

where $f(t_0)$ is the lag time function given by

$$f(t_0) = t_0 \left[1 - \exp\left(\frac{-t}{t_0}\right) \right] \quad (10.52)$$

t is, again, the dissolution time.

8.11 Appearance of Tablets and Capsules

A stability program should record the appearance of tablets as a function of storage time. This is most often done by subjective description, or by a rating index (0 for unchanged, 5 for vastly changed). Quantitative methods exist and are the following:

Comparison with color chips or charts (Rothgang, 1974)

Dissolving the dosage form and measuring the solution spectrophotometrically (Hammouda and Salakawy, (1971)

Photography (Armstrong and Marsh, 1974)

Reflection measurements (Matthews et al. (1974/75), Carstensen et al. (1964), Carstensen (1964), Goodhart et al. (1967), Turi et al. (1972), Wortz, R. B., (1967)

In the case of the second and fourth methods, a qualitative appearance description is always necessary, because the instrument will "average" the product. Comparison with chips can be used but is somewhat subjective. Such color charts have triangularly arranged chips, and the operator matches the object with a chip, which has a coordinate number. In fact the degree of whiteness (L), redness, (a) and yellowness (b) can be calculated from this, and it will be seen later on that this will allow for quantitative treatment of the change of the color of a pharmaceutical tablet or capsule.

Photography, of course, is relying on stringent adherence to conditions (exposure, aperture, and development) to insure that it is actually the tablets that are being compared, not the procedure for making the photograph.

Reflection measurements are often carried out in tristimulus meters and have been used quite extensively with varying degrees of success. If a tablet (or other surface) is placed in the meter, then reflectance values at three spectral regions are registered and recorded as x , y and z values. Rowe (1985) has reviewed these and points out that the whiteness index is $4(100Z/Z_0) - 3Y$, and the yellowness index is $100[1 - (100Z/\{Y \cdot Z_0\})]$, where $Z_0 = 118.1$. In actuality, the degree of whiteness, L , the degree of redness, a , and the degree of yellowness, b , are given by the formula (for a Hunter tristimulus meter):

$$L = 100 \left(\frac{Y}{100} \right)^{1/2}$$

$$a = 175 \frac{(X/98.041) + (Y/100)}{(Y/100)^{1/2}}$$

$$b = 70 \frac{(Y/100) - (Z/118.103)}{(Y/100)^{1/2}}$$