

DEPENDENCE OF APPARENT FRACTURE STRESS ON TABLETS ON TEST METHOD

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Several devices are available for the determination of the mechanical strength of tablets; a number of authors, e.g. Bavitz & others (1973), have considered the interpretation of test results from such devices. Fell & Newton (1970) have stressed the need to ensure tensile failure when determining the breaking strength under diametral compression, if reproducible results are to be obtained. Nevertheless, even if tensile failure is ensured, the brittle nature of many pharmaceutical materials will still result in a variable value for the breaking load of nominally identical tablets. Under certain conditions, this component of variability can be represented reciprocally by the modulus m of the Weibull distribution (Newton & Stanley, 1974). The performances of 2 commercially available strength testing devices, the Erweka and the Schlueniger, have been compared with that of a controlled loading test unit, which operates at a 1 mm min^{-1} strain rate. Fifty nominally identical tablets, prepared at known pressures from directly compressible materials, containing 1% magnesium stearate, were tested using each of the 3 devices. The values for mean fracture stress $\bar{\sigma}_f$, Weibull modulus m and coefficient of variation C for each test batch are given in the table. The value of $\bar{\sigma}_f$ for tablets of a given material varies with the method of testing although the relative order of the mean fracture stresses given by the 3 devices is consistent. Also important is the greater variability, as indicated by m or C , of the results from the 2 commercial devices. (An additional feature was the poor fit to the Weibull distribution given by the results from these 2 devices). This additional variability suggests that test results from Erweka and Schlueniger devices should be treated with caution.

Table. Test results from (1) compression unit, (2) Erweka device and (3) Schlueniger device.

Material	Mean fracture stress ($\bar{\sigma}_f$) MNm ⁻²			Weibull modulus (m)			Coefficient of variation (C) %		
	1	2	3	1	2	3	1	2	3
Spray dried lactose	1.73	1.06	1.80	15.32	6.27	9.69	6.86	16.67	16.25
Emcompress	1.54	1.09	2.20	34.68	6.77	5.10	3.79	14.52	20.53
Sta Rx	0.78	0.59	0.89	13.49	8.15	13.74	9.40	24.24	8.84
Cellutab	1.38	1.16	2.04	10.91	5.86	8.53	10.50	17.7	12.70

Bavitz, J.F., Bokdar, N.R., Karr, J.I. & Restanio, F.A. (1973). *J. pharm. Sci.*, 62, 1520-1524.

Fell, J.T. & Newton, J.M. (1970). *Ibid*, 59, 688-691.

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