

(5C) Volume 423 l, Na⁺ 142 mmol/l pH 7.10 T.P. 46.6 g/l

Appearance of filtrate *Clear* * 15g NaCl, 80 mg NaOH

Volume of filter wash 1

Handed to filling team at hr.

Remarks & Variations from Standard Procedure

SPPS WASH VOLUME RECORD

82

The filter wash/unfilled volume is to be sterile filtrate after the batch of SPPS has been completed and before the bubble point test is carried out. The can identification label must be carefully inspected for details of batch, type of wash and volume. The can is to be immediately transferred to the drying plant with this form and handed over to the technician.

Batch: P1145
Volume: 32L
Sterile Filter: YES

Type of Wash: FKS

No. of Cans: 1

Signed: GRO-C

Date: 22/4/83

Samples Taken: S. Mahon

Protein Assay: ✓

Colony Count: ✓

Date and Time to -40°C Cold Room: 20/4/83 at 1450

Signed: GRO-C

Protein Result (g/l) 27.4
Colony Count (cols/ml) 21
Limulus (dilution) 1/10
Pyrogen (0.4°C) 0.2°C
HB Ag Neg.

Microbiology Filtrate Added: ✓

Volume: 6L

Date: 22/4/83

Signed: S. Mahon

After clearance, washes (maximum of 3 per batch) are removed from the -40°C Cold room the night before use:

CLEARANCE TO USE ☒
CLEARANCE TO RETURN FOR RE WORK ☐
CLEARANCE TO DISCARD ☐

Signed: GRO-C

Removed from -40°C Cold Room: Date: 8/5/83 Signed: GRO-C

Added to Batch SPPS: P1184/1145

Date: 8/5/83

Signed: GRO-C

SMALL

20

Analysis Request

Requested by: GRO-C

Date: 9/5/83

Return to: *Stark*
*Henry*If Urgent: ☒

Special Requests:			Sample			
P1194/1195			5A	5B	5C	
X	Test	Man. Licence No.	Unit			
X	Total Protein	0.01	g/L	76.5	76.5	76.0
	Fibrinogen	0.01	g/L	47.7	47.2	46.6
	% Clot		%			
	CAE	0.02				
	% Alb		%			
X	Sodium	0.04	mmol/L	64	133	142
X	Potassium	0.04	mmol/L	0.32	0.31	0.50
	Chloride	0.05	mmol/L			
X	pH	0.08		7.22	6.95	7.10
	Conductivity	0.07	µho			
	Ethanol	0.09	mmol/L			
	Citrate	0.10	mmol/L			
	Phosphate	0.11	mmol/L			
	PEG		g/L			
	Lipiduria	0.70				

Special Requests:			Sample			
X	Test	Man. Licence No.	Unit			
	Total Protein	0.01	g/L			
	Fibrinogen	0.01	g/L			
	% Clot		%			
	CAE	0.02				
	% Alb		%			
	Sodium	0.04	mmol/L			
	Potassium	0.04	mmol/L			
	Chloride	0.05	mmol/L			
	pH	0.08				
	Conductivity	0.07	µho			
	Ethanol	0.09	mmol/L			
	Citrate	0.10	mmol/L			
	Phosphate	0.11	mmol/L			
	PEG		g/L			
	Lipiduria	0.70				

Date Reported:

Signature:

Result to follow:

Report complete:

Date: 9/5/83

Signature:

GRO-C

LARGE

20

Analysis Request

Requested by: GRO-C

Date: 9/5/83

Return to: *Blank*
Fillney

/ If Urgent: ☒

Special Requests:			Sample		
P1194/1195			5A	5B	5C
X Test	Man. Licence No.	Unit			
Total Protein	9.01	g/l	76.52	76.54	76.86
Fibrinogen	9.01	g/l	49.90	49.8	46.6
% Clot		%			
CAE	9.02				
% Alb		%			
%		%			
Sodium	9.04	mmol/l	72	138	142
Potassium	9.04	mmol/l	0.44	0.39	0.50
Chloride	9.05	mmol/l			
pH	9.06		6.94	6.89	7.10
Conductivity	9.07	µmho			
Ethanol	9.09	%			
Citrate	9.10	mmol/l			
Phosphate	9.11	mmol/l			
PEO		g/l			
Limulus	9.70	g/l			

