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REVIEW ARTICLE

Pharmaceutical Sciences—1975: Literature Review of Pharmaceutics I ▲

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Keyphrases □ Pharmaceutical sciences—1975 literature review of pharmaceutics □ Technology, pharmaceutical—sterility, dosage forms, cosmetics, packaging equipment, dental products, biomedical devices, 1975 literature review □ Stability—solids, solutions, injectable products, antibiotics, and vitamins, kinetics, 1975 literature review □ Dosage forms—tablets, suspensions, emulsions, suppositories, aerosols, controlled-release devices, 1975 literature review □ Cosmetics—formulation and technology, microbiological contamination, 1975 literature review □ Instrumentation—in pharmaceutical technology, 1975 literature review □ Literature review—pharmaceutical sciences, 1975

CONTENTS

This review article is a continuation of the annual review of pharmaceutics begun in 1963. As in past reviews in this series (1–14), the scope has been limited to the overall area of pharmaceutics since other specific subjects in pharmaceutical sciences are published elsewhere. The authors have used selected sections of *Chemical Abstracts* as well as 40 journals as the sources for this article.

It is hoped that this review will be of continued usefulness to the pharmaceutical scientist whenever pharmaceutical information is needed. The overall format remains essentially the same as that of the last several years; however, some changes have been made to reflect minor organizational improvements.

GENERAL PHARMACY

Two articles reported on the pharmaceutical industry; the first (15) reviewed the development of the industry, drug nomenclature, drug regulation, product classification, research, manufacturing, and quality control. The second (16) summarized the development

▲ *Editor's note:* Part II of this article will appear in the August 1976 issue of the *Journal of Pharmaceutical Sciences.*

of the pharmaceutical industry in Poland over the last 30 years. Process capability analysis, a quality control tool utilizing computer and statistical analysis, was described using data from laboratories and manufacturers (17).

A review of the drugs of veterinary medicine included topics such as drug products, commercial usage, manufacturing, distributing firms, compounding, ranges of application, and commercial forms (18). The types of infant formulas together with their composition as well as the compositions of human and cow milks were reported (19). Digestive and electrolyte problems sometimes occur because of measurement errors. A review of current aspects of pharmaceutics covered chemical stability, physical pharmacy, drug dissolution and absorption, microbiological studies, particulate contamination, and packaging (20).

Preservatives—The use of preservatives in biological products as currently regulated in the pharmacopoeias of various European countries, the United States, and the European Pharmacopoeia and by the World Health Organization was discussed (21). With six microorganisms as test organisms, a method was developed for testing liquid pharmaceutical preparations which centered on whether preservatives were needed. A 0.1% methylparaben–propylparaben mixture (8:2) preserved adequately, being more effective than a 0.05% mixture or 0.1% methylparaben (22).

The effectiveness of three preservatives currently used in various multiple-dose biological products was measured by monitoring the number of viable cells present at 7-day intervals following inoculation of 10^5 cells/ml of product (23). Certain toxoids, vaccines, and antiserums of blood group A were selected containing thimerosal, phenol, and sodium azide as preservatives. A significant difference in the ability of each type of preservative to reduce the number of viable organisms was found.

The availability of preservatives in emulsified systems was reported. The equations used to characterize the interaction of preservatives with other components of the formulation, particularly nonionic surfactants, were questioned; some equations were said to overestimate grossly the total concentration of preservative necessary to provide the required free concentration (24). Another paper reported on the interrelationship between preservative activity and the amounts of both oil and emulsifier (25). A standard cream formulation was used to evaluate thimerosal[1] sodium, *p*-chlorocresol, and a methylparaben–propylparaben mixture with a number of microorganisms; thimerosal sodium was the most effective (26).

Frequently isolated microorganisms from aqueous based products are *Pseudomonas cepacia* and *Ps. putida*; *Ps. aeruginosa* had increased resistance to various antimicrobials when grown in water (27). The partitioning of methyl-, ethyl-, propyl-, and butylparabens into flavoring oils from aqueous systems was studied and found to be dependent on the concentration of flavoring oil, the pH of the aqueous medium, and the nature and concentration of additives (28). Five preservatives were evaluated for their effectiveness in simple syrup after challenge by a number of test microorganisms (29). Benzoic acid was most effective at pH 3, and thimerosal sodium and benzyl alcohol were the most effective at pH 5.5.

The interaction between saccharin sodium and various parabens was demonstrated by solubility studies (30). The interaction of sorbic acid and parabens with nonionic agents was stronger than with polyethylene glycol 400, 1500, or 4000 when tested by serial dilution or dialysis methods (31). The combination of propylparaben with octyl gallate was about 10% more effective than octyl gallate alone in retarding the autoxidation of ethyl oleate (32). Differences were less pronounced when the same paraben was used in conjunction with nordihydroguaiaretic acid or butylated hydroxyanisole. Binding studies of methylparaben and chloroxylenol with sodium lauryl sulfate suggested that the palisade layer of the sodium lauryl sulfate represents the secondary binding sites of cetomacrogol (33).

The role of some nonionic additives to saturated dialdehyde solutions can display powerful bactericidal synergism when added in the proper proportion (34). Three formaldehyde-releasing cosmetic preservatives were studied to determine their quantitative release (35). The importance of neutralization of free formalin in biological products before freeze drying was stressed (36). The presence of free formalin, which is concentrated during the freeze-drying process, can have a deleterious effect on the antigens and adversely affect the immunogenicity of the product. It was demonstrated that pH and concentration were insignificant in determining the free aldehyde content in aqueous glutaraldehyde solutions (37). Therefore, the rates at which equilibria are established are important in determining antibacterial activity. The effects of aminosidine (paromomycin) with and without organism pretreatment with bacteriostatic agents were studied (38). The minimum concentration for cidal action increased with increasing concentrations of nutrients and with decreasing pH.

The activity of a number of other preservatives and antioxidants was studied. Commercial glycerin, analyzed for microbial contamination, showed no growth; therefore, its antimicrobial activity was determined using four organisms (39). After 7 days, significant bacterial concentrations were present. Catgut contamination with up to 94×10^6 nonsporulating microorganisms/ml (23 strains) was completely sterilized after a 24-hr exposure to ethanol (40). Alkylparabens are capable of being degraded to phenol by bacteria (41). It was suggested that ester hydrolysis occurs in the presence of *Ps. aeruginosa* with subsequent decarboxylation in the presence of *Klebsiella aerogines*. Butyl-, propyl-, ethyl-, and methylparabens showed a broad spectrum of activity against microorganisms most commonly contaminating pharmaceutical products (42). In general, they were more active against fungi than against bacteria and more active against Gram-positive than against Gram-negative bacteria. The activity of paraben mixtures was additive and complementary.

Thimerosal was compatible with more eye drop for-

[1] Merthiolate, Lilly.

Table I—Additional References on Preservatives

Reference	Topic
46	Microwave sanitization of color additives used in cosmetics
47	Preservatives used in biological reagents and their stability
48	Effectiveness of bronopol and five other compounds as cosmetic preservatives
49	Review of classification of preservatives according to their chemical structure and bactericidal activity
50	Review of preservation of cosmetics
51	Review of antimicrobial preservatives for pharmaceuticals and cosmetics
52	Investigation and determination of alkyl esters of *p*-hydroxybenzoic acid, sorbic acid, and benzoic acid
53	Spoilage of surfactants in cosmetic products and evaluation of bis(trichloromethyl)sulfone (chlorosulfons)
54	Usnic acid as a natural preservative deodorant and antimicrobial agent in cosmetic systems
55	Comparative antioxidant activity of 6-hydroxy-5,7,8-trimethyl-2-chromancarboxylic acid and other antioxidant compounds
56	Antioxidants used in pharmaceutical formulations and their determination by TLC
57	Antimicrobial preservatives in biologics
58	Essential oils as possible preservatives in cosmetic products

mulations than was chlorhexidine acetate, but the latter inhibited *Ps. aeruginosa* and *Candida albicans* faster than did thimerosal (43). Thimerosal had no adverse effect on purified meningococcal polysaccharide vaccines of serol A or C when used at a 0.01% concentration (44). The addition of disodium ethylenediaminetetraacetate (edetate disodium) prolonged antibiotic activity during storage in liquid or complex dry media at temperatures of 26° or less and exerted antimicrobial activity against common bacteria, especially *Bacillus subtilis* (45).

Additional references on preservatives are listed in Table I.

Flavor, Aroma, and Color—The formulation of liquid pharmaceutical products was reviewed with particular emphasis on the choice of sweeteners, flavor enhancers, flavors, and colors as well as various stability aspects (59). Amino acid esters of acetaminophen were less bitter than the parent drug but were susceptible to hydrolysis, thus making them unacceptable for liquid formulations (60). The palatability of carbon slurries was improved by the addition of thickening agents, sodium alginate, carboxymethylcellulose sodium, carrageenan, bentonite, and gelatin (61). The adsorption properties of the charcoals investigated were not affected by the thickeners.

The physical, chemical, organoleptic, and metabolic properties of fructose were compared to sucrose, dextrose, and high fructose corn syrup (62). The replacement of sucrose by lower costing high fructose corn syrup was discussed (63). Another article discussed the properties of high levulose (fructose) corn syrups and reported taste comparisons to sucrose and invert sugars (64).

A review of the formulation, life, fixation, and solubilization of perfume material and the use of instrumentation to control perfume formulations was presented (65). The decrease of odorant concentration in the gas phase after application of an odor eliminator and specific solvents was quantitatively determined by GC. It was shown that the so-called odor eliminators have no selectivity for malodorous materials (66). Numerous essential oils and aromatic chemicals commonly used in soap perfumes were tested for safety, and results were presented to assist perfume compounders in selecting odorant materials (67).

The Food and Drug Administration (FDA) status of food colorants was reviewed, and a list of approved food color additives exempt from certification was presented (68). A computerized color-matching and batch correction method was described for use by cosmetic manufacturers (69). The surface color of a series of color dispersions containing certified dyes in sucrose syrup was examined using an integrating sphere colorimeter (70). Color differences were calculated to develop color specifications for tablets, liquids, and creams. The stability of betalaine, a mixture of natural red beet pigments, was determined (71).

Additional references on flavor, aroma, and color are given in Table II.

Stability—A review of the factors that limit drug stability, with emphasis on traces of multivalent elements and the role of chelating agents, was published (91). The poor stability of certain pharmaceuticals containing polyethylene glycols was attributed to the presence of peroxide; however, peroxide levels can be reduced by pretreatment with water and butylated hydroxytoluene or propyl gallate in concentrations of 0.005–0.05% (92). Under normal storage conditions and on sterilization, the peroxide number of polyethylene glycol and its alkyl ethers increased to a significant level with oxidation, showing the characteristics of a chain reaction (93). The peroxide formation rate was increased by increasing temperature, the presence of copper ions, decreasing pH, surfactant concentration, and prior treatments such as bleaching or heat sterilization.

