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Review Article

Pharmaceutical Sciences—1962. Part I

A Literature Review

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CONTENTS

[Contents for Part II will accompany the concluding part of Dr. McKeehan's Review Article next month.]

THIS REVIEW covers the literature of pharmaceutical sciences reported in readily available journals or abstracted in the Pharmaceuticals or Pharmacodynamics sections of *Chemical Abstracts* in 1962. It is intended to be reasonably comprehensive; but the large volume of literature published last year prevented the inclusion of some papers, and others may have been inadvertently overlooked. The general aim is to aid the reader in becoming better acquainted with recent developments by presenting a representative sample of papers appearing in various areas of pharmaceutical science.

Some of the literature related to pharmaceutical sciences has been adequately reviewed elsewhere on an annual basis and is omitted. For such associated papers in analytical chemistry, antibiotics, bacteriology, biochemistry, biology, cancer, medicine, medicinal chemistry, microbiology, organic chemistry, pharmacology, physical chemistry, physiology, and plant physiology, the reader is referred to reviews in those areas. The *Advances in . . .* series, the *Annual Reviews of . . .* series, and the *Progress in . . .* series are particularly pertinent.

For the purpose of this review, the selected references have been divided into eight sections. These sections have been subdivided further, where necessary, in order to group related papers. The divisions were established arbitrarily and have no special significance other than to facilitate organization.

GENERAL PHARMACY

Included in this rather broad area are various portions of the literature which did not blend easily into the other divisions. Breunig and King discussed problems and effectiveness of modern statistical methods in acceptance sampling of finished pharmaceutical products (1). Investigations of the influence of seaweed products on the absorption of drugs were reported (2). Publications have appeared concerning the compatibility and manipulation of guar gum (3) and the incompatibilities of various compounds in pharmaceutical preparations (4, 5). Suspension sampling, studied by Anderson and Shaw, yielded the most consistent results when samples were obtained by weight (6). The influence of pH on surface charactertistics of silica gel in aqueous solutions was investigated (7). Brooks, *et al.*, cataloged solid pharmaceutical dosage forms for use in forensic toxicology (8), and Wagner suggested the use of a manually sorted punched-card system for pharmaceutical literature (9). Other writers discussed physical and physiological aspects of collyria (10) and the organization and economics of drug research (11).

Preservatives.—Bailey discussed and classified various antioxidants according to their mechanism of action (12). Physicochemical aspects of preservative selection for emulsions (13) and a manometric method for evaluation of preservatives (14) were reported. In the latter paper, Wailes suggested using the Warburg apparatus for screening potential preservative agents. Factors influencing the stability of antibacterial preservatives in parenteral solutions were explored by Lachman, *et al.* (15). The interaction of preservatives with certain macromolecules was also studied (16). Dimethoxane, a new preservative, retained its activity in the presence of nonionic emulsifiers (17).

Several papers concerning the use of hydroxybenzoate esters as preservatives were published in 1962. The role of alkyl *p*-hydroxybenzoate esters as pharmaceutical preservatives was reviewed (18). Matsumoto and Aoki studied the inactivation of *p*-hydroxybenzoic acid esters in the presence of surfactants (19, 20). Activity appeared to be dependent on the amount of material in the aqueous phase outside of the surfactant micelle. Another monograph reported research on the fungistatic activity of methyl and propyl hydroxybenzoates (21), and mixed parabens were used by Nuppenau for the preservation of hexachlorophene cream (22).

Humberstone found that chlorhexidine diacetate was not a suitable preservative for eyedrops in the presence of sulfate ions (23). Potassium metabisulfite had no inhibiting influence on the cleavage of Novocaine in solution (24). The antioxidant action of phenols was explored by McGowan and Powell (25). In a study of the preservation and degradation of adrenaline solutions, sodium pyrosulfite was added as a stabilizer to solutions of various adrenaline salts (26). A preliminary report was published on the effect of a quaternary ammonium compound on polyvinyl chloride (27).

Flavoring.—Pharmaceutical flavoring and its importance to the patient and the physician were reviewed by Moorish (28). The psychology, physiology, and physicochemical aspects of flavor and taste have been discussed (29, 30). A trained taste panel was used in studying the effectiveness of monosodium glutamate for masking bitter taste (31). Mauer continued his series on flavors and per-

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fumes from various flowers and leaves (32, 33); and many publications appeared on the isolation, identification, and pharmaceutical applications of essential oils (34–39). The utilization and evaluation of natural and synthetic sweetening agents were reported (40–42). Vasic has discussed the perfuming of various types of cosmetic formulations (43).

Adjuvants.—A study of the influence of solvent composition on the activity of various bacteriostats and bactericides was reported (44). The current status of certified colors has been summarized (45). Swartz and Cooper reviewed the chemistry, applications, and properties of various colorants (46), and Hamilton discussed the selection of colors and their effects (47). The properties and uses of linalyl esters as perfumes were investigated (48). Reviews were published on the utility of sorbitol in pharmaceutical liquids (49) and the use of sulfur in pharmacy and cosmetics (50). Pail and Todd discussed functions and formulations of three silicones (51), and Secard dislcosed some new pharmaceutical uses of Carbopol (52). Surfactant applications in pharmacy and cosmetics have been reviewed (53–55). Lower compiled a comprehensive listing of British surface-active agents (56–63). In studying the germicidal activity of hexachlorophene, Banks and Huyck investigated the effects of some wetting agents (64). Russell and Hoch described processes for the preparation of clear detergent solutions containing lanolin oil (65). A polyethylene oxide ether–fatty acid alkanolamide mixture was used to solubilize the lanolin oil.

