SCHEDULE 1

GOOD LABORATORY PRACTICE PRINCIPLES(BASED ON SECTION II OF THE ANNEX TO COUNCIL DIRECTIVE 87/18/EEC,AS AMENDED BY COMMISSION DIRECTIVE 1999/11/EC)

PART VII

STANDARD OPERATING PROCEDURES

1. A test facility should have written standard operating procedures approved by test facility management that are intended to ensure the quality and integrity of the data generated by the test facility. Revisions to standard operating procedures should be approved by test facility management.

2. Each separate test facility unit or area should have immediately available current standard operating procedures relevant to the activities being performed therein. Published textbooks, analytical methods, articles and manuals may be used as supplements to these standard operating procedures.

3. Deviations from standard operating procedures related to the regulatory study should be documented and should be acknowledged by the study director and any principal investigators, as applicable.

4. Standard operating procedures should be available for, but not be limited to, the following categories of test facility activities. The details given under each heading are to be considered as illustrative examples—

Test and reference items

(a) receipt, identification, labelling, handling, sampling and storage;

Apparatus, materials and reagents

(b) (i) *apparatus:* use, maintenance, cleaning and calibration,

(ii) *computerised systems:* validation, operation, maintenance, security, change control and back-up,

(iii) *materials, reagents and solutions:* preparation and labelling;

Record keeping, reporting, storage, and retrieval

(c) coding of studies, data collection, preparation of reports, indexing systems, handling of data, including the use of computerised data systems;

Test system (where appropriate)

(d) (i) room preparation and environmental room conditions for the test system,

(ii) procedures for receipt, transfer, proper placement, characterisation, identification and care of test system,

(iii) test system preparation, observation and examinations, before, during and at the conclusion of the regulatory study,

(iv) handling of test system individuals found moribund or dead during the regulatory study,

(v) collection, identification and handling of specimens including necropsy and histopathology,

(vi) siting and placement of test systems in test plots;

Quality assurance procedures

(e) operation of quality assurance personnel in planning, scheduling, performing, documenting and reporting inspections.