or that type, but so far as we are concerned, we do not know whose tablets they are. They come in numbers or letters.

I understand that the Medical Letter obtains these tablets through various pharmacies, and then they repack them in these unlabeled vials, except for the code marks.

We follow the U.S. Pharmacopeia requirements and test exactly, wherever possible.

During the past 3 years we have made three series of tests. In 1964 we tested an antihistamine known as chlorpheniramine maleate. There we tested 20 samples of tablets from 20 different manufacturers.

The U.S. Pharmacopeia requires for this particular drug that first it shall contain that drug, and our tests showed that all of the samples did contain that drug; secondly, that the tablets disintegrate within a certain time limit, 30 minutes in this case, under certain specified conditions.

Senator NELSON. Was this the USP standard?

Dr. FITELSON. This is the U.S. Pharmacopeia standard, that when the tablets are shaken in water at a certain temperature in a certain way, they will fall apart completely within 30 minutes.

Senator NELSON. This is a test for this particular drug?

Dr. FITELSON. It is a test for a tablet.

Senator NELSON. A tablet?

Dr. FITELSON. The drug has nothing to do with it except that disintegration times may vary with different tableted drugs. In the case of this particular tablet, the U.S. Pharmacopeia requires 30 minutes as a maximum disintegration time.

Senator NELSON. For a different kind of tablet it may require——

Dr. FITELSON. Some disintegration times are more rapid, others are much longer. It depends on the tablet.

In this case all of the tablets complied with the U.S. Pharmacopeia requirement for disintegration time. The U.S. Pharmacopeia also requires that the tablets shall each have a certain weight within limits. The limitations vary with the size of the tablet. The smaller the tablet, the greater the percentage allowed because it is more difficult to maintain rigid limits there. The tablets did vary in size; some manufacturers prefer to put more excipient in the tablet so you will have larger tablets, with the same dosage of this drug.

Senator NELSON. But when you say weight, are you talking about the weight of the——

Dr. FITELSON. The weight of the total tablet, not the amount of drug in the tablet but the weight of the total table and the Pharmacopeia has certain ranges, and all of these 20 samples fell within those required ranges so far as the weight of individual tablets concerned.

Then we made the final test for assay, which is a chemical analysis of the amount of drug in the tablet. The Pharmacopeia has again a range limit for each particular drug. I do not recall what it is for this particular drug, but in most cases it is plus or minus 10 percent.

In other words, it may have 90 to 110 percent of the labeled amount of drug. In some cases it is a narrower range. In the case of chlorpheniramine maleate, all fell within the required range of the Pharmacopeia.

The results of this particular survey were published in the Medical Letter of February 26, 1965, on pages 18 and 19.