Stability.—As indicated by the references which follow, the pharmaceutical scientist has shown considerable interest in the development of better methods for evaluating product stability. The influence of light on pharmaceutical formulations has been reported (66). In a short communication, Ramwell and Shaw suggested that aqueous solutions of picrotoxin are stable to light if stored in acid-washed glassware (67). Several investigators reported their work on the stability of tetracycline and its various derivatives (68–70), and the stability of nystatin in dry preparations was demonstrated (71). Physicochemical studies on the stability of various penicillin derivatives have been published (72–74). Citri and Garber concluded that the side chain of a penicillin may confer resistance to hydrolysis by penicillinase (75). A study of the stability of penicillin G sodium in the presence of nonionic surface-active substances was made (76). The stability of *p*-aminosalicylic acid in aqueous solution has been studied (77, 78). Various buffer salts were used by Tanaka and Takino to examine the stability of *p*-aminosalicylic acid and its salts (79). Research on stability and stabilization of acetylsalicylic acid in aqueous solutions was reported (80, 81). Hydrolysis of the undissociated acetylsalicylic acid molecule was suppressed by anionic, cationic, and nonionic surfactants. Decomposition of amethocaine hydrochloride solutions was accelerated by heat and high pH (82). Pantocaine solutions showed no detectable decomposition immediately after sterilization as measured by the diazo reaction, but solutions at several pH values gave a positive test after storage (83). Samuelsson investigated the stability of digitoxin in galenical preparations (84). The stabilities of solutions containing papaverine hydrochloride (85) and some reputedly unstable vegetable drugs (86) were examined.

The stabilization of arsenic solutions (87) and solutions of ferrous gluconate (88) has been studied. Bamann, *et al.*, considered the decomposition of phosphoric acid esters by metal ions at acid pH (89). An experimental method for studying the stability of cortisone and hydrocortisone was published by Takubo, *et al.* (90). Sodium metabisulfite was recommended as an antioxidant for solutions of isoprenaline (91). Most of the racemization of *l*-noradrenaline hydrochloride solutions was found to occur during the first 30 days (92). Nielsen found that poly(vinylpyrrolidinone) prolonged the effect of vasopressin and oxytocin but decreased the thermal stability of their solutions (93). Reports have appeared on the stabilization of solutions of thioproperazine (94) and chlorpromazine hydrochloride (95). Nicotinamide protected the latter from discoloration by light. The combined use of polyhydric alcohols and calcium acetate produced a stable bacterial alkaline proteinase solution (96). In another study, calcium was used to stabilize trypsin in a polyethylene glycol ointment base (97). Nogami and Awazu investigated the stabilization of methantheline bromide in aqueous solution by surface-active agents (98). Other investigations were made on the effect of surfactants on the stability of some pharmaceuticals (99) and the effect of ultrasonic waves on the stability of surfactants, sulfonamides, and *p*-aminobenzoic acid (100). Accelerated aging was used in the evaluation of pharmaceutical fat vehicles (101). Stability studies on buffer solutions (102) and pepsin elixir (103) have been reported. This elixir began to lose its pepsin activity after storage for 5 months. The influence of additives on the stability of glucose solutions was investigated by Parke (104).

Stability Kinetics.—Chemical kinetics has become a very useful tool in studying the stability of different formulations and in the prediction of shelf life. Sesaki, *et al.*, explored the application of chemical kinetics to the stability of chemicals (105). A method of plotting kinetic data to determine reaction order and specific rate constant has been suggested; evaluation of data up to 99% conversion was possible (106). Hochanadel described a simple device for determining slopes using the glass-rod method (107). In testing the stability of pharmaceutical preparations in a homogeneous liquid phase, the van't Hoff-Arrhenius relation was found useful (108). The kinetics of degradation of epinephrine in solution by molecular oxygen was studied by Sokoloski and Higuchi (109). An extensive study was conducted by Riegelman and Fischer on the stabilization of epinephrine—chelation of the catechol nucleus with boric acid gave marked stabilization (110, 111). Rates of degradation, half-life, and the effect of pH on the degradation of potassium phenethicillin in aqueous solution were discussed (112). The kinetics of degradation of glutethimide (113) and the stability of chloral hydrate solutions (114, 115) have been investigated. Studies on the aging of pharmaceutical preparations were reported by Inami, *et al.* (116, 117). The stability of pyridine-2-aldoxime methiodide in aqueous solutions was evaluated at different temperatures and pH values, and general equations for its half-life were derived (118). Chemical kinetics was used by Heimlich to study glucose degradation in acid solution (119) and by Zajta to develop a rapid method for investigating the stability of phenobarbital sodium solutions (120). Work carried out by Tishler, *et al.*, on phenobarbital degradation in solution was published (121). Nelson compared rate constants for sulfonamide acetylation *in vivo* with oil-in-water partition coefficient (122). Rates of oxidative destruction and alkaline saponification of some steroidal esters were determined—the sulfobenzoates, phosphates, and hexahydrobenzoates gave maximum stability (123). Schroeter stated that the reaction between bisulfite or sulfite ion and salicyl alcohol followed second-order kinetics over a wide pH range (124). Degradation of *l*-ascorbic acid solutions was found to be a pseudo-first-order reaction and dependent on pH and temperature (125). Kinetic studies were conducted by Rippie and Higuchi on the reaction between molecular oxygen and 2,3-dimercapto-1-propanol in aqueous solution (126).

Stability prediction, a very important part of pharmaceutical formulation, was reviewed in depth by Garrett (127). Scott and Lachman investigated the influence of nonequilibrium sample temperature on stability predictions extrapolated from elevated temperature studies (128). Stability prediction methods for liquid pharmaceuticals were reported (129). In a series of articles on pharmaceutical stability prediction, Garrett (130), Garrett and Royer (131), and Garrett and Umbreit (132) described detailed kinetic studies on steroids and antibiotics. The theory and practice of stability prediction in cosmetic formulation were treated by Lachman (133).