A method for the rapid determination of oxidation

Table II—Additional References on Flavor, Aroma, and Color

Reference	Topic
72	Instrumental methods for measurement of texture, color, and flavor
73	Codex Alimentarius: the way to a worldwide food and flavor regulation
74	Flavors: the future and the FDA
75	International standardization of essential oils
76	Components of Japanese spearmint oil
77	Methodological approach to flavoring
78	Physiological aspects of food flavoring
79	Food and cosmetic toxicology; monographs on fragrance of raw materials
80	Monographs on fragrance of raw materials, 1,1-dimethyl-2-phenylethanol
81	Monographs on fragrance of raw materials, α,α-dimethylphenethyl acetate
82	Sensory properties of acetals and ketals of 1-phenyl-1,2-ethanediol
83	Progress in perfumery and flavoring materials (31st annual article)
84	Flavoring of pharmaceutical products
85	Pharmaceutical aromatization and its relation to olfactory and gustatory phenomena in drug ingestion
86	Perfumery and chemistry, a symbiosis of art and science
87	Ceylon cinnamon bark oil: its use as a fragrance and flavor and its toxicity
88	Use of FD&C lakes to replace soluble dyes
89	Use and stability of carotenoid esters as colorants
90	Use of carotenoids as food colorants

stability of cosmetics was described in which the test material was heated to 120° and oxygen was blown into it (94). The disadvantages of accelerated tests for determining the stability of perfume components or perfumed products, such as talcs, and the possible lack of correlation between results of accelerated tests and actual market product performance were discussed (95). The correlation between long-term stability tests and accelerated tests conducted at higher temperatures was investigated.

Other general references on drug stability are listed in Table III.

Solids—The stability of aspirin in tablets was reviewed (106). The decomposition of acetylsalicylic acid (aspirin), acetyl-5-nitrosalicylic acid, and acetyl-5-chlorosalicylic acid in the solid state by water vapor was studied to elucidate the decomposition mechanisms of organic crystals by water vapor (107). A kinetic analysis was given as well as the results of a microscopic examination and comparative rates for the three compounds. The effects of formulation methodology and excipients on the stability of aspirin tablets were reported; comparisons included both wet and dry granulation methods and the effect of buffers (108).

In digitalis leaf capsules, purpurea glycosides A and B were most stable when digitalis powder was prepared by lyophilization (109). In tablets, the direct compression method was better than two granulation methods with respect to lanatoside content, both after preparation and after storage. Increased dissolution rates of phenylbutazone tablets BP on aging were reported, and the tendency toward longer dissolution could be simulated in short periods by using elevated temperatures (110).

Several brands of stabilized nitroglycerin tablets were studied, and one brand was superior to all others when placed under stress conditions (111). The same tablets were stable in medication cups for 7 days or in foil–foil or foil–cello strips. In another study, the stability of solid pharmaceutical compositions containing nitroglycerin was highly dependent on temperature and the type of container (112). Products were generally stable at 20°; but at 40°, tablets in hard gelatin capsules and timed-release tablets with compressed diffusion pellets showed especially low stability.

The influence of light, time of storage, and relative humidity of the surrounding atmosphere on the surface color and total color content of effervescent colored mouthwash tablets was studied (113). There appeared to be no correlation between fading at the surface of the tablets and the actual concentration of the coloring agent when measured in solution. The recovery of two aromatic ingredients from gum arabic, lactose, and potato starch supports and starch[2] capsules by extraction before and after 1 year of storage at 4° showed that the capsules provided the most stable form (114).

The effect of various additives on the rate of transformation of the metastable anhydrous succinylsulfathiazole Form I to the water-stable dihydrate Form II in aqueous suspensions was studied (115). Some additives, such as methylcellulose, showed significant transformation-retarding effects; others, such as glycerin, increased the rate of transformation. In another study by the same researchers, the transformation was studied by using a projecting microscope; particle-size distribution of Form I succinylsulfathiazole was determined (116).

Other references on the stability of solids are listed in Table IV.

Solutions—Methyldopa syrup preparations were made by dispersing tablets into unpreserved simple syrup and acidified simple syrup (128). Both preparations were stable after 14 days of storage in the dark. The hydrolysis of pilocarpine in carbomer hydrogels was studied and related to viscosity (129). The hydrolysis of procaine was also studied in the same gel system at pH 6, and the influence of ionic strength was determined (130). The activation energy was not influenced by the viscosity of the medium, but the second-order rate constant was significantly reduced. The rate constant–pH profile of the rate of sulfite-induced disappearance of epinephrine from aqueous solution under anaerobic conditions was determined at 81° in the 3.63–5.00 pH range at an ionic strength of 0.2 (131). The aerobic rate showed buffer catalysis above pH 4.4, and metabisulfite was more catalytic than either bisulfite or acetone bisulfite.

The hydronium-ion-catalyzed racemization of 0.2% levarterenol bitartrate in water was found to be dependent on the ionic strength and polarity of the solvent

Table III—Additional References on Drug Stability

Reference	Topic
96	Hydrolytic degradation of drugs
97	Drug stability trials
98	Purification and stability of ^{125}I-insulin
99	Factorial design for testing drug stability
100	Stability of prostaglandins
101	Incompatibility phenomena of galenic pharmaceutical preparations
102	Review of stability testing of pharmaceuticals
103	Influence of physical factors (heat, humidity, atmospheric pressure, and solar irradiation) on stability of pharmaceuticals
104	Room temperature stability of drug products labeled for refrigerated storage
105	Aging inhibition of aluminum hydroxide by mannitol and fructose

Table IV—Additional References on Stability of Solids

Reference	Topic
117	Microencapsulation and stability of ferrous sulfate microcapsules
118	Microencapsulation of three easily oxidized drugs [ascorbic acid, methylene blue, and phenazone (antipyrine)]
119	Photolytic decomposition of ethionamide salts
120	Effect of preservatives on stability of short ragweed pollen extract
121	Stability of antigen E in commercially prepared ragweed pollen extracts
122	Stabilization of dihydroepiandrosterone enanthate in powder mixtures
123	Solid-state decomposition of *para*-substituted salicylic acids
124	Decomposition of *p*-aminosalicylic acid in solid state
125	Prediction of shelflife of menthyl valerate tablets
126	Use of diffuse reflectance spectroscopy in preformulation screening and final product control
127	Stability of a tablet containing L-ascorbic acid and ferrous nicotinate

[2] Dry Flo.

(132). The stability of scopolamine hydrobromide drops, 0.25%, was significantly increased by addition of 2.5% polyvinyl alcohol or 1% polyacrylamide, and the preparations were not harmed by heat sterilization (133). Oral insulin preparations, particularly water-in-oil and micelle insulin emulsions as a means of protecting insulin from digestive enzymes, were reviewed (134).

Photodecomposition of a number of compounds was reported. The critical micelle concentration (CMC) of three phenothiazine derivatives, chlorpromazine, triflupromazine, and homophenazine, was studied by several means to determine the degree of aggregation (135). In a second study, the photoinstability of these compounds was shown to be dependent on their colloidal characteristics (136). Both sodium dodecylbenzenesulfonate and sodium dodecyl (lauryl) sulfate were decomposed by UV light at 254 nm (137).

A study of the effects of various storage conditions on the rate and products of degradation of the quinolinemethanol antimalarial agent, α-[(dibutylamino)-methyl]- 6,8-dichloro-2- (3′,4′-dichlorophenyl)-4-quinolinemethanol, was reported (138). Thioridazine hydrochloride in aqueous solution was subjected to high temperature (80°) as well as UV radiation of 254 nm (139). One decomposition product was isolated after heat treatment, but eight products were isolated and identified by TLC and other techniques. Solutions of thiacetazone (amithiozone) were decomposed by exposure to a 250-w mercury lamp, and the resulting irradiated solutions were characterized by several methods (140).

The stability of aspirin in decaglycerol tetraoleate, octaoleate, and decaoleate was studied at various temperatures (141). Fatty acid esters of acetaminophen were prepared with the acetate and all even-numbered fatty acids through the octadecanoate (142). Hydrolysis at pH 7.8 in the presence of lipase demonstrated that the short chain esters were hydrolyzed at the most rapid rate whereas the longer chain esters were the most stable of the group. The decomposition of amitriptyline hydrochloride was investigated in aqueous solution, and three major decomposition products were identified (143).

The hydrolytic degradation of 5-azacytidine was studied as a function of pH, temperature, and buffer concentration (144). The apparent first-order rate constants associated with formation of 5-azacytosine and 5-azauracil were reported. The hydrolysis of mazindol in aqueous solutions at various temperatures, pH values up to 7.6, and an ionic strength of 0.2 was studied (145). Kinetic relationships were reported as well as the effect of various buffers. Ergotoxine solutions at pH 3–4 decomposed due to hydrolysis of salt forms, but an accelerated decomposition occurred due to oxidation at pH less than 3 (146).

Changes in the color of amidopyrine (aminopyrine) solutions were due to the presence of noramidopyrine impurities formed at the alkylation stage during production (147). The oxidation rate of *N*-hydroxyamphetamine and *N*-hydroxyphentermine in aqueous solution was shown to be pH dependent, with oxidation taking place around the pKa (148). Kinetic equations for the hydrolysis of narcotine (noscapine) and lactonization of narcotic acid were published (149). Oxidative degradation products of phenothiazine in a hydroalcoholic solution saturated with oxygen were isolated after storage in the dark at 80° for 96 hr (150).

Table V—Additional References on Stability of Drugs in Solution

Reference	Topic
158	Stability of 1,4-benzodiazepines
159	Quantitation of barbiturate stability by TLC
160	Molecular orbital study on solvolysis of aspirin derivatives and acyl-α-chymotrypsin
161	Quantitation of procaine stability by TLC
162	Stability of *p*-aminosalicylic acid in malt extract
163	Stability of amphetaminil
164	Stability of aza analogs of methaqualone
165	Accelerated degradation of nonsteroid anti-inflammatory drugs at carbon black–water interface
166	Stability of tetrahydrocannabinols
167	Stability of oxyfedrine
168	Solvolytic decomposition of certain ethionamide salts
169	Stability of cocarboxylase hydrochloride
170	Effect of temperature on hydrolysis of carboxylase hydrochloride
171	Penicillamine as stabilizer of apomorphinium chloride solutions
172	Stability of nafiverine in aqueous solution
173	Bisulfite-ion-catalyzed degradation of fluorouracil
174	Stability of 1,3-bis(2-chloroethyl)-1-nitrosourea in aqueous solutions
175	Kinetics of hydrolysis of cytosine, cytidine, and arabinosylcytosine
176	Effect of briefly heating cyclophosphamide solutions

Streptokinase stability measured at various temperatures and times up to 48 hr was excellent in gelatin and 3% albumin solutions, intermediate in 10% dextran and 5% levulose (fructose), and poor in isotonic sodium chloride solution, 5% glucose, and Michaelis buffer solutions (151). The kinetics of indomethacin hydrolysis in ethanol–water and polyethylene glycol–water mixtures at pH 7–10 were reported (152). The decomposition of codeine and codeine phosphate was first order in aqueous solution, and the rate was accelerated by increasing the pH (153). The stability of a codeine phosphate syrup was attributed to the presence of sucrose and citric acid, which inhibited the autoxidation process (154).

Factors that participate in the decomposition reactions of itobarbital (butalbital) in tromethamine buffer were studied by differences observed in equilibrium constants, and second-order rate constants were subsequently calculated (155). The degradation of hexobarbital in alkaline aqueous solutions was investigated at pH 10.5 and 13 in a 5–40° temperature range, and a degradation scheme was proposed (156). The hydrolysis of chlordiazepoxide was determined over a broad pH range; both general acid catalysis and general base catalysis were observed, with a number of specific buffer ions having an accelerating conversion to lactam (157).

