

Audit Report

QA AUDIT SECTION

INCIDENT
REPORT NO.PROTEIN FRACTIONATION CENTREREPORT OF INCIDENT WITH POTENTIAL IMPLICATIONS FOR PRODUCT QUALITY
(Relates to SOP NO. 90 154 0002)SECTION 1 IMMEDIATE REPORT OF DETAILS OF INCIDENTDATE OF INCIDENT: WED 24.7.91
THUR 25.7.91TIME OF INCIDENT: A.M.DEPARTMENT: ProductionSECTION: ROOM NO: VICAR / STERILE STOREPRODUCT: HP FungiBATCH NO: HP 1-002PROCESS STAGE: VIRUS INACTIVATION / CHROMATOGRAPHYPSBR SECTION NUMBER (WHERE APPLICABLE): N/APERSONNEL INVOLVED IN INCIDENT: N/A

1.1 DESCRIPTION OF INCIDENT:

Sterile Store Pressure Differentials out of spec.

As part of the audit of the above process the manometer readings (printouts) for the VICAR and Sterile Suite were examined on 26.7.91. (Data appended)

WED 24/7/91 - The VICAR had several readings where the pressure was higher relative to the Sterile Store or Sterile Suite. Air pressure should be such that air flows from the Sterile Store to the VICAR not the other way round.

SOP1540002 THUR 25/7/91 - From 0926 - 12.27 hrs. The VICAR had a higher pressure than the Sterile Store.

SECTION 1 CONTINUED

1.2 IMMEDIATE ACTION TAKEN:

The sterile store pressure differentials were also out of spec. for at least 15-30 minutes during this period. Pressure should be ≥ 20 pa 17.5 and 10-3 pa were recorded. The security of the sterile suite was close to being compromised. Pressure differentials while the VICAR was not in operation a well (7/7 & 18/7) last week were OK.

1.3 COMMENTS:

Findings discussed with Roy Robson and incident reported filed as result.

Require to obtain differential records for the first H&FV run on 12/6 - 13/6/91 from archive disk.

Require to reexamine settings while VICAR is in operation to prevent possible compromise of virally inactivated FV and the sterile suite.

1.4 INCIDENT ALSO REPORTED IN PSBR: ☒ Y/N

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COPIES ISSUED TO:

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SIGNED:

Katherine A. ReidDATE: 26-7-91.