Degradation of a large number of therapeutically important compounds takes place by way of hydrolysis. Hence, knowledge of the kinetics of hydrolytic reactions is of importance in the formulation of stable pharmaceutical preparations. Windheuser and Higuchi (134) and Heathcote and Wills (135) have studied the kinetics of thiamine hydrolysis; the rate approximated a first-order reaction and was influenced by general base catalysis. In another paper, Finholt and Higuchi determined rates of hydrolysis of niacinamide (136). Kinetic studies on the hydrolysis of tropine esters were reported (137). Data published by Garrett and Weber showed that the stability of N-butylformamide to acid and enzymatic hydrolysis greatly exceeded any stomach retention time (138). Mitchell investigated the hydrolysis of ethyl benzoate, diethyl phthalate, and benzocaine in cetrimide solutions (139), and the hydrolysis of *p*-chlorobenzaldoxime has been related to its oral inefficacy (140). A kinetic study of the base-catalyzed hydrolysis of 3,5,5-trimethyl-2,4-oxazolidinedione was conducted (141). Suzuki employed chemical kinetics to evaluate the stability of aqueous succinylcholine chloride solutions (142, 143). Velocity constants were determined for hydrolysis of this choline derivative as a function of pH. A report on the hydrolytic kinetics of calcium acetylsalicylate carbamide in the presence of high concentrations of additives was published (144). Garrett has discussed the solvolysis of symmetrical and mixed aspirin anhydrides (145) and of 21-hydrocortisone esters and hemi-esters (146).

Vitamin Stability.—The general area of vitamin stability was reviewed by Parrak (147). Guillory and Higuchi investigated the solid state stability of some crystalline vitamin A derivatives (148). Of the derivatives studied, vitamin A benzhydrazone and vitamin A succinate triphenylguanidine salt were the most stable. Other writers reported the effects of pH, antioxidants, metallic impurities, chelating agents (149), and thiamine hydrochloride (150) on the stability of liquid formulations containing vitamin A. The stability of cyanocobalamin in liver preparations used in the treatment of pernicious anemia was examined at different times and pH values (151). Spontaneous modifications of certain properties of vitamin B_{12}-Co^{60} during storage have been explored (152). Vitamin B_{12} stability in the presence of other vitamins has also been investigated (153, 154). Experimental work on the stability of some new thiamine derivatives was reported (155, 156), and various stabilizers for ascorbic acid in solution were compared (157).

Multivitamin preparations were the object of many stability investigations. Wai, *et al.*, studied the stability of vitamins A, B_1, and C in selected vehicles—formulation, method of combination, and manufacturing procedures were evaluated for their influence on stability (158). Also investigated were the stabilities of some polyvitamin products containing vitamins A_1, B_1, B_2, and C (159). The shelf life of different oral formulations containing vitamins B_1, B_2, B_6, and niacinamide was evaluated (160). In a preliminary report, Bonn, *et al.*, stated that some liquid multivitamin preparations were deficient in one or two ingredients before opening (161). Storage of vitamins B_1, B_2, B_6, and niacinamide was examined (162).

PHARMACEUTICAL TECHNOLOGY

This section of the review is primarily concerned with the technological aspects of pharmaceutical dosage forms. Cooper reviewed pharmaceutical technology in industrial pharmacy (163), while a similar review by Ullmann and Thoma dealt with pharmaceutical technology in research and education (164). Also reviewed were oral polio vaccine production (165), the technology of vitamin C (166), and micro-capsules—a new pharmaceutical dosage form (167). Progress in industrial mixing processes was reviewed by Baird (168). Barnett and James studied the particle-size distribution of marble after wet ball-milling and found that varying the solid-liquid ratio changed the mean particle size of the product (169). Some aspects of inhaler technology (170) and dermatological vehicle formulation (171) were reported. Faust has reviewed some of the newer materials used in cosmetics and dermatologic vehicles (172). Basic conditions for drying pharmaceutical residues have been investigated (173). Spray-drying of antibiotics and some other synthetic drugs (174) and the effectiveness of protective colloids in spray-drying of powdered flavoring materials (175) were evaluated. Selleri and Caldini studied some pharmaceutical compositions containing vitamin B_{12} and a new vitamin C derivative (176). They reported that gelatin capsules containing an anhydrous lipophilic substance provided better stability than syrups. The preparation and film-forming properties of synthetic glycerides were investigated by De Freitas (177).

Small amounts of belladonna tincture were made by a new extraction process for the preparation of tinctures (178). A study on the pH of pharmaceuticals dealt with various aspects of hydrogen-ion concentration and buffer capacity in tinctures (179). Kochhar and Lofgren studied the preparation of stable, sterile injections of physostigmine sulfate and salicylate (180). Sodium metabisulfite appeared to be the best stabilizer. Sciarrone explored some of the problems encountered in the preparation of isotonic solutions (181). Parenteral medication was the topic of two papers: one discussed parenteral solutions of vitamin B_{12} (182), while another described the use of wetting agents in the preparation of aqueous injectable solutions of oil-soluble vitamins (183). In another report, Gilroy and Mayne investigated the efficiency of a method for deaerating aqueous solutions (184).

Tablets.—The tablet is one of the most widely used forms of oral medication. Kovac reviewed its future with regard to automation and machinery (185, 186). Another discussion on automation suggested a punched-tape program for making tablets (187). Progress in coated and multilayered tablets was also reported (188). Research on tablet granulations was disclosed in the following three papers: in one, Perlman described the use of calcium sulfate granulations as a dry-blended tablet base (189); another proposed silicone oil as a good antiadherent in tablet granulations (190); and the third presented physicochemical studies on factors affecting granule strength and apparent granule density (191). Particle size of the powder was found to be an important element of both granule strength and apparent granule density. Some physical characteristics of compressed tablets were studied by Henderson (192).

