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Investigation of the properties of phenacetin tablets: dependence on the concentration of binding and disintegration agents

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The combination of Avicel PH-101 and Explotab as a disintegrator has not been used up to now, although each of these substances was applied in the technology of tablet production for other purposes (Copper and Rees, 1972; Esnard et al., 1973; Hüttenrauch and Keiner, 1976; Lieberman and Lachman, 1981; Lowenthal, 1972; Reier and Shangraw, 1966).

Our intention was to investigate the influence of a combined disintegrator consisting of Avicel PH-101 and Explotab on the properties of phenacetin tablets produced by the wet granulation method. The investigation also included determination of the correlation coefficient between the tablet properties and the pressure applied during the compacting, a function of the disintegrator applied.

In our investigation we used the following substance: phenacetinum (Ph. Jug. IV), Avicel PH-101 (Select Chemies, Zürich), Explotab (AHB D.D.R.), Talc (Ph. Jug. IV), Gelatin (Ph. Jug. IV).

Phenacetin tablets were prepared by the wet granulation method. Phenacetin granules were made with a 5% and 10% aqueous gelatin solution.

For granulating a 0.75 sieve (Ph. Jug. IV) was used. Phenacetin granules were dried at room temperature for 48 h, and then sieved through the sieves of 0.75 and 0.30. The combined disintegrator, Avicel PH-101 with 3% of Explotab was added to the final granules in a concentration of 10%. Comparative investigation was performed with phenacetin granules to which Avicel PH-101 was added in the same concentration. As an accessory agent for sliding and antiadhesion, 3% of talc was used.

Tablets were compressed in a Steinbuch machine for tableting with plain surface pistons of 12.1 mm in diameter. Certain pressure values of 22.75 MPa, 72.80 MPa, 136.40 MPa and 200.00 MPa during compaction were provided by using the momentum wrench.

In order to estimate the quality of phenacetin tablets, the disintegration time, the hardness and the friability of tablets were tested. The correlation coefficient between the properties of tablets were tested. The correlation coefficient between the properties of tablets and pressure applied was also determined considering the presence of disintegrator as well (Snedecor, 1956).

The rate of tablet disintegration was determined in the Erweka apparatus, type ZT 3, in distilled water at 37°C. The results obtained presented the

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average values of six separately tested samples.

Tablet hardness was also determined in the Erweka apparatus type TB 24. A friabilator Erweka type TA 3 was used to determine friability percentage. Rotating time of the friabilator was 5 min, rotating speed was 20 rotations/min.

On the basis of these investigations it can be concluded that the phenacetin tablets made with a 5% gelatin solution containing 10% Avicel PH-101 in combination with 3% Explotab as a disintegrating agent have the shortest disintegrating time. According to the disintegration rate, phenacetin tablets made with 10% gelatin solution containing 10% of the combined disintegrator have the next shortest disintegrating time.

Phenacetin tablets made with a 5% solution of binding agent and 10% of Avicel PH-101, are characterized by an even longer disintegration time. The longest disintegration time was determined for the tablets with 10% solution of

binding agent and 10% of Avicel PH-101. That means that the disintegration time of phenacetin tablets depends directly on the concentration of binding agent solution and the pressure applied during the compacting. The presence of Explotab in a tablet shortens disintegration time (Fig. 1).

Phenacetin tablet hardness depends directly on the concentration of binding agent applied in tablet processing. This dependence is reversed with the presence of Explotab and the pressure applied during the compaction (Fig. 2).

The percentage of friability also depends directly on the concentration of binding agent and pressure during the compaction and inversely on the concentration of Explotab present (Fig. 3).

Correlation coefficient values for disintegration of phenacetin tablets made by the wet granulation method differs slightly between the tablets containing Avicel PH-101 only and the tablets containing the combined disintegrator. The correlation coefficient values for hardness are lower in

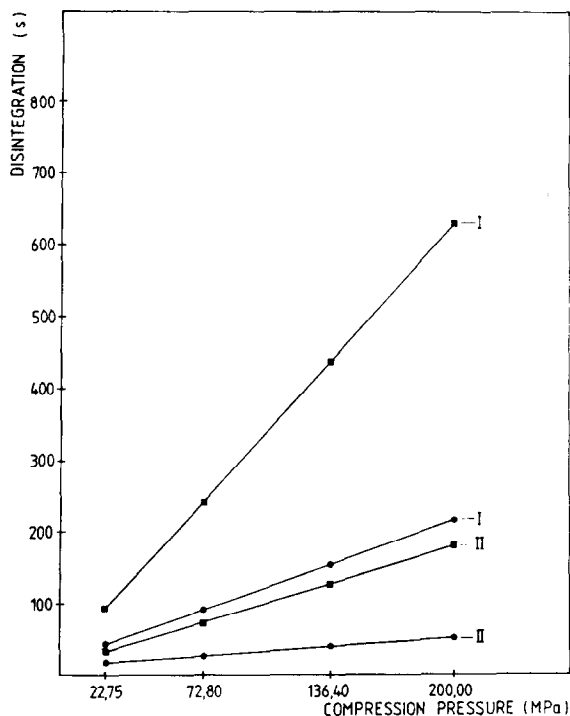


Fig. 1. Disintegration time of phenacetin tablets as a function of pressure. ●, 5% gelatin solution; ■, 10% gelatin solutions; I = 10% Avicel PH-101; II = 10% Avicel PH-101 with 3% Explotab.