Other papers dealing with the stability of drugs in solution are listed in Table V.

Injectable Products—Three dexamethasone injections were found to be unstable when exposed to light; a light-resistant container was suggested for this product (177). The hydrolytic degradation of atropine sulfate was studied in an aqueous solution at pH 8 by a nonisothermal method (178, 179). The stability of a commercial product[3] containing amidopyrine (amino-

[3] Rheopyrin.

pyrine) and phenylbutazone was determined (180). Phenylbutazone was stable but amidopyrine was not. The autoxidation decomposition of glaucine hydrochloride injection was second order; the effects of pH, temperature, ionic strength, and traces of metallic ions on the reaction rate were studied (181).

The half-life, optimal pH, and general stability were determined for an injectable form of gentamicin (182). Eight decomposition products of morphine hydrochloride injection were identified by two-dimensional TLC (183). One decomposition product, dehydromorphine, was identified; solutions sealed under an inert gas were much more stable. In nonsulfite-containing solutions of morphine sulfate stored for 1 year, morphine *N*-oxide and 2,2′-dihydromorphine were found (184). In sulfite-stabilized solutions, dehydromorphine-8-sulfonic acid was identified.

Additional references on the stability of injectable products are listed in Table VI.

Kinetics—A continuous nonisothermal–isothermal method for stability prediction was developed (195). The experimental procedure involved changing the temperature of the samples being studied until degradation was rapid enough to proceed at a convenient isothermal rate for a sufficient number of half-lives. A multilevel nonisothermal method that estimates stability from the degradation ratio after a specific period of a straight temperature increase was proposed (196). It was suggested that Weibull probability paper be used, rather than the usual methods, because of its convenience and accuracy for prediction of reaction kinetics (197). Examples of its usefulness include acetylsalicylic acid (aspirin) and ascorbic acid solutions. Two computation procedures for the study of drug stability were described, one for comparison of high temperature degradation of drugs contained in different formulations and the other for estimation of stability prediction based on the Arrhenius law (198).

Other topics on kinetics include a kinetic study of melting (199), a computerized program to model the hydrolysis of local anesthetic drugs (200), the kinetics of the most frequent complex drug degradation reactions (201), a calculation flow chart for application of reaction kinetics in stability testing (202), and the kinetics and mechanism of aqueous degradation of Baker's Antifol (NSC 113,423) (203).

Table VI—Additional References on Stability of Injectable Products

Reference	Topic
185	Stability of hydroxyzine hydrochloride and atropine sulfate mixture
186	Stability of dopamine hydrochloride in large-volume parenteral solutions
187	Compatibility of papaverine hydrochloride with other injectable solutions
188	Stability and compatibility of nafcillin sodium injection
189	Connections between plasma quality and impurities of γ-globulin and albumin preparations
190	Predicting drug stability in parenteral mixtures
191	Stabilization of aminazine (chlorpromazine) solution for injection
192	Stability of amino acid infusion solutions
193	Stabilization of aminazine solution for injection
194	Properties of mannitol injection after repeated autoclaving

Antibiotics—The stabilities of three antibiotics (chloramphenicol, tetracycline, and phenoxybenzyl penicillin), all solid dosage forms in conventional packages, were determined at high temperature and humidity conditions which simulated storage on ships in tropical zones (204). Kinetic analyses were carried out, and a recommendation was made for special protective packaging. A comparative study of cephalosporins in an aqueous solution over a broad pH range was reported (205). The log k_{pH}–pH profiles for the hydrolyses of cephalothin, cephaloridine, cephaloglycin, and some related compounds were given.

The chemical stability of penicillin G potassium intravenous infusion solutions was related to the initial pH of the solutions and the ability of the buffer to maintain a constant pH during aging (206). Carefully prepared and purified penicillin G sodium was quite stable for long periods even at 30° and was more stable at pH 6–7 than at pH 5.0–5.5 (207). Ampicillin was degraded 10% in a 0.9% sodium chloride solution during 24 hr, whereas 5–12% decomposition took place in dextrose solutions within 2 hr (208). Another study reported that ampicillin partially degraded in an aqueous solution to yield ordered molecules with molecular weights varying between 1000 and 5000 (209).

Addition of 1% polysorbate 80[4], polysorbate 60[4], or ethanol decreased the degradation of ampicillin sodium; however, antioxidants such as rongalite, sodium dithionite, sodium metabisulfite, sodium bisulfite, sodium sulfite, and sodium ascorbate accelerated the degradation of the antibiotic (210). The influence of concentration, vehicle, dextrose, and temperature on the stability of oxacillin sodium solutions was determined using a chemical kinetic approach (211). The degradation of carbenicillin sodium in aqueous solution at constant ionic strength, a pH range of 1–10.7, and a temperature of 35° was reported to be first order (212). Maximum stability was at pH 6.5, and anions were found to catalyze the reaction.

The stability of oxytetracycline hydrochloride in solution was studied in 0.1 *N* hydrochloric acid and at pH 3–7 (213). The stability and physical compatibility of tobramycin sulfate in commonly used intravenous fluids were evaluated; most solutions were stable for 48 hr at room temperature (214). Storage of gentamicin solutions at pH 4 and 60° for 35–180 days did not significantly affect the concentration of the preparation, but its concentration decreased 8–30% at a pH greater than 4 (215). In another comprehensive report, the hydrolysis of gentamicin injections was studied as a function of time, temperature, and pH (216). The most favorable pH was reported to be in the 6–8 range, which gave gentamicin sulfate injections a stability up to 3 years.

No loss in the activity of neocarzinostatin injection occurred during 2 years of storage at 8°, but it was inactivated by reducing agents such as bisulfite and ascorbic acid as well as by urea and thiourea (217). Kinetic studies on the inactivation of the drug in aqueous solution showed that thermal inactivation was an apparent first-order reaction (218). In solid form, am-

[4] Tween.

photericin B and amphotericin B methyl ester free base exhibited similar stability, but acid salts of the methyl ester derivative stored under identical conditions were less stable (219). In solution, amphotericin B was generally more stable than its methyl ester salts.

Polyethylene glycol gels containing 1% concentrations of four antibiotics [chloramphenicol, tetracycline, erythromycin, and stamycin (mystatin)] were examined by TLC after 3 or 9 months of storage (220). Decomposition products and the activity of these preparations were reported. Cephapirin sodium was shown to be stable as a dry powder at high temperature and at 25° for 33 months (221). Aqueous solubility exceeded 500 mg/ml, and reconstituted solutions were stable. The stability of hamycin–tetracycline hydrochloride mixtures in capsules with various diluents was studied (222). Mannitol was the best diluent, with lactose the next best.

Several other antibiotic stability studies were reported including the X-ray diffraction characteristics of Bulgarian tetracycline (223), the effect of cupric ion and sodium lauryl sulfate on the degradation rate of penicillin G (224), and the stability of cephradine in infusion solutions (225).

Vitamins—Syrups containing ascorbic acid and B complex vitamins could be stabilized by replacing sucrose, vanillin, and various aldehyde-rich essential oils with sorbitol, saccharin sodium, citric acid, edetate disodium, and essence of banana or apple (226). The improved formula had a better taste and was less discolored after 18 months of storage at room temperature in the dark. Ascorbic acid tablets were reported to have the greatest stability when prepared by direct compression with a mixture of microcrystalline cellulose and milk sugar and then coated with a colored nonaqueous suspension of Eudragit (227).

Cupric and ferric ions had the most deleterious effect on ascorbic acid stability (228). Other salts such as sodium glycerophosphate, cobalt chloride, and calcium gluconate had little effect while manganese sulfate was practically without effect. Because of its antioxidant and chelating properties, 2,3-dimercaptopropane sodium sulfonate was reported to be a better stabilizer for ascorbic acid injection solutions than metabisulfite, cysteine, and ethylenediaminetetraacetic (edetic) acid (229). A kinetic study of the degradation of ascorbyl monolaurate in aqueous solution under aerobic conditions was reported (230). The rate of degradation was determined at 45, 60, and 80° at pH 3.1–10.1 and an ionic strength of 0.1. A microencapsulation technique for ascorbic acid using polyethylene glycol was developed (231).

Vitamin B_{12} (cyanocobalamin) was formulated by various methods into tablets containing thiamine and pyridoxine (232). In an ordinary formulation, a 43.6% loss of B_{12} occurred in 2 years. Alternative formulations such as use of B_{12} granules, multilayer tablets, or application of the vitamin in the sugar coating syrup greatly enhanced the stability. The transamination reaction of the thiazole moiety of thiamine by aromatic amine in the presence of bisulfite was studied kinetically and found to be second order with respect to thiamine and the aromatic amine, whereas the reaction rate was independent of the concentration of bisulfite (233).

Table VII—Additional References on Vitamin Stability

Reference	Topic
237	Vitamin D_3 stability in solubilized aqueous solutions
238	Stability of vitamin D_2 (ergocalciferol) tetraacetylglucoside
239	Vitamin A palmitate stability in solubilized systems
240	Influence of antioxidant compounds on stability of cod liver oil
241	Stability of riboflavin in tablets and injectable solutions
242	Review of vitamin B_{12} formulation
243	Stability of ascorbic acid tablets with special talcs

A kinetic study was made of the effect of 9-aminomethylacridan on the electronic excited states of riboflavin 5-phosphate to postulate a mechanism for the flavor-sensitized oxidation, and several mechanisms were suggested (234). Riboflavin was fused with urea, various ureides, and hydrotropic salts, which improved the solubility of the vitamin (235). The effect of these substances on hydrolytic and photolytic decomposition was reported, and thiourea and sodium salicylate gave maximum stabilizing effectiveness against both types of decomposition. The effect of selected antioxidants on the stability of vitamin D_3 (cholecalciferol) in solubilized aqueous solutions was reported (236). With ascorbic acid and nordihydroguaiaretic acid or butylated hydroxyanisole, 82% of the original amount of vitamin D_3 remained; without antioxidant, only 57% of the vitamin remained.

Additional references on vitamin stability are listed in Table VII.

PHARMACEUTICAL TECHNOLOGY

Sterile Products—A symposium was presented to review regulatory guidelines prohibiting the use of asbestos and glass fiber filters in the preparation of parenteral products (244). The principles of parenteral product formulation were reviewed and included methods of blood level modification, solubility, stability, and isotonicity considerations (245). Training for personnel to be employed in sterile product manufacturing was reported (246, 247). Incompatibilities occurring upon the addition of drugs to intravenous fluids and drug interactions in syringes were discussed with regard to the practice of adding multiple drugs to injections in hospitals (248). The chemical and physical compatibility of metampicillin sodium and sodium phosphocreatinine with other compounds was determined in solution (249), and the compatibility of four kinds of vitamin B_1 (thiamine hydrochloride) derivatives with 126 other parenteral solutions was reported (250).

The design and development of an elastomeric closure formulation were reviewed, including factors that affect polymer selection and functional performance as well as procedures for determining the general chemical, toxicological, and functional characteristics of a new closure formulation (251). Comparative chemical testing of plugs from three countries used for sealing infusion bottles was examined according to the criteria in Hungarian Pharmacopoeia VI. All three plugs met all standards for heavy metal contamination, acidity–alkalinity, and reducing substances; one plug did not meet the requirements for ammonia content (252).