Several articles on the disintegration of tablets were surveyed. One examined the influence of surfactants on the disintegration of tablets (193), and two others discussed the use of sodium bicarbonate–tartaric acid mixtures as disintegrating agents for tablets (194, 195). In still another, ten tablet disintegrants were evaluated in the formulation of tablets of two drugs of differing water solubility (196). Richter and Steiger-Trippi investigated tablet disintegration testing (197). The influence of the addition of mucilage to artificial gastric juice on tablet disintegration time has also been studied (198). In another study, the relationship between rate of dissolution and disintegration time was examined (199). Kaplan and Kish described a modification of the U.S.P. tablet disintegration apparatus (200). An apparatus was recommended by Krueger and Vliet for the *in vitro* testing of timed-release tablets and capsules (201).

A preliminary study of the temperature dependency of colorant loss in tablets was reported by Swartz, *et al.* (202), and Lachman, *et al.*, investigated the effect of ultraviolet absorbers on the photostability of colored tablets (203). Tablets of pyrilamine resin adsorbate with aspirin and vitamin C were more stable than control tablets containing the maleate salt of pyrilamine (204). Another paper discussed medicinal-Aerosil adsorbates in tablets (205). Castello and Mattocks studied the discoloration of tablets containing amines and lactose (206). No darkening occurred when amine salts were used with lactose. Of three emodin tablet formulas investigated, a lactose base provided the best stability (207).

Tablet coating with syrup (208) and the age stability of sugar coatings (209) were studied. Other researchers investigated the addition of moisture-resistant waterproof coatings to sugar-coated tablets (210, 211). In a series on protective coatings for tablets, Ida, *et al.*, studied amphoteric poly(vinylpyridine) derivatives (212). Another paper in this series reported research on the enteric coating properties of internally plasticized acrylic and methacrylic acid derivatives (213). Lappas and McKeehan described the use of synthetic polymers as enteric and sustained-release coatings (214). The use of cellulose acetate succinate (CAS) as an enteric coating for some compressed tablets was also reported (215). Using talc as a dusting powder, satisfactory tablets were obtained when CAS was applied from an acetone–ethyl acetate solution by a modified pan method. Fennell studied the development of an enteric coating (216), and enteric tablets prepared by coating or direct mixing have been described (217).

Emulsions.—In 1962 reviews were published on the theory (218) and on the structure and stability (219) of emulsions. Becher reviewed the theoretical aspects of emulsification with particular emphasis on factors affecting stability (220). Electrophoretic methods for evaluating various emulsions were studied (221), and dielectric constants of water-in-oil emulsions were employed in studying agglomeration (222). Higuchi, *et al.*, proposed a method for studying aggregation in oil-in-water emulsions (223). Other investigators explored the relationship between electrical resistance and dispersed-phase concentration of oil-in-water emulsions (224, 225). An equation was developed which would explain the results.

Many publications have appeared on the subject of emulsion stability. Riegelman discussed the theory of emulsions as applied to stability (226), and Riegelman and Pichon demonstrated that emulsion stability need not be related to the HLB values (227). A turbidimetric method for testing the stability of oil-in-water emulsions has been developed (228). In a quantitative theoretical study of the physical degradation of emulsions, Higuchi and Misra considered various factors governing the degradation rate of emulsions when the process is strictly molecular diffusion-controlled (229). An investigation of the dispersion and stability of several emulsions was published (230). Two investigations on the preparation of stable paraffin oil emulsions were also reported (231, 232).

Prediction of emulsion stability, including types of instability and test methods, has been discussed (233). The ultracentrifuge has been employed in studies relating to the stability of emulsions. In one study Garrett found the ultracentrifuge an excellent tool for evaluation and prediction of emulsion stability (234), and in another the ultracentrifuge was used for quantitative determination of emulsion stability (235). Still another, by Rehfeld, described a new rapid method for quantitatively studying the mechanical stability of emulsions using the ultracentrifuge (236). Coagulation of emulsions was separated into two distinct steps—namely, aggregation and coalescence.

Wachtel and La Mer have investigated the preparation and size distribution of some monodisperse emulsions (237). Phase inversion by homogenizer processing was explored by Shimamoto

(238). Factors affecting flavor loss after spray-drying of peppermint oil-acacia-water emulsions were also studied (239).

The use of various hydrocolloids in emulsions was reviewed by Schwarz (240). These materials have found their greatest use primarily as stabilizers. Ethoxylated higher fatty-alcohol emulsifiers for various types of emulsions have been investigated (241). Bogs and Naumann described an apparatus for measuring the strength of films around oil globules in emulsions (242). In another study by the same writers, viscosity determinations were employed in the evaluation of pharmaceutical emulsifying agents (243). Research on the development of fat emulsions for intravenous administration has also been published (244, 245).

Suppositories.—A penetrometer method for estimating the melting point of suppositories (246) and a method for measuring solution time of glycerin suppositories (247) were discussed. Another investigator explored deformation time and ability to liberate therapeutic substances as criteria for the evaluation of modern suppository bases (248). Setnikar and Fantelli developed an apparatus which reproduces conditions of the rectum for determining liquefaction time of rectal suppositories (249). The preparation and testing of "tropic proof" suppositories have been reported (250), and in a series on pharmaceutical preparations, Beral, *et al.*, have discussed the testing of suppositories (251). A rotational viscosimeter was employed in a study of the rheological properties of some suppository masses in the molten state (252). Measurements of *in vitro* activity were used to study the stability of chloramphenicol in several suppository bases (253).

Ointments.—The utility of methylcellulose (254), sodium carboxymethylcellulose (255), and water-soluble polyethylene glycol (256) as ointment bases has been reviewed. Mueller found that dextrans in combination with plasticizers produced good ointment bases (257). Belen, *et al.*, developed a modified vanishing cream base for chlorothymol ointments (258). The importance of the HLB system in ointments has been investigated (259). Also studied was the hydration of wool wax alcohols and their use as ointment bases (260). Determination of the water content of ointment bases (261) and rheological standardization of Hebra's lead ointment (262) have been reported. Steigleder and Raab discussed a new method for studying the protection by various ointments of the skin surface against contact with water (263). They found that ointments have prolonged influence on skin surface, even when protection from water is partially lost.

