(a) The establishment of master records containing appropriate specifications for each component used in drug production and a description of the test procedures used to check them, including provision for testing adequately representative samples. Such records shall also provide for appropriate retesting of materials subject to deterioration.

(b) The establishment of appropriate specifications, when needed, for drug preparations in the course of processing, and a description of the test procedures to check them, including provision for testing adequately representative samples.

(c) The establishment of appropriate finished-product specifications and a description of laboratory test procedures to check them, including provision for testing adequately representative samples.

(d) Adequate provision for checking the identity and strength for all active ingredients of drugs, for assuring the sterility of articles purporting to be sterile, and the freedom from pyrogens of articles that should be tested for freedom from pyrogens.

(e) Adequate provision to check the reliability, accuracy, and precision of any laboratory test procedures used.

(f) A reserve sample of at least twice the quantity of drug required to conduct all the tests performed on the batch of drug shall be retained at least 2 years after distribution has been completed.

(g) Provision for complete records of all data concerning laboratory tests performed, including the dates and endorsements of individuals making the tests, and provision for specifically relating the tests to each batch of drug to which they apply. Such records shall be retained for at least 2 years after distribution has been completed.

(h) Firms that manufacture nonpenicillin products, including certifiable antibiotic products, on the same premises or use the same equipment as that used for manufacturing penicillin products, or that operate under any circumstances that may reasonably be regarded as conducive to contamination of other drugs by penicillin, shall test such nonpenicillin products to determine whether any have become cross-contaminated by pencillin. Such products shall not be marketed if intended for use by man and the product is contaminated with an amount of pencillin equivalent to 0.05 unit or more of pencillin G per maximum single dose recommended in the labeling of a drug intended for parenteral administration, or an amount of penicillin equivalent to 0.5 unit or more of penicillin G per maximum single dose recommended in the labeling of a drug intended for oral use.

§ 133.12 Distribution records.

Complete records shall be maintained of the distribution of each batch of drug in a manner that will facilitate its recall if necessary. Such records shall be retained for at least 2 years after distribution has been completed, and shall include the name and address of the consignee, the date and quantity shipped, and the lot or control numbers identifying the batch of drug.

§ 133.13 Stability.

Adequate provision shall be made for testing the stability of components, drug preparations in the course of processing, when needed, and finished drugs. Such stability tests shall:

(a) Make adequate provision for determining the reliability and specificity of stability test methods employed.

(b) Make adequate provision to determine the stability of products in the containers in which they are marketed to assure, among other things, that the container is suitable, in that it is not reactive, additive, or adsorptive to an extent that significantly affects the identity, strength, quality, or purity of the drug.

(c) Provide for stability studies of any solution prepared as directed in the drug labeling at time of dispensing.

(d) Provide for suitable expiration dates to appear in the labeling of the drug when needed to assure that the drug meets appropriate standards of identity, strength, quality, and purity at time of use.

§ 133.14 Complaint files.

Records shall be maintained of all written or verbal complaints for each product. Complaints shall be evaluated by competent and responsible personnel and, where indicated, appropriate action taken. The record shall indicate the evaluation and action.