The migration of zinc stabilizer from plasticized polyvinyl chloride was studied using blood serum, water, and other blood serum products (253). The profiles and rates of extraction of zinc and zinc mercaptobenzothiazole from rubber stoppers were evaluated, and the mechanism of extraction was found to be diffusion controlled (254). Blood plasma stored in plastic bags was found to contain 40–120 μg/ml of bis(2-ethylhexyl) phthalate (255). The perfusates from polyvinyl chloride hemodialysis tubings were investigated, and diethyl phthalate as well as other unidentifiable substances were found (256). Another study reported the presence of bis(2-ethylhexyl) phthalate in plastic bags used for the storage of transfusion blood (257).

According to a *Federal Register* notice, filters must not be of asbestos or glass unless the product cannot be manufactured without it, in which case an additional filter of 0.22 or 0.45 μm subsequently must be used (258). Cellulose particles of 15-μm size were injected into the tail veins of mice, and granulomas were later detected in the lungs and kidneys (259). The literature covering phlebitis as associated with intravenous administration of drugs was reviewed (260). The incidence of infusion phlebitis was found to be significantly reduced when an in-line 0.45-μm membrane filter was used (261). The greatest reduction of infusion phlebitis was in the filter groups receiving unbuffered solutions and no set change over 72 hr of therapy. In two other reports, no significant differences were found in the incidence of infusion phlebitis between groups utilizing in-line final filtration devices and those not using such devices (262, 263).

Particulates from natural rubber stoppers were formed after autoclaving, and it was suggested that stoppers should be sterilized by ethylene oxide (264). A study was conducted to determine the effectiveness of 0.22- and 0.45-μm pore size membrane filters in retaining microorganisms over 72 hr (265). With lactated Ringer's injection, the 0.45-μm filter was effective in retaining all microorganisms for 6 hr; however, *Escherichia coli* and *Ps. aeruginosa* began passing between 6 and 8 hr after seeding. No microorganisms passed through the 0.22-μm filter during the 72-hr study period.

A number of articles reported on methods of detecting particles in intravenous fluids; the methods were scanning electron microscopy (266), the Emhart Autoskan inspection system using the EVOP method (267), the Coulter counter (268, 269), the Nucleopore Prototron counter (270), and detection of scattered light from particulates using a laser beam (271). The feasibility of using membrane filters to remove particles from intravenous infusions of amphotericin B in dextrose 5% (a colloidal solution) was studied using six commercial membrane filters of pore sizes from 0.45 to 1.0 μm (272). The effects on particulate matter and stability of three parenteral containers of 0.9% sodium chloride injection were studied (273). A correlation appeared to exist between the quantity of particulate matter and the amount of unfiltered drug solution added.

A system for providing pyrogen-free water for pharmaceutical manufacturing was described; the aspects discussed included source, distillation, storage, distribution, and quality maintenance (274). Two papers described the principles, applications, and limitations of the Limulus test for pyrogen in parenteral drugs (275, 276). The effect of antibiotics and osmotic change on the release of endotoxin by bacteria retained on intravenous in-line filters was studied (277). An aseptic system for prefilling radiopharmaceutical kit vials and syringes was described (278). The system combines ultrafiltration with a method for monitoring for bacterial contamination and can be used for any vial- or syringe-filling operation.

Glass infusion bottles treated with ammonium chloride and made in Hungary were compared to borosilicate glass bottles (279). Buffered solutions retained a similar pH in each type of bottle, but solutions of higher pH decomposed the surface of treated bottles. Seven brands of intravenous fluid administration sets were studied to determine their functionality as measured by the most consistent flow rates, effect of the type of fluid container, and ability to determine the theoretical amounts of fluid (280). A method was described to measure changes in pressure inside a bottle during autoclaving without determining the integrity of the seal; if the rubber liner was unable to maintain the seal, air leaked slowly from the bottle during both the heating up and early sterilization period (281).

A new method for intermittent administration of intravenous fluids, which maintains the advantages of the piggyback system but at a lower cost, was described (282). A prototype in-line intravenous final filter with a large filtration area and an air elimination feature was evaluated (283). Freezing-point and differential thermal analysis data were presented for 19 pharmaceutical preparations (284). By means of thermal treatments or modification of different pharmaceutical formulas, it may be possible to modify the thermal behavior of these solutions to improve the quality of lyophilized products.

Numerous reports on specific parenteral product formulations appeared in the literature. The apparent solubility of hexamethylmelamine in aqueous solutions suitable for intravenous use was increased by complexation with gentisic acid (285). Six parenteral mannitol solutions analyzed for 5-hydroxymethylfurfural showed various levels of this impurity (286). Peroxide levels of ethyl oleate were lowered by treatment with an aqueous solution of sodium metabisulfite and hydrochloric acid followed by aqueous sodium carbonate (287). Sodium sulfate was added, and the oil was filtered and stored in well-filled containers protected from light.

Silicone coating of bottles prolonged the lifetime of parenteral sodium bicarbonate solutions, and those prepared with edetate disodium and hydrochloric acid were stable for 5 months (288). Sodium bicarbonate injection solution saturated to pH 7.3 with carbon dioxide and stabilized with edetate disodium remained clear during 3 years of storage at room temperature (289). The preparation of a glycerol solution for intravenous administration of sodium ascorbate was described (290). A method for the preparation and standardization of nitroglycerin injection was reported (291).

Other papers on various aspects of sterile products are listed in Table VIII.

Table VIII—Additional References on Sterile Products

Reference	Topic
292	Fat emulsion vehicle for intravenous administration of an aqueous insoluble drug
293	Preparation of sorbitol-containing solutions for intravenous infusion
294	Hyperosmolar cold-storage kidney preservative solution
295	Development of long-term stable blood-substituting solution
296	Evaluation of preparations of patent blue (alphazurine 2G) dye for parenteral use
297	Yttrium-90 citrate colloid for radioisotope synovectomy
298	Relationship among colloid association, physical stability, and acute toxicity on azo dyes in injection solutions
299	Recommended methods for compounding intravenous admixtures in hospitals
300	Soaking time in bottle-washing machines
301	Review of injectable solution formulation
302	Selection of optimum manufacturing systems for injectable solutions
303	Carrier solutions for low level intravenous insulin infusion
304	Preparation and control of sterile solutions of arginine monohydrochloride for clinical practice
305	Characterization and purification of insulin
306	Toxicity of intravenous benzyl alcohol
307	Combination of prodigiozan with glycine
308	Use of inactivators in evaluation of disinfectants
309	Variability of heparin preparations in clinical use
310	Incompatibilities of drugs for intravenous administration

Ophthalmics—The retention of technetium Tc 99m by human and rabbit eyes was decreased by blinking and, in decreasing order of activity, by saline solution, 1% methylcellulose, 1.4% polyvinyl alcohol, and white petrolatum–mineral oil (6:4) ointment (311). By using a stationary dialysis technique, it was found that the release of procaine hydrochloride in eye drops was retarded in solutions of methylcellulose and polyvinylpyrrolidone (povidone) but was not affected by carboxymethylcellulose; atropine sulfate was significantly retarded by carboxymethylcellulose (312). Drocinonide phosphate potassium formed an insoluble complex with neomycin sulfate in aqueous solution (313). Dibasic sodium phosphate was employed in an ophthalmic formulation to prevent the formation of this precipitate without affecting the stability of the steroid or the bioactivity of the antibiotic.

An aqueous neutral epinephrine[5] eye drop formulation containing 0.5 *M* borax, 0.3 *M* boric acid, phenylmercuric nitrate, 0.0002 *M* sodium metabisulfite, 0.3 *M* 8-hydroxyquinoline, and 0.02 *M* buffer, adjusted to pH 7 with sodium hydroxide, was recommended (314). The formulation packaged under nitrogen showed almost no decomposition after 5 months. The effects of wetting and suspending agents on the formulation of hydrocortisone acetate eye drops were determined (315). Octoxynol[6] and cetylpyridinium bromide were better wetting agents than benzalkonium chloride and polysorbate 80. Similarly, 1% polyvinyl alcohol with 0.1% octoxynol[6] was the most satisfactory suspending agent. It was shown in rabbits that when polyvinyl alcohol and methylcellulose were compared on a viscosity basis, there was essentially no difference in the two vehicles with regard to their influence on ocular drug bioavailability (316). The relationship between viscosity and contact time or drainage loss was discussed.

[5] Adrenalin, Parke-Davis.
[6] Triton X-100, Rohm and Haas.

Table IX—Additional References on Ophthalmics

Reference	Topic
320	Purification of cod liver oil for ophthalmological use with aid of adsorbents
321	Use of dimethyldodecylbenzylammonium chloride for eye drops containing pilocarpine hydrochloride
322	Review of formulation aspects of eye lotions
323	Review of preparation of eye drops
324	Formulation and technology of ophthalmological preparations
325	Preparation of ophthalmological preparations in pharmacy
326	Structure stability of ointment gels
327	New process for manufacture of sterile ophthalmic ointments
328	Antipseudomonal activity of contact lens solutions

The history, uses, and composition of conventional hard lenses, scleral lenses, and soft lenses were discussed (317). The composition and use of cleaning and disinfecting products were reviewed, as well as the indications for use of soft lenses. The requirements relating to antimicrobial activity of solutions employed for storing, cleaning, and wetting contact lenses were reviewed; the activities of preservatives and sterilizing agents employed in these products were discussed (318). Soluble ophthalmic inserts were made from various plastics and contained drugs such as neomycin, kanamycin, atropine, pilocarpine, and dexamethasone; activity was obtained for 34–72 hr (319).

Additional reports on ophthalmics are listed in Table IX.

Sterility and Sterilization—The techniques and equipment needed for obtaining clean and sterile air were surveyed (329). The design and use of a sterile holding tank and its integration with high-speed vial-filling lines were reported (330). Six commercially available biological indicator systems containing spores of *Bacillus stearothermophilus* were evaluated for resistance to 121 and 131° (250 and 270° F) saturated steam, and some manufacturers' labeled claims were not substantiated in the study (331).

The effect of holding heated and unheated *B. stearothermophilus* spores for 0, 40, 80, and 120 min in parenteral and buffer solutions at 0 and 22° was determined (332). The holding time, holding temperature, and the solution affected the number of organisms that were able to form colonies. Immersion of rubber and plastic medical equipment in a 0.5% aqueous solution of chlorhexidine gluconate at 70° produced complete sterility in 3 hr insofar as live bacteria and their vegetative forms and mold spores were concerned (333).

Additional references on sterility and sterilization are listed in Table X.

