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Review Article

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A Literature Review

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THIS COMPILATION is the third annual literature review of the pharmaceutical sciences published in *J. Pharm. Sci.* (1, 2). The survey represents a comprehensive cross section of the research and development efforts in various disciplines of pharmaceutical science. Numerous periodicals and *Chemical Abstracts'* Pharmaceuticals and Pharmacodynamics sections published during 1964 were searched and selectively abstracted.

Some of the literature related to pharmaceutical science has been reviewed on an annual basis in other publications and is omitted here. 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 these areas of study. The "Advances in . . ." series, the "Annual Review of . . ." series, and the "Progress in . . ." series are particularly pertinent.

To maintain continuity with the previous pharmaceutical science reviews of *J. Pharm. Sci.*, their general format was retained. Of particular interest was an article listing drug information sources on a national and international basis (3).

GENERAL PHARMACY

Those articles, which are general in nature and cannot be classified specifically, are included in this broad category. The Food and Drug Administration regulations for investigational drugs continue to be a major topic of discussion in industrial pharmacy. The numerous requirements and problems encountered in the introduction, manufacture, control, and evaluation of new drugs were reviewed in various publications (4–6). Hein discussed the impact of the new food and drug laws and their regulations on sponsors of clinical trials (7). Clinical testing problems of the physician (8) and his qualifications and responsibilities (9) were noteworthy subjects in separate papers. The necessity of preclinical safety evaluation was stressed in other publications (10, 11). Prevention and control of adverse reactions were discussed by Friend (12), and various factors for consideration in clinical experimental design were presented by Freis (13).

A commentary on the impact of the drug laws on quality control appeared in the literature (14); disclosures on the precautions involved in meeting government packaging standards were also published (15). Toxicity and safety requirements for future proprietary medicines were reviewed by Tainter (16), while the effect of recent regulations on the clinical investigation of new drugs in dentistry was discussed by Kutscher and Zegarelli (17). The attitude of the Food and Drug Administration, the precautions and feasibility of sustained-release products were also surveyed (18).

Cleveland suggested that drug information be made available through a perpetual drug monograph service (19), and Feldmann set forth basic requirements for a satisfactory compendium monograph as part of a control procedure (20). A substitute ranking measure was proposed, *in lieu* of the therapeutic index, that would specify the optimal dose over a wide range of conditions (21). A historical survey of the naming procedures for medicinal agents has been conducted by Schriever; he urged the use of rational and systematic names based on uniform rules (22). Kanig and Rogosta prepared a compendium and cross-correlation of generic-trademark designations of commonly used drugs (23). A system was devised for classifying the marking or impressions on certain proprietary tablets and capsules (24). Various dosage forms for use in oral therapy (25) and new medicinal preparations in ophthalmology (26) were outlined in other publications.

Preservatives.—The preservation of drugs and galenicals was reviewed (27), and recommendations for storage-time limits were made for 24 concentrates prepared in pharmacies (28). In a study of the preservation of sucrose, acacia, and tragacanth mucilages, various chlorinated esters were evaluated for their effectiveness (29).

Anderson compared various cationic preservatives in bactericidal ophthalmic vehicles between pH 5 to 7.5 (30). Other investigators reviewed and assessed several preservatives for ophthalmic solutions—benzalkonium chloride was deemed most reliable (31, 32). A thimerosal–zinc complex was shown to have effective antiseptic action in biological preparations (33). Preservatives for poliomyelitis (Salk) vaccine were also investigated: Tracy *et al.* investigated formaldehyde and esters of *p*-hydroxybenzoic acid (34); Pivnick *et al.* studied the efficacy of 2-phenoxyethanol in combination with streptomycin and neomycin (35). An article was published on a new class of quaternary ammonium compounds having reduced toxicity and increased stability (36). Sorbic acid was found to be a suitable preservative for drugs containing surface-active, nonionized substances (37). Wickliffe and Entrekin determined the relationship of pH to preservative effectiveness at neutral and alkaline pH levels (38). Glutaraldehyde, alkalinized with buffer, revealed antimicrobial action and lower degree of stability than acid glutaraldehyde (39). Wedderbun cited 153 references in a comprehensive review of the preservation of emulsions against microbial attack (40). In another review, the preservation of emulsions and creams was considered (41). The order of hemolytic activity was established for various antibacterial preservatives (42). Sodium bisulfite and benzoic acid have been used to stabilize sealed ampuls of novocaine solutions up to 2 years (43). The bactericidal activity of chlo-

roxylenol in water and in aqueous solutions of a nonionic surfactant was noted by Mitchell (44).

Progress on methods and materials used as disinfectants was reviewed by Walters in two reports (45, 46). Under controlled conditions, β-propiolactone was found to be a rapid and effective sterilant for microbiologically contaminated aerosol chambers (47). Other studies supported the view that quaternary ammonium compounds are the most desirable skin disinfectants (48).

Flavor, Aroma, and Color.—Swaine reviewed flavor enhancers and potentiators (49), while Bottle surveyed materials available as synthetic sweetening agents (50). The action of acetylcholinesterase on bitter taste was studied to elucidate the mechanism of taste production (51). Two methods—"taste threshold" and "palatability at therapeutic dosage levels"—have been proposed for evaluating vehicle effectiveness; the palatability of some potassium salts in flavored vehicles was compared with these techniques (52). A comparative study of the taste quality of sodium chloride solutions above and below the adapting concentrations was conducted (53). The essential factors to be considered in the coloration and aromatization of a product were the topic of another paper (54). Appell claimed that vapor pressure, rather than evaporation rate, is the basic element for consideration in aromatization (55). Six methods for measuring vapor pressure were described; vapor pressure curves for more than 100 materials were listed (56). In another paper, a method for measuring odor intensity was expressed mathematically (57). Color legislation has been reviewed by McMurray (58). Raff illustrated a method to delineate colors obtained with FD&C aluminum lakes (59).