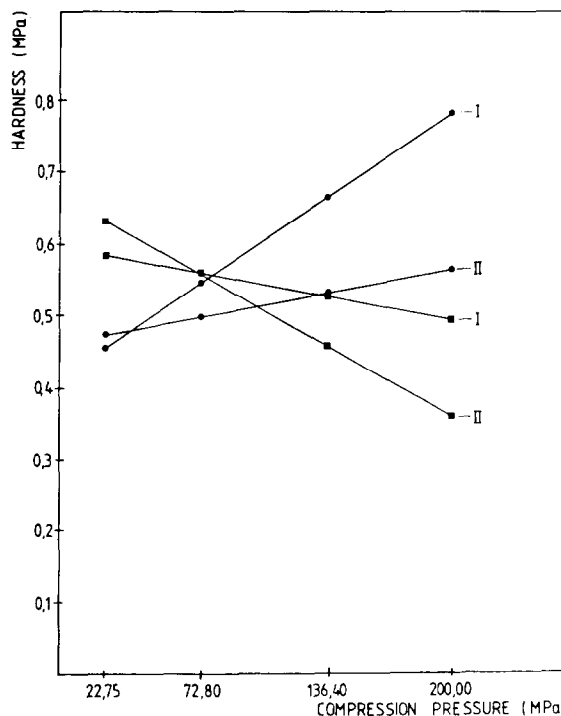


Fig. 2. Hardness of phenacetin tablets as a function of pressure. ●, 5% gelatin solution; ■, 10% gelatin solution. I = 10% Avicel PH-101; II = 10% Avicel PH-101 with 3% Explotab.

TABLE 1
CORRELATION COEFFICIENTS OF PHENACETIN TABLETS CONTAINING 5% GELATIN SOLUTION (I) AND 10% GELATIN SOLUTION (II)

Type of disintegrator	Concentration (%)	Correlation coefficient		
		disintegration	hardness	friability
Avicel PH-101 (I)	10	0.97	0.99	0.82
Avicel PH-101 (II)	10	0.97	0.98	0.78
Avicel PH-101 with 3% Explotab (I)	10	0.98	0.71	0.91
Avicel PH-101 with 3% Explotab (II)	10	0.98	0.69	0.91

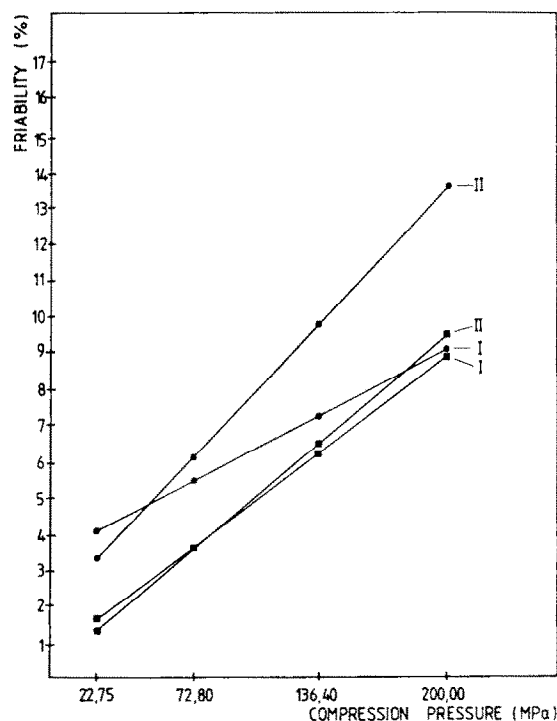


Fig. 3. Friability of phenacetin tablets a function of pressure. ●, 5% gelatin solution; ■, 10% gelatin solution, I = 10% Avicel PH-101; II = 10% Avicel PH-101 with 3% Explotab.

the tablets containing combined disintegrator than in tablets containing Avicel PH-101. This indicated that the presence of Explotab reduced the hardness of these tablets causing the friability to a

greater extent which the correlation coefficient values prove (Table 1).

There are slight differences in the correlation coefficient values between disintegration rate and type, for phenacetin tablets made with 10% of gelatin solution. However, the correlation coefficient values between tablet hardness and type of disintegrator differ to a greater extent. The correlation value between the tablet hardness and Avicel PH-101 is lower than the correlation value in tablets with the combination of Avicel PH-101 and 3% Explotab. This is reflected in tablet friability as well (Table 1).

References

- Copper, J. and Rees, J.E., *Tableting research and technology*, J. Pharm. Sci., 61 (1972) 1511-1555.
- Esnard, J.M., Clerc, J., Tebbi, H., Duchene, D., Levy, J. and Puisieux, F., *Etude d'excipients pour compression, directe purs, et en présence de phenobarbital, sur machine alternative*. Ann. Pharm. Fr., 31 (1973) 103-16.
- Hüttenrauch, R. and Keiner, J., *Wie kristallin sind mikrokrystalline Cellulosen*. Pharmazie, 31 (1976) 183-185.
- Lieberman, H.A. and Lachman, L., *Pharmaceutical Dosage Forms*. Vols. 1 and 2, Marcel Dekker, New York-Basel, 1981, pp. 137, 163, 178.
- Lowenthal, W., *Disintegration of tablets*. J. Pharm. Sci., 61 (1972) 1695-1711.
- Reier, G.E. and Shangraw R.F., *Microcrystalline cellulose in tableting*. J. Pharm. Sci., 55 (1966) 510-514.
- Snedecor, G., *Statistical Methods*, Ames, Iowa, 1956, p. 167.