Special Requests:			Sample		
X Test	Man. Licence No.	Unit			
Total Protein	9.01	g/l			
Fibrinogen	9.01	g/l			
% Clot		%			
CAE	9.02				
% Alb		%			
%		%			
Sodium	9.04	mmol/l			
Potassium	9.04	mmol/l			
Chloride	9.05	mmol/l			
pH	9.06				
Conductivity	9.07	µmho			
Ethanol	9.09	%			
Citrate	9.10	mmol/l			
Phosphate	9.11	mmol/l			
PEO		g/l			
Limulus	9.70	g/l			

Date Reported:

Signature:

Result to follow

Report complete

Date: 9/5/83

Signature

GRO-C

20

Analysis Request

Requested by:

GRO-C

Date:

10-5-83

Return to:

S/F Mung

/ if Urgent: ☐

Special Requests:

Sample

X	Test	Man. Licence No.	Unit					
	Total Protein	9.01	g/l	7.9				
	Fibrinogen	9.01	g/l	12.9				
	% Clot		%					
	CAE	9.02						
	% Alb		%					
	%		%					
	Sodium	9.04	mmol/l					
	Potassium	9.04	mmol/l					
	Chloride	9.05	mmol/l					
	pH	9.06						
	Conductivity	9.07	ms/cm					
	Ethanol	9.09	/l					
	Citrate	9.10	mmol/l					
	Phosphate	9.11	mmol/l					
	PEG		g/l					
	Limulus	9.70						

	Special Requests:							
X	Test	Man. Licence No.	Unit					
	Total Protein	9.01	g/l					
	Fibrinogen	9.01	g/l					
	% Clot		%					
	CAE	9.02						
	% Alb		%					
	%		%					
	Sodium	9.04	mmol/l					
	Potassium	9.04	mmol/l					
	Chloride	9.05	mmol/l					
	pH	9.06						
	Conductivity	9.07	ms/cm					
	Ethanol	9.09	/l					
	Citrate	9.10	mmol/l					
	Phosphate	9.11	mmol/l					
	PEG		g/l					
	Limulus	9.70						

Date Reported:

Signature:

Result to follow:

Report complete:

✓

Date 12.5.83

Signature:

GRO-C

ALBUMIN : RESOLUTION AND VACUUM DISTILLATIONBATCH : P1194/1195 (C600/601)RESOLUTIONDATE : 9/5/83WEIGHT OF PASTE : 80.2 kgRESOLUTION VOLUME : 190 LFINAL VOLUME : 213 LFINAL PH : 6.97SIGNED

GRO-C

VACUUM DISTILLATION (CENTRITHERM) : DATE 9/5/83START VOLUME : 213 litresNUMBER OF CENTRITHERM PASSES : 2FINAL CONCENTRATED VOLUME : 73 LitresCONCENTRATE TO : STERILE FILLINGVOLUME : 73 LitresDATE : 9.5.83TIME : 14.25SIGNED

GRO-C

NOTES

100 mls of final concentrate to
C. Thimble (R&D).

21194

Analysis Request

CENTRIFUGAL P1194/1195

20

Requested by

Date

9/5/83

Return to

Dipina
KhanIf Urgent: ☒

GRO-C

Special Requests:

Sample

				36 I	1C	3A	3B II
X	Total Protein	Man. Licence No.	Unit	7605.1	7611.5	7611.6	7611.7
	Fibrinogen	9.01	g/l	322.0	98.0	158.0	288.0
	% Clot	9.01	g/l				
	CAE	9.02					
	% ALD						
	%						
	Sodium	9.04	mmol/l	428	135	226	443
	Potassium	9.04	mmol/l	284	286	1.5	372
	Chloride	9.05	mmol/l				2.0/6
	pH	9.06					
	Conductivity	9.07	mb				
X	Ethanol	9.08	g	2.430	97.8	16.0	2.35
	Citrate	9.10	mmol/l				
	Phosphate	9.11	mmol/l	2.25			
	PEG			Enzyme null			
	Liquor	9.70	g/l				

