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 III

FACILITIES

General

1.—(1) The test facility should be of suitable size, construction and location to meet the requirements of the regulatory study and to minimise disturbance that would interfere with the validity of the regulatory study.

(2) The design of the test facility should provide an adequate degree of separation of the different activities to assure the proper conduct of each regulatory study.

Test System Facilities

2.—(1) The test facility should have a sufficient number of rooms or areas to assure the isolation of test systems and the isolation of individual projects, involving substances known or suspected of being biohazardous.

(2) Suitable facilities should be available for the diagnosis, treatment and control of diseases, in order to ensure that there is no unacceptable degree of deterioration of test systems.

(3) There should be storage rooms or areas as needed for supplies and equipment. Storage rooms or areas should be separated from rooms or areas housing the test systems and should provide adequate protection against infestation, contamination and deterioration.

Facilities for handling test and reference items

3.—(1) To prevent contamination or mix-ups, there should be separate rooms or areas for receipt and storage of the test and reference items, and mixing of the test items with a vehicle.

(2) Storage rooms or areas for the test items should be separate from rooms or areas containing the test systems. They should be adequate to preserve identity, concentration, purity, and stability, and ensure safe storage for hazardous substances.

Archive Facilities

4. Archive facilities should be provided for the secure storage and retrieval of study plans, raw data, final reports, samples of test items and specimens. Archive design and archive conditions should protect contents from untimely deterioration.

Waste Disposal

5. Handling and disposal of wastes should be carried out in such a way as not to jeopardise the integrity of regulatory studies. This includes provision for appropriate collection, storage and disposal facilities, and decontamination and transportation procedures.