The prediction of the tensile strength of tablets

Pharmaceutical tablets usually consist of more than a single ingredient, but there appears to be no way of quantitatively predicting the properties of the tablets from a consideration of the properties of the individual components, even for a simple system. We have found for a single material, lactose, which exists in 3 forms, α-anhydrous, β-anhydrous and α-monohydrate, that it is possible to predict the strength of tablets prepared from mixtures of the three forms from measurements of the strength of tablets prepared from the individual components.

Tablets were prepared from 0·5 g. of each of the 3 forms of lactose (particle size 0–32 μm) and from 2 and 3 component mixtures of the different forms. The compaction was made at several loads at slow rates with an Instron Physical Testing Instrument modified to take a 1·27 cm flat-faced punch and die system.

The tablets produced were subjected to the diametral compression test described by Fell & Newton (1968). A typical example of tensile failure is shown in Fig. 1. To

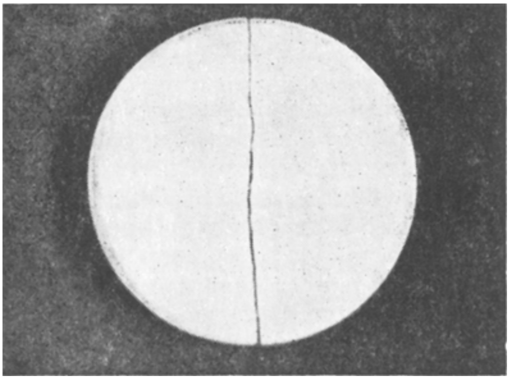

FIG. 1. A typical example of tensile failure of the tablet submitted to the diametral compression test.

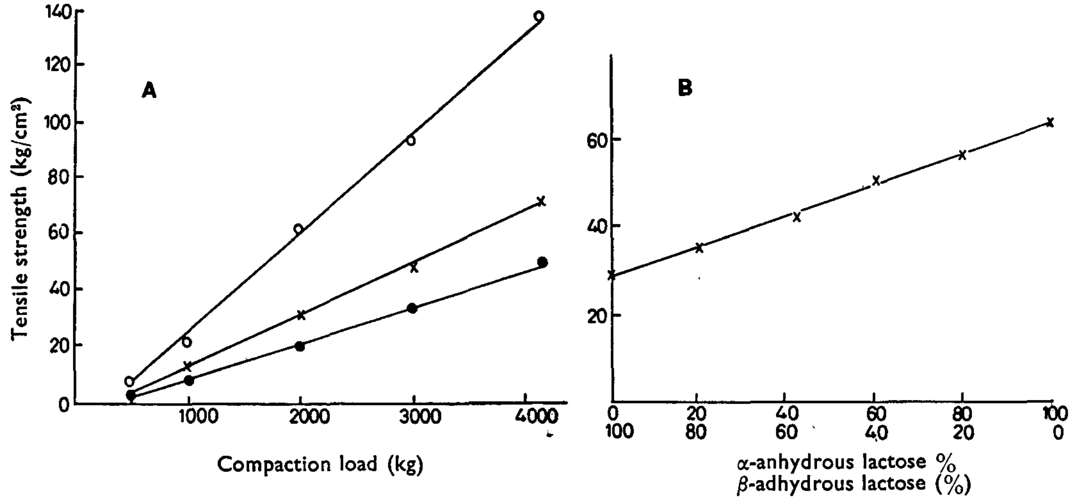

FIG. 2A. The tensile strength of lactose tablets prepared at different compaction loads. ○ = α-anhydrous. × = β-anhydrous. ● = α-monohydrate.

B. The tensile strength of tablets prepared from mixtures of α- and β-anhydrous lactose at 2000 kg compaction load.

Table 1. *The predicted and experimental values of the tensile strength of tablets prepared from mixtures (I–III) of different forms of lactose*

	I		II		III	
Compaction	Tensile strength kg/cm²		Tensile strength kg/cm²		Tensile strength kg/cm²	
load kg	Experimental	Predicted	Experimental	Predicted	Experimental	Predicted
500	5·2 (0·22)*	5·6	5·9 (0·47)	4·9	5·2 (0·27)	5·4
1000	13·4 (0·22)	15·5	15·2 (0·81)	13·7	14·9 (0·50)	14·9
2000	40·9 (1·59)	43·2	35·6 (1·93)	37·4	40·4 (0·91)	41·1
3000	66·4 (1·34)	68·6	58·2 (1·78)	59·8	62·0 (1·07)	65·5
4150	106·8 (1·07)	102·0	90·1 (2·07)	89·0	94·5 (0·63)	97·3

	Amounts of different forms of lactose %		
	I	II	III
α-Anhydrous	45	33	39·4
β-Anhydrous	55	45	57·6
α-Monohydrate	0	22	3·0

* The experimental values are the mean of 5 values, the figures in parentheses indicate the standard deviation of the mean values. The standard deviation of the results in Figs. 2A and B are of the same order as those reported above.

ensure that the tablets fractured along the diametral plane joining the lines of contact of the specimen and loading platens (the criteria of tensile failure given by Rudnick, Hunter & Holden, 1963), the test procedure was modified by the insertion of 3 sheets of blotting paper, each 0·03 cm thick, between the tablets and the platens. The value of the tensile strength is increased by the presence of padding, for reasons discussed by Rudnick & others (1963) and hence, the present results for α-lactose monohydrate are not directly comparable with those for the same material (crystalline lactose) reported in the previous paper (Fell & Newton, 1968), where no padding was used.

The tensile strength of tablets prepared from the individual forms of lactose shows a linear increase with the compaction load used to prepare the tablets (Fig.2A). Each form of lactose produces tablets of different strength for a given compaction load. When α-anhydrous and β-anhydrous lactose were mixed in a range of proportions, the tensile strength of tablets prepared at 2000 kg compaction load was directly related to the proportion of the components present in the system (Fig. 2B). Thus, for mixtures of these two forms of lactose, it was possible to predict the resultant tensile strength of the tablets, from a knowledge of the tensile strength of tablets of the individual components. The existence of a linear relation between tensile strength and compaction load for all 3 components should ensure that it is possible to predict the tensile strength of mixed component tablets produced at loads in addition to 2000 kg. In a similar manner, prediction of the tensile strength of tablets of a three component system could be possible. The agreement between experimental and predicted values is shown in Table 1.

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December 2, 1969

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