For example, in the case of a capsule filled with defects, it is obvious we cannot eliminate these defects by analyzing the final product.

A surprisingly large number of individuals still regard analysis as the only basis for establishing and maintaining quality. Testing by official methods *after* the product is produced and *after* most products are in commercial distribution offers inadequate assurance of quality.

Total quality control on the other hand uses analysis or testing only as a check to make sure that the manufacturing processes have been properly controlled.

Testing merely indicates, in part, that minimum legal or other requirements have been satisfied.

Testing does not show maximum levels of quality.

What are these minimum requirements. They are the tests and requirements as set forth in the USP, NF, and FDA antibiotic certification regulations.

It is important to note that industry considers the USP, NF, and FDA antibiotic regulations as essential and the tests and standards contained in them to be the strongest in the world. However, we must realize that these standards are not all-inclusive, and by no means should they be the sole basis for judging whether a product is suitable for use by a patient.

Analysis of a product and adherence to the standards established by the official compendia does *not* mean that two products containing the same active ingredient will necessarily perform the same way in the body.

Unfortunately, technology has not yet provided adequate laboratory tests to assure the pyhsiological equivalence of drug products. Therefore, the gap must be filled with a complete program of strict adherence to the total quality control concept.

As we started earlier, quality must be built into a product during its developmental stage. This must be followed by strict adherence to a system which assures that the quality which is built into a product will remain when it reaches the consumer. This is the ultimate goal of total quality control.

An understanding of this inadequacy of official tests and standards to control a product completely can be best demonstrated by specific examples.

One of the basic problems involved in relying strictly on chemical tests to ascertain the therapeutic equivalency of a drug is the nonspecificity of some of the tests. Many of the official monographs for the final dosage form of a drug utilize tests which detect a group or chemical class of drugs rather than a particular molecular arrangement of the drug.

The logical question evoked from this discussion is—why not develop new and more specific tests? Well, this is being done.

The ethical pharmaceutical industry in conjunction with the official compendia and academic research laboratories is constantly looking for newer and better chemical and biological tests. However, this is a slow and tedious job, requiring years, or even decades of work.

Another example of the limitations of official standards can be seen in the latest revision of the United States Pharmacopeia. A statement in the general notices section reads as follows: "Variations in composition are undesirable and substantial differences in the content of active ingredients between individual capsules, tablets, and other dosage units are to be avoided."

Yet, until just recently, most of the official monographs in the United States Pharmacopeia and National Formulary did not require tests to assure the uniformity of composition of each dosage form.

What does this mean? It means that some unit of a product could have 150 percent of label claim, others 50 percent of label claim, while still others may have no active ingredients present at all. The reason for this was that the assay required only that the *average* of a number of units fall within a range, for example, of 90 to 110 percent of label claim. Consequently, the product, though defective, would pass the official requirement.

Another example is illustrated by the lack of standards established for the particle size of a drug substance.

One of the big fallacies of the theory of "drug product equivalency" can be illustrated by the following example. Let me start by saying that the result of an assay of a product does not necessarily mean that the determined amount of active ingredients will be available to the patient upon ingestion. Thus, potency and purity of a product are not the only important characteristics of the quality