Adjuvants.—Current knowledge of the structure of starch and its physical properties and enzymatic hydrolysis was outlined in a publication (60). Block reviewed the medicinal and pharmaceutical aspects of dimethyl sulfoxide (61), and Marson described its use in the preparation of soluble agglomerates (62). A survey of various new types of diatomaceous earth was published (63). The use of montmorillonite clays in pharmaceuticals (64) and the changes in their basal spacing in electrolytic solutions were reported in separate investigations (65). Other researchers examined various bentonite products for their swelling activity (66). The mechanism of the spreading of organo-bentonites on water was also probed (67).

In a series of papers, Patel presented descriptive tabulations of hydrocolloids and their general properties (68–70). Thixcin R, a unique thixotropic agent, was described in terms of its potential application in pharmaceutical preparations (71). Sorokin *et al.* investigated the physicomechanical properties of agaroid gels (72).

Stability.—The effect of various chemical and physical factors was considered in a review of pharmaceutical dosage form stability (73). Tingstad presented a detailed commentary and analysis of the physical stability testing of pharmaceuticals (74), and Awazu reviewed a new aspect on decomposition of drugs in solution (75). In one paper, the homogeneous catalysis in drug solutions was investigated (76); in another, a mechanistic approach was advocated to predict the course of reaction vulnerable to attack by acids or bases (77). A survey of the use of antioxidants in pharmacy was presented in two articles by Alemany (78, 79), and the mechanism of auto-oxidation in relation to antioxidants and drugs was discussed by other authors (80). The melting point depression of pharmaceutical powders was used to predict the stability of compounded formulations (81).

The thermal stability of digitalis tinctures and tablets was determined by Ghosh and Das (82). A comparative study revealed that digitalis tinctures were less stable than adonis and convallaria tinctures (83); others studied the stability of various alcoholic extractions of belladonna and cola (84). The stability of senna and rhubarb tinctures was evaluated by Lemli (85), while Adamski and Gstirner recommended a 6-month stability check for tannin tinctures (86). A list of the stability-time relationship for many reconstituted commercial drugs was published (87). Experimentation was conducted to prevent the oxidation of sulfacetamide in eye drops (88). Stability kinetics of oleandomycin revealed decomposition to be rapid in alkali and slow in weak acidity (89). A hypothesis of "selective inhibition" for the antioxidant retardation by phenol has been proposed by Lloyd and Lange (90).

Temperature and humidity conditions for the stability of acetylsalicylic acid in the presence of antacids were determined by Kubo *et al.* (91); the stability of acetylsalicylic acid and its aluminum salt was also compared by the same authors (92). Other researchers ascertained the stability of acetylsalicylic acid in powder mixtures (93). In a study of the decarboxylation of salicylic acid, Kaeding determined the influence of various metal salts of benzoic acid on the rate constants (94).

One study analyzed the thermal polymerization of glucose (95), and another report attributed the

browning of spray-processed lactose to the presence of 5-(hydroxymethyl)-2-furaldehyde (HMF) (96). Kuettel recorded the effect of surface-active agents on the stability of aqueous phenobarbital solutions at various temperatures (97). Data were presented on the hydrolysis of idoxuridine over a wide pH range (98). 1-Piperidino-2-methyl-3-(*p*-tolyl)-3-propanone-HCl (PMP) in aqueous solution was claimed to be most stable at pH 2 (99). In an analysis of the degradation of thioxolone, various products and the pH of their formation were identified (100). Mitchell determined the effect of surface-active agents on the alkaline hydrolysis of emulsions and solutions of *n*-propyl benzoate (101). The alkaline degradation product of chlorothiazide (102) and its degradation mechanism have been described (103). Penicillin solutions and ointments were examined in relation to their stability (104). Trace metal impurities and hydrogen ion concentration were found to be major factors in the stability of prednisolone in aqueous solution (105); pH, temperature, air, and light were considered in the stability evaluation of aqueous solutions of 2-pyridine aldoxime methiodide (PAM) (106). Ophthalmic solutions of dilute thimerosal appeared to be most stable when stored in light-resistant containers at pH 6 to 7 (107).

Citric acid has been recommended to stabilize amidopyrine in combination with caffeine and procaine (108). The stability of xylocaine was examined after several hours at 120° in the autoclave (109); the decomposition of tetracaine during sterilization was also investigated (110). In the preparation of solutions for injection, Kubiak and Materski noted the method of mixing prevented decomposition of procaine (111). The stability of procaine in deuterium oxide was examined over a pH range of 8 to 11 and at 40° and 100° (112). In a preliminary report, data were presented to illustrate the decomposition products of idoxuridine ophthalmic solution in acidic media (113).

