

Coag. Factor Study Group Item 3(i) of
14.10.86

MODEL VIRUS STUDIES

CURRENT STATUS OF DRY - HEAT INACTIVATION EXPERIMENTS

1. Old FVIII Product (N.Y.)

Vaccinia	0.5 - 1.0 logs in 24 hours/68 °C
SLFV	1 - 3 logs in 24 hours/68 °C

2. Defix

Vaccinia	3.3 - >5.7 logs in 72 hours/80 °C
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Variable Under Study Include:

- a. Formulation - NaCl
- ATIII
- b. Freeze-Drying Parameters

3. Z8

FORMULATION 1

Vaccinia	3.9 logs in 72 hours/80 °C
SLFV	>6.0 logs in 48 hours/80 °C

Other Studies Currently Underway Include:

- a. Inactivation in Formulation 1 at 75 °C
- b. Inactivation in revised formulations
- c. Impact of freeze-drying cycles on virus recovery/heatability

4. BPL 8Y

Material dried and being tested to appended protocol.

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