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The effect of compression pressure on hardness value in Avicel, lactose and mannitol tablets

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In manufacturing tablets, considering the behaviour of powders under applied pressure is of great importance. It has been observed that by increasing compaction force, hardness value increases. The manner of this effect in different substances, depends on various factors such as compactibility and mechanism of compaction. In the present study, hardness sensitivity to compression pressure for some diluents is investigated.

The following materials were used for the study: avicel PH 101 (FMC Corp., distributed by Akbarieh Co., Tehran, IRAN), anhydrous lactose (May and Baker, Canada), lactose monohydrate (Alpavit, Germany), D-(-)-mannitol (Merck, Germany).

The granules were prepared in a granulator (Lodige mixer), one from lactose monohydrate (Alpavit, Germany) and the other from D-(-)-mannitol (Merck, Germany), using 50% alcohol solution. Different series of tablets (1-from avicel, 2-from anhydrous lactose, 3-from granulated mannitol, and 4-from granulated lactose) were compressed in a hydraulic press (specially designed in Iran) using flat 12mm punches. They were prepared at five different compaction pressures from P1, the lowest, to P5, the highest. Tablet weight was 500 mg. Hardness values were then measured using hardness tester.

Granulated lactose in pressures less than 120 kg/cm^2 can not take the shape of a tablet, which is due to its low compactibility. The curve of hardness against compression pressure shows a sharp slope in pressure 120-150 kg/cm^2, because of rapid fragmentation and forming new bonding surfaces, which explains the sensitivity of hardness to pressure in this pressure range. In pressures higher than 150 kg/cm^2, the slope is lower and hardness sensitivity to pressure decreases. It is suggested to be due to the decreasing rate of fragmentation.

In the case of granulated mannitol, while tablet formation begins from low pressures, about 20 kg/cm^2, hardness value gradually increases by raising the pressure. This means that granulated mannitol shows low hardness sensitivity to applied pressure, as well as good compactibility. Its high compactibility in relation to granulated lactose is due to the higher volume of granulating solution used (Sheth et al. 1985) and the plastic deformation of mannitol as well as its fragmentation (Juppo et al. 1995).

In the case of anhydrous lactose, like granulated lactose, a gentle slope can be seen after the sharp slope in the graph of hardness against compression pressure. It is suggested that the first phase observed is due to rapid fragmentation and forming new bonding surfaces up to the pressure of about 100 kg/cm^2 after which, fragmentation rate decreases.

In the case of avicel, tablets were formed at very low pressures, about 5 kg/cm^2, and hardness increased sharply by increasing the pressure, so the diagram shows a very high slope. This indicates the high hardness sensitivity of this substance to pressure, as well as its high compactibility. It seems to be due to formation of hydrogen bonds beeween hydrogen groups on adjacent cellulose molecules and plastic deformation during compression (Sheth et al. 1985).

It is concluded that although avicel has high compactibility, because of its high hardness sensitivity to compression pressure, is not suitable for DC, at high percentages. Granulated lactose is not an ideal DC vehicle, due to the high hardness sensitivity at low pressures, as well as its relatively low compactibility. Among the vehicles studied, both anhydrous lactose and granulated mannitol show good compactibility, but granulated mannitol is suggested to be superior as a DC vehicle, because of relatively high compactibility, as well as low hardness sensitivity to compression pressures.

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