Ewald *et al.* noted that the addition of 5% glucose retarded particle formation in dextran solutions on long-term storage (114), and Mohay and Kedvessy discussed the incompatibilities of dissolved dextran and its potential as a vehicle for parenterals (115). The stability of heparin solutions was observed with respect to time, temperature, and pH; optimal stability was observed at pH 7.0 to 8.0 (116). Whittet and Robinson claimed the N.F. method was best for the preparation of stable sodium *p*-aminohippurate solution for injection (117). In another publication, the stability of 10% injection of calcium gluconate was discussed (118). A stable formula for adrenaline solutions was presented (119), and the incompatibility of adrenaline and protargol in solutions was also reviewed (120). Chemical changes in aqueous epinephrine solutions and its stabilization have been studied (121). Other workers demonstrated the heat stability of serum thyroxinelike iodine (122). Salt formation between salicylic acid and zinc oxide in the presence of water was another topic of investigation (123). The stabilizing effect of boric acid on lanolin and lanolin–oil mixtures was found to be greater than phenolic antioxidants (124). Jaffe and Lippmann presented a quantitative determination of the degree of dye migration and the inhibitory action of certain additives (125). Other investigators studied the decomposition of dimethyl sulfoxide in the presence of ethylene glycol, acetamide, and related compounds (126); the dehydration of alcohols and diols in dimethyl sulfoxide was also investigated (127). Data were presented to support the view that addition of calcium or aluminum ions stabilized pertussis vaccine in the presence of benzethonium chloride (128). The degradation of straight chain alkyl benzene sulfonate under various conditions was disclosed in another publication (129).

Stability Kinetics.—A review, citing 70 references, was presented on the application of chemical kinetics in studying the stability of drugs (130). Kennon employed heats of activation to predict the shelf-life of drugs (131); Comer and Howell used solubility analysis as a reference assay in heat-degradation studies (132). In another study, the utility of Hammett graphs in stability programs was demonstrated (133); mathematical analysis for the kinetics of parallel, reversible, and consecutive reactions was also discussed (134).

Felmeister and Discher demonstrated zero-order kinetics in the photodegradation of chlorpromazine hydrochloride with pH variation (135). A kinetic study of the stability of fluprednisolone acetate in aqueous solution has been conducted (136). Rate–pH profiles in the solvolysis of various alkyl sydnones were presented (137), and the kinetics of solvolysis of porfiromycin was quantified in pharmaceutically useful pH ranges (138). In two papers, accelerated stability of aqueous solutions of atropine sulfate was investigated over a wide pH range (139) and at elevated temperatures (140).

It was suggested that interactions of citric acid with aromatic amines may be responsible for loss of activity of some drugs formulated with this buffer (141). Another paper was published on the kinetics of degradation of 4,6-diamino-1-

(3,5) - dichlorophenyl - 1,2 - dihydro - 2,2 - dimethyl-1,3,5-triazine in dilute aqueous solutions (142). The initial rate of decomposition of 2-hydroxyiminomethyl-1-methyl-pyridinium methanesulfonate was described as first order with respect to its concentration (143); pseudo first-order hydrolysis was ascribed to a Mannich base compound (144). Data were presented to illustrate the kinetics of the decarboxylation of *n*-butylmalonic acid in the molten state and in solution (145). Rate constants have been determined for the decarboxylation of *p*-aminosalicylic acid in the solid state (146). Goldstein and Flanagan presented a method and apparatus for the study of the heat degradation of solids below 200° (147). The kinetics of degradation of neutral and acidic molecules which form acidic products in unbuffered solutions was also reported (148).

Vitamin Stability.—In one paper, the shelf-life stability of vitamins in liquid pharmaceutical preparations was examined (149); in another article, the formulation for a stable, oral multivitamin liquid preparation was presented (150). The influence of numerous vehicles on the stability of vitamins in liquid oral preparations was studied (151). Sabri and Rao evaluated the effect of casein hydrolyzate, tocopherols, and phosphatides on the stability of vitamins A, B_1, and ascorbic acid in oral liquid formulations (152).

Data indicated the log of the first-order rate constant for the degradation of vitamin A in excess water was related linearly to the water vapor pressure (153). Other researchers observed the effect of *d,l*-α-tocopherol on the stability of vitamin A in aqueous solution (154). In a thermal degradation analysis, various products of β-carotene were identified (155). Rigamonti studied the influence of six antioxidants on the stability of vitamin B_1 (156), while Kurchenko and Konev examined the stability of 5% thiamine hydrochloride solutions for injection (157). A list of the most effective combinations of stabilizers and vehicles tested for the stability of vitamin B_1 and ascorbic acid has been published (158). A reversible association complex between riboflavin and borate buffer decreased the hydrolysis rate of riboflavin (159). Adami presented a review of vitamin B_{12} in terms of its structure, metabolism, and stability (160). Marcus and Stanley described the first-order degradation of hydroxocobalamin in various buffer systems (161); other investigators also studied the stability of hydroxocobalamin aqueous solution (162).

A report on the effect of elevated temperatures on the stability of ascorbic acid in aqueous vehicles was published (163). In two papers, Gan reported the following: the antioxidative action of methyl thiouracil in sodium ascorbate solutions for injection (164); the stabilizing influence of benzoic acid on ascorbic acid and sodium ascorbate in water (165). Otani revealed a linear relationship between color formation of *l*-ascorbic acid in aqueous solution and the formation of furfural (166, 167). Removal of trace amounts of a metal ion stabilized ascorbic acid in various preparations (168); the stability of ascorbic acid in the presence of ferrous and ferric ions was also observed (169). In a study of the oxidation of ascorbic acid in injectable solutions, Kedvessy and Stieber attributed heavy metal contamination as the causative factor in the degradation (170).

