

were 19 different manufacturers' products tested. The U.S. Pharmacopeia has the same four tests for this product as it had for the chlorpheniramine maleate.

Senator NELSON. Which one is this?

Dr. FITELSON. Meproamate or Miltown. It has the identification tests, the disintegration test, time for disintegration, the variation in weights of individual tablets, and finally, the assay of the amount of material in the product, and these tablets met all of the specifications of the USP. They are published in the Medical Letter of April 23, 1965, on pages 34 and 35. They also include the price, this table here includes the price per 100 tablets.

Shall I continue?

Senator NELSON. Yes, go ahead.

Dr. FITELSON. And finally, we recently made a test on prednisone tablets, these are 5-milligram tablets.

Prednisone is a rather potent drug and the U.S. Pharmacopeia, in addition to the four tests I mentioned before, has two additional tests.

One is a test related to foreign steroids. There are chemical compounds closely related to prednisone, which might be present, if the prednisone were not manufactured properly, and the U.S. Pharmacopeia permits up to 2 percent of such related foreign steroids. This is a special test, and none of the 22 different samples showed more than 2 percent of such related foreign steroids. They came within the Pharmacopeia limits.

Another special test on prednisone is a new one for this Pharmacopeia. The present Pharmacopeia is USP, Volume 17, which became effective September 1965, and at that time a new test was introduced entitled "Tablet Uniformity Test" or "Content Uniformity Test."

This does more than weigh each tablet. You must make a chemical test of each tablet to determine exactly how much drug is in that tablet. All of the chemical tests of the U.S. Pharmacopeia are really tests on composites. That is, we grind 20 tablets together, and then we mix it up and take a small sample for our chemical tests or assay.

In this new test you actually grind only one tablet, and use that whole tablet for the test to see exactly how much prednisone is in that tablet.

You also make what is known as the assay test, which is made on the composite of 20 tablets. On these individual tablets, the U.S. Pharmacopeia allows, permits not more than one out of 30 to show more than 15 percent variation from the declared amount.

On the composite it has a much narrower range. As I recall, it is 90 to 110 percent of the declared amount. This tablet content uniformity test is a very rigid test, and some years ago I recall running, oh, 7 or 8 years ago I recall finding quite a big variation in individual tablets, but these 22 tablets all complied with the U.S. Pharmacopeia test in all respects.

Senator NELSON. Did you only do one tablet for each company?

Dr. FITELSON. The U.S. Pharmacopeia requires testing 10 individual tablets for each company.

Senator NELSON. From the same batch?

Dr. FITELSON. Plus a composite.

In other words, you first take 20 tablets and mix them up, grind them, mix them up and run a test of that composite. Then you take 10 separate individual tablets and run each one separately.