as it was at the time of manufacture, and more importantly, it may not meet the minimum required for efficacy. For a solution, a precipitate may have occurred. This may not affect the chemical content, but for a parenteral product it would, obviously, be quite unacceptable, and for an oral solution it would also be unsatisfactory, because the dispensing pharmacist would rightfully question the integrity of the product. The caking of a suspension impairs the dispensing of a known amount of drug in a teaspoon, and a separated or broken emulsion or cream obviously will not have the same emollient properties as would a proper product.

Physical stability will be treated by product category in the same order as in the case of chemical stability.

1. PHYSICAL STABILITY OF SOLUTIONS

Solutions are broadly divided into two categories: oral and parenteral solutions. Appearance, in both cases, is an important factor. In the case of oral solutions, organoleptic properties are also of great importance. Organoleptic evaluation is usually done subjectively, i.e., a tester (operator, technician), will judge the product and score it, either numerically or descriptively or both. In the case of appearance of solutions, there should always be a subjective statement (quantitative or subjective description) even if more quantitative instrumental parameters are recorded. A few words are therefore in order regarding organoleptic and appearance testing.

1.1. Organoleptic Testing

For organoleptic testing it is important to establish a test panel early in the stability program. (Or if a stability program is in place, but no such testing is carried out, a test panel should be selected at the first opportunity when a product with important taste or odor properties is placed on stability.) Many companies utilize just one tester for the task of organoleptic testing, but this can be shortsighted, because the tester may leave, go on vacation, or become ill, and in that case the logical solution is to assign someone else to the task. There may be an evaluational bias between the two testers, and this should be established at the onset.

First of all, the depth of organoleptic capacity should be tested. This can be done by asking the tester to taste serial dilutions of a bitter substance (e.g., quinine). Hence a sensitivity level can be established. A control of e.g. water or high dilutions should always be part of the protocol.

It should be noted that the technicians are not taste testers in the ordinary sense. That is, it is not necessary to match their "likings" to that of the general public. Rather, it is important that they can (a) duplicate their results and (b) remember them, since they will be asked to taste a preparation that they originally tested 3 or 6 months earlier. In so doing they would have to score the degree of flavoring, e.g., is it less than originally present, i.e., is the flavor being lost? They would also have to be able to describe the flavor well originally. For example, if the chemical is slightly anesthetizing, the duration of the anesthesia would be important. If there is interaction with a plastic bottle, are off flavors appearing in the product? Finally it is important to screen several testers to ascertain that they give the "same result."

In describing the flavor, several categories can be used (degree of sourness, degree of saltiness, level of flavor, type of flavor). Each of these may be assigned