PHARMACEUTICAL TECHNOLOGY

Fifty-three references were surveyed in a discussion of physical concepts of grinding operations (171). Pharmaceutical engineering was reviewed by Fowler in terms of size reduction, size separation, mixing, and compaction of solids (172). Practical mixing problems and the relationship between the degree of mixing and properties of the final mixture were also disclosed (173). A presentation was made of the progress achieved during 1963 in the development of useful theories and design concepts in filtration processes (174). Progress in the pharmaceutical engineering of fluid systems was surveyed (175). In addition, a manufacturing process for spray-drying ascorbic acid was disclosed (176).

In two monographs, Lees discussed the pharmaceutical aspects of fine particles and their evaluation (177, 178). The determination of particle size was conducted by an optical method that also produced a permanent photograph (179). Small particle shape was expressed mathematically by Davies (180); the influence of particle size and its distribution on segregation kinetics of particulate solid systems was also investigated (181). The latter work was extended by Rippie *et al.* to the analysis of the particle density–size interactions and wall effects (182). Other researchers examined the relationship between average particle size of a spray-congealed product and several of the process variables using a centrifugal wheel atomizer (183). Groves and Major recommended the Coulter counter to detect particulate matter in electrolyte solutions for injection (184).

A physical model was proposed by Ruckenstein for a homogeneous fluidized bed (185), and the behavior of a powder bed in flowing air was the

topic of another publication (186). A simple, automated film-coating procedure was developed for hydraulic atomization of cellulose derivatives (187); a method was illustrated for coating aspirin crystals of various mesh size with cellulose derivatives using an air-suspension apparatus (188). In an analysis of the flow properties of magnesia, Pilpel (189) examined the effect of particle size and its distribution on the angle of repose—the relationship between fluidity and interparticle cohesion of medicinal powders has been studied by others (190).

A spectrophotometric reflectance method for matching the color of nontransparent dosage forms was announced (191). Isotonic concentrations of 50 drugs, calculated by methods based on the laws of Raoult and van't Hoff, were listed (192). One reviewer cited 57 references in a commentary of silicones and their applications in pharmacy (193); another surveyed the technology and testing procedures for enteric coatings (194). Coletta and Kennon described a new air-suspension coating-reacting technique for effervescent products (195). The stability of empty and filled capsules was determined as a function of temperature, humidity, and container (196, 197). An *in vitro* method for measuring the disintegration of gelatin capsules has been described (198). Two reviews covering fatty acids appeared: one was concerned with pharmaceutical formulation and therapeutic use of essential fatty acids (199); the other commented on the use of branched fatty acids in cosmetics (200).

Parenterals.—Hemolytic values and isotonic sodium chloride equivalents were tabulated for various substances used in intravenous solutions (201). Ansel discussed the effect of commercial parenteral solutions on human erythrocytes in relation to pH values and isotonicity (202). More than 100 parenteral solutions were examined for incompatibility with various drugs (203), and 16 types of injection solutions were investigated for their stability after storage (204). Pyrogenous substances, their composition, properties, methods of control, and removal from injection solutions were discussed in a treatise covering 149 references (205). Ethyl oleate was assessed as an excipient for injections (206), and requirements for sunflower oil as a parenteral vehicle were established (207). Several formulations of castor oil as a vehicle for the parenteral administration of steroid hormones have been prepared and tested *in vivo* (208). In a monograph, Koechel provided data on the use, occurrence, production, and assay of mannitol in sterile solutions (209).

Sterility.—A critical survey of the tests for sterility of pharmaceutical products was made by Russell and Gilbert (210). Contemporary trends in heat sterilization were the subject of a review with 31 references (211). In a paper concerning the sterilization of pharmaceutical preparations, the classical and modern methods were described (212). Murrell discussed resistance in relation to bacteriological aspects of heat sterilization (213). Colombo reviewed the use of ethylene oxide for sterilization in the pharmaceutical industry (214); ethylene oxide has been demonstrated to be an effective sterilant for radium sources (215). Changes of ethylene oxide concentration during gaseous sterilization processes were noted by Satas (216). Sterilization of a viscous, alcoholic pharmaceutical preparation was effective using liquid ethylene oxide (217). Other workers advocated the use of ethylene oxide for sterilization of thermolabile substances (218).

Low dose rates of cobalt 60 γ-rays were economically feasible in the sterilization of aqueous solutions for injection (219). A comparative stability study was conducted on some alkaloids sterilized by γ-radiation in aqueous solution (220). Hydrolysis of procaine (221) and its reaction with glucose under sterilizing conditions were investigated in separate papers (222). In the study of the sterilization of ophthalmic solutions, a new filtration unit was described (223). The equipment and techniques used to prepare sterile ophthalmic solutions in a pharmacy were also reviewed (224). Sterilization at 100° for 1 hr. at pH 7 was satisfactory for heparin solutions (225); the autoclaving of various buffers revealed a constancy of pH (226).

Tablets.—Shlanta and Milosovich commented on the theory and instrumentation of the compression of pharmaceutical powders (227), while David and Paksy investigated the preparation of hypodermic tablets (228). One hundred and twenty-nine tablet preparations in the new "Pharmacopoea Nordica" have been discussed (229). Identification of unknown tablets by a systematic classification method was suggested by Mueller (230). A double sampling plan for tablet acceptance was presented (231), and the variability in several stages of tablet manufacture was also evaluated (232). In another dissertation, an equation was established to express vertical pressure on the bottom of tablets packed in a cylindrical vessel (233).

