SCHEDULE 1

GOOD LABORATORY PRACTICE PRINCIPLES **[**[F1](BASED ON SECTION II OF ANNEX I TO THE EUROPEAN PARLIAMENT AND COUNCIL DIRECTIVE 2004/10/EC)**]**

F1 Words in Sch. 1 heading substituted (27.4.2004) by The Good Laboratory Practice (Codification Amendments Etc.) Regulations 2004 (S.I. 2004/994), regs. 1, **2(d)**

PART IV

APPARATUS, MATERIALS AND REAGENTS

1. Apparatus, including validated computerised systems, used for the generation, storage and retrieval of data, and for controlling environmental factors relevant to the regulatory study, should be suitably located and of appropriate design and adequate capacity.

2. Apparatus used in a regulatory study should be periodically inspected, cleaned, maintained, and calibrated according to standard operating procedures. Records of these activities should be maintained. Calibration should, where appropriate, be traceable to national or international standards of measurement.

3. Apparatus and materials used in studies should not interfere adversely with the test systems.

4. Chemicals, reagents and solutions should be labelled to indicate identity (with concentration if appropriate), expiry date and specific storage instructions. Information concerning source, preparation date and stability should be available. The expiry date may be extended on the basis of documented evaluation or analysis.

Changes to legislation:
There are currently no known outstanding effects for the The Good Laboratory Practice Regulations 1999, PART IV.