

For meeting 16 March

3/189

NOTES ON THE (S)8 MEETING HELD ON TUESDAY 28TH FEBRUARY 1989 AT 9.30AM

Present: M. Crowston  
A. Dickson  
N. Docherty  
B. Cuthbertson  
W. McBay  
B. Griffin  
P. Foster  
R. McIntosh

3/03/89



1 DOCUMENTATION

Discussion ensued concerning the Titrant Tris and PSBR in which there were found to be no significant problems. It was noted that the Heparin used in the first clinical batch will be that supplied and tested by QC. The availability of personnel was confirmed and in addition the quantity of plasma used would be 930Kg. The whole batch once processed would be spun frozen. Hence no need for dispensing into vials and lyophilisation.

2 REAGENT MANUFACTURER

It was confirmed that the Titrant and Tris were manufactured and with no difficulties.

3 PROCESSING TIMES ESTIMATE

These have been outlined in the previous memo circulated and found to be reasonably accurate.

4 ANY OTHER BUSINESS

It was recommended that due to various pressures we should bring forward the first full clinical trial production run. The two dates available would be Monday 20 March or Tuesday 28 March 1989. After long deliberation we concluded that the existing date of the 3rd April 1989 should remain. The following reasons confirm this decision.

- a) Modification to the diafiltration buffer is still ongoing.
- b) The formulation process is still requiring fine tuning.
- c) Lyophilisation - the freezing and super cooling aspect of this is still under investigation in R&D and thus cannot be established at this moment in time nor after the scheduled run of March 6th.
- d) Modifications to the Zinc precipitation reagent is ongoing and final decisions will not be apparent until further information is available.



- e) We still have to have a certified method of opening the vials safely for the Heparin preparation and certification that the Heparin itself is within our specifications.
- f) We are still endeavouring to establish a procedure for preparing the rubber closures that are used in the stoppering procedure ie. ensure that the moisture content is of a satisfactory nature.
- g) Over the Easter weekend we are having a "disruptive maintenance" period. We have already scheduled the programme for using our "fall back" programme should the PCU not be functioning correctly. In addition the PCU is receiving substantial maintenance at this time and hence we could not justify bringing the (S)8 production trial forward without jeopardising product quality. This would compromise any results that R&D will obtain from processing plasma under these conditions.

#### CONCLUSIONS

To bring forward The (S)8 trial to Monday 20th of March would create further difficulties. Information gleaned from the trial on Monday 6th March would not be available within a two week period. In addition for the maintenance of the cooling towers and the annual loss of electrical power over this weekend we cannot schedule any freeze drying activities. We thus cannot bring forward the clinical trial batch in any way.

Next meeting of the (S)8 group will be on Tuesday 14th March 1989 at 9.30am in the Seminar Room.

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