Tablets and Capsules—Recent progress in tablet technology and its application in the development of new tablet formulas were reviewed (362). A report discussed instruments used to determine tablet properties and forces in tableting (363). A book on tablet manufacture was published (364). Evolutionary operation as it applies to optimizing tablet manufacture was discussed, with particular reference to translating research formulations to production more efficiently (365). In a publication on the factors that influence the physical

Table X—Additional References on Sterility and Sterilization

Reference	Topic
334	Review of pertinent aspects of dosimetry in radiation sterilization equipment and choice of optimum parameters for sterilization of medical products
335	Effect of gamma irradiation on properties of polymeric materials
336	Surface area stability of micronized steroids sterilized by irradiation
337	Influence of steam and temperature on sterilizing action of ethylene oxide–etoxiate gas mixtures
338	Selection of sterilization process for parenteral solutions
339	Review of ethylene oxide sterilization and other types of chemical sterilization
340	Selection of packaging materials for medical products satisfactory for sterilization process
341	Challenge tests for antimicrobial agents
342	Chemical sterilants for aseptic packaging
343	Quality control of absolute bacteria removal filters
344	Manufacture of sterile topical products
345	Review of ethylene oxide sterilization
346	Sterilization of 33% ethanol with steam
347	Gas sterilization for medical purposes
348	New ways to sterilize ointment bases and oils
349	Sterilization by filtration in pharmaceutical industry
350	Effectiveness of ethylene oxide gas sterilization
351	Propylene oxide as sterilizing agent
352	Sterility testing of radiopharmaceuticals
353	Effect of gamma radiation on pilocarpine hydrochloride
354	Radiation sterilization of 0.9% sodium chloride ampuls and procaine powder
355	Effect of gamma irradiation on properties of polymeric materials
356	Optimum conditions for ethylene oxide sterilization of syringe barrels
357	Efficiency of ethylene oxide sterilization of plastic products for medical purposes
358	Sterilization of medical supplies using ethylene oxide
359	General principles of sterilization with ethylene oxide
360	Bulk sterilization of powders
361	Radiation sterilization of dextran irradiated in the dry state

properties of tablets, it was reported that an increase of the capillary network as a function of time involved structural changes reflecting the physical properties of tablets (366).

Gelatin capsules appearing in various pharmacopeias were reviewed (367). Soft gelatin capsules did not dissolve in simulated gastric fluid in the presence or absence of pepsin after 60 min (368). After exposure to this treatment, they generally disintegrated in simulated intestinal fluid of pH 7.5 in the presence of pancreatin within 4 min. Methods for preparing enteric hard gelatin capsules were reviewed with a description of the original technique used for enterocaps (369). The dosator system of a Zanasi LZ/64 capsule-filling machine was modified and fitted with strain gauges; these were used to measure the forces on the powder being filled during compaction and ejection (370). Special preparation techniques were reported, including decreasing the crystallinity of aspirin by spray drying with surfactants (371), microencapsulation of charcoal (372), and a review of microencapsulation (373).

Comminution, Mixing, Granulating, and Drying—Certain aspects of particulate contamination in tablet manufacture were discussed (374). The methods and equipment employed for granulation were reviewed (375). Methods were developed to test the consistency of granulates by a penetrometer measurement and the hardness (plasticity) by the Brinell number (376). The evaluation of flow properties of powders and granulated materials with respect to the preparation of solid dosage forms was reviewed (377). Intragranular migration of sodium chloride in granules made by the wet massing of heavy kaolin BP with salt solution was studied in batches dried by fluidization and by a vacuum tumbling method (378). The larger granules from the fluidized batch exhibited considerable intragranular variation while vacuum-dried granules had less migration.

A factorial design was found useful in the preparation of spherical particles by an extrusion–spheronization process (379). Another study, using the same apparatus, reported on formulations containing microcrystalline cellulose as well as spheronization speeds (380). Different stages in massing a granulation were measured by strain gauges and power input (381). Properties of the final granulation were independent of the addition rate of the binder solution and massing time but dependent on the amount of water in the binder solution. An air suspension technique was found to be satisfactory for the coating of moisture-sensitive materials with aqueous systems (382). The data demonstrated that solvent-sensitive materials can be encapsulated with little effect on the material when proper drying conditions are maintained.

Tablet crushing strength was greatly reduced when mixing times were prolonged in blends of amylose and magnesium stearate, and this finding was attributed to a lubricant film on the substrate (383). The mixing of antipyrine with lactose was followed by using colored lactose as the third component (384). The degree of mixing in a twin-shell blender was determined by making color measurements. The homogeneity of milled and unmilled cyclopenthiazide (1%) was determined in both coarse and fine lactose (385). The milled material demonstrated a segregating effect. The Nauta mixer was used to evaluate the mixing of a multicomponent tablet preblend of phenobarbitone (phenobarbital), butobarbitone (butethal), quinalbarbitone (secobarbital), and lactose; each component behaved in a unique manner (386, 387). The application of nonparametric statistics to the sampling in solids mixing was reported (388). The mixing of solid particles during fluidization in a conical apparatus was described (389).

The use and advantages of microwave radiation to dry tablet granulations were described, and available equipment was mentioned (390). The effects of the granule size and density on the drying rate kinetics of tablet granulations were studied, using lactose and sulfathiazole granules prepared with acacia mucilage and povidone solution (391). In a study comparing granulations prepared by the fluidized-bed method and by the traditional process, flow properties of fluidized-bed-dried granulations were generally better than those that were oven dried (392). In another study by the same group, tablets of lactose and phenacetin made by both processes were characterized (393). The kinetics of drying granulated sulfadimezine and its stability at various temperatures were reported (394).

Powder and Granule Characteristics—A continuum theory for the flow of granular materials with incompressible granules was described (395). Powder failure testing equipment was used successfully to study the effect of glidants on the flowability of two cohesive pharmaceutical powders, lactose and calcium hydrogen

phosphate, using the flow factor as the flowability parameter (396). Fine silica, magnesium stearate, and talc were investigated as glidants, and an optimum concentration was observed beyond which no further increase in flowability occurred. Static and dynamic wall pressures, measured by a small pressure-sensitive radiopill in axial–symmetrical and plain–strain experimental Perspex mass flow hoppers, were reported (397). The experimental results suggested the existence of radial stress fields in the convergent section of the hoppers and agreed with theoretical results.

A method of size grading powders using an automated sedimentation balance was described (398). The effectiveness of siliconized talc on the flow rates of L-ascorbic acid, aspirin, sulfaguanidine, sulfathiazole, oxytetracycline[7], and chloramphenicol palmitate was investigated (399). All materials except chloramphenicol palmitate showed a remarkable increase in their flow rate under the influence of siliconized talc as compared to nonsiliconized talc. The relationship between water absorption by δ-D-gluconolactone and subsequent drying was determined by a crushing strength measurement, and it was suggested that caking was caused by solid bridges formed by crystallization (400).

Compression—The surface acidity of compressed calcium and cadmium sulfates was measured after compression at various forces and temperatures, and acidities of both solids varied on compression (401). Powder X-ray diffraction, differential thermal analysis, and IR absorption were used to study the relationship between acidity and structural changes. The physical properties of tablets of identical composition but prepared by three different processes (wet granulation, dry granulation, and direct compression) were studied as a function of compressive force (402). Methods for determining the energetic work involved in tablet compression were presented and were applicable in predicting properties and quality of tablets (403).

The compaction behavior of various materials such as potassium chloride and lactose was studied and compared (404). Different particle sizes of lactose and potassium citrate were compacted, and the strain was measured at relatively low compaction forces (405). The yield strength and consolidation behavior were compared to those obtained for potassium and sodium chlorides. In another report on the same materials, various aspects of the physics of tablet compression were described further (406). A direct compression mixture of dicalcium phosphate and a cation-exchange resin was evaluated for disintegration and dissolution characteristics after compression at different compaction forces (407).

Compressed tablets of aspirin, dicalcium phosphate dihydrate, calcium phosphatocarbonate, alumina, and microcrystalline cellulose were made at several compaction pressures by a standardized technique, and their disintegration properties were evaluated by measuring particle sizes (408). The transmission of force to the die wall was measured by a piezoelectric sensor, and compression cycles of lactose granules of different shapes were compared (409). Two other studies on die wall pressures resulting from tablet compression were published (410, 411).

The pore structure of tablets made from wet massed granules and from crystalline granules was compared (412). The pore structure of a polymer compact was dependent upon the morphology of the initial particle and the mechanism of compaction (413). Mercury intrusion porosimetry was used to study both effects, and scanning electron photographs were used to confirm the interpretation obtained from mercury penetration. The rate of dissolution of sulfamethoxydiazine (sulfameter) tablets in three formulations of various moisture levels and compressed at various force levels was determined (414). Factors of interest in the physics of tablet compression including important features of granulated materials were reviewed (415).

Effects of Excipients—A factorial design was used to evaluate the compatibility between drugs and excipients in multicomponent mixtures (416). Chemical interactions could be detected and quantified in multicomponent mixtures, and the excipients responsible for them could be pinpointed. Nine direct compression fillers were evaluated for physical stability, compressibility, and lubricity with an instrumented tablet press (417). Four grades of commercially available microcrystalline cellulose were examined for appearance, particle-size distribution, specific surface area, pore size distribution, and surface energy (418).

The disintegration behavior of three direct compression formulations containing microcrystalline cellulose was reported (419). Aspirin tablets made by the dry method had good properties when microcrystalline cellulose, carboxymethylcellulose, ethylcellulose, carboxymethyl starch, anhydrous lactose, polyvinylpyrrolidone (povidone), dextrose[8], Silartex, and crystalline lactose binders were used (420). Sulfanilamide tablets made with various starches were evaluated for *in vitro* dissolution rates; barley starch was superior to plain starch and rice, wheat, potato, and arrowroot starches in giving the lowest disintegration time and highest release (421). Various excipients (potato starch, tricalcium phosphate, wheat starch, talc, and magnesium stearate) were evaluated in sulfanilamide tablet formulations (422). Properties of the granulations and compressed tablets were reported.

Starch sodium glycolate was evaluated as a disintegrant in tablets of sodium benzoate and calcium lactate and compared with starch and cellulose (423). Disintegration and dissolution were best with starch sodium glycolate. The same compound was evaluated by another investigator in direct compression formulations and was found to be a better disintegrant than alginic acid, corn starch, and microcrystalline cellulose (424). In another study, carboxymethyl starch was found superior to corn, wheat, potato, and rice starches but less effective than guar gum and magnesium aluminum stearate (425).

Additional references on excipients, *i.e.*, disintegrants, binders, and other substances that impart spe-

[7] Terramycin, Pfizer.

[8] Celutab, Penick and Ford.

Table XI—Additional References on Excipients

Reference	Topic
426	Water sorption properties of starch, carboxymethylcellulose sodium, sodium starch glycolate, and a cation-exchange resin
427	Evaluation of different viscosity grades of carboxymethylcellulose sodium as tablet disintegrants
428	Influence of surfactants on dissolution rate
429	Effect of tragacanth on disintegration time of tablets
430	Preparation of effervescent tablets
431	Use of sugarcane wax in preparation of tablets having prolonged action
432	Techniques for preparing slow-release drug forms for oral administration
433	Influence of moisture on rate of dissolution of sulfamethoxydiazine (sulfameter) tablets
434	Factors affecting dissolution rate of tablets
435	Effect of binders on physical standards and dissolution characteristics of ephedrine hydrochloride tablets
436	Influence of cellulose derivatives on physical properties of tablets
437	Interaction between hydroxyzine and dicalcium phosphate dihydrate
438	Use of native bentonite for direct tableting
439	Nu-Tab as a chewable direct compression carrier
440–443	Materials as dry binders for direct compression of tablets
444	Comparative evaluation of excipients for direct compression
445	Starch-containing cachets
446	Effect of various starches on physical properties of sulfaguanidine tablets
447	Review of components and formulation of effervescent tablets
448	Use of mannitol in tablets and other formulations
449	Formulation of mercaptopurine tablets
450	Optimum conditions for tableting 2-mercaptobenzothiazole with papaverine hydrochloride
451	Evaluation of binding substances used for the granulation of medical carbon
452	Optimum conditions for tableting 2-mercaptobenzothiazole with levomycetin (chloramphenicol)
453	Effect of techniques and components on formulation of nitrofurantoin tablets
454	Development of optimum technology for 2-mercaptobenzothiazole tablets
455	Use of colloidal silicon dioxide in pharmaceutical preparations including tablets
456	Intragranular starch: comparison of starch USP and modified corn starch
457	Direct compression of sulfamethoxydiazine (sulfameter) polymorphic forms
458	Methyl vinyl ether–maleic anhydride copolymer as a dry binder for direct compression
459	Dry binders for direct compression in tablet manufacture
460	Comparative study of lubricants in direct compression
461	Disintegration behavior of three direct compression formulations containing microcrystalline cellulose

cial properties to tablets, are listed in Table XI.