Suspensions.—Polderman has reviewed the use of suspensions as oral, topical, and injectable pharmaceutical vehicles—many references were cited (264). In another publication, Polderman discussed the physical chemistry of suspension systems with regard to stability, particle size, sedimentation, crystal growth, and zeta-potential (265). The grinding and evaluation of powders for suspension preparation were investigated (266), and a statistical investigation into the dispersibility of powdered drugs was conducted (267). Several advantages of using Cab-o-sil as a suspending agent were reported (268). Anderson and Plein published a pharmaceutical investigation on the geology, identification, and testing of selected Alberta bentonites (269, 270). Calamine lotion was the subject of two publications: one reviewed the application of bentonite as a suspending agent in calamine lotion (271); in the other, Swafford found that use of polyethylene oxide water-soluble resin as a suspending agent for calamine lotion produced a more elegant and more stable preparation (272).

Sterility.—Kirsch has reviewed new developments and problems in sterile pharmaceutical packaging (273). In a study of multiple-dose injectables, the effect of repeated withdrawals on sterility was investigated (274). The use of ethylene oxide gas in sterilization has been reviewed (275), and two more papers reported experimental work in chemical sterilization (276, 277). Gold studied sterilization of pharmaceutical preparations with ultrasonic energy (278). Steam sterilization of hollow containers has also been discussed (279). In another study, the sterilizing capacity of cationic exchangers in the preparation of demineralized water was investigated (280). Membrane filtration has been applied to testing the sterility of antibiotic materials (281).

Packaging.—Methods of testing pharmaceutical glassware have been reported (282, 283). Two papers discussed the utilization of plastics in pharmaceutical packaging (284, 285). In another, a comparison of different methods of washing, filling, and sterilization of ampuls was reported (286). Experimental data on rubber preparations and their effect on distilled water has been published (287). Strip packaging of pharmaceuticals was explored by Webb (288), and Frey considered packaging defects and methods of reducing them (289).

Aerosols.—A review with several references was published on the use of aerosols in the pharmaceutical field (290). An article by Sciarra and Eisen surveyed the formulation of various dermatological aerosols (291); while another, by Hart and Cook, reviewed emulsions as applied to various types of aerosols (292). Other papers discussed the advantages and problems of powder aerosols (293) and the improvement of aerosol packaging (294). The advantages of having a contract filler for aerosols were summarized by Peterson (295). Ruyssen reviewed the constitution and stability of foams (296). A report on the physical chemistry and stability of aerosols has also been published (297). As vehicles for bronchodilator drugs, Segal found aerosols to be of value for relief of bronchospasm (298).

PHYSICAL PHARMACY

Since its recognition in the late 1940's, physical pharmacy has grown to a place of prominence in pharmaceutical science. In this area, the principles of physics and physical chemistry are applied to the solution of pharmaceutical problems. Many papers were published on this theme in 1962.

Publications by Kamada on the applications of surfactants to pharmaceutical preparations described a temperature-scan method for studying solubilization (299, 300). Another investigator studied the interaction of pharmaceuticals with sucrose and hyprose esters (301). In a series of papers on the surface activation of medicinals, Utsumi and Harada (302–305), Harada (306), and Utsumi, *et al.* (307), explored the physical chemistry of several alkylsulfate derivatives. Salts of several basic drugs were prepared and examined for micelle formation, complexation, and solubility. Two film studies were presented: in one, some physical properties of interfacial films of potassium arabate were investigated (308); the other, by Kanig and Goodman, described evaluative procedures for pharmaceutical film-forming materials (309). Fuehrer (310) published a review on hydrogen bonds, and Huggins (311) discussed the physicochemical aspects of hydrogen bonds and their application to biology.

The validity and limitations of pH determinations (312) and the determination of activity coefficients with the glass electrode (313) were discussed. In another article, a nonlinear least-squares method was advocated for the calculation of activity coefficients from osmotic coefficient data (314). A discussion of the measurement and interpretation of dissociation constants of akaloids was published (315). Along this same line, Chatten studied the relationship between aqueous dissociation constants of organic bases and their half-neutralization potentials in organic solvents (316). A spectrophotometric method was employed for investigation of the acid dissociation constants of phenylalkanolamines (317). Chilton and Stenlake have investigated dissociation constants of some compounds related to lysergic acid (318), while Miyamoto and Brochmann-Hanssen investigated dissociation constants of certain γ-pyrone dicarboxylic acids (319).

A photoextinction-sedimentation method was recommended for the size analysis of barium sulfate powders (320). Gledhill has shown that particle-size distribution determination by turbidimetry is comparable with electron-microscopic analysis (321). Investigations of the particle-size distribution of monodispersed barium sulfate prepared by the EDTA method (322) and the physical properties of chloramphenicol particles (323) were reported.

As evidenced by the following reports, there is still considerable interest in the development of methods for studying medicament release from pharmaceuticals. Release of medication from various emulsified ointment bases was discussed by DeKay (324). An agar-plate test was used in studying the influence of different particle sizes of chloramphenicol on diffusion from a lipophilic hydrocarbon base (325). Wood, *et al.*, described a new diffusion cell for the measurement of salicylate diffusion within hydrophilic ointments (326). Ointment-base influence on the diffusion of other medicaments was also studied (327). In a study of various proflavine salts, Fenton and Warren found that the *n*-valerate exhibited the best diffusion from a cream base (328). Higuchi analyzed recently published data on medicament release from ointments and reported good agreement with theory (329). The diffusion of oxygen, nitrogen, and carbon dioxide through thin Teflon and silicone membranes has been investigated (330). In studying membrane permeability of various ions, Nakagaki, *et al.*, used a membrane electrode method (331). Membrane permeabilities, diffusion constants, and degree of association were determined for some phenoxazone compounds (332, 333).

