

February 3, 1967, p. 6) It is clear, therefore, that the performance of American industry is less than satisfactory.

We can now turn to the results that we have obtained in our laboratory. During the past year, we have examined 23 brands of sugar coated phenylbutazone tablets, four brands of enteric coated phenylbutazone tablets, twelve brands of prednisone tablets, and four brands of p-aminosalicylic acid tablets.

1. Phenylbutazone Tablets (Sugar Coated)

Of the 23 brands, two contained less than 95 per cent of label claim—the legal minimum. One product failed to disintegrate in 60 minutes. This means that 13 per cent of the brands failed to comply with minimum requirements.

2. Phenylbutazone Tablets (Enteric Coated)

We examined four brands. One brand failed to disintegrate in 60 minutes. Just to make sure, we checked a second lot of the same brand. It too failed to disintegrate in 60 minutes. This means that 25 per cent of the products tested failed to meet minimum requirements.

3. Prednisone Tablets

We checked twelve brands. One of the twelve brands contained more than 110 per cent of the amount claimed on the label—the legal maximum. This means that 8.3 per cent of the products tested failed to meet minimum requirements.

4. p-Aminosalicylic Acid Tablets

We checked four brands. All complied with pharmacopeial standards.

During the past year, we checked a total of 43 products. Five of these, or 11.6 per cent failed to comply with minimum standards. We checked far fewer products than did the Food and Drug Administration in Washington but arrived at about the same conclusion—this being that there appears to be something wrong with about eight to eleven out of every one hundred products tested.

II. COMPLIANCE TO PHARMACEUTICALLY ACCEPTABLE STANDARDS

Many pharmaceutical analysts stop their assessment of products at this point. They conclude that if a product is legally acceptable, it must be therapeutically effective. Other pharmaceutical analysts conclude that they do not know this to be a fact and, for this reason, subject products to certain other tests. One of these tests is described in the United States Pharmacopeia and in the National Formulary, another is used by those researchers who study generic equivalency in depth, and the last is used by some drug manufacturers to assess their own products.

Without going into detail, I will outline the nature of these tests and their significance.