observed on the other materials (up to 30% overall). The mean Brinell hardness for each tablet is summarized in Table 1, which shows that the hardness of the direct compression base tablets falls in the range 30 to 50 MN m^{-2}. The test can also show the effects of formulation changes, as indicated by the increase in hardness of paracetamol tablets prepare from powder, a granulation (with PVP and 8% starch) and a direct compression form respectively. Similarly, Asagran produces harder tablets than aspirin crystals.

Table 1

Brinell hardness	MN m^{-2}
Sucrose	61·2
Emcompress	50·0
Sta-Rx 1500	49·0
Paracetamol DC	35·7
Asagran	34·4
Avicel PH 101	32·8
Celutab	30·8
Aspirin gran. crys.	27·6
Paracetamol grans.	27·1
Lactose anhyd.	18·6
Paracetamol powder	12·3

Table 2

Height of relaxation (μm) / Indentn under load (μm)	Elastic Quotient
Avicel PH 101	0·61
Paracetamol grans.	0·60
Paracetamol DC	0·53
Lactose anhyd.	0·53
Paracetamol powder	0·51
Celutab	0·50
Sucrose	0·43
Emcompress	0·41
Sta-Rx 1500	0·39
Asagran	0·36
Aspirin gran. crys.	0·35

It is suggested that tableting materials which deform plastically with little elastic recovery should produce better quality tablets than more resilient materials. Thus, an elastic quotient has been calculated; this is the fraction of the indentation which rebounds elastically on removal of the load. The quotients are listed in Table 2 which indicates that the tablets prepared from the aspirin and direct compression bases generally have a lower elastic recovery than the poorer tableting materials e.g. paracetamol. An exception is Avicel which shows a high elastic recovery. This may be explained by its hollow microfibrillar structure (Marshall, Sixsmith & Stanley-Wood, 1972).

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The characterization of the mechanical strength of tablets

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Although it has been shown by Fell & Newton (1970) that the "scatter" in the fracture strength of nominally identical tablets can be reduced by ensuring that the specimens fail in tension, variations in strength will be observed, no matter how carefully controlled the test conditions. This variability is an inherent feature of a material which cannot deform plastically under increasing stress (i.e. a *brittle* material) and, because of it, a statistical treatment is essential for a full definition of the mechanical strength of such materials.

The Weibull distribution (Weibull, 1951) offers a valid mathematical model of this particular form of variability (Davies, 1971) and is being increasingly used for material characterisation and component failure predictions in the case of high-strength ceramics (Stanley, Sivill & Fessler, 1974). The two principal assumption are (i) that the material is isotropic and contains a statistically uniform distribution of flaws and (ii) that once a crack has initiated from a flow it will propagate without further increase in load, resulting in fracture. The

probability (P_f) that a specimen from a large batch will exhibit a tensile strength of σ_t is given by the expression:

$$P_f = 1 - \exp\left\{-\left(\frac{1}{m}!\right)^m\left(\frac{\sigma_t}{\bar{\sigma}_t}\right)^m\right\}$$

where m, the Weibull modulus, is a reciprocal measure of the strength variability of the material; (1/m)!, the "gamma" function, is a standard tabulated function and $\bar{\sigma}_t$ is the mean tensile strength of the batch. The applicability of this approach to pharmaceutical materials has been studied.

A batch of 30 flat-faced cylindrical tablets prepared from a -90, $+63$ μm size fraction of α- lactose monohydrate, using identical compaction conditions, has been tested in diametral compression. Having determined tensile strengths from the individual fracture loads, a "best" value of m was computed from the above equation using a "least squares" fitting procedure, with "mean ranking" values of P_f. The best m value was 13·0; the root mean square deviation of fit was 0·0307; the mean tensile strength ($\bar{\sigma}_t$) was 3·52 MN m^{-2}.

The root mean square deviation value indicates that the Weibull distribution satisfactorily models the strength variability of this material. The strength properties are therefore completely characterized in terms of the *two* quantities $\bar{\sigma}_t$, the mean tensile strength, and m, the Weibull modulus, rather than the former alone.

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A preliminary evaluation of a mercury intrusion method for assessing film continuity on coated tablets

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Film continuity and the presence of pinholes in a film coated tablet are important parameters to be considered when assessing the advantages of a new film former in a coating formulation or the efficiency of the coating procedure adopted. For insoluble films these parameters can be assessed either by measuring the amount of drug released in the case of sustained release polymer films, or by monitoring the resistance of the tablet to solutions of varying pH in the case of entero-soluble films. In both cases the presence of pinholes in the film coating will result in more than the theoretical amount of drug being released. This technique is not applicable to tablets coated with water soluble films since the film coating does not remain intact. Because of this drawback the possibility of using a mercury intrusion method for assessing film continuity has been investigated.

Since mercury will not penetrate holes or pores in a film unless an external pressure is applied, it follows that the proportion of film coated tablets penetrated by mercury under a constant intrusion pressure will be a comparative measure of the continuity of the film and hence the efficiency of the coating procedure. Experiments have shown that provided an intrusion pressure in excess of 5 MN m^{-2} is used the method is very reproducible. In our case the intrusion pressure was standardized at 100 MN m^{-2} using a mercury penetration porosimeter [Model 65H, Carlo–Erba Scientific Instruments Division]; twenty tablets were used in each determination and the number of tablets penetrated determined either by individual weighings or visual inspection.

Results illustrating the effect of tablet size and the presence of imprints on film continuity are shown in Table 1. The higher proportion of imprinted tablets failing the test indicates that film continuity is worst at the edges of the impressions. The effect of tablet size and