Tablet Coating—The composition of enteric coatings, the methods of application, the theory of enteric coatings and their properties, and factors affecting disintegration time and stomach emptying were discussed (462). Tablet film coatings, film-coating materials, plasticizers, and solvents used to ensure drug protection and good *in vivo* diffusion were reviewed (463). Film coating by the immersion tube process, where both coating solution and liquid are applied within the tablet bed, was reported (464). Zein and hydroxypropyl methylcellulose and various plasticizers were evaluated for film coating tablets (465). Application of hydroxypropyl methylcellulose from an ethanol–chloroform solution was carried out at various temperatures and flow rates, and the strength of the coatings was evaluated (466).

Three different subcoating powders were evaluated by application in simple syrup or gelatin–acacia syrup (467). A suspension coating containing polyvinylpyrrolidone (povidone), magnesium carbonate, talc, titanium dioxide, colloidal silicon dioxide[9], and water was used for coating tablets (468). The disintegration, dissolution, and stability of cyclothiazide and reserpine tablets were examined initially and periodically up to 1 year at various temperatures (469). Polyvinyl alcohol coating and sugar coating were compared and evaluated (470). A microscope photometer was used to measure the color uniformity and gloss of tablets (471). The influence of processing variables and type of dye on color uniformity was reported, and the use of the instrument to optimize the polishing of coated tablets was discussed.

Suspensions—The history of water-soluble gums (*e.g.*, seaweed extracts) was discussed including the effect of climatic conditions, collections, and harvestings, and some predictions about their future were reported (472). Factors affecting the stability of aggregates in dispersed systems were reported; the ζ-potential, the pH of the system, the electrolyte forms, and the surfactant type and concentration that affect stability of aggregates of dispersed drugs were discussed (473).

The stability of suspensions was discussed by viewing agglomeration as a process of microscopic segregation (474). The influence of size and porosity of agglomerates on the rate of settling was demonstrated with the aid of theoretical and experimental results. The viscosity compatibility of acacia, methylcellulose, and tragacanth with ethanol was reported, and it was found that the addition of colloidal silica counteracted the viscosity decrease caused by alcohol addition (475). The mechanism of coagulation of particles in suspensions during freeze–thaw cycles was reviewed (476).

Acacia and sodium alginate powders were sterilized by cobalt-60 irradiation to a total dose of 2.5 Mrad with no increase in residual radioactivity as a result of the treatment (477). The viscosities of acacia solutions were somewhat reduced by the treatment, while the viscosities of sodium alginate solutions were greatly reduced. It was concluded that this dose of irradiation was not an appropriate method of sterilization for these gums. Erythromycin and sulfadimezine were formulated into suspensions for treatment of bovine mastitis using polyethyl siloxane and esilon-5; physical and chemical stability studies were carried out (478).

The suspension-stabilizing ability of five suspending agents used for sulfisomidine suspensions was studied, and the addition of sodium citrate increased the sedimentation volume and degree of flocculation in suspensions containing carboxymethylcellulose sodium (479). Aluminum hydroxide gel was found to lose reactivity on aging or dilution with double-distilled water (480). The loss of reactivity was directly related to the degree of dilution, but dilution with dioxane or mother liquor had no effect on reactivity. The stability of sulfadimezine suspensions was studied using bentonite, methylcellulose, and carboxymethylcellulose sodium (481).

[9] Aerosil.

Emulsions—Various aspects of the formation and breaking of emulsions were reviewed (482). A modified phase inversion method was compared to the original method for the determination of the emulsifying potential of polysorbates 60 and 80 (483). The mechanism of phase inversion and surfactant location on the formulation of oil-in-water emulsions was reported (484). The effects of heat, agitation, and rheological properties on the production of emulsions on an industrial scale were studied, and a laboratory procedure was adopted for simulating large-scale production (485). The effects of tank size and impeller on the degree of liquid–liquid dispersion by mechanical agitation were studied (486). The influence of pH, emulsifier, and accelerated aging on preservative requirements of oil-in-water emulsions was reported (487).

Emulsions of mineral oil and cottonseed oil stabilized by nonionic surfactants have a substantial ζ-potential (488). The hydrophilic–lipophilic balance of surfactants was determined by using the emulsifier solvent power which, in turn, was related to ethanol value (489). A method for determining ethanol value was given. The formation and stability of emulsions made from 1:1 mixtures of water and octane were studied using various types and concentrations of surfactants (490). The phase inversion method was used to determine hydrophilic–lipophilic balance values of paraffin oil, rape oil, methyl silicone oil, olive oil, soybean oil, and oleic acid, using nonphenol adducts of ethylene oxide and other surfactants (491). The hydrophilic–lipophilic balance values obtained were comparable to values obtained by the Griffin procedure. The dielectric behavior of reverse emulsions during flocculation was studied (492).

The release of benzoic acid from oil-in-water emulsions was studied, and a dependence on the hydrophilic–lipophilic balance of the emulsifier, the viscosity, and the degree of dispersion was found (493). Oil-in-water emulsions of perfluorooctyl bromide for use as radiopaque media were stable and nonirritating (494). The particle-size distribution of a fluorocarbon emulsion was determined by centrifugal sedimentation (495).

Additional reports on emulsions are listed in Table XII.

Semisolids—The mechanical and storage effects on various ointment bases were studied (501). The influence of purity, components affecting pH, homogenization, and storage time on the color changes of zinc oxide paste with 20% resorcinol was followed by reflectance measurements (502). All factors, especially alkaline ingredients, affected the decomposition of resorcinol. The application properties of creams and ointment bases were reviewed (503). By means of fluid mechanics, subjective spreadability, viscosity, and stickiness perceived with the fingers were predicted (504). The effectiveness of different comminution techniques for salicylic acid and prednisolone was reported (505).

The water absorbancy of ointments containing polyethylene glycols, carbomer 934, emulsifiers, cetyl alcohol, and zinc stearate was determined (506). The quality and stability of ointments containing zinc oxide and one containing zinc oxide, fish oil, petrolatum, and lanolin were studied (507). The release of sulfathiazole and salicylic acid from white petrolatum containing ethoxylated surfactants of varying ethylene oxide chain lengths was evaluated by a dialysis method (508). The release rates of benzocaine[10] from two ointment bases were compared using an *in vitro* dialysis method as well as an *in vivo* method by determining blood levels in rabbits (509). Various methods were evaluated for determining the dispersion of benzocaine in ointments (510).

A study was undertaken to determine the water absorption capacities of pastes used in the treatment of conditions encountered particularly in veterinary medicine (511). The purposes of the study were to develop an *in vitro* method for the measurement of the absorptive rate and capacity of the pastes and to measure formulation effects and effects due to the physical state of the formulation.

Additional references on semisolids are listed in Table XIII.

Suppositories—A review on suppository formulation, especially the choice criteria for excipients, was published (531). Five bases were evaluated for suitability in preparing suppositories containing antibiotics (532). One base was suitable for oxacillin sodium, chloramphenicol was stable in two bases, while tetracycline hydrochloride was stable in all bases except polyethylene glycol. The release of these three antibiotics was studied by an *in vitro* method (533). The influence of preparation techniques and the composition

Table XII—Additional References on Emulsions

Reference	Topic
496	Preparation and stability of cosmetic water-in-oil emulsions
497	Use of hydrophilic–lipophilic balance system for studying paraffin emulsion
498	Emulsion for insulating and protecting the skin
499	Transparent emulsions
500	Cosmetic emulsions

Table XIII—Additional References on Semisolids

Reference	Topic
512	Tocopherol acetate ointments
513	Effect of limonin–limonene mixture on tissue permeability
514	Semisolid bases containing hydroxypropylcellulose
515	Effect of emulsifier on hydration number of petrolatum
516, 517	Use of hydrogenated cod liver oil in ointment preparation
518	Testing quality of pharmaceutical petrolatum
519	Review of emulsions and emulsion ointment bases
520	Study of air inclusion in ointments
521	Rheological interaction of emulsifiers with ointment bases
522	Stability of vitamins A and D_3 (cholecalciferol) in oil and water emulsions
523	Use of diethylene glycol stearate as emulsifier in ointment bases
524	Technological review of ophthalmic ointments
525	Coagulation structure formation in protective ointments
526	Properties of cold cream with triethanolamine and beeswax as emulsifying agents
527	Preparation of commercial petrolatum products from Soviet petrolatum
528	Rheological study of ointments containing ethonium and dodeconium additives
529	Topical vehicle design
530	Gelled vegetable oils as ointment bases using aluminum stearates

[10] Anesthesin, Abbott.

of aminophylline suppositories were examined 8 months after preparation (534). With some formulations and techniques, the unwanted late effects of the interaction between the active ingredients and vehicles could be prevented. A method of preparing hemorrhoidal suppositories of good quality was suggested (535).

A model system was developed for evaluating drug absorption in the rabbit doe (536). Drug disappearance from the drug reservoir followed first-order kinetics and was reproducible. The mechanical strengths and elastic moduli of blocks of polyethylene glycol with a range of molecular weights were determined (537). The release characteristics of prednisolone from similar blocks were determined and were correlated with the physical properties of the polyethylene glycols.

The bioavailability of aspirin from five brands of aspirin rectal suppositories was determined in an adult panel (538). At best, only 40% of the dose was available, but four out of five brands gave substantially lower absorption. The absorption of chloramphenicol from three types of suppository bases was studied in the rabbit (539). The absorption was higher with emulsified bases than with oleaginous bases. Surfactants in concentrations above the CMC had no effect on the release of soluble phenazone (antipyrine) or propylphenazone (540). Indomethacin release from suppositories containing polyoxyethylene decreased with the increasing molecular weight of the polymer (541). Also, indomethacin was absorbed into the bloodstream of rabbits faster when administered in polyethylene glycol suppositories than from those made with a glyceride base (542).

Chloramphenicol bioavailability was tested in rabbits and compared using various routes of administration: intravenous, intramuscular, rectal from an oil-in-water base, and oral (543). Physiological availability was highest for the suppository due to the first-pass effect of the liver.

Suppositories containing aspirin, dimethylaminophenazone (aminopyrine), phenacetin, and sulfanilamide of three different particle-size distributions were prepared (544). The effect of particle size on finished suppository physical properties was reported.

Coloring of suppositories was achieved by incorporation of colored powdered cellulose, which was made by treating with an alcoholic solution of a food coloring and drying (545). Color measurements were made, and the light fastness was determined. The use of insoluble organic coloring agents, mainly lake dyes, in suppositories was described (546).

Additional references on suppositories are listed in Table XIV.

