interaction, but this interaction was first noticed in a light test and was photocatalyzed.

The regulations on light testing suggest the use of xenon lamps. In these a very high intensity light is applied in a very short period of time (minutes), and the effect on the dosage form (and the drug and the drug product) is recorded. The correlation of this with "real time and exposure" is unknown, and a database will have to be established before it can be rationally analyzed.

14. DIAGNOSTIC PAPERS

There is very little in literature regarding the stability of diagnostic product. In the case of diagnostic papers, the reagent is adsorbed on filter paper. The adsorption is usually governed by a Langmuir isotherm; there will, however, be active sites on the paper, and these may bind part (often a large percentage) of the reagent. Hence there will be an initial "loss" of reagent, and this will have to be compensated for by excesses, since only the reagent that is not chemisorbed will be available for the reaction in the diagnosis.

Stability data are gauged on the basis of initial assay (not theoretical content). Usually the stability is evaluated in a semiquantitative manner by an in-use test, i.e., an operator will carry out the diagnosis initially. For example, if it is a test that monitors sugar content (e.g., in urine), the filter paper will be judged against sucrose solutions of various concentrations. The instructions may state that the reaction is "positive" if a certain color is achieved (i.e., the concentration of sucrose is above a level, L) and negative if the response level is below another concentration, L^*, where $L^* < L$. The area in between is then "doubtful," and this would call for a retest. Initially the test should evoke the correct response (since the batch is, presumably, quality control released). As time goes by there will be a certain decomposition, which will vary from strip to strip, so at time t, a fraction of all the strips, q, may give an incorrect response. The best parameter to follow, stability-wise, is this parameter q, which should be such that it could be said at the expiration date with 95% confidence that q is below 5%.

15. EXPIRATION PERIODS

It was shown in the chapter dealing with statistics and expirations periods that there are mathematical means of calculating expiration periods from chemical stability data. This is not directly possible with physical testing. The reason for this is often the difficulty that exists in quantitating the physical property. Davis et al. (1977) state broadly that "the physicochemical changes that can occur ... upon storage or after processing or other external influence, should not be such that they can alter the therapeutic efficacy of the product." This is a good guideline, but the only way to test it is somehow to transform the experimental data into some quantity that can be extrapolated.

For instance, a suspension may start caking, but there are degrees of caking, and if it still can be shaken up in a reasonable length of time, then it should be all right. Here, a criterion must be set by the investigator, the quality control group, and the regulatory group within an organization. Such a criterion can be set up much like a test panel. Several containers of different degrees of caking can be