S8 File

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NOTE OF S8-GROUP MEETING 10 MAY 1989

PRESENT: N Docherty, W McBay, M Crowston (part), A Dickson, J Sinclair (part), B Griffin, B Cuthbertson, R V McIntosh

COPIES ALSO TO: P R Foster, R J Perry

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1. CONTINUING DEBRIEF ON 001 (See tables 1 and 3)

1.1 Additional out of spec item is Fibronectin. This is consistent with previous comments on high heparin content and low specific activity.

1.2 62% increase in moisture content across HT - dried bungs omitted from process.

2. BEGINNING DEBRIEF ON 002 (See tables 1, 2, 3 and 4)

2.1 Still low pH and low yield on extraction.

2.2 Losses (FVIII) on down titration improved but still significant.

2.3 Specific activity up on 001 but still not high enough for existing formulation.

2.4 UF recovery improved - see previous comments on process changes.

2.5 Solubility on unheated product vastly improved from 001 but still "one or two" particles - no heparin interference.

2.6 Product specification low on FVIII and still high (but closer) on heparin.

3. OUTSTANDING PROBLEMS AND R&D REQUIRED (See table 5)

The major R&D priorities are reducing heparin content and (because it is related) improving specific activity. We can carry the remaining problems.

4. R&D DATA SO FAR (See table 6 to 9)

4.1 These suggest that priority problems can be tackled by reducing the Heparin concentration used in the Zn/Heparin step and increasing the PEG concentration during Zn/Heparin precipitation.

4.2 However even with these improvements the protein content for 200-250 iu/ml FVIII content will be at its least 10g/l which is at the upper limit of the current formulation. Potential modifications to the formulation have already been made and the material is on the SMJR.

5. OPTIONS FOR 003 (See table 10)

The group unanimously adopted June 5th.

6. CHECK LIST FOR 003

This is laid out for May 22nd a revised list for June 5th will be circulated before then with the date for next meeting.

DR R V MCINTOSH
16 May 1989