Yamaoka *et al.* determined the effects of binders on hardness and disintegration time of tablets (234). In two papers, Katona studied the potential use of polymeric materials as binding

agents: poly(ethylene oxides) for the manufacture of pills (235) and poly(vinylpyrrolidone) in the preparation of tablets (236). Organic solvent gels, with bentonite as the gelling agent, were examined as granulating and binding agents for tablets of hydrolabile drugs (237). A comparative study indicated slippery elm mucilage was more efficient than starch or gelatin as a tablet granulating agent (238). Melichar *et al.* conducted an evaluation of 22 lubricants for use with granulated lactose (239), and Maly also prepared and evaluated mixed lubricants for tablets (240). A report was published which compared two disintegrating agents to cornstarch in compressed tablets of sodium bicarbonate and acetylsalicylic acid (241).

The theory and design of the continuous production of tablet granulations in a fluidized bed has been considered by Scott *et al.* (242); other workers investigated the possibility of developing a carrier tablet granulation for blending with medicament and subsequent tableting (243). A method was given for the rapid drying of tablet granulations—15 min. with 50° forced hot air (244). A description of the continuous manufacture of granulated acetylsalicylic acid was presented; preference was stated for the crystalline material in various tablet formulations (245). Data were published by Hadgraft and Smith on the formulation and stability testing of effervescent calcium gluconate tablets (246). Preliminary screening of some variables in the physical factors affecting the subcoating of compressed tablets was discussed (247); dioctyl sodium sulfosuccinate was offered as a substitute for sugar coating (248). In studies of powder compression, the time-dependent effects and mechanism for compaction were noted (249), and acetylsalicylic acid was used to examine elastic formation of tablets (250). The flow and compression characteristics of fused mannitol in the preparation of compressed tablets were reported by Kanig (251). A relationship was established between apparent dielectric constant of compressed tablets and their water content (252). Studies of the retention of water in varying concentrations of gum arabic and sucrose in troches were also presented (253). An attempt was made to correlate the water absorption of various tablets with the tablet disintegration time (254); the homogeneity and mixing time of tablet vehicles with radioisotopes were investigated (255). The role of the mixing process and its influence on the accuracy of dosage in tablet preparations was determined using reserpine as a model (256).

Visual observations and reflectance measurements were used to extrapolate the appearance of tablets and powders from accelerated storage tests. The data were then evaluated with the Arrhenius equation (257). Improved stability has been noted after the acid-washing of talc in a study of selected U.S.P. talcs on acetylsalicylic acid tablet stability (258). The contribution of various additives and conditions were studied by Okano *et al.* in the decomposition of aspirin during tablet manufacture (259). An examination of the thermal degradation of phenylephrine hydrochloride in tablet formulations containing aspirin was also conducted (260). The amidopyrine tablet discoloration was minimized in a neutral or slightly basic environment (261), and the fading rates of FD&C Red No. 3 and its aluminum lake were ascertained in tablet formulations (262). Yen evaluated the effects of pharmaceutical formulation of tablets on the dissolution rate of the drug; the results were related to data obtained with the U.S.P. disintegration test (263). In a similar treatise, other workers revealed marked variation in the dissolution rates of tolbutamide tablets was not related to the official disintegration time (264). Microcrystalline cellulose has been studied in relation to the binding, disintegration, drug release, compressibility, and stability of tablet forms (265). A method for preparing sustained-release sulfamethazine in small batches was presented (266); various binders were used to control the dissolution rate of granules for sustained-release chloramphenicol tablets (267).

Suspensions.—In a comprehensive review with 107 references, Hiestand discussed the treatment of coarse suspensions in formulation (268). A simplified mathematical model, derived from the Smoluchowski equation, was developed to express flocculent growth in a stirred suspension (269). Yield values of gum systems were plotted against pourability index to facilitate selection of the best gum for a desired suspension (270). Another report evaluated panwar (*Cassia tora*) gum as a suspending and emulsifying agent (271). In an effort to improve diagnostic media, Brown offered a high-density barium sulfate suspension (272). Separate investigators evaluated polysorbitan monooleates for stability of sulfanilimide suspensions (273) and aqueous sulfur suspensions (274). The preparation of stable suspensions of Corinal using surface-active agents has also been reported (275).

Various articles by Wilson and Ecanow revealed the surface chemistry of bismuth subnitrate in aqueous suspension (276) and its incompatibility with tragacanth mucilage in terms

of surface chemical reaction (277). The effect of solid content on adsorption and flocculation behavior of silica suspensions was revealed—the adsorption mechanism was found to obey a Langmuir-type equation (278). Deflocculation of clay suspensions with ion-exchange agents was the topic of a paper by Komrska (279). Differences in agitation rate in the preparation of Veegum dispersions effected significant rheological changes (280). In another publication, it was found that mutual flocculation between zinc oxide and titanium dioxide could be described entirely from particle size consideration (281).

Emulsions.—Carrier published the second revised edition of his classification of emulsifiers for cosmetic chemists—600 compounds were cataloged (282). Emphasis was placed on viscosity measurements in a review of the flow properties of emulsions (283). Engineering principles were applied to the processing of cosmetic emulsions (284), and the potential of large-scale manufacture of emulsions by shock cooling was also considered (285). A spectrophotometric method was used to predict rapidly the stability and efficiency of wax emulsions (286); in another monograph, ζ-potential measurement was applied for the control of dispersions (287).

