Tablet Hardness Determinations

(錠剤硬度測定法)

This General Information summarizes the principle, type, instrument configuration and points to be considered in the tablet hardness determination. Results, together with other information on physical integrity of tablets such as friability, are used to ensure their mechanical strength against stresses such as impact and pressure they experience from manufacturing process to usage.

The measurement is usually performed by placing a tablet between two platens and moving the one platen at a constant speed to obtain the force (N) just before the tablet is broken. The tablet hardness values reflect either the breaking force with which a compressive load generates breakage in a specific tablet plane, or the crushing strength with which substantial breaking cause the loss of structure, or both, depending on an apparatus used. In some cases, the tablet appearance may be lost after breakage. Criteria of the tablet hardness obtained by this measurement is different from the definition of hardness generally used in the field of materials science etc. (the resistance of a surface against penetration and pushing by a small probe).

Multiple hardness testers with different structure of the tablet-mounted part, the transfer mechanism of the platen, the measurement method of force, etc. are used. Manual or relatively simple-structured hardness testers include Monsanto (Stokes) tablet hardness tester which compresses a tablet with an indenter via a spring gauge and a screw, Pfizer tablet hardness tester which applies pressure to a tablet with a plier, Strong Cobb hardness tester which applies a load to a tablet by compressed air, and Erweka tablet hardness tester which applies a load to a tablet with an indenter using an electrically-powered weight load. Apparatuses which automate the process of hardness determination, correspond to various measurement modes and have a data correction function, etc. are also used.

The measurement of tablet hardness is affected by the shape, size, and orientation of a sample tablet, as well as the structure of an apparatus and the measurement conditions. Therefore, it is important to record the name of apparatus and conditions as well as results. The direct comparison of data requires measurements under the same conditions. The following points should be also considered in the measurement.

(i) Platen: Two platens with smooth area contacting a tablet should be used in parallel. The contact surface should be larger than the area of contact with the tablet. Make sure that tablets should be free of displacement by bending or twisting when the load is applied.

(ii) Loading rate: An apparatus having the mechanism which keeps the constant loading rate of compression force by platens should be used for the measurements. Or, moving the platen at a low rate from a certain point immediately before contact with a tablet should be performed to suppress the variation of the loading rate. Faster movement of the platen would allow rapid measurement, while possible variation in the loading rate often leads to uncontrollable crushing and the rapid accumulation of compressive loads.

(iii) Measurement unit and calibration of apparatuses: An apparatus calibrated with accuracy of 1N or less should be used for the measurement.

(iv) Change of apparatus: It is desirable to change an apparatus to that having a similar mechanism because the mechanism such as the loading method of compression force and the measuring method force would vary between them. The risk due to the apparatus change should be controlled by considering their measurement mechanisms and by comparing the results obtained by multiple measurement parameters such as the loading rate, and the moving speed of platens, using the sample in a same lot.

(v) Tablet orientation: A round non-scored tablet is usually placed between two platens to allow the compression occurs across the tablet diameter. In the measurement of a scored tablet, the tablet is placed so that the score is perpendicular or parallel to the platens. In the case of tablets with unique or complicated shape, it is desirable to place them in the same orientation that can be easily reproduced. In general, a load is applied either across the diameter or parallel to the longest axis.

(vi) Unit: As a unit of tablet hardness, kgf, kp or Strong Cobb Unit (SCU), etc. as well as N is used. Since SCU is expressed by pressure, the unit conversion must be viewed with caution.

(vii) Number of samples: In addition to the average of the measured values of tablet hardness, their variation should be also important. Therefore, the number of samples should be statistically appropriate for the purpose of measurement. Usually 6 or more samples, often 10 samples, are measured.