Nogami and Nagai (334, 335) and Nogami, *et al.* (336), have studied the acid-neutralizing reaction of various antacid compounds, particularly dried aluminum hydroxide gel. They developed equations for acid-neutralizing velocity, one for the calcium carbonate-type antacid and another for the dried aluminum hydroxide gel type. Experimental data demonstrated that the reaction between dried aluminum hydroxide gel and acid followed the proposed equation.

Solubility.—The solubility of solids in liquids is a very important aspect in the formulation of many types of pharmaceutical preparations. The literature of the physics and engineering of dissolution has been reviewed (337). Three monographs dealt with the relationship between agitation and dissolution. Larese, *et al.*, studied high-speed stirring techniques in solubility determination (338). At approximately 30,000 r.p.m. equilibrium is reached within 1 hour. Results were comparable with those obtained by conventional agitation. The second paper presented an investigation of the dissolution of particles in a stirred liquid (339). In the third, Hamlin, *et al.*, discussed loss of sensitivity in distinguishing real differences in dissolution rates due to increasing intensity of agitation (340). The relationship of chemical kinetics and dissolution was the subject of two investigations (341, 342). Reports of studies on the velocity of polymer dissolution were also found (343, 344). The relationship between *in vitro* dissolution rates, solubilities, and LT_{50}'s in mice for some salts of benzphetamine and etryptamine has been investigated—salt formation as a means of obtaining sustained release or prolonged action was also discussed (345).

An experimental method for studying growth rates of particles in aqueous media was developed by Higuchi and Lau (346). Electrical conductivity measurements were used to investigate the mode of action of solution adjuvants (347). Papers were published on the use of an approximate dielectric constant in solubility studies (348) and the correlation of solubility parameters and dielectric constants (349). The role of ionic strength, ion association, and solubility on the properties of electrolytes in solution has been reported (350). Another investigator studied the influence of inorganic salts on the solubility of organic pharmaceutical compounds (351). Levy and Procknal found that the dissolution rate of aluminum acetylsalicylate decreases with time because of the formation of a basic water-insoluble aluminum compound on the surface of the solid particles (352). Kato reported that glycols with hydroxyls on either terminal end or in 1,2 positions formed micelle-like structures in aqueous solution (353), and Mulley and Metcalf investigated the critical micelle concentration of some polyoxyethylene glycol monohexyl ethers in binary and ternary systems (354). In another solubility study, Higuchi and Misra examined the effect of solvent chain length on the solubilization of water by dioctyl sodium sulfosuccinate (355).

Investigations of the solubility of sucrose in aqueous mixtures of organic solvents (356) and the solubility of opium alkaloids in various organic solvents (357) were published. In another article, benzyl alcohol was suggested as a solvent for injectable solutions of quinine (358). Burnstine and Schmid found that the solubility of bilirubin in aqueous solutions was critically dependent on pH and ionic strength (359). Partition coefficients between water and butyl acetate were determined for various concentrations of benzylpenicillin (360). Debye and Coll used vapor-pressure measurements in studying the association of α-monoglycerides in nonaqueous solutions (361). Physicochemical investigations of aqueous sodium salicylate solutions were also reported (362, 363).

Two reviews on the solubilization of vitamins A and D were published (364, 365). Solubilization of benzoic acid derivatives in aqueous solutions with polyoxyethylene stearates was the subject of a monograph by Goodhart and Martin (366). Research on the solubilization of essential oils and oil constituents (367) and the use of amine salts of fatty acids for the solubilization of cholesterol (368) has also been published. Conductivity and surface tension measurements were used to study solubilizing properties of liquorice (369). Another report discussed the solubilizing ability of some polyethylene glycols and their esters (370).

Complexation.—The use of complexation in the stabilization of pharmaceuticals (371) and the application of chelating compounds in pharmacy and medicine (372) were reviewed. Walker has discussed the use of complexation in pharmaceutical systems (373). In another publication, Kennon and Chen presented a new approach to probability and complexation (374). They described and illustrated a method which considers the ability of the ionic atmosphere surrounding a drug in solution to form "probability complexes" with the drug.

Solubility experiments were used in studying the complexation of organic acids and bases with their salts in aqueous solution (375). A new molecular complex of tetracycline and urea was reported (376), and Guttman summarized results of a preliminary investigation of the effect of molecular interactions on velocities of reactions involving riboflavin (377). The stability of anionic complexes of some barbituric acid derivatives and silver was studied by Leyda and Harris (378). Chelates of pyridine-2-aldoxime (379), metal chelates of mercapto-acid amides (380), and copper chelates of *l*-ephedrine (381) have been studied. Complex formation between boric acid and glycerin at elevated temperatures has been investigated (382). A method combining radioisotopes and ion exchange was used to study complexation of alkaline earth metals with citric acid and its derivatives (383). Metal complexes of nuclear-substituted salicylic acids and their biological effects were investigated by Foye and Turcotte (384). Two discussions on the preparation and properties of iron-carbohydrate complexes for injectable use were published (385, 386).

Surface Phenomena.—The importance of colloid and surface chemistry to biologically oriented and chemically oriented students has been reviewed—course content and methods of teaching were discussed (387–389). In a similar review, Wilson discussed the application of colloid and surface chemistry to problems in industrial research (390). Bailey, *et al.*, considered the meaning and function of average quantities in colloid science (391). They pointed out that the experimental method often determines the nature of the average obtained.

Barriers on the surfaces of dispersed particles (392) and the use of gelatin as a protective colloid (393) were the subjects of papers by two other investigators. In studies on the effect of deflocculating agents on suspensions of calamine and zinc oxide, Wood, *et al.*, measured particle size at various concentrations of sodium citrate (394). A new deflocculant and protective colloid for barium sulfate has also been reported (395).

