

CORRELATION BETWEEN TABLET DISINTEGRATION
AND IN VITRO DISSOLUTION

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The effect of aging on the mechanical properties of tablets has not been thoroughly investigated in the past. A recent article (1) addresses this problem in respect to tri-calcium phosphate tablets and exhibits the parameters of importance in tablet storage. Two of the aspects studied were dissolution and disintegration.

When problems with dissolution occur, it is a frequent practice to attempt to increase the in-vitro drug dissolution rates by e.g. increasing particle surface area (decreasing the particle size) of the active ingredient. This is quite logical in cases where the dissolution is the rate limiting step. However, often the disintegration of the tablets in the dissolution apparatus are rate-limiting (2-4) and in such cases the dissolution rate is improved merely (and solely) by decreasing the disintegration time.

Fig. 4 of the reference article, Ref. 1, is a point by point plot of disintegration time (D) as a function of time of storage (T). Fig. 5 of the reference article, Ref. 1, is a point by point plot of dissolution half time (t) as a function of storage time. Pairs of points from each storage time have been plotted in Fig. 1 of this article, giving the dissolution half time, t , as a function of disintegration time (D). It is obvious that a correlation exists and obvious consequences of

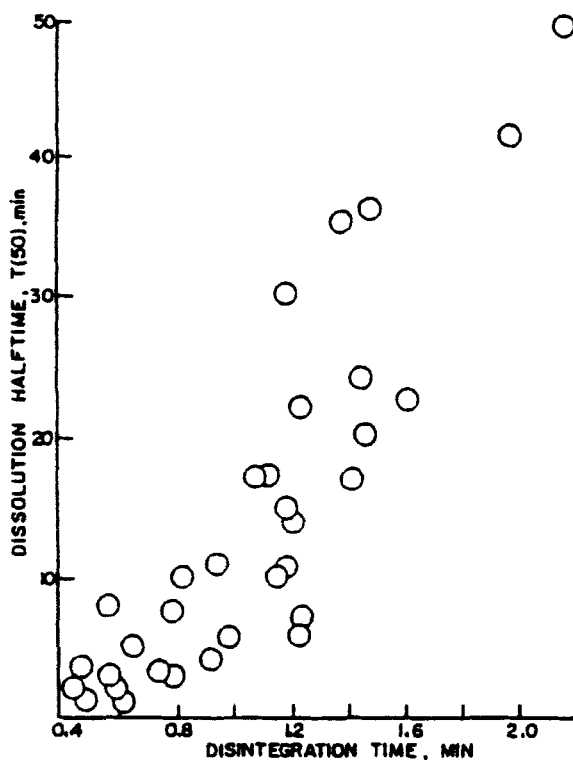


FIGURE 1

Dissolution half time plotted as a function of disintegration time, Data from Fig. 4 and Fig. 5 of Ref. 1

data of this type are attempts to ameliorate the dissolution by improving disintegration.

This type of correlation shows not only that formulation problems are best established by first investigating whether or not such a correlation exists, but it also points to the wisdom of maintaining a disintegration test in the U.S.P.

References:

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