

consistent with the particle size distribution data. Apparently, the angles of repose of all granulated excipients were well within the range of 20° to 40° seen for most pharmaceutical powders; this indicates that they all possessed good flowability.

Bulk density may partially describe the packing behavior of granules. A higher bulk density is advantageous in tableting because of the reduced fill volume of the die. As reported previously,<sup>17</sup> both bulk and tapped densities of all dicalcium phosphate granules were significantly higher than those of lactose granules. On the other hand, most values of Carr's index calculated from density data were less than 10. This further indicates the fair to excellent flow properties of these granules, which are important characteristics for a directly compressible excipient.

The physical properties, including thickness, hardness, and friability, of lactose (L1-L5) and dicalcium phosphate (D1-D5) matrix tablets obtained by compression at a constant force with the addition of a fixed

ratio of nifedipine (SDA) or its solid dispersion systems (SDB-SDD) are tabulated in Table 3. Results show that the thicknesses of these tablets produced from lactose matrix granules with the addition of any form of nifedipine were larger than those produced from dicalcium phosphate matrix granules with the corresponding forms of nifedipine. This is undoubtedly due to the higher density of dicalcium phosphate matrix granules. Differences in the thicknesses of tablets produced from matrix granules of either lactose (L1-L5) or dicalcium phosphate (D1-D5) with the same forms of nifedipine were insignificant. Since the density of lactose particles is lower than that of dicalcium phosphate, results indicate that granulation with a film-forming material caused no significant change in the density of the original particles of lactose or dicalcium phosphate. A lower percentage (at most 5) of EC and HPMC (50 cps, at most 4) was obviously able to impart only a limited influence on the density modification of lactose or dicalcium phos-

**Table 3. Physical Properties of Lactose and Dicalcium Phosphate Matrix Tablets with the Addition of Nifedipine and Its Solid Dispersion**

Formulation	Thickness (mm)	Hardness (kg)	Friability (%)	
SDA (20:180) <sup>a</sup>	L1/D1	3.74 (0.02)/2.96 (0.01) <sup>b</sup>	7.51 (0.75)/6.65 (0.55) <sup>b</sup>	0.20/0.19 <sup>c</sup>
	L2/D2	3.77 (0.02)/2.96 (0.01)	7.58 (0.88)/8.50 (0.70)	0.20/0.14
	L3/D3	3.80 (0.02)/2.96 (0.01)	6.64 (0.79)/6.38 (0.52)	0.25/0.21
	L4/D4	3.81 (0.01)/2.91 (0.01)	7.58 (0.70)/6.87 (0.79)	0.24/0.17
	L5/D5	3.77 (0.01)/2.94 (0.02)	8.50 (0.76)/5.69 (0.51)	0.20/0.20
SDB (40:160)	L1/D1	3.87 (0.03)/3.16 (0.05)	7.09 (0.80)/7.39 (0.70)	0.10/0.07
	L2/D2	3.86 (0.02)/3.18 (0.02)	9.72 (1.07)/8.67 (0.82)	0.06/0.03
	L3/D3	3.89 (0.02)/3.18 (0.02)	6.85 (1.06)/6.26 (1.05)	0.01/0.10
	L4/D4	3.88 (0.01)/3.18 (0.02)	8.84 (1.01)/7.68 (0.96)	0.04/0.03
	L5/D5	3.86 (0.01)/3.16 (0.01)	8.36 (0.88)/6.16 (1.08)	0.03/0.06
SDC (40:160)	L1/D1	3.86 (0.01)/3.21 (0.01)	14.42 (1.04)/6.93 (0.61)	0.12/0.10
	L2/D2	3.88 (0.01)/3.20 (0.02)	15.51 (1.06)/11.13 (0.82)	0.01/0.03
	L3/D3	3.92 (0.02)/3.19 (0.02)	13.89 (1.10)/8.18 (0.39)	0.08/0.06
	L4/D4	3.92 (0.03)/3.22 (0.02)	14.00 (1.10)/9.14 (0.67)	0.05/0.05
	L5/D5	3.86 (0.02)/3.18 (0.01)	8.11 (0.90)/6.96 (0.78)	0.02/0.07
SDD (80:160)	L1/D1	4.67 (0.02)/3.95 (0.02)	12.97 (0.24)/8.20 (0.61)	0.08/0.05
	L2/D2	4.66 (0.01)/3.92 (0.03)	12.59 (0.92)/8.97 (0.54)	0.03/0.03
	L3/D3	4.70 (0.02)/3.98 (0.03)	9.55 (0.69)/6.67 (0.47)	0.09/0.09
	L4/D4	4.75 (0.02)/3.97 (0.03)	11.71 (1.09)/7.68 (0.53)	0.10/0.09
	L5/D5	4.66 (0.02)/3.93 (0.03)	8.43 (0.88)/6.32 (0.36)	0.05/0.06

SDA, nifedipine alone; SDB, nifedipine: PVP = 1:1; SDC, nifedipine: HPMC, 1:1; SDD, nifedipine: HPMC = 1:3.

<sup>a</sup>Weight ratio of solid dispersion form of nifedipine to matrix granules; <sup>b</sup>mean (S.D) (standard deviation,  $n = 10$ ); <sup>c</sup>average of 10 tablets.