

REFERENCES



1. Finholt, P. "Influence of Formulation on Dissolution Rate." in Dissolution Technology., p. 106-139. Edited by L.J. Leeson and J.T. Carstensen. Washington, D.C. : I.P.T. Academy of Pharmaceutical Science, 1974.
2. King, R.E. "Tablets, Capsules and Pills" in Remington's Pharmaceutical Science., p. 1578-1580. Edited by J.E. Hoover. Easton, Pa : Mack Publishing Co., 1975.
3. American Pharmaceutical Association. The United States Pharmacopeia. 19th rev. Easton, Pa : Mack Publishing Co., 1975.
4. American Pharmaceutical Association. The National Formulary. 14th ed. Easton, Pa : Mack Publishing Co., 1975.
5. American Society of Hospital Pharmacists. American Hospital Formulary Service. Washington, D.C. : American Society of Hospital Pharmacists Inc., 1964.
6. Jantrarasakul, S., et al. "Study of Efficiency and Quality of Commercial Dipyrone Tablets from Their Dissolution Profiles." Th.J.Pharm.Sci. 4 (Nov.-Dec. 1979) : 357-370.
7. Jacob, J.T., and Plein, E.M. "Factors Affecting the Dissolution Rate of Medicaments from Tablets I : In Vitro Dissolution Rate of Commercial Phenobarbital Tablets." J.Pharm.

- Sci. 57 (May 1968) : 798-805.
8. Omray, A.K., Sharma, A.K., and Chauhan, P.A. "Influence of Diluents on Properties of Diazepam Tablets and In Vitro Evaluation of Commercial Tablets." Indian J.Pharm. 40 (Jan.-Feb. 1978) : 8-10.
9. Hirschorn, J.O., and Kornblum, S.S. "Dissolution of Poorly Water-Soluble Drugs. II : Excipient Dilution and Force of Compression Effects on Tablets of a Quinazolinone Compound." J.Pharm.Sci. 60 (March 1971) : 445-448.
10. Marlowe, E., and Shangraw, R.F. "Dissolution of Sodium Salicylate from Tablet Matrices Prepared by Wet Granulation and Direct Compression." ibid. 56 (April 1967) : 498-504.
11. Levy, G., Antkowiak, J.M., Procknal, J.A. and White, D.C. "Effect of Certain Tablet Formulation Factors on Dissolution Rate of the Active Ingredient II." ibid. 52 (November 1963) : 1047-1050.
12. Baveja, S.B., and Kakkar, A.P. "Effect of Formulation Factors on the Dissolution Rate of Sulphadimidine Tablets." Indian J. Technol. 11 (1973) : 137.
13. Solvang, S., and Finholt, P. "Effect of Tablet Processing and Formulation Factors on Dissolution Rate of the Active Ingredient in Human Gastric Juice." J.Pharm.Sci. 59 (January 1970) : 49-52.
14. Jacob, J.T., and Plein, E.M. "Factors Affecting Dissolution of

- Medicaments from tablets II. Effect of Binder Concentration, Tablet Hardness, and Storage Conditions on the Dissolution Rate of Phenobarbital from Tablets." ibid. 57 (May 1968) : 802-805.
15. Oudtshoorn, M.C.B., Potgieter, F.J., de Blaey, C.J., and Polderman, J. "The Influence of Compression and Formulation on the Hardness, Disintegration, Dissolution, Absorption and Excretion of Sulphadimidine Tablets." J.Pharm.Pharmac. 23 (1971) : 583-586.
16. Sakr, A.M., and Elsabbagh, H.M. "Delayed Released in Compressed Nicotinic Acid Tablets." Mfg.Chem.& Aerosol News. 43 (December 1973) : 41-42, 45.
17. Shubair, M.S., and Dingwall, D. "Effects of Starch Concentration on Dissolution." ibid. 46 (October 1976) : 52, 55-56.
18. Chalmers, A.A., and Elworthy, P.H. "Oxytetracycline Tablet Formulations : Effect of Variation in Binder Concentration and Volume on Granule and Tablet Properties." J.Pharm.Pharmac. 28 (1976) : 228-233.
19. Shukla, A.K., and Verma, K.C. "Influence of binding agent on Paracetamol Tablets." Indian J.Pharm.Sci. 40 (Nov.-Dec. 1978) : 200-202.
20. Yen, J.K.C. "The Dissolution Rate Principle in Practical Tablet Formulation." Can.Pharm.J. 97 (1964) : 493-499.
21. Mendell, E.J. "An Evaluation of Carboxymethyl Starch as a Tablet

- Disintegrant." Pharm.Acta Helv. 49 (1974) : 248-250.
22. Rubinstein, M.H., and Price, D.J. "In Vivo Evaluation of the Effect of Five Disintegrants on the Bioavailability of Frusemide from 40 mg. Tablets." J.Pharm.Pharmac. 29, Suppl. (1977) : 5P.
23. Khan, K.A., and Rooke, D.J. "Effect of Disintegrant Type upon the Relationship between Compressional Pressure and Dissolution Efficiency." ibid. 28 (1976) : 633-636.
24. Levy, G., and Gumtow, R.H. "Effect of Certain Tablet Formulation Factors on Dissolution Rate of the Active Ingredient III Tablet Lubricants." J.Pharm.Sci. 52 (December 1963) : 1139-1144.
25. Ahmed, M., and Enever, R.P. "Influence of Magnesium Stearate on the Dissolution and Biological Availability of Sulphadiazine Tablets Formulation." J.Pharm.Pharmac. 28, Suppl. (1976) : 5P.
26. Iranloye, J.A., and Parrott, E.L. "Effect of Compression Force, Particle Size and Lubricants on Dissolution Rate." J.Pharm.Sci. 67 (April 1978) : 535-539.
27. Kitazawa, S., et al. "Effects of Hardness on the Disintegration Time and the Dissolution Rate of Uncoated caffeine Tablets." J.Pharm.Pharmac. 27 (1965) : 765-770.
28. Society of Japanese Pharmacopoeia. The Pharmacopoeia of Japan. 8th ed. Tokyo, Japan : Yakuji Nippo., 1973.

29. Varcel, L. "Spectrophotometric Determination of Noramidopyrine-methansulfonate Sodium in Analgin Spofa Veterinary Injections." Cesk.Farm. 16 (1967) : 494-495. Through Chemical Abstracts Vol. 68 (1968) : 81453 d.
30. Marshall, K. "Solid Oral Dosage Forms." in Drugs and the Pharmaceutical Sciences Volume 7 Modern Pharmaceutics, p 372 Edited by G.S. Banker and C.T. Rhodes. New York, Marcel Dekker Inc., 1979.
31. Nyma B.V. "It's Time to Disintegrate Your Problems with Nymcel." Mfg. Chem. & Aerosol News. 48 (May 1977) : 59.
32. Nürnberg, E. "Experimental Testing of Directly Compressed Tablet Bases. Part I." Drug Made Ger. 16 (1973) : 48.

**APPENDIX**

Table 14 Weight Variation and Percent Labeled Amount of Dipyrone  
Tablet (Formula 1-30, Hardness 5-6 kg.)

Formula	Average Weight, gm. $\pm$ S.D.	% C.V.	Percent Labeled Amount*
1	0.5969 $\pm$ 0.0030	0.51	100.91
2	0.6193 $\pm$ 0.0030	0.48	99.07
3	0.6229 $\pm$ 0.0043	0.69	99.58
4	0.6213 $\pm$ 0.0026	0.42	99.84
5	0.6240 $\pm$ 0.0018	0.29	98.66
6	0.5978 $\pm$ 0.0059	0.99	99.44
7	0.6272 $\pm$ 0.0041	0.66	100.93
8	0.6245 $\pm$ 0.0034	0.55	100.77
9	0.6286 $\pm$ 0.0034	0.54	99.34
10	0.6188 $\pm$ 0.0039	0.64	99.00
11	0.5964 $\pm$ 0.0030	0.50	100.21
12	0.6213 $\pm$ 0.0037	0.59	98.68
13	0.6262 $\pm$ 0.0035	0.56	101.49
14	0.6298 $\pm$ 0.0041	0.65	99.32
15	0.6174 $\pm$ 0.0028	0.46	100.32
16	0.6004 $\pm$ 0.0017	0.28	99.91
17	0.6279 $\pm$ 0.0048	0.76	100.12
18	0.6249 $\pm$ 0.0023	0.38	100.56
19	0.6234 $\pm$ 0.0033	0.54	97.90
20	0.6231 $\pm$ 0.0029	0.46	98.37
21	0.5989 $\pm$ 0.0029	0.48	100.53
22	0.6272 $\pm$ 0.0030	0.48	99.16
23	0.6255 $\pm$ 0.0027	0.43	101.20
24	0.6256 $\pm$ 0.0029	0.46	101.64
25	0.6243 $\pm$ 0.0044	0.71	102.38
26	0.5936 $\pm$ 0.0056	0.95	103.16
27	0.6282 $\pm$ 0.0037	0.60	101.74
28	0.6212 $\pm$ 0.0028	0.46	103.10
29	0.6206 $\pm$ 0.0029	0.46	101.40
30	0.6260 $\pm$ 0.0035	0.55	101.60

\* Mean of two determinations.

Table 15 Weight Variation and Percent Labeled Amount of Dipyrone  
Tablet (Formula 1-30, Hardness 9-10 kg.)

Formula	Average Weight, gm. $\pm$ S.D.	% C.V.	Percent Labeled Amount*
1	0.5994 $\pm$ 0.0028	0.46	101.33
2	0.6217 $\pm$ 0.0043	0.68	98.69
3	0.6243 $\pm$ 0.0028	0.44	99.56
4	0.6220 $\pm$ 0.0042	0.67	99.94
5	0.6244 $\pm$ 0.0026	0.42	98.73
6	0.5963 $\pm$ 0.0050	0.84	99.20
7	0.6284 $\pm$ 0.0036	0.57	100.50
8	0.6248 $\pm$ 0.0027	0.44	100.82
9	0.6282 $\pm$ 0.0041	0.66	99.28
10	0.6220 $\pm$ 0.0032	0.52	99.50
11	0.5982 $\pm$ 0.0031	0.52	100.52
12	0.6219 $\pm$ 0.0037	0.59	98.78
13	0.6265 $\pm$ 0.0026	0.42	101.85
14	0.6283 $\pm$ 0.0036	0.57	99.08
15	0.6184 $\pm$ 0.0024	0.39	100.48
16	0.6011 $\pm$ 0.0029	0.48	100.22
17	0.6282 $\pm$ 0.0029	0.41	100.17
18	0.6250 $\pm$ 0.0028	0.45	100.58
19	0.6232 $\pm$ 0.0032	0.52	97.90
20	0.6225 $\pm$ 0.0028	0.45	98.28
21	0.6003 $\pm$ 0.0018	0.31	100.77
22	0.6270 $\pm$ 0.0031	0.49	99.12
23	0.6241 $\pm$ 0.0040	0.64	100.97
24	0.6219 $\pm$ 0.0027	0.44	101.87
25	0.6212 $\pm$ 0.0030	0.49	101.87
26	0.5971 $\pm$ 0.0064	1.08	102.56
27	0.6262 $\pm$ 0.0047	0.76	101.42
28	0.6223 $\pm$ 0.0031	0.50	103.27
29	0.6226 $\pm$ 0.0056	0.90	103.35
30	0.6244 $\pm$ 0.0033	0.52	101.34

\* Mean of two determinations

Table 16 Tablet Hardness and Friability of Dipyrone Tablet (Formula 1-30, Hardness 5-6 kg.)

Formula	Hardness (kg. <u>+S.D.</u> )	% C.V.	Friability (%)
1	5.90 <u>± 0.23</u>	3.89	0.92
2	5.62 <u>± 0.46</u>	8.20	1.20
3	5.89 <u>± 0.36</u>	6.12	1.01
4	5.46 <u>± 0.51</u>	9.35	0.96
5	5.50 <u>± 0.22</u>	4.06	0.87
6	5.88 <u>± 0.26</u>	4.40	0.59
7	5.58 <u>± 0.50</u>	9.02	0.78
8	5.64 <u>± 0.39</u>	6.97	0.58
9	5.72 <u>± 0.31</u>	5.46	0.44
10	5.44 <u>± 0.30</u>	5.53	0.53
11	5.64 <u>± 0.42</u>	7.46	0.71
12	5.70 <u>± 0.47</u>	8.33	0.87
13	5.64 <u>± 0.33</u>	5.79	0.96
14	5.77 <u>± 0.54</u>	9.43	0.57
15	5.51 <u>± 0.43</u>	7.89	0.93
16	5.20 <u>± 0.43</u>	8.25	0.93
17	5.83 <u>± 0.48</u>	8.15	0.79
18	6.94 <u>± 0.55</u>	7.95	0.78
19	5.74 <u>± 0.54</u>	9.35	0.50
20	5.87 <u>± 0.17</u>	2.86	0.81
21	5.62 <u>± 0.24</u>	4.35	0.50
22	5.72 <u>± 0.46</u>	8.12	0.76
23	5.59 <u>± 0.45</u>	8.14	0.78
24	5.75 <u>± 0.42</u>	7.23	0.54
25	5.88 <u>± 0.17</u>	2.83	0.45
26	5.83 <u>± 0.30</u>	5.15	0.69
27	5.44 <u>± 0.42</u>	7.82	0.90
28	5.65 <u>± 0.43</u>	7.65	0.75
29	5.58 <u>± 0.34</u>	6.04	0.69
30	5.63 <u>± 0.18</u>	3.28	0.85

Table 17 Tablet Hardness and Friability of Dipyrone Tablet (Formula 1-30, Hardness 9-10 kg.)

Formula	Hardness (kg. <u>±S.D.</u> )	% C.V.	Friability (%)
1	9.79 ± 0.71	7.23	0.84
2	9.44 ± 0.78	8.32	0.99
3	9.65 ± 0.69	7.18	0.72
4	9.46 ± 0.56	5.94	0.61
5	9.44 ± 0.22	2.38	0.78
6	9.26 ± 0.58	6.26	capping
7	8.72 ± 0.47	5.37	0.71
8	9.86 ± 0.43	4.38	0.47
9	9.47 ± 0.52	5.55	0.36
10	9.74 ± 0.35	3.56	0.28
11	9.59 ± 0.73	7.71	0.50
12	9.68 ± 0.85	8.78	0.53
13	9.60 ± 0.67	7.02	0.62
14	9.64 ± 0.79	8.22	0.35
15	9.43 ± 0.39	4.16	0.66
16	9.78 ± 0.52	5.34	0.46
17	9.41 ± 0.57	6.04	0.74
18	9.85 ± 0.36	3.63	0.61
19	10.04 ± 0.57	5.73	0.21
20	9.81 ± 0.30	3.07	0.68
21	9.81 ± 0.31	3.21	0.38
22	9.52 ± 0.68	7.14	0.57
23	9.98 ± 0.74	7.44	0.50
24	9.67 ± 0.53	5.49	0.38
25	9.67 ± 0.48	5.00	0.35
26	9.44 ± 0.42	4.50	0.52
27	9.64 ± 0.40	4.13	0.70
28	9.88 ± 0.62	6.28	0.63
29	9.73 ± 0.74	7.57	0.42
30	9.61 ± 0.25	2.57	0.62

Table 18 Weight Variation and Percent Labeled Amount of Dipyrone  
Tablet (Formula A-H)

Formula	Average Weight, gm. $\pm$ S.D.	% C.V.	Percent Labeled Amount*
A	0.5639 $\pm$ 0.0039	0.68	102.20
B	0.5896 $\pm$ 0.0033	0.56	101.54
C	0.5716 $\pm$ 0.0046	0.81	98.44
D	0.5901 $\pm$ 0.0037	0.63	99.46
E	0.6106 $\pm$ 0.0025	0.41	97.72
F	0.6387 $\pm$ 0.0044	0.69	99.64
G	0.6288 $\pm$ 0.0050	0.80	99.02
H	0.6468 $\pm$ 0.0032	0.49	100.35

\* Mean of two determinations.

Table 19 Tablet Hardness and Friability of Dipyrone Tablet  
 (Formula A-H).

Formula	Hardness, kg. $\pm$ S.D.	% C.V.	Friability (%)
A	6.42 $\pm$ 0.32	5.06	0.43
B	6.34 $\pm$ 0.32	5.05	0.40
C	5.88 $\pm$ 0.40	6.75	0.26
D	5.55 $\pm$ 0.38	6.80	0.40
E	5.61 $\pm$ 0.25	4.40	0.89
F	6.14 $\pm$ 0.24	3.94	0.62
G	6.24 $\pm$ 0.32	5.13	0.46
H	6.19 $\pm$ 0.36	5.89	0.41

Table 20 Disintegration time and Dissolution Time ( $t_{90\%}$ ) of  
Dipyrone Tablet (Formula A-H).

Formula	Disintegration Time, min. $\pm$ S.D.	Dissolution Time ( $t_{90\%}$ ), min. $\pm$ S.D.
A	4.60 $\pm$ 0.10	12.34 $\pm$ 1.85
B	5.15 $\pm$ 0.13	11.92 $\pm$ 1.02
C	4.85 $\pm$ 0.10	9.33 $\pm$ 0.18
D	5.32 $\pm$ 0.16	11.38 $\pm$ 0.45
E	5.08 $\pm$ 0.10	8.78 $\pm$ 0.28
F	5.29 $\pm$ 0.07	10.39 $\pm$ 0.45
G	5.26 $\pm$ 0.11	8.58 $\pm$ 0.33
H	5.62 $\pm$ 0.15	10.19 $\pm$ 0.10

Table 21 Weight Variation and Percent Labeled Amount of Dipyrone  
Tablet (Formula I-XVIII).

Formula	Average Weight, gm. $\pm$ S.D.	% C.V.	Percent Labeled Amount *
I	0.5639 $\pm$ 0.0039	0.68	102.20
II	0.5817 $\pm$ 0.0037	0.64	99.30
III	0.5896 $\pm$ 0.0033	0.56	101.54
IV	0.5877 $\pm$ 0.0032	0.55	100.36
V	0.6082 $\pm$ 0.0056	0.92	100.92
VI	0.6194 $\pm$ 0.0032	0.52	100.39
VII	0.6106 $\pm$ 0.0025	0.41	97.72
VIII	0.6259 $\pm$ 0.0026	0.41	99.38
IX	0.6387 $\pm$ 0.0044	0.69	99.64
X	0.5716 $\pm$ 0.0046	0.81	98.44
XI	0.5779 $\pm$ 0.0045	0.78	99.68
XII	0.5901 $\pm$ 0.0037	0.63	99.46
XIII	0.6020 $\pm$ 0.0037	0.62	98.17
XIV	0.6113 $\pm$ 0.0034	0.56	99.47
XV	0.6228 $\pm$ 0.0037	0.60	99.43
XVI	0.6288 $\pm$ 0.0050	0.80	99.02
XVII	0.6427 $\pm$ 0.0030	0.47	100.00
XVIII	0.6468 $\pm$ 0.0032	0.49	100.35

\* Mean of two determinations.

Table 22 Tablet Hardness and Friability of Dipyrone Tablet  
(Formula I-XVIII).

Formula	Hardness, kg. $\pm$ S.D.	% C.V.	Friability (%)
I	6.42 $\pm$ 0.32	5.06	0.43
II	6.45 $\pm$ 0.30	4.72	0.56
III	6.34 $\pm$ 0.32	5.05	0.40
IV	6.25 $\pm$ 0.59	9.45	0.58
V	5.80 $\pm$ 0.35	6.07	0.69
VI	5.97 $\pm$ 0.38	6.40	0.66
VII	5.61 $\pm$ 0.25	4.40	0.89
VIII	5.83 $\pm$ 0.40	6.78	0.72
IX	6.14 $\pm$ 0.24	3.94	0.62
X	5.88 $\pm$ 0.40	6.75	0.26
XI	5.71 $\pm$ 0.43	7.57	0.33
XII	5.55 $\pm$ 0.38	6.80	0.40
XIII	5.64 $\pm$ 0.25	4.36	0.50
XIV	5.72 $\pm$ 0.37	6.44	0.50
XV	6.21 $\pm$ 0.26	4.23	0.40
XVI	6.24 $\pm$ 0.32	5.13	0.46
XVII	6.28 $\pm$ 0.21	3.40	0.46
XVIII	6.19 $\pm$ 0.36	5.89	0.41

Table 23 Disintegration Time and Dissolution Time ( $t_{90\%}$ ) of  
Dipyrone Tablet (Formula I-XVIII).

Formula	Disintegration Time, min. $\pm$ S.D.	Dissolution Time ( $t_{90\%}$ ), min. $\pm$ S.D.
I	4.60 $\pm$ 0.10	12.34 $\pm$ 1.85
II	5.11 $\pm$ 0.04	12.85 $\pm$ 1.02
III	5.15 $\pm$ 0.13	11.92 $\pm$ 0.90
IV	4.85 $\pm$ 0.08	9.80 $\pm$ 0.91
V	4.94 $\pm$ 0.09	9.82 $\pm$ 0.36
VI	5.11 $\pm$ 0.04	9.94 $\pm$ 0.70
VII	5.08 $\pm$ 0.10	8.78 $\pm$ 0.28
VIII	5.18 $\pm$ 0.08	9.92 $\pm$ 0.12
IX	5.29 $\pm$ 0.07	10.39 $\pm$ 0.45
X	4.85 $\pm$ 0.10	9.33 $\pm$ 0.18
XI	5.12 $\pm$ 0.04	10.36 $\pm$ 0.25
XII	5.32 $\pm$ 0.16	11.38 $\pm$ 0.45
XIII	5.24 $\pm$ 0.06	9.22 $\pm$ 0.61
XIV	5.26 $\pm$ 0.08	10.78 $\pm$ 1.41
XV	5.67 $\pm$ 0.09	11.68 $\pm$ 1.02
XVI	5.26 $\pm$ 0.11	8.58 $\pm$ 0.33
XVII	5.61 $\pm$ 0.09	10.05 $\pm$ 0.35
XVIII	5.62 $\pm$ 0.15	10.19 $\pm$ 0.10

## VITA

Mr. Thawatchai Ounarom was born on September 16, 1954.  
He got his degree in Bachelor of Pharmacy in 1977 from Faculty  
of Pharmacy, Chiengmai University.

