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International Journal of Pharmaceutics 294 (2005) 271–272



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Reply to The Letter to the Editor

Anomalous effect of compression pressure on the brittle fracture tendency of α -cellulose tablets

Dear Sir.

We thank you for bringing to our attention the criticisms raised by Professors Podczeck and Newton on the calculation of the brittle fracture propensity (BFP) of the tablets. Our response is as follows.

We provided information on the specifications of the equipment used in the measurements, which should obviate the need for stating the sensitivity of every equipment used in the study. However, we hereby state that the Monsanto hardness tester, which was used to measure tablet fracture load, can be read accurately to $0.25 \, \mathrm{kg}$, and the digital micrometer for measuring tablet thickness, to $0.01 \, \mathrm{mm}$. The calculation of tablet tensile strength (T) was based on the mean value of the individually measured fracture loads, the variability of which was within $\pm 5\%$ of the mean value.

On the use of the new formula developed by Podczeck and Newton (2003) we feel that there is not enough support for it in the literature yet to warrant our use of their formula in the calculation of T and BFP values. We would want to see how many more workers in this field support their theory before we can accept it as a replacement for the Hiestand formula. Podczeck and Newton (2003) appeared to have based their new formula on the theories of fracture stress by Stanley (2001), which unfortunately did not include the case for compacts with a center hole and therefore not applicable to our system.

Podczeck and Newton, in their letter, were of the view that we had not considered the effect the center hole would have on the stress state at the center of the tablet. This is not correct. Perhraps these people over-looked the fact that the calculation of *T* was based

on experimentally measured values of fracture loads, which determination is also a measure of the effect of the center hole on the stress state. For instance, tablets with a center hole generally displayed lower fracture loads (and hence lower T values) compared with tablets without a center hole. This finding is attributable to the higher concentration of stress at the center in the case of the former. Therefore to make further adjustment to the calculation of T, after the effect of the center hole has been measured, would be erroneous. Any adjustment would only be necessary if the T values for perfect tablets (i.e. without a center hole) were being used to simulate T values for imperfect tablets, with a center hole. This was not the approach in our study.

It is not surprising that the results obtained by Podczeck and Newton differed from ours, because the system they studied also differed from ours. Our study was based on formulated tablets of α -cellulose and lactose. We have therefore used the materials in the form in which they would normally be used in tablet manufacture, i.e. lactose as granules and α -cellulose as a direct compression base (i.e. without preliminary granulation). Our interest was to investigate how these materials in the formulated forms (i.e. in the practical situation of use) would respond in their mechanical properties (T and BFP) to changes in compression pressure. From this perspective the approaches adopted for the study were in order. Yes, lactose was granulated with 20% solution of starch, but this does not mean that the resulting lactose granules contained 20% starch.

We want to make it clear that our objective was not to compare the compaction properties of α -cellulose and lactose powder, the title of the paper does not reflect that either. Hence, the data published relate to α -cellulose and lactose tablets.

References

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