THE EFFECT OF EXCIPIENT SOURCE ON THE PHYSICAL PROPERTIES OF A TABLET

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The physical properties of tablets prepared to the same composition in two separate laboratories, A and B, were found to be different. Those produced in laboratory A were harder, less friable and dissolved more rapidly. The difference in dissolution rate became more marked after storage: the % dissolution in 30 mins for tablet A increased from 97.8% to 100% after 8 months at 37°C, compared with a decrease from 86.6% to 37.4% for tablet B.

An investigation was carried out to determine the effect of changes in the excipient source and processing conditions on the initial properties and physical stability of the tablets. A standard process was defined and a series of batches were made altering one factor at a time.

All tablets contained gelatin as a binder, wheat starch as a disintegrant and lactose and mannitol as diluents, and were prepared by a conventional wet massing technique. In the standard process, the wheat starch was partly intra and partly extragranular; the granules were fluid bed dried, passed through a 20 mesh and, after blending with the extragranular ingredients, compressed on an instrumented single punch tablet machine. The effects of variations from this process on the dissolution and disintegration properties of the tablets are shown in the table.

	% Diss^{n} after 30mins		Disintegration Time (mins)	
Batch Variations	Initial	4M/37°C	Initial	4M/37°C
1- Source of gelatin	93.6	96.1	13.1	13.1
2- Source of starch	92.6	73.3	15.9	22.7
3- All starch extragranular	93.2	92.3	10.5	12.5
4- Less water at massing stage	90.8	96.1	13.7	13.2
5- More water at massing stage	90.7	87.4	18.4	15.3
6- Longer massing time	93.9	92.2	17.8	13.6
7A Tray drying	81.8	96.6	13.7	14.7
7B Standard process	84.3	97.7	16.6	15.5
8A 10 Mesh granules	79.5	96.6	11.5	18.0
8B Standard process	95.7	96.4	15.6	18.2
9A Rotary tablet machine	99.2	98.3	14.3	14.6
9B Standard process	98.2	96.4	11.9	13.8

The most significant difference between the properties after storage occurred when the source of starch was varied (Batch 2).

The differences between the batches of starch were investigated by several techniques eg. scanning electron microscopy, size analysis, moisture contents and swelling characteristics. The starch properties were examined both initially and after storage for 2 months at 50°C. Starch A was found to have a greater weight median diameter and a lower moisture content. The swelling characteristics were determined by equilibrating a known weight of starch and water for 30 mins at 37°C. The suspension was centrifuged and the residue weighed to indicate the amount of swelling of the starch grains. Starch A showed a % weight increase of 92.7% initially and 130.4% after storage, and starch B 90.7% and 102% respectively. The increased swelling power of Starch A after storage may be the cause of the differences in the tablet properties. The measurement of swelling power may prove useful as a quality control test for starch.