

APPENDIX II

A separate batch-production and control record shall be prepared for each batch of drugs produced and shall be retained for at least 2 years after distribution has been completed or at least 1 year after the batch expiration date, whichever is longer. The batch production and control record shall be numbered to permit the identification of all laboratory-control procedures and results on the batch and all lot or control numbers appearing on the labels of drugs from the batch. The records must also show an accurate reproduction of the appropriate master-formula record, checked and endorsed by a competent, responsible individual.

133.8 Production and control procedures

Production and control procedures shall include all reasonable precautions, to insure that the drugs produced have the identity, strength, quality, and purity they purport to possess.

Each significant step in the process, such as the selection, weighing, and measuring of components; the addition of active ingredients during the process; weighing and measuring during various stages of the processing; and the determination of the finished yield shall be performed by a competent, responsible individual and checked by a second competent, responsible individual. If such steps in the processing are controlled by precision automatic mechanical or electronic equipment, their proper performance shall be adequately checked by one or more competent, responsible individuals.

133.9 Product containers and their components

Suitable specifications, test methods, cleaning procedures, and, when indicated, sterilization procedures shall be used to insure that containers, closures, and other component parts of drug packages are suitable for their intended use. They shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug or its components beyond the official or established requirements and shall furnish adequate protection against deterioration or contamination of the drug.