ble individual and checked by a second competent, responsible individual, or if such steps in the processing are controlled by precision automatic mechanical or electronic equipment their proper performance is adequately checked by one or more competent, responsible individuals.

(b) All containers and equipment used in producing a batch of drugs shall be clearly labeled at all times to identify fully and accurately their contents, the stage of processing, and the batch, and shall be stored and handled in a manner adequate to prevent mixups with other drugs.

(c) Equipment, utensils, and containers shall be thoroughly cleaned and previous identification removed between batches and in continuous batch operations at suitable intervals, to prevent contamination and mixups.

(d) Appropriate procedures control the hazard of contamination with microorganisms in the production of parenteral drugs, ophthalmic solutions, and any other drugs purporting to be sterile, and appropriate procedures to control the hazard of cross-contamination of nonpenicillin products by penicillin in those establishments that manufacture, store, or handle penicillin products and nonpenicillin products.

(e) To assure the uniformity and integrity of products, there shall be adequate in-process controls, such as checking the weights and disintegration time of tablets, checking fill of liquids, and checking the adequacy of mixing, the homogeneity of suspensions, and the clarity of solutions.

(f) Competent and responsible personnel shall check actual against theoretical yield of a batch of drug, and in the event of any significant unexplained discrepancies, key personnel shall prevent distribution of the batch in question and other associated batches of drugs that may have been involved in a mixup with it.

§ 133.9 Products containers.

Suitable specifications, test methods, cleaning procedures, and when indicated, sterilization procedures shall be used to assure that containers, closures, and other component parts of drug packages are suitable for their intended use, in that they are not reactive, additive, or absorptive to an extent that significantly affects the identity, strength, quality, or purity of the drug, and furnish adequate protection against its deterioration or contamination.

§ 133.10 Packaging and labeling.

Packaging and labeling operations shall be adequately controlled to assure that only those drugs that have met the specifications established in the master-formula records shall be distributed; to prevent mixups between drugs during the packaging and labeling operations; to assure that correct labeling is employed for the drug; and to identify finished products with lot or control numbers that permit determination of the history of the manufacture and control of the batch of drug. Packaging and labeling operations shall:

(a) Be performed with adequate physical segregation of such operations from operations on any other drugs to avoid mixups.

(b) Provide that each type of labeling used shall be stored in a manner that avoids mixups between labelings and shall be carefully checked for identity and conformity to the labeling specified in the batch-production records.

(c) Provide adequate control of the quantities of labeling issued for use with the drug. (Competent, responsible personnel shall reconcile any discrepancy between the quantity of drug finished and the quantity of labeling issued. In the event of any significant unexplained discrepancy, key personnel shall prevent distribution of the batch in question and other associated batches of drugs that may have been involved in a mixup.)

(d) Provide for an inspection of the facilities to be used prior to labeling a drug to assure that all the previously used labeling and other drugs have been removed.

(e) Provide for adequate examination or laboratory testing of adequately representative samples of finished products after packaging and labeling to safeguard against any error in the finishing operations, and to prevent distribution of any batch until all specified tests have been met.

§ 133.11 Laboratory controls.

Laboratory controls shall include the establishment of adequate specifications and test procedures to assure that components, drug preparations in the course of processing, and finished products conform to appropriate standards of identity, strength, quality, and purity. Laboratory controls shall include: