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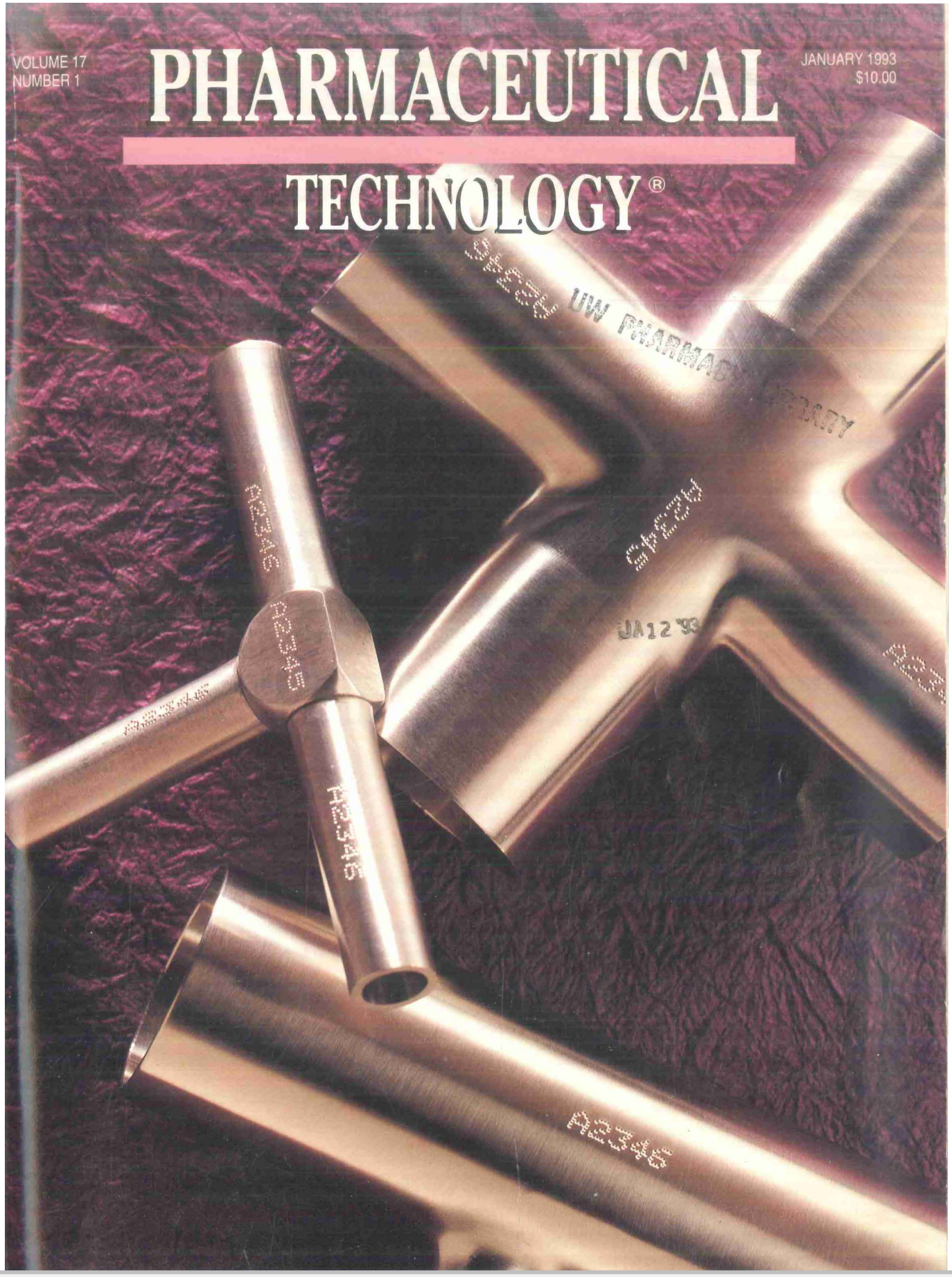

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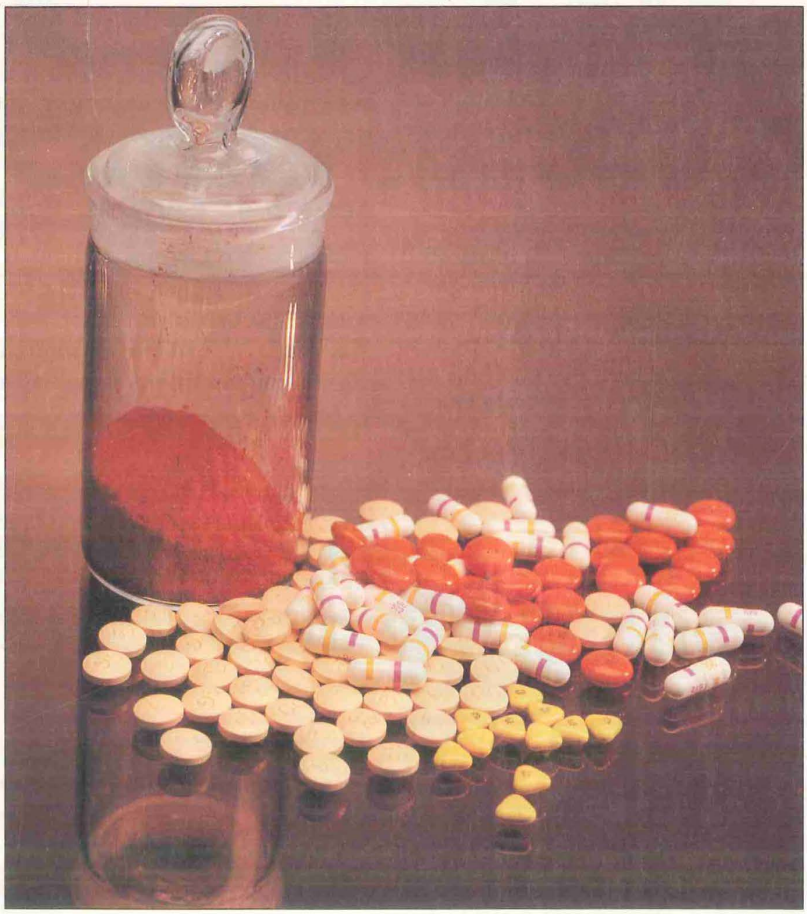
A Survey of Current Industrial Practices in the Formulation and Manufacture of Tablets and Capsules

Ralph F. Shangraw* and Dudley A. Demarest Jr.



MIKE DEAN

Dramatic changes in the formulation and manufacture of pharmaceutical dosage forms have occurred during the 15 years of *Pharmaceutical Technology*'s existence. Many of these changes have been motivated by the introduction of new processing equipment and new pharmaceutical excipients. Although marketing surveys by equipment and excipient suppliers have been conducted, most of the results are unpublished. In order to obtain a better understanding of industry attitudes toward both excipients and manufacturing processes, the authors designed a questionnaire to assess current industrial practices. The results of our survey are described in this article.

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Questionnaires were mailed to one person at each of 68 different companies. Although an attempt was made to identify a person who would most likely be able to complete the questionnaire, addressees were asked to forward it to a more appropriate person if necessary. Questions were generally posed in the context of what recipients or their companies were doing at present, thus attempting to determine current attitudes of formulators rather than what had been done in the past. A total of 58 questionnaires were returned, representing 30 innovator pharmaceutical companies, 14 generic companies, 8 nonprescription drug companies, and 6 vitamin and nutritional supplement companies.

The questionnaire was divided into several sections. The first two sections asked formulators about their use of excipients in tablets and capsules. The last two sections inquired about their companies' current formulation policies and general excipient use.

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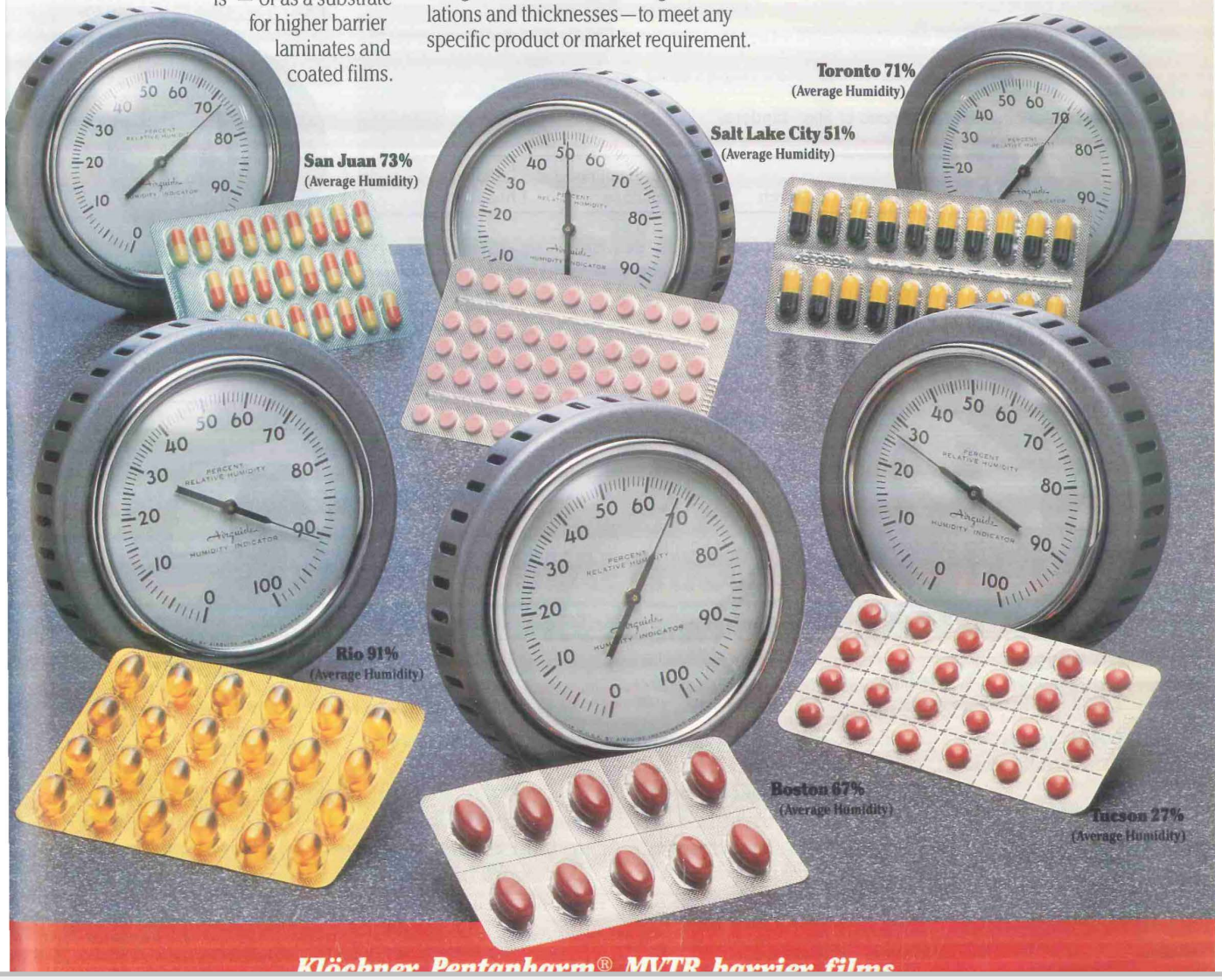

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TABLETS

The first question asked respondents to rank filler binders in terms of first, second, third, etc., choices. The results in Figure 1 show that lactose and microcrystalline cellulose were preferred. The reasons for this preference are shown in Table I. Lactose was chosen because of its solubility and compatibility and microcrystalline cellulose because of its compactibility, compatibility, and uniformity of supply. In contrast, dicalcium phosphate was chosen mainly because of compatibility with no perceived benefit from solubility.

The different types of filler binders preferred are shown in Figures 2a–c. Modified lactose (alpha monohydrate) was preferred over other types of lactose, which may indicate a preference for its utility in direct compression. Those using starch preferred the pregelatinized form. For calcium phosphate, the preference (in descending order) was

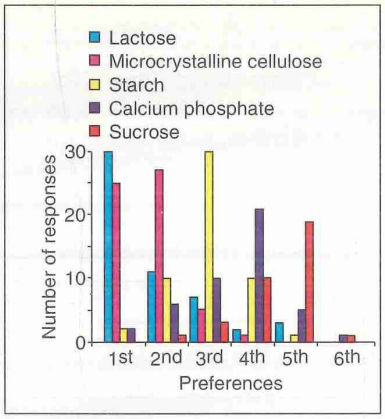

Figure 1: *Preference for tablet filler–binders (58 responses).*

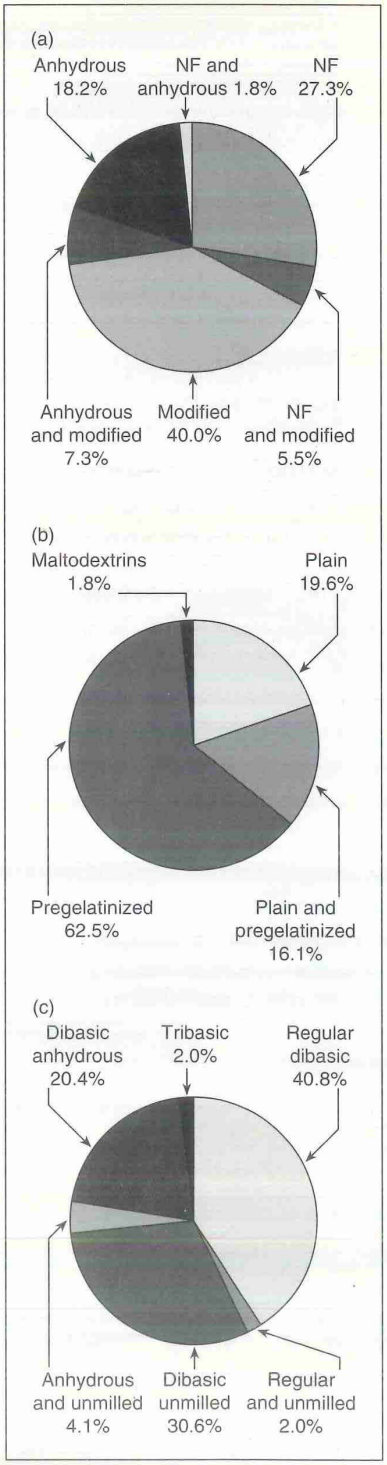

Figure 2: *(a) Filler–binder preference: (a) lactose (55 responses), (b) starch (56 responses), (c) calcium phosphate (49 responses).*

Table I: Reasons for preferences of filler–binders.

Reasons	Lactose	Starch	Microcrystalline Cellulose	Calcium Phosphate
Solubility	19	4	9	1
Cost	15	6	3	2
Tradition	21	9	18	4
Compatibility	20	7	33	3
Uniformity of supply	14	4	26	3
Compactibility	17	6	46	8
Handling	8	3	11	0
Physiological inertness	8	1	16	2
Total selections	41	12	52	8

Table II: Reasons for preferences of disintegrating agents.

Reason	Starch	Sodium Starch Glycolate	Croscarmellose	Crospovidone
Disintegration/ dissolution	11	27	40	17
Cost	9	2	0	1
Tradition	12	16	8	3
Compatibility	6	12	12	7
Uniformity of supply	3	13	23	8
		Concentrations		
Common	10%	5%	2%	—
Range	5–20	0.5–15	0.5–8	0.5–4
Total selections	20	34	44	18

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