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The pharmaceutical sector faces the challenge of brittle fracture during tableting.

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Abstract

When the tablet dies at the time of ejection from the machine, a brittle fracture occurs, causing the tablet to cap and laminate. The existence of low density areas or trapped air (voids) in the tablets is the main cause of the issue. The second area, known as the low density zone, occurs when the tablet does not compress evenly. Cracks in the tablet may start and spread from the voids or low-density areas when it's exposed to diametral stress, such die wall pressure. Therefore, stress accumulation at the void or low-density region's edge causes brittle fracture. There is a clear association between the plasto-elasticity of materials and the brittle fracture index (BF1) of the resultant tablets, which supports the idea that sudden elastic recovery after tablet ejection from the die might be a source of brittle fracture.1- 3. This indicates that brittle fracture is more common in materials with a high degree of elastic modulus compared to plastics. However, the idea that cracks propagate from points of stress concentration at void edges is more widely accepted. Since plastics easily distort under stress, they mitigate brittle fracture by distributing the force that would have otherwise built up at the void's periphery.4-5.To quantify the brittle fracture index (BFI)

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may be calculated as follows:

$$BFI = 0.5 (T/T_0 - 1)$$

where To and T are the tensile strengths of tablets with and without a centre hole, respectively. The centre hole (≤ 0.6 mm) 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 =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 .

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.

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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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