Aerosols—A number of review articles appeared in the literature, including reviews of aerosol techniques (552), physicochemical systems for formulating pharmaceutical aerosols (553), aerosol hair products (554), the technology of aerosol cosmetics (555), aerosol foams (556), and alternatives to aerosols (557).

Table XIV—Additional References on Suppositories

Reference	Topic
547	Preparation of suppositories containing digitalis powder
548	Effect of melting point of suppositories on membrane diffusion
549	Use of Suppocire BML in suppositories
550	Thermal expansion of glycerol esters of some higher fatty acids used in suppository bases
551	Review of rectal administration of drugs

The causes of respiratory irritation by deodorant sprays that provoked cough were investigated, and several deodorant spray formulations were quantitatively evaluated for cough stimulation in a large number of subjects (558). A dexamethasone timed-release aerosol, employing the drug in microcapsules, was developed and evaluated (559). An aerosol dosage form of insulin was developed by dispersing insulin zinc crystals in a fluorocarbon propellant along with a dispersant (560).

A method of stabilization of nonionic aerosol emulsions was reported (561). Fatty alcohols in the propellant were added to the aqueous surfactant phase, which formed a surfactant–fatty alcohol complex. The binding of three fluorocarbon surfactants in an aqueous 5% human albumin solution was studied using the partition method, and the fraction of fluorocarbon bound was highly dependent on fluorocarbon concentrations (562). A new particle-size analysis technique of aerosols and fine powders was developed using an ultramicroscope and a sedimentation method (563).

The physicomechanical factors affecting spray from aerosol cans with centrifugal nozzles were studied using aqueous glycerin solutions (564). A practical method of employing carbon dioxide in cosmetic aerosols was presented; although it is not the ideal propellant, it does offer some advantages (565). Other articles discussed aerosol propellants (566, 567).

Controlled-Release Preparations—Cyclic iminocarbonates of dextran with coenzyme B_{12}, insulin, levarterenol, amphetamine, and procaine[11] were prepared and exhibited prolonged activity and increased stability (568). Sustained-release formulations of diphenhydramine hydrochloride were made using carnauba wax and stearyl alcohol, and some diluents also were evaluated for their effect on drug release (569). A new sustained-release tablet formulation of procainamide, in which the active component particles were coated with a thermoplastic substance, was tested *in vitro* and *in vivo* (570). It was reported that a sustained-release ascorbic acid tablet was not as bioavailable as an ordinary tablet, and this finding was attributed to ascorbic acid absorption, predominantly in the proximal small intestine (571).

The release of potassium from six different commercial formulations was compared, and the rate of release was markedly dependent on composition (572). In another study, three brands of slow-release potassium chloride tablets were tested for *in vitro* dissolution, using the Tingstad–Riegelman apparatus and a specific potassium-ion electrode as the monitoring device (573). A slow-release preparation of lithium sulfate was made by dispersion of the drug in a fat (574). Plasma levels of this new preparation and lithium carbonate tablets were obtained, and a higher frequency of diarrhea with the

[11] Novocain, Winthrop.

slow-release preparation was noted. The *in vitro* releases of six brands of quinidine bisulfate tablets were determined; four tablets were long acting, one was enteric coated, and one plain (575). Great differences were found in the quinidine release, depending on pH and time. The addition of starch to phenobarbital capsules increased the drug release rate (576).

Variables affecting the release of a drug from an inert plastic matrix were reviewed (577). The rate of release of water-soluble inorganic salts from tablets employing a polyethylene matrix was studied (578). Eight different slow-release tablet formulations on the Spanish market were examined for various physical properties as well as dissolution (579). The application of microencapsulation to alter the release properties of drugs was reported (580, 581).

The release of steroids and steroid esters from various drug delivery systems including water, vegetable oils, and polymer implants *in vivo* and *in vitro* was discussed (582). The controlled release of anticancer agents from composites with poly(lactic acid) was studied in rats (583). Silicone rubber implants were impregnated with drug by treatment with solutions of chloramphenicol or lincomycin hydrochloride (584). The release of these antibiotics from the implants was tested with *Sarcina lutea* as the test organism. The intravaginal release of ethynodiol diacetate from silicone devices in rabbits was studied, and *in vitro–in vivo* correlations were made (585). The release of progesterone from solid silicone rubber implants in sheep was superior to implants made from silicone rubber tubing containing solid progesterone (586). The release of caffeine and salicylic acid from cast ethylcellulose films was described, and release rate data were analyzed (587).

Various types of matrixes (plastics, waxes, and ion-exchange resins) used to control the release of drugs and the factors that affect their release were reviewed (588). The delivery of drugs from soft contact lenses composed of hydroxyethyl methacrylate–vinylpyrrolidinone polymer or polyhydroxyethyl methacrylate was discussed (589). Factors affecting the permeability of drugs through polymeric matrixes were described in quantitative terms, with particular reference to the use of pilocarpine.

A new delivery system for drugs, the osmotic pump, which delivers the agent by an osmotic process at a controlled rate, was reported (590). With immobilized enzymes, drug release in microcapsules was found to be zero order (591). The release of nicotinamide, isoniazid, acetylsalicylic acid (aspirin), and nalidixic acid from ion-exchange resins was studied (592). The kinetics of release of carbutamide from polymethacrylic acid derivatives were reported (593).

Additional references on controlled-release preparations are listed in Table XV.

Table XV—Additional References on Controlled-Release Preparations

Reference	Topic
594	Review of oral sustained-release and prolonged-action medication
595	Dry sustained-release oral drugs
596	Prolonged-action tablets prepared using vegetable mucilage
597	Significance of matrixes in prolonged-release oral administration
598	Preparation of coated micropellets and their use in pharmacy
599	Long acting steroid preparations
600	Evaluation of release rate of active substances from oral forms of drugs with prolonged action
601	Principles of retardation
602	Use of selected permeable membranes for biocompatible drug delivery systems
603	Oral retard preparation of verapamil hydrochloride

Cosmetics—*Microbiological Contamination*—A membrane filtration method for estimation of *Ps. aeruginosa* contamination of an oily cream was described (604). Various bactericides used in cosmetics and their activity were reviewed (605). The procedure for the preservation of talc according to the French and Italian pharmacopoeias was examined, antibacterial compounds were evaluated, and the manufacture of sterile talc for cosmetics was reported (606). Ethylene oxide sterilization of cosmetics was discussed, with particular reference to the proportion of residual amounts and reaction products that can cause toxicity problems (607).

Formulation and Technology—Similarities and differences in the development of a cosmetic product and that of a pharmaceutical preparation were reviewed (608). The responsibility of the cosmetic chemist to the public, as reinforced by legal codes requiring a product to match its promise to the consumer, was discussed (609).

Factors that determine the skin irritation potential of soaps and detergents were studied (610). Strongly anionic surfactants such as sodium lauryl sulfate had considerable activity, whereas nonionic ethoxylates had a minimal effect on the stratum corneum. Another study reported a new analytical approach for estimating the chemical interaction between surfactants resembling human skin and hair (611). The percutaneous absorption of some ^{14}C-labeled anionic surfactants was measured *in vivo* in rats after both consumer-type applications and applications of longer duration (612). Results obtained using isolated rat skin and human epidermis were compared. The absorption of ^{3}H-labeled triclosan[12] through rat skin treated with shampoo and with aerosol deodorant was measured (613). The concept of exaggerated exposure in topical irritancy and sensitization testing was discussed (614).

The structure and composition of the outer layers of the skin, the usefulness of various emulsions, and active ingredients useful in cosmetics were reviewed (615). Advantages and disadvantages of different methods for the determination of skin lipids were presented (616). The three disorders of the skin lipid systems that are of concern with seborrhea and related diseases were the amount, the composition, and the physical behavior of the lipid film on the skin's surface. The last factor was the most important.

A skin cream containing lactic acid or sodium lactate and adjusted to pH 4 was more beneficial for skin dryness and flaking than were control lotions (617). Measurements on extensibility and water-holding capacity

[12] Irgasan DP 300.

in isolated animal corneum showed that conventional humectants such as glycerol, sorbitol, and sodium lactate could be effective but the effect was lost when rinsed with water. Lactic acid was also effective and did not lose its effect when rinsed with water. The skin-moisturizing effect of baby oil was studied using 106 adult females who exhibited roughened, cracked, and inflamed skin of the elbows, knees, shins, and heels (618).

The experimental design and data analysis procedures associated with axillar antiperspirant tests were discussed; a new procedure, which does not require preliminary testing or establishment of "control ratios," was suggested (619). Silica gel moisture-absorbing tins strapped to the body side of the axilla were used to evaluate the effectiveness of antiperspirant agents under normal and near normal conditions (620). New trends in the formulation and testing technology of antiperspirant preparations were reviewed (621). One study involved the inhalational, histological, and dermatological aspects of aluminum chlorhydroxide, an active constituent in antiperspirant preparations (622).

^{35}S-Labeled zinc pyrithione in a shampoo formulation was adsorbed onto hair and skin; the degree of adsorption was dependent on time, pH, temperature, and concentration (623). The velocity of an aerosol hair spray was determined by measuring the gas velocity within the spray with a pilot-static tube (624). Measurements of the capture and penetration of hair spray droplets into a model array of hair fibers indicated that coarse sprays gave better penetration than fine sprays. The fastness of human hair colorings to crocking, washing, water, and light was determined (625). The causes of split ends of hair were reviewed (626). The usefulness and effect of hair conditioners, lacquers, setting lotions, and rinses on hair were reviewed (627).

A hairless mouse was used as an experimental model for evaluating the effectiveness of sunscreen preparations; the best protection was obtained with two sunscreens, 5.4% *p*-dimethylaminobenzoic acid and 2.7% alkyl *p*-aminobenzoate (628). Solar protective preparations were evaluated by *in vivo* and *in vitro* techniques (629). In another study, the photoprotective capabilities of propyl gallate, acetylcysteine, ascorbic acid, and 30 other compounds were tested, and no correlation between *in vivo* and *in vitro* effectiveness was identified (630). The effectiveness of titanium dioxide incorporated into 11 formulations was evaluated *in vitro* and *in vivo* (631).

A number of physical methods using a tensiometer[13] were used to characterize dentifrices and other semisolids (632). The cleaning power of toothpaste was evaluated by allowing stain to build up on teeth for 5 weeks using a nonabrasive toothpaste and then testing the cleaning activity of new pastes to remove stain (633). A mathematical relationship was developed to express the ability to remove stain. The physical characteristics of solid particles and heterogeneities in the liquid phase(s) of a toothpaste as it is extruded from the tube were studied by electron microscopic techniques (634).

[13] Instron.