Ikegami and Imai investigated the precipitation of polyelectrolytes by salts (396). Experiments on the flocculation of quartz and other suspensions with gelatin have been reported (397). Results indicated that gelatin must have a small positive charge for optimum flocculation of a negatively charged suspension. In his studies on the coagulation process, Packham investigated the effect of pH and turbidity (398). A new method was described which reduces pH variation. In a second paper Packham studied the effect of pH on the precipitation of aluminum hydroxide and measured the degree of precipitation by measuring the change in turbidity and the amount of residual soluble aluminum (399).

The sorption of water vapor by synthetic lecithin and cephalin has been studied (400). B-E-T plots showed that the synthetic compounds absorbed less than the corresponding natural compounds. An investigation of water vapor sorption and diffusion through hard gelatin capsules was also reported (401). A paper by Blank dealt with monolayer permeability and the properties of natural membranes; differences between bulk and monolayer processes were discussed (402). Methods for measuring gas adsorption on solids and their application to pharmaceutical products have been reviewed (403). Strickland studied water vapor sorption by pharmaceutical powders (404), and Gross examined the adsorption of some anticholinergic drugs by various antacids (405). Another investigator reported on the adsorption capacity of activated carbon (406).

Gillespie and Wiley considered the determination of London–van der Waals constants from suspension and emulsion viscosity and surface energy data (407), and other researchers employed solution adsorption in the measurement of specific surface areas of a wide variety of finely divided solids (408). In an experimental investigation of the behavior of a single droplet at an oil-water interface, Jeffreys and Hawksley found coalescence to be a stepwise phenomenon (409). Retention of liquids on solid surfaces was considered in two articles: a theory for spray retention based on the sliding of liquid drops on solid surfaces was developed in one (410); the other reported studies on the retention of aqueous suspensions on leaf surfaces (411). Surfactants were used for estimating the charges in gelatin at the isoelectric point (412). In a series on nonionic surface-active compounds, Becher studied the effect of electrolyte on micellar properties of some polyoxyethylene derivatives of lauryl and tridecyl alcohol and nonyl phenol in aqueous solutions (413). Another paper by Becher described a spectral dye method for the determination of critical micelle concentration (414). The effect of sucrose and cyclamate on the gel strength of gelatin, carrageenan, and algin has been studied (415). Another article reported the preparation of two-phase gels of iodinated poly(vinyl alcohol) (416).

Rheology.—In a series of papers on the subject of rheology in pharmacy, Lordi has discussed fundamental concepts (417), Newtonian flow (418), and non-Newtonian flow (419). Two papers on the swelling of polymer systems in solvents were published (420, 421): the first presented a method for obtaining complete swelling-time curves, while the second considered the mathematics of diffusion. Review articles on the use of the Brookfield Synchro-Lectric viscometer for rheological investigation of pharmaceutical preparations (422) and theories of liquid viscosity (423) were also published. In the latter, Brush dealt with basic principles involved and some theories of current interest and cited almost 600 references. The role of viscosity and viscosity-enhancing materials in the compounding of pharmaceutical preparations has been discussed (424). Gold studied interfacial viscosity measurements and their relationship to selected emulsion systems (425).

A study of the coalescence of liquid drops in electric and shear fields was conducted (426). Umemura, in his studies on pharmaceutical dispersion, investigated the relationship between viscoelasticity and non-Newtonian flow (427, 428). In a third paper of this series, he extended the mathematical relationship of previous work to study temperature dependence of six dispersion systems (429). Haines has studied the caking of liquid dispersions (430). Theoretical calculations of sedimentation volume for the case of spherical particles attracted by cohesive force were presented (431), and Levine and Bell discussed an extension to the stability theory of lyophobic colloids (432). Effects of emulsification temperature and cooling rate on certain physical properties of a beeswax-mineral oil emulsion were studied by Boylan, *et al.* (433). Other researchers investigated the intrinsic viscosity of gelatin (434), and the influence of pH, concentration, time, dilute electrolyte, and functional groups on the gelation of gelatin and modified gelatins (435, 436).

Several papers were published on the rheological behavior of both aqueous (437) and organic (438–440) dispersions of Aerosil. Levy has investigated changes on aging of plain and polysorbate-80 containing dispersions (441). Another article by Levy dealt with the kinetics of structural recovery of thixotropic montmorillonite dispersions (442). In an investigation of unit layer interaction in hydrous montmorillonite systems, Van Olphen studied competition between double-layer repulsion forces and van der Waals attractive forces (443). The rheological behavior of clay-water systems was also discussed by Van Olphen (444). Application of the Verwey and Overbeek theory to the stability of kaolinite-water systems was described by Holtzman (445). A general method was presented for measuring adsorption of various anions on kaolinite.

Hydrodynamic studies on sodium carboxymethylcellulose in aqueous solutions have been conducted (446). An investigation was made of the rheological properties of corn oil emulsions with methylcellulose; a new equation was derived to explain flow properties (447). In another rheological study, consistency curves for procaine pencillin G aqueous suspensions were obtained at different concentrations (448). Non-Newtonian flow was observed in these suspensions at low shear rates, but Newtonian flow was found at high shear rates. The viscous behavior of a barium sulfate–water system has been studied (449). Rheological properties of aluminum stearate in benzene (450) and poly-(ethylene oxide) in aqueous solutions (451) were investigated. Simonelli and Higuchi explored melting behavior, thermodynamic equilibrium, rate of crystal growth, and rate of melting of methyl stearate (452). Polymorphism in some pharmaceutically important lipid materials was examined by Eriksen, *et al.*, with the aid of heating and cooling curves (453).

PHARMACEUTICAL CHEMISTRY

For the purpose of this review, pharmaceutical chemistry is loosely defined as the area primarily concerned with the chemical aspects of pharmaceutical science. New drugs and drug products of 1961 (454, 455), principles and chemistry of central analgesics (456), crystallography (457, 458), and the use of quaternary ammonium compounds in medicinal chemistry (459, 460) were subjects of review articles published in 1962. A table of melting points of medicinals and index of synonyms has also been published (461). Melting points from 30 to 351° were listed. Several additional publications discussed properties and uses of enzymes in pharmacy and medicine (462–466). In another study on enzymes, the effect of sulfate content of anionic polymers on the *in vitro* activity of pepsin was investigated (467).

