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Investigation of the properties of Compactrol tablets relative to the type of disintegrant used

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According to the literature data, Compactrol (calcium-sulphate dihydrate) is a suitable filler/binder for tablets prepared by direct compression (Elsabbagh et al., 1985; Bolhuis et al., 1979). Ac-Di-Sol (croscarmellose sodium), Primojel (sodium starch glycolate), Polyplasdone XL (cross-linked polyvinylpyrrolidone), Plasvita TSM (formaldehyde-casein or methylene-casein) and Xylan (polymerization product of the xylose) are disintegrants with different disintegration mechanisms (Khan and Rooke, 1976; Fenyvest et al., 1984; Mendell, 1974). Ac-Di-Sol and Polyplasdone XL improve the disintegration by absorbing water through capillary action, with a secondary swelling effect (Kornblum and Stoopak, 1973). While Primojel has strong swelling properties (Bolhuis et al., 1981; 1984), the influence of Plasvita TSM on disintegration depends solely on capillary activity (Awe et al., 1960). An essential disintegrate mechanism of Xylan is swelling of the primary particles (Paronen, 1983; Steffens et al., 1980).

The aim of the present work was to evaluate the influence of 5 disintegrants on disintegration time and mechanical properties of Compactrol tablets, as so as to compare those disintegrants with respects to their suitability for direct compression.

In this investigation the following substances were used: Compactrol (Mendell, U.S.A.), Primojel (Avebe, The Netherlands), Ac-Di-Sol (FMC, Philadelphia), Polyplasdone XL (GAF, F.R.G.), Plasvita TSM (Dynamit Nobel, Troisdorf, F.R.G.), Xylan (Kemi, Finland), Cab-O-Sil (Cabot Co., Tuscola, U.S.A.).

Compactrol tablets were prepared by the method of direct compression. The filler/binder (Compactrol) was dry mixed with 2% of the disintegrant to be tested in a Turbula mixer at 90 rpm for 10 minutes, and the blending was continued for next 5 minutes after adding 3% of lubricant (Cab-O-Sil).

All tablets were prepared with an excenter press, exerting a compression force of 10 kN. Each tablet weighed 500 mg, with a diameter of 12 mm.

The estimation of Compactrol tablets included determination of both disintegration time and the crushing strength. The disintegration time was measured at $37 \pm 0.5\,^{\circ}C$ in distilled water, using the "Erweka" apparatus type ZT 3. The crushing strength was determined by "Erweka" apparatus

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TABLE 1

Compactrol tablets: disintegration time and crushing strength

Values are means ± S.D.

Disintegrant	Disintegration time (s)	Crushing strength (kg)
Ac-Di-Sol	7.0 ± 0.84	3.75 ± 0.146
Primojel	9.0 ± 0.71	4.40 ± 0.198
Polyplasdone XL	12.5 ± 0.65	5.00 ± 0.190
Xylan	23.5 ± 0.85	5.75 ± 0.179
Plasvita TSM	33.5 ± 0.53	6.25 ± 0.110

type ZT 3. The crushing strength was determined by "Erweka" apparatus type TB 24.

The results are given in Table 1 and represent the mean values of 6 determinations. As indicated by the results, disintegration time and crushing strength depend only on the type of disintegrant.

The shortest time of disintegration (7.0 ± 0.84 s) and the smallest crushing strength (3.75 ± 0.146 kg) were obtained for Compactrol tablets with Ac-Di-Sol as disintegrant. Tablets containing Primojel, Polyplasdone XL and Xylan showed higher values for disintegration time and crushing strength, respectively. The Compactrol tablets with Plasvita TSM had the longest disintegration time (33.5 ± 0.53 s) and the greatest crushing strength (6.25 ± 0.110 kg).

It can be concluded that Ac-Di-Sol is the best disintegrant for Compactrol tablets and the suitable adjuvant for tablets prepared by the method of direct compression.

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