Higuchi used the Coulter counter to study the rate of solute transport out of emulsion droplets in the micron-size range (288). Temperature and pressure were significant factors in size reduction of emulsion globules by steam injection (289). The effect of electrolytes on ultracentrifugal stability of emulsions was determined (290), and the physical and biological changes during storage of artificial fat emulsions were noted (291). Dye was used to follow the stability of water-in-oil emulsions against coalescence (292). The preparation of liquid paraffin emulsions containing 4 to 12.5% acacia was described by Jaisual and Mital (293).

Ointments.—White mineral oils and petrolatum in cosmetics were topics of a review (294). A physical testing procedure was established to determine the acceptability of petrolatum samples (295)—other researchers devised chemical and physical methods for characterization of ointment bases of the triglyceride type (296). Evaluation of a new fat base for ointments was presented in a preliminary report by Neuwald *et al.* (297). In a study of nonionic surfactants and water absorption, a modification of the method for determining water numbers of ointment bases was developed (298). The effect of hydrophile–lipophile balance (HLB) of the system was studied relative to diffusion of chloramphenicol from petrolatum base (299). In separate papers, the stability of bentonite was studied in a gelled mineral oil base (300) and in hydrophilic bases (301). A stable hydrocortisone ointment has been formulated by Tanaka *et al.* with *N,N*-bis(2-hydroxyethyl) lauramide (HS-12-P) (302). Ward and Sperandio established the optimal degree of hydrolysis of polyvinyl alcohol for film-forming, emulsion-based creams (303). In the evaluation of vinyl carboxylic polymers as hydrogels, basic neutralization was observed to aid in absorption (304).

Thermal stability of anhydrous lanolin was examined at 100–150° (305); the temperature stability was also investigated for oil-in-water ointments (306). In another stability study of ointment bases, acidic and alkaline hydrolysis of higher fractions of ethoxypolysiloxane were measured (307). The Haake-Viskowage and Penetrometer have been used by Berneis *et al.* to determine the penetration depth and practical yield point of hydrocarbon ointment gels (308). Comparative setting points of suppositories and ointment bases were best studied by the hanging drop method (309).

Suppositories.—The influence of temperature of the cocoa butter mass for suppositories was determined in relation to density and resistance to fracture (310). In another study the behavior of amidopyrine and phenobarbital on the melting point of the suppository mass was noted (311). Regdon and Kedvessy observed the effect of raw material viscosity on homogeneity of suppositories prepared by a casting method (312). Esterification of glycerol with mixtures of lauric acid and monostearin was investigated for its potential as a suppository base (313).

Packaging.—Cross discussed the use of plastics in packaging on the basis of chemical resistance, permeability, and shelf-life (314). Factors determining the type of containers for proprietary and dispensed medicines were subjects of another publication (315). Black and Tester commented on the use of the unit-dose concept to improve dispensing systems in a hospital pharmacy (316). A new machine was described for the strip-packaging of tablets, capsules, and suppositories with aluminum foil (317); a new method for packaging cylindrical objects, especially ampuls, was also revealed (318). Lachman studied the stability of various drugs in relation to packaging in a wide range of storage conditions (319). Various methods for packaging of moisture-sensitive drugs were disclosed (320), and the packaging of tablets, capsules, and suppositories in low-ductile foil was

announced (321). Corrosion of ointment tubes in the presence of mercury compounds was also observed (322). Another study was conducted on the suitability of paperboard containers for dispensing creams, ointments, and pastes (323).

The action of liquid pharmaceuticals on plastic and rubber materials was investigated—a tabulation of compatibility in varying concentrations was offered (324). The physical properties of polypropylene for receptacles of aqueous pharmaceutical solutions were examined (325); five polymers were evaluated as potential container materials for U.V.-sensitive drugs (326). Braun reviewed the legislation, toxicology, chemistry, and analysis of plastic parenteral containers (327). Twenty-seven references were cited in a discussion of the requirements for rubber stoppers for injectables—testing methods were suggested (328). Another report analyzed the sorption of preservatives and leaching of extractives in lined and unlined rubber stoppers for multiple-dose vial solutions (329). Specifications have been established for rubber stoppers for use with strepto- and dihydrostreptomycin (330). Factors affecting the concentrations of thimerosal in aqueous solutions and in vaccines stored in rubber-capped bottles were topics of another research paper (331). A discussion of the physical and chemical control of glass containers for pharmaceutical use was of interest (332). Fagard observed the stability of phenylephrine HCl as a function of container composition (333), and Steiger and Lehmann detected the effect of various formulations on the corrosion of zinc ointment tubes (334).

Aerosols.—The role of aerosols in medicine was surveyed (335). Yakubik presented a general discussion of the formulation of aerosols (336); Troadec considered the essential properties in selection of aerosol valves (337). A discussion of the technical problems and advances in European aerosol production was presented in another review (338). Aerosol drug forms were cataloged by trade name and therapeutic class by Enezian (339). The use of vinyl chloride as a constituent of aerosol propellants (340) and the vapor pressures of solvents and propellant mixtures (341) were reported in separate publications.

Azeotropic aerosol propellants, consisting of binary and ternary mixtures of fluorohydrocarbons, were discussed in terms of their potential use (342). Numerous factors such as particle size, particle definition, and analytical methods for aerosols were ascertained (343). Particle size distribution in aerosols was evaluated by Kerker *et al.* by a polarization ratio method (344). Statistical experimental design has been applied to examine some of the factors on the properties, stability, and spreading power of aerosol shaving creams (345).

