

Thus, it is assumed that if the active ingredient in two or more chemically equivalent products reaches the blood (or other fluid or tissue)--and becomes biologically or physiologically available--at the same time and in the same amounts, their therapeutic effects will be essentially the same.

Among the formulation factors which may be involved here, and involved in any possible nonequivalency of orally ingested products, are particle size; crystal form; the pressures and other conditions used in tablet-making; and adjuvants, such as substances incorporated as fillers, lubricants, binders, coatings, flavorings, colorings, and tablet-disintegrating agents.

Attention has also been directed toward physico-chemical tests which might be used to indicate biological equivalency--and, in turn, clinical equivalency. Perhaps the most important of these is the dissolution rate. Once a drug is dissolved in the gastrointestinal fluid, absorption is usually rapid. It is not surprising, therefore, that reported instances of clinical nonequivalency are rare among drugs which are highly soluble or administered in solution but most frequent among drugs