

Bob — Next 28 Mtg
11 am Fri 3rd Oct

Bob P.

2.46

Notes of Z8 Meeting Held on Friday 26 September 1986

Seminar Room 2.00pm

Present P Foster
R Howieson
R Perry (part)
W Grant
R McIntosh

1. Processing

In Z8-6008 the extracted protein level per litre of plasma on cryo resolution was not reduced despite omitting sucrose from the cryo resolution buffer (Table 1). However the cryo precipitation weight per litre of plasma was higher than in previous Z8 batches.

2. Dispensing

Z8-6-008 still contained a large amount of foam. An experiment in the Sterile suite is planned for Wednesday 1 October using reconstituted Z8 to determine optimal conditions for filling and flow rate at which the filling nozzle is withdrawn from the vial.

3. Freezing

Z8-6-008 was loaded on to a +10° shelf and given 1 hour to equilibrate before rapid cooling. Supercooling was apparent on all traces.

4. Freeze Drying

In 30 random vials from Z8-6-008 all had plugs very similar in appearance with no large crystals but still some crystalline structure visible.

Moisture results on Z8 batches (Table 2) show that with the exception of Z8-6-005 SM200 all products have <2% moisture (current final product limit) and in general amorphous plugs have a lower moisture content.

5. Heating

Results on previous Z8 batches at 75 °C have been completed up to 48 hours with encouraging results (82 ± 7% recovery ; 9 ± 4 min.s solubility n = 4 batches) Results up to 72 hours will have been completed by the next meeting.

Results from Z8-6-008 at 75 °C and 80 °C will also be available for the next meeting.

6. Z8-6-009

As the sterile suite is down this product will be processed to the 0.45um filtration step prior to ultrafiltration then spun frozen as 350ml aliquots in DIN bottles and stored at -40 °C (a la RFII)

7. Next Meeting

Thursday 2nd October 1986

Seminar Room 2.00pm

● DR R V McINTOSH