EQUIPMENT

Kessel commented on the use of reinforced plastic equipment in pharmaceutical manufacturing in relation to corrosion resistance (346). In two articles, Butterworth reviewed the factors affecting filter performance (347) and determined the effect of electrostatic charges on filter fabrics (348). One hundred and sixteen references concerning new applications of various types of dryers were reviewed by McCormick (349), and another article updated the methods applied to classification and selection of continuous dryers (350). The economics of the steam ejector and a refrigerated condenser system were compared in the selection of freeze-drying vacuum equipment (351). Equipment and procedures for large-scale spray-drying of antibiotics have also been surveyed (352).

The design and performance of an automatic pipeting machine with a range of 0.01 to 1.09 ml. was announced (353). A container for the aseptic transport of injectable solutions during manufacture was illustrated (354); a micro filter stick, designed to replace the conventional sintered-glass filter sticks, was also described (355). Price and Osborne designed an instrument to facilitate photochemical decomposition studies (356, 357). An a.c. polarization electrode was fabricated to monitor distilled water automatically (358), and ADG 100 was developed for mechanization of visual inspection of ampuls (359). In other papers, an automatic instrument for direct reading of absolute surface tension was presented (360), and static yield values were measured in fluids by varying the electromagnetic field (361). A modified tackmeter has been used to determine relative tackiness in skin formulations (362).

Steinberg considered the advantages of spray coating and described two types of automatic tablet coating systems (363, 364). High-speed photography was utilized to study the mechanism of a tablet counting and filling machine (365). An instrument was developed to quantitate the roughness of subcoated tablets—Tablet Roughness Recorder (366). Rankell *et al.* commented on the operation and performance of equipment for continuous production of tablet granulations in a fluidized bed (367). Another study revealed that temperature was the most critical variable in a new air suspension apparatus for coating

discrete solids (368). The U.S.P. tablet disintegration apparatus was redesigned to create more uniform attrition on all sides of the tablets (369). A simple programmed thermoregulator for use in kinetic studies has been discussed by Scott *et al.* (370), and a precision apparatus for dissolution-rate determinations has been designed by Levy and Tanski (371). A monograph was published on ultrasonic emulsification and the Rapisonic homogenizer (372). Isolation of drugs from biological fluids with a simple rotary extractor was discussed in another article (373).

PHYSICAL PHARMACY

The evaluation of pharmaceutical problems by physicochemical means continues to receive great attention, evidenced by the many reports on this subject. Numerous references were covered in a treatise of organic physical chemistry in the pharmaceutical field (374). Czetsch-Lindenwald studied the hygroscopicity of numerous pharmaceutical substances over a wide range of humidities (375). In a review of adsorption and condensation processes, it was noted that predictions from thermodynamic and kinetic analyses were related to practical systems (376). A simple, nonemulsifying rocking apparatus was described for measuring distribution coefficients (377). Fusibility of the binary systems salol–chloral hydrate and salol-pyramidon was studied by differential thermal analysis (378). The physical chemistry of pure fatty acids has been the subject of another review (379).

Ionization.—In a study of dissociation, one paper listed the dissociation constants of 31 aromatic monocarboxylic acids (380). Another researcher determined the ion association constants of some acetates using pH measurements (381). Freeman and Scatchard discussed the electrokinetic behavior of an ion-exchange resin (382). In a communication, the purification of lecithin through ion-exchange resins was reported (383), and observations on cation-exchange resins in relation to insulin binding were also made (384).

Solubility.—Tyrrell reviewed the origin and present status of Fick's diffusion law (385). The effects of interacting colloids on transport rates were discussed (386); ion solvation and solvent basicity were considered in another publication (387). The simultaneous influence of reaction, adsorption, and viscosity on dissolution rate of a slightly soluble, acidic solid was reported by Wurster and Polli (388). An analysis was made of the relationship between diffusion-controlled dissolution rate and solubility in a reactive medium (389). Isothermal absorption was the method used to study the properties of drug hydrates (390). The influence of hydrate and solvate formation on rates of solution and solubility of crystalline drugs was also published (391). A report was noted on dissolution rate studies of methylprednisolone polymorphs using the rotating disk method (392). Milosovich determined the solubility of a metastable polymorph (393), and Sanchez examined the solubility of the polymorphic forms of sulfathiazole (394).

Mulley abstracted 178 references in a comprehensive review of solubility in systems containing surface-active agents (395). Concentrated aromatic solutions were prepared by solubilization with polyoxyethylene sorbitan monooleate (PSMO) for use in drug flavoring (396); the solubilizing effect of PSMO on some poorly soluble medicaments in water was also reported (397). Other workers established a relationship of apparent solubility of weakly acidic and basic drugs to pH and surfactant concentration (PSMO) (398). Solubilization and inactivation of preservatives by nonionic detergents have been disclosed by Evans (399). Dielectric constants and solubility were discussed in three papers. In the first, a linear empirical equation was established to connect Hildebrand solubility parameters and dielectric constants of pure liquids (400); the second expressed a possible means for quantitative evaluation of solubility in homologous solvent series and blends (401); in the third, some observations were communicated concerning the possible relation between dielectric constant and solubility of nonelectrolytes (402). Another presentation was concerned with the solubility of salicylic acid as a function of dielectric constant in pure and binary solvent mixtures (403). Arnett and Douty investigated sulfolane, a weakly basic aprotic solvent with high dielectric constant (404).

