1. Content Uniformity Test

The weight variation test is assumed to control dose variation. If the granulation that is fed into the tablet machines is properly mixed and if the mix is not disrupted during the tabletting process, this assumption is probably valid. However, if the product is not properly mixed, tablets may pass the weight variation test but certain tablets may contain much more or much less than the amount claimed on the label.

The content uniformity test attempts to control this type of situation. The analyst selects 30 tablets, assays ten individually, and then tests compliance to the standard. If all of the ten tablets contain not less than 85 per cent and not more than 115 per cent of label claim, the product is satisfactory. If one tablet contains less than 85 per cent or more than 115 per cent of label claim, the remaining 20 tablets are assayed. Not more than one tablet out of 30 may contain less than 85 per cent or more than 115 per cent of label claim.

2. The Dissolution Test

The disintegration test is a physical test. The dissolution test is chemical in that the analyst must determine the actual amount of drug released from the tablet to the test medium.

In general, a tablet (or tablets) is placed in a basket suspended on the end of a stirring shaft. The basket is then submerged into a specified volume of simulated gastric or intestinal fluid. The analyst sets the stirrer in motion and then samples the medium over a period of time. He can then draw a dissolution curve (mg. in solution versus time) and can calculate a $T_{50\%}$ value, that is, the time required for the tablet to release one half of its drug content.

3. In Vivo Tests

There are many in vivo tests. Tablets can be given to a patient, blood samples taken at suitable time intervals, and these blood samples can be analyzed for drug content. It is then possible to draw a graph of drug concentration in the blood versus time. The area under the curve for one product can then be compared with the area under the curve for another product.

Another approach to *in vivo* product testing is based on product failure. The doctor notes that a particular brand does not produce a therapeutic effect. He administers a second brand. This product does produce a therapeutic effect. If an analyst can study the dissolution characteristics of the products, he can calculate $T_{50\%}$ values and use these to assess other products containing the same drug.

We may now turn back to the products we have studied in our laboratory.

1. Phenylbutazone Tablets (Sugar Coated)

One of the 23 brands failed the content uniformity test. Another product was so variable that we put it into the unsatisfactory classification. Most phenylbutazone tablets have a dose range of about 7 mg. This product had a dose range of about 25 mg.

We next checked the dissolution characteristics of 12 of the products. Most of the products released their phenylbutazone content to the simulated intestinal