Surfactants were the subject of considerable research. Raphael reviewed detergents and surface-active agents (468). The surface activity of glycerol ethers (469) and some synthetic nonionic detergents (470) has been studied. Applications of polysorbate 60 in pharmaceutical compounding were described (471). Ullmann and Moser investigated the effect of polyoxyethylene-adducts on the antibacterial activity of antibiotics (472).

Many investigations have been published on phenothiazine derivatives. Borg and Cotzias examined structure-reactivity correlations, formation of free radicals, and the theory of the interaction of trace metals with phenothiazine derivatives (473–475); and photodecomposition of thioproperazine was investigated by Yamamoto and Fujisawa (476). Other investigators have studied reduction products of santonin (477) and some difficultly hydrolyzable flavonosides (478). Ugai prepared codeine phosphate crystals with 0.5, 1, and 1.5 molecules of water of crystallization in stable form (479). Structural modifications in the search for new drugs (480) and the chemistry of thiamine and allied compounds (481) have been reviewed. Campbell (482) and Campbell and Slater (483) reported the alteration of physical properties of some therapeutic agents through the formation of N-cyclohexylsulfamate-drug salts. Several such drug-salts were prepared and evaluated; both taste and stability were good. Correlation of taste and structure of α-D-mannose and β-D-mannose was discussed (484). The chemistry and properties of a new plasma expander were also described (485).

Antibiotics.—Almost 400 references were cited in a review on the chemistry and pharmacology of antibiotics from 1956 to 1961 (486). The chemistry, pharmacy, and pharmacology of pencillin were also reviewed (487, 488). Synthesis of C^{14}-benzylpenicillin for tracer studies from C^{14}-phenylacetic acid and 6-aminopenicillanic acid was described by Nettleton, *et al.* (489). Several tasteless chloramphenicol derivatives have been prepared and evaluated—the best compound appeared to be the dodecylsuccinate (490). Research on properties and chemical purification of nystatin was reported (491).

The tetracycline antibiotics have been the subject of considerable experimental effort. Stempel has reviewed their development (492). Three different papers were concerned with tetracycline production and purification methods (493–495). The isolation and characterization of two new tetracycline antibiotics (496) and a new soluble tetracycline (497) have been reported. Remmers, *et al.*, described a new alkaline-stable species for selected members of the tetracycline family (498). Extensive use of half-life was made in measuring stability of the new derivatives. Demethylchlortetracycline was reviewed by Gill (499).

Ion Exchange.—The applications of ion-exchange resins in cosmetics, medicine, and pharmacy have been reviewed (500, 501). Hirscher and Miller discussed drug release from cation-exchange resins (502), and Schlichting described preparation, assay, and release rates of six new carbinoxamine cation-exchange resin salts (503). An experimental test of the theory of particle-diffusion controlled ion-exchange was reported (504). Bonner, *et al.*, employed measurements of ion-exchange equilibria as a rapid and convenient method for estimation of ionization constants of acids in the 10^{-3} to 10^{-1} range (505). The behavior of ion-exchange resins in aqueous ammonia solutions (506) and the behavior of ascorbic acid on redox ion-exchange resins (507) were studied. Adsorption of vitamin B_{12} by various cation exchangers was discussed by Morita and Tanaka (508). Carboxylic cation-exchange resins were used for the separation and purification of antibiotics (509). Ion-exchange resins have also been employed for the extraction of codeine (510) and the removal of inorganic salts from concentrated streptomycin solutions (511). In another study, ion-exchange resins and electrodialysis were combined for isolation and purification of mixtures of plant alkaloids (512).

Polymers.—In a study of the constitution of alginic acid, Drummond, *et al.*, confirmed the presence of 1,4′-linked L-guluronic acid units (513). Schweiger prepared some algin acetates and studied their viscosity (514) and reaction with calcium and other divalent ions (515). He concluded that gelation or precipitation of alginates with calcium ions occurs through a complex involving two carboxyl groups from neighboring units and two hydroxyl groups in a unit of probably another chain. Another investigator described conditions for the isolation of alginic acid from algae of the Adriatic Sea (516). Equilibrium dialysis studies were used in determining the extent of binding of alkaloids to carrageenan and other hydrocolloids (517).

Studies on the electrochemistry of azrechtic acid were published (518). Murty, *et al.*, studied the physical chemistry of water chestnut starch (519), while Greenwood and Thomson described the fractionation and characterization of starches from various plant origins (520). Complexes of pepsin with sulfates of oxidized starch and its reduced products have been reported (521). Cohen examined the interaction of pharmaceuticals with the Schardinger dextrins (522), and Blatz described the synthesis and preliminary characterization of new polyelectrolytes (523). Thermally stable salts of poly(vinylphthalic acid) were also investigated (524). The interactions between certain chemicals and some water-soluble macromolecules were studied (525, 526).

Methodology.—Paper chromatographic procedures were published for the characterization of antibiotics (527) and the separation of codeine, morphine, and nalorphine (528). Brochmann-Hanssen and Svendsen described an extremely sensitive method for the separation and identification of barbiturates and some related compounds by means of gas-liquid chromatography (529). Thin-layer chromatography has been used to study the identity and purity of some fats and oils (530) and for separation of some pharmaceutically important corticosteroids (531). The preparation of microcrystalline progesterone using ultrasound was described by Principe and Skauen (532). Methods for the separation of sterols by countercurrent crystallization (533) and the purification of organic compounds by continuous zone freezing (534) have been reported. Automatic pH control of the preparation of medicinal compounds has been investigated (535).

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[1] *Index Medicus* abbreviations were used for journals not listed in *Chemical Abstracts.* In a few instances where the writer was unable to obtain late 1962 issues, references were obtained from *Current Contents.*

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