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Editorial

Brittle fracture during tableting – a problem for the pharmaceutical industry

Brittle fracture refers to capping and lamination of tablets, which occurs at the point of ejection of the tablets from the machine dies. The problem is attributable primarily to the presence of entrapped air (voids) or low density regions in the tablets. The latter (low density region) is in turn associated with an uneven consolidation of the tablet during compaction. The voids or low-density regions constitute weak points in the tablet from which cracks emanate and propagate when the tablet is subjected to diametral stress (e.g. die wall pressure). Brittle fracture is thus a result of stress concentration at the edge of the void or low-density region. Sudden elastic recovery following tablet ejection from the die has been implicated as a possible cause of brittle fracture, supported by the evidence of direct correlation between the plasto-elasticity of materials and the brittle fracture index (BF1) of resulting tablets[1-3]. This means that predominantly elastic materials are more prone to brittle fracture than plastic materials. Nevertheless the theory of stress concentration at the edge of a void and the subsequent crack propagation from it is more acceptable. Plastic materials ameliorate brittle fracture because they deform readily under stress to relieve the stress that would have concentrated at the edge of the void[4-5].

Hiestand *et al*[4] applied crack theory to develop a quantitative expression for the measurement of the brittle fracture tendency. Thus, the brittle fracture index (BFI) of a tablet is give by;

$$BFI = 0.5\ (T/T_o - 1)$$

where To and T are the tensile strengths of tablets with and without a centre hole, respectively. The centre hole (≤0.6mm) is a built-in model defect to simulate actual void formed in the tablet during compression. For brittle fracture to occur, the ratio T/T_o=3. By subtracting 1 and multiplying by 0.5 the maximal BFI value is 1 (unity). The BFI value thus has a range of 0 (no fracture tendency) to 1 (maximal fracture tendency). Tablet samples with BFI values (≥0.5) displayed a high fracture incidence during actual tableting[4].

Brittle fracture during tableting is considered a problem for the pharmaceutical industry because it is associated with formulation factors such as insufficient binder, a high plastoelasticity of the tableting base, and process factors such excessive compression pressures and overdrying of granules/ powders. Very often tableting is halted as soon as brittle fracture is observed; the

batch is either rejected or reprocessed, which is un-economical.

It is therefore recommended that the Hiestand mathematical expression for BFI could be used to test and select tablet formulations and tableting conditions that will give low fracture tendency. Such tests are to be carried out on small tablet samples during product development which will provide a basis for the rational selection of optimal conditions of formulation and processing for large scale production of tablets.

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