Table XVI—Additional References on Formulation and Technology of Cosmetics

Reference	Topic
635	Aerobic microflora of outer eye
636	Formulation of high foaming cosmetic products
637	Aspects of skin penetration by collagen and proline
638	Microemulsions: formation and stabilization
639	Surfactants in personal care products
640	History of perfume industry
641	Raw materials for perfume industry
642	Adhesion and fixing of perfumes
643	Cosmetic emulsions, creams, and milks
644	Chemical constituents of skin and effects of cosmetics on skin
645	Methods of evaluating hair lacquers
646	Manufacturing methods and emulsion stability of cosmetic water–oil emulsions
647	Formulation of cosmetic emulsions
648	Review of hair straighteners
649	Review of face powders
650	Review of foundation makeup
651	Review of hand creams and lotions
652	Lipstick formula variations and lipstick properties
653	Classification and utilization of lanolin derivatives
654	Sarcosinates as base products for cosmetics
655	Review of polyethylene glycols
656	Review of emulsified and solid fragrances
657	Fingernail elongators and accessory nail preparations
658	Review of bath preparations
659	Review of shampoos
660	Review of depilatories
661	Preshave and aftershave preparations
662	Review of shaving preparations: soaps, creams, oils, and lotions
663	Sulfosuccinic acid half esters and their use in cosmetics
664	Gelatin hydrolysate use in cosmetic creams
665	Review of mouthwashes
666	Properties of cold cream with triethanolamine and beeswax as emulsifying agents
667	Review of cleansing creams and lotions
668	Role of essential fatty acids in regulatory processes of malpighian cell membranes
669	Body care aids
670	Synthetic bar soaps from sodium primary alkylsulfonates
671	Toilet soaps with disinfecting and therapeutic prophylactic additives
672	Hair conditioner formulation
673	Use of polyoxyethylene 20 sorbitan isostearate as emulsifier and solubilizer for cosmetics, drugs, and toiletries
674	Pigment dispersion technology for cosmetic application
675	Use of acyl lactylates in cosmetics and toiletries
676	Peroxides in polyethylene glycols and polyethylene glycol derivatives
677	Vegetable lecithin in cosmetic lotions
678	Cosmetic application of high oleic safflower oil
679	Role of research in development of cosmetic products
680	Evaluation of synthetic oily materials as bases for lipsticks, cleansing milks, and foundation emulsions
681	Determination of required hydrophilic–lipophilic balance of oil-in-water emulsions by phase inversion titration
682	Biphasic gels
683	Use of silicones in formulation of eye shadow sticks
684	Physical properties of basic aluminum complexes as related to their efficacy
685	Shampoo formulations
686	Cellulose polymers in cosmetics and toiletries
687	Cationic surfactants in low pH shampoos
688	Shampoo surfactants
689	Collaborative study of rabbit eye irritation tests
690	Dandruff and its treatment
691	Aerosol foam shampoos
692	Microbiology of shampoos
693	Trends and aspects of contemporary shampoos
694	Theory and practice of shampooing
695	Perspiratio insensibilis control by specific associations of lipids
696	Cosmetic regulation in Germany; main facts of 1974 law
697	Stability of basic aluminum chlorides in antiperspirant formulations
698	Lipstick formula variations and lipstick properties
699	Use of microencapsulation in cosmetics

Table XVI—(*Continued*)

Reference	Topic
700	Conditioning shampoos; digest of patents issued in 1970–1974
701	Critical review of antiperspirant efficacy testing
702	Role of prostaglandins in UV erythema
703	Analysis of shampoos containing anionic and nonionic surfactants
704	Assessment of auxiliary detergents in shampoo mixtures
705	Use of hydroxypropylcellulose acetates as gelling agents for organic solvents
706	Protective skin care
707	Direction of international perfumery
708	Importance of acetylenic compounds in perfumery
709	Utility of amine oxides in oil/water cosmetic systems
710	Occurrence of *Ps. aeruginosa* and *Staphylococcus aureus* in orbital area
711	Action and fate of sodium pyridinethione applied topically to rabbits
712	Implications of enlarged European Economic Community on quality and safety of cosmetics
713	Detection of chrysotile asbestos in talcs by differential thermal analysis
714	Properties of ethoxylated lanolin derivatives and their effect on cosmetic application
715	Cholesterol in cosmetic formulation
716	Cosmetic activity of emulsions
717	Phytogels and their possible cosmetic uses
718	Conditioning shampoo containing a mixture of wax and rosin
719	Cosmetic uses, structure, and asbestos contamination of talc
720	Cosmetic emulsion compounding
721	Use of cosmetic water-in-oil emulsions
722	Waxes in cosmetic preparations
723	Use of surfactants in cosmetics
724	Perfuming cosmetic products
725	Use of chelation as stabilizer in cosmetics
726	Practice of compounding cosmetic emulsions
727	Potential applications of urea for skin disease
728	Quaternary ammonium compounds in cosmetics
729	Shorter methods for evaluating antidandruff agents
730	Animal model for estimating relative sting potential of shampoos
731	Influence of protein vehicles on penetrability of sunscreens

Additional references on cosmetic formulation and technology are listed in Table XVI.

Packaging—The requirements of plastic materials for pharmaceutical packaging were reviewed (732). An identification method for pharmaceutical containers and packaging materials by IR spectroscopy was described, and a compilation of spectra was included (733). Extraction rates of marker compounds from rubber closures for parenteral use were reported (734). A model for predicting the maximum vinyl chloride concentration in bottle contents was developed from knowledge of the vinyl chloride monomer in polyvinyl chloride bottles (735). Octyltin-stabilized polyvinyl chloride was analyzed using food-simulating solvent to replace actual products (736).

The stability of promethazine hydrochloride solutions was compared in polyethylene and glass containers (737). Red-colored plastic and brown glass gave the best protection. Methods for the determination of synthetic organic colors in plastic packages for pharmaceutical use were reported (738), and trace amounts of colorant released to pharmaceutical preparations were detected. Various single-unit packages for syrups dispensed in hospitals were evaluated, and stabilities were determined (739). A study was made on the blister packaging of pharmaceutical products which included a description of the process, materials used for packaging, suitable machinery, and limitations (740). Various silicates were found to have a protective effect on aluminum tubes filled with toothpastes and shaving creams. This finding was attributed to the formation of a colloidal aluminum silicate on the aluminum surface, which was dependent on pH and the concentration of the corrosive agent (741).

Table XVII—Additional References on Packaging

Reference	Topic
742	Development of mechanical methods of testing child-proof containers
743	Packaging primer for drugs and cosmetics; polyethylene and polypropylene
744	Problems of using thermoplastic containers for dermal pharmaceutical products
745	Review of packaging in pharmaceutical industry
746	Environmental influence on seal performance
747	Use of adhesive-cohesive polyethylene to form cold-seal pouches
748	Properties of polyethylene in flexible packaging
749	New child-resistant closure systems for use in United Kingdom
750	Low adhesion properties of package laminates for peel property
751	Closures and seals for pharmaceutical containers
752	Sachet filling and forming machines
753	Testing and control of plastic containers for pharmaceuticals
754	Problems of labeling small and awkwardly shaped items

Additional references on packaging are listed in Table XVII.

Instruments and Equipment—The advantages of an electropolished stainless steel surface over mechanical surface treatment were discussed (755). The preliminary planning, design, and construction of a new sterile manufacturing plant were reported (756). The application of reverse osmosis for purification of water for sterile products was reviewed (757). The effect of the size of the tank and impeller on liquid–liquid dispersions by mechanical agitation was studied (758). The control of airborne dust was discussed, including such factors as filter types, ducts, and hooding devices (759).

Automatic checkweighers currently available were listed, and their pharmaceutical applicability was described (760). The use of a programmed checkweighing system in the packaging of drugs and cosmetics was discussed (761). Processes and equipment for agglomerating, instantizing, and spray drying food products were surveyed (762). Newer techniques mentioned were the steam-swept wheel process, the two-stage drying process, and a combination spray dryer–fluidized bed. The applicability of the Poisson distribution to suspension spray drying was studied (763). *In vivo* studies

Table XVIII—Additional References on Instruments and Equipment

Reference	Topic
765	Automatic placement of valves and tips on aerosol cans
766	Equipment for cosmetic and pharmaceutical industries
767	Aspects of electronic weighing
768	New, inexpensive device for making individually prepared capsules
769	Establishment of a nuclear pharmacy
770	Effect of method of freezing and pulverization of pancreas gland on yield of insulin

Table XIX—Additional References on Dental Products and Materials

Reference	Topic
774	Bond strength of dental amalgam joined to cast silver–tin alloys
775	Effects of sand blasting on surface of silver–tin alloy casts
776	Rugosimetric evaluation of two brands of amalgams using two techniques
777	Effect of particle sizes on compressive strength of dental silicate cements
778	Etching techniques for pit and fissure sealants
779	Factors influencing creep behavior of poly(methyl methacrylate) cements
780	Comparison of effects of linear and cyclic phosphates on adsorption of proteins by human enamel
781	Enhancement of antiplaque value of antibacterial agents by enamel-conditioning methods
782	Kinetics and mechanisms of reactions of human tooth enamel in buffered solutions of high fluoride concentrations
783	Laboratory properties of polyacrylate cement
784	Effect of salts commonly found in tap water on expansion of inlays

Table XX—References on Biomedical Devices and Materials

Reference	Topic
785	Evaluation of a metal–ceramic composite hip prosthesis
786	Composite implants for orthopedic applications; *in vivo* evaluation of candidate resins
787	Chronic heparin anticoagulant in dogs by continuous infusion with a totally implantable pump
788	Third-generation artificial kidney; pH and concentration control
789	Porous calcium sulfate dihydrate as a biodegradable implant in bone
790	Thermodifferential analysis of ceramic implants
791	Comparison between mercury and lithium chemical systems for pacemaker energy source applications
792	Soft tissue response to series of dense ceramic materials and two clinically used biomaterials
793	Hydrophilic polymers for biomedical materials
794	Required properties for biofunctional materials
795	Interfacial behavior of ceramic implants
796	Engineering and biological studies of metallic implant materials
797	Materials characterization of implantable porous electrodes
798	Polymeric materials for medicinal products of frequent use
799	Review of thrombogenic behavior of polymers and polymers potentially useful as implants
800	Method for methacrylate polymer (Hydron) impregnation of silicone rubber
801	Compatibility and versatility of natural and synthetic polymers as biomedical materials
802	Characterization and evaluation of springy polypropylene as prosthetic device
803	*In vitro* investigation of the anodic dissolution and capacitative behavior of 316L stainless steel as surgical orthopedic implant material
804	*In vitro* studies of lipid uptake by medical grade silicone rubbers used for heart valve balls
805	Physical characteristics and performance of synthetic wound dressings
806	Biological testing of surface-modified acrylic polymers
807	Absorbable artificial vas deferens for vasovasotomy
808	Medical use of organic porous polymer membrane
809	Review on polymer prosthesis and sutures
810	Development of biomedical polymers emphasizing collagen
811	Slow crack growth in acrylic bone cement
812	Survey of metallic implant materials
813	Review of materials for biomedical applications
814	Fractography of poly(methyl methacrylates)
815	Microstructure of two-phase poly(methyl methacrylates)
816	Review of chemical and physical properties of methacrylate polymer (Hydron)

with human volunteers compared the neutralizing effect of various antacid dosage forms using the Heidelberg capsule (764). A suspension and chewable tablet gave similar results, whereas a tablet for swallowing gave less prompt effects and a shorter duration of action.

Additional references on instruments and equipment are listed in Table XVIII.

Dental Products and Materials—A literature review of dental materials was published (771). Properties of dentifrices, including the function of a dentifrice, therapeutic dentifrices, dentifrice ingredients, abrasives, surfactants, humectants, binders, flavors, and fluorine compounds were reviewed (772). The absorption, distribution in body fluids, and bioavailability of fluoride were studied after various doses (773). The concentration of fluoride in saliva and plasma was found to be nearly equal.

Additional references on dental products and materials are listed in Table XIX.

Biomedical Devices and Materials—This year a separate section on implants, prosthetic devices, and the materials used in them is included because of increased research and development in these areas. References on these topics are listed in Table XX.

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