[7.57 mg/ETOH | g/PROT]

Special Requests:

Sample

				1D	2D
X	Total Protein	Man. Licence No.	Unit	7614.8	7614.9
	Fibrinogen	9.01	g/l	0	7614.9
	% Clot	9.01	g/l		
	CAE	9.02			
	% ALD				
	%				
	Sodium	9.04	mmol/l		
	Potassium	9.04	mmol/l		
	Chloride	9.05	mmol/l		
	pH	9.06			
	Conductivity	9.07	mb		
X	Ethanol	9.08	g	217.0	254
	Citrate	9.10	mmol/l		
	Phosphate	9.11	mmol/l		
	PEG				
	Liquor	9.70	g/l		

Date Reported:

Signature:

Result to follow:

Report complete:

✓

Date 9.5.83

Signature:

GRO-C

CENTRITHERM BATCH

C601.

P1195

70

PASTES FROM PROCESS

NO.	TYPE	% ALB	WT.	SOURCE PLASMA
14035-05 12	1V ₂ 4V	90	11.7	Ny 756, 757
14034-05 7	"	93	16.0	Ny 756, 757
14033-05 12	"	92	13.2	Ny 756, 757
			40.9	

70

CENTRITHERM BATCH

PASTES FROM PROCESS

P1194

NO.	TYPE	% ALB	WT.	SOURCE PLASMA
4033-05	IV	58	11.9	N4 755, 756 D: 100, 701
4032-05	"	43	12.1	N4 755, 756 D: 701
4035-05	"	40	15.5	N4 756, 757
			39.5	

A7

165

REQUISITION FOR PRODUCT IDENTIFICATION MATERIALS

PRODUCT AlbuminBATCH NO. P194FILLING DATE 10-5-83

	Number Requested	Initial	Number Issued	Date	Initial	Number used	Number Spoiled	Number Returned for Destruction	Date	Initial
In House Labels										
Final Labels	Bottle					522	96	—	—	—
	Carton									
Boxes VIAL A										
OUTER B										
Leaflets										
Albumin Tags				8/5/83	PA	65	—	—	10/5/83	GRO-C
Pyrogen Agg. Labels			62	1/83						

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Check list for final finishing of product

		<u>Initial</u>
LABELS	Labels printed correctly	<u>17</u>
	Checked	<u>AB</u>
	Batch information correct	<u>17</u>
	Checked	<u>AB</u>
BOTTLES/ VIALS	Card Check on cages (SPFS only)	<u>✓</u>
	Number of units on filling sheet	<u>596</u> *
	Number of units labelled	<u>470</u> *
	* Account for difference below	
	<i>10 samples 1 Pyrogen 1 Toxicity 110 Reagents</i>	
	Signature	GRO-C
	Signature	

Affix batch label(s) in space below

SCOTTISH NATIONAL BLOOD TRANSFUSION SERVICE
STABLE PLASMA PROTEIN SOLUTION
 450 ml. of 45g/l protein of human venous plasma origin
 Contains 8mmol/l caprylic acid, 130-150 mmol/l sodium
 3-10 mmol/l citrate and <0.05 mmol potassium per gram of protein.
 The contents should be used or discarded within 4 hours of opening.
 STORE AT A TEMPERATURE BELOW 28°C, PREFERABLY
 IN A COOL, DARK PLACE.
 DO NOT FREEZE.
 DO NOT USE UNLESS SOLUTION IS CLEAR
 AND FREE FROM DEPOSIT.
 PLEASE ENTER BATCH NUMBER IN PATIENT'S NOTES.
 Protein Fractionation Centre
 41-43 Gair Road, Edinburgh EH17 7QJ.
STABLE PLASMA PROTEIN SOLUTION
 NHS BLOOD

Batch No. 1184

Expiry Date MAY 1988

P.O.M.

