

8.0 TEST METHOD DATA QUALITY

8.1 Extent of Adherence to GLP Guidelines

Studies were not conducted in compliance with national or international GLP guidelines, nor were they generally conducted at facilities at which GLP studies are normally conducted.

8.2 Results of Data Quality Audits

The NTP Quality Assurance (QA) Unit conducted a limited audit of the FETAX Phase III.3 Validation Study. In this audit, the data provided in the published report were compared for accuracy, consistency, and completeness when compared to original records of the studies, as supplied by the three participating laboratories. A number of the values tabulated in the report could not be confirmed, because of omission of corresponding data in the provided summary sheets, illegible print, or inadequate description of statistical methods used to compute the values. General findings include:

- Data trails, study records, and results analysis procedures were not sufficient to support a QA audit;
- Some calculations apparently used the formula for standard deviation of a sample while others used that for a population; and
- The presence of transcriptional errors between the published report and the original data.

8.3 Impact of GLP Deviations and/or Data Audit Non-Compliance

A review by NICEATM of the discrepancies noted in the QA data audit by the NTP QA Unit did not reveal any that significantly altered the general conclusions presented in the FETAX Phase III.3 Validation Study report (Bantle et al., 1999). However, the audit results do indicate the general lack of GLP compliance in the validation studies.

8.4 Section 8 Conclusions

Studies were not conducted in compliance with national or international GLP guidelines, nor were they generally conducted at facilities at which GLP studies are normally conducted. A review by NICEATM of discrepancies noted in the QA data audit by the NTP QA Unit did not reveal any findings that significantly altered the general conclusions presented in the FETAX Phase III.3 Validation Study report (Bantle et al., 1999). However, the audit results do indicate the general lack of GLP compliance in the validation studies. It is recommended that future validation studies be conducted in compliance with national and international GLP guidelines.