§ 792.135 Physical and chemical characterization studies.

(a) All provisions of the GLPs shall apply to physical and chemical characterization studies designed to determine stability, solubility, octanol–water partition coefficient, volatility, and persistence (such as biodegradation, photodegradation, and chemical degradation studies).

(b) The following GLP standards shall not apply to studies designed to determine physical and chemical characteristics of a test, control, or reference substance:

Section 792.31 (c), (d), and (g)
Section 792.35 (b) and (c)
Section 792.43
Section 792.45
Section 792.47
Section 792.49
Section 792.81(b) (1), (2), (6) through (9), and (12)
Section 792.90
Section 792.105 (a) through (d)
Section 792.113
Section 792.120(a) (5) through (12), and (15)
Section 792.125(a) (5) through (8), (10), (12), and (14)
Section 792.195 (c) and (d)

Subparts H–I [Reserved]

Subpart J—Records and Reports

§ 792.185 Reporting of study results.

(a) A final report shall be prepared for each study and shall include, but not necessarily be limited to, the following:

1. Name and address of the facility performing the study and the dates on which the study was initiated and was completed, terminated, or discontinued.

2. Objectives and procedures stated in the approved protocol, including any changes in the original protocol.

3. Statistical methods employed for analyzing the data.

4. The test, control, and reference substances identified by name, chemical abstracts service (CAS) number or code number, strength, purity, and composition, or other appropriate characteristics.

5. Stability, and when relevant to the conduct of the study, the solubility of the test, control, and reference substances under the conditions of administration.

6. A description of the methods used.

7. A description of the test system used. Where applicable, the final report shall include the number of animals or other test organisms used, sex, body weight range, source of supply, species, strain and substrain, age, and procedure used for identification.

8. A description of the dosage, dosage regimen, route of administration, and duration.

9. A description of all circumstances that may have affected the quality or integrity of the data.

10. The name of the study director, the names of other scientists or professionals and the names of all supervisory personnel, involved in the study.

11. A description of the transformations, calculations, or operations performed on the data, a summary and analysis of the data, and a statement of the conclusions drawn from the analysis.

12. The signed and dated reports of each of the individual scientists or other professionals involved in the study, including each person who, at the request or direction of the testing facility or sponsor, conducted an analysis or evaluation of data or specimens from the study after data generation was completed.

13. The locations where all specimens, raw data, and the final report are to be stored.
§ 792.195 Retention of records.

(a) Record retention requirements set forth in this section do not supersede the record retention requirements of any other regulations in this subchapter.

(b)(1) Except as provided in paragraph (c) of this section, documentation records, raw data, and specimens pertaining to a study and required to be retained by this part shall be retained in the archives for a period of at least ten years following the effective date of the applicable final test rule.

(2) In the case of negotiated testing agreements, each agreement will contain a provision that, except as provided in paragraph (c) of this section, documentation records, raw data, and specimens pertaining to a study and required to be retained by this part shall be retained in the archives for a period of at least ten years following the publication date of the acceptance of a negotiated test agreement.

(3) In the case of testing submitted under section 5, except for those items listed in paragraph (c) of this section, documentation records, raw data, and specimens pertaining to a study and required to be retained by this part shall be retained in the archives for a period of at least five years following the date on which the results of the study are submitted to the agency.

(c) Wet specimens, samples of test, control, or reference substances, and specially prepared material which are relatively fragile and differ markedly in stability and quality during storage, shall be retained only as long as the quality of the preparation affords evaluation. Specimens obtained from mutagenicity tests, specimens of soil, water, and plants, and wet specimens of blood, urine, feces, biological fluids, do not need to be retained after quality assurance verification. In no case shall retention be required for longer periods than those set forth in paragraph (b) of this section.

(d) The master schedule sheet, copies of protocols, and records of quality assurance inspections, as required by