Three different techniques were compared in a study of the solubility of certain barbituric acid derivatives (405); the use of refractometry for determining the solubility of barbituric acid derivatives was illustrated in another paper (406). Four surfactant aminoalcohols were found to be effective solubilizers of phenobarbital (407). Phase solubility technique has been employed to examine the formulation of complex salts of triamterene (408). The effect of sulfur-containing anions on solubility of caffeine and benzoic acid was reported (409); in another report, the water-soluble properties of orotic acid salts were ascertained (410). Aqueous solubil-

ities of sulfanilimide, sulgin, and sulfadimesine at different pH and temperature levels were also announced (411). In a study of the solubility of caffeine and benzoic acid, the effect of chlorine- and nitrogen-containing anions was revealed (412); other researchers examined the solubility of benzoic acid and related compounds in a series of *n*-alkanols (413). Another paper related the turbidity and irritating action of vitamins A and D to solute and solubilizer (414). Kritchevsky and Tepper determined the solubility of cholesterol in various fats and oils (415), and Miyazaki *et al.* studied the solubilization of corticosteroids in higher fatty acid diethanolamide derivatives (416). In separate publications, different methods of analysis produced new values for the solubility of benzaldehyde in water (417, 418). Mitchell and Wan also determined the solubility of benzaldehyde and methylbenzaldehyde in aqueous solutions of polyoxyethylene glycol ethers (419).

Complexation.—Metal complexes of drugs were surveyed by Doornbos and Faber (420); another review covering 140 references was concerned specifically with metal–gluconate complexes (421). A method has been described for the determination of the electrolyte type of ionized complexes in aqueous and nonaqueous solvents (422). Ethylenediaminetetraacetic acid was discussed relative to its application in pharmaceuticals and medicine (423). Data were published which suggested dimeric and trimeric iron–tartrate complexes could be formed in addition to monomeric complexes (424). Other researchers commented on a new phosphorus-based sequestrant which combined most effects of polyphosphates and organic chelating agents (425). Hydrogen-bonding between montmorillonite clay and polyacrylates or polyamides was shown to be greatest at pH 4 and minimal at pH 7 (426). Interactions between sodium lauryl sulfate and water-soluble or water-insoluble macromolecules were explored (427). Equilibrium dialysis technique was used to study thermal effects on binding of parabens and phenols of polysorbate 80 (PSMO) and polyethylene glycol 4000 (428). Robinson *et al.* reported that the interaction of low molecular weight polyethylene glycols with sorbitol solution produced a single-phase solid material (429).

The physical-chemical aspects of binding between nitrofurans and serum proteins were observed (430), and the mechanism of serum albumin binding of several sulfonamides was also studied (431). In another study of protein–drug binding, the ultracentrifuge was a valuable analytical tool (432). Bahal and Kostenbauder studied binding of chlorobutanol, benzyl alcohol, and phenylethyl alcohol by macromolecular nonionic agents (433). A complex of iodine and nonionic surface-active agent has been evaluated for its antibacterial activity (434). In one paper, the interaction of nonionic detergents and swelling clays was discussed (435); in another, incompatibility of cationic antiseptics with sodium alginate was noted (436). Dialysis was used to examine the interaction of sucrose and propoxylated sucrose esters with various pharmaceuticals—the functional group and its position were significant for reactivity (437). Rodell *et al.* investigated the interaction of sorbic acid with nylon 66 at various concentrations and temperatures (438). The molecular association between antipyrine and aminopyrine was illustrated by solubility and cryoscopic methods (439); other investigators showed complex formation between chloroquine and ferrihaemic acid *in vitro* (440).

In two papers, Remmers *et al.* described the pharmaceutical properties of metal–acid complexes with tetracycline derivatives (441) and developed stable, preconstituted parenteral formulations (442). Complexation in the organic phase was the subject of a presentation by Hull and Biles (443); others studied the complexation of organic substances in aqueous solution by hydroxyaromatic acids and their salts (444). The heat of immersion and absorption isotherms were measured to determine the interaction of water with lithium kaolinite surface (445). Orange II and selected long-chain quaternary ammonium salts have also been investigated for complexation (446). Lach and Chin observed that β-cyclodextrin retarded the base-catalyzed degradation of benzocaine (447). Interactions with mono-halogenated benzoic acids and aminobenzoic acids were also noted (448).

Surface Phenomena.—Some of the factors controlling the adsorption of nonelectrolytes from solutions were reviewed by Kipling (449). The adsorptive nature and surface area of aluminum oxide, titanium dioxide, carbon, and other organic pigments were also surveyed (450). A theory containing several features of all adsorption processes with simple equations for isotherms was developed—its basis was the capillary condensation concept (451). The adsorption of iodine from solution by microorganisms and by serum was studied (452); also noted were the physical aspects of stearic acid adsorption from solution by oxide adsorbants (453). The adsorption mechanism of a surfactant at the solid–liquid interface has been re-

ported to be dependent on its chain length (454). In separate papers, wetting and adhesion in two-component systems (455) and interfacial properties of phenothiazine derivatives were discussed (456). Fowkes calculated heats and free energies of adsorption of gases on solid surfaces directly from measurement of surface tension and contact angles (457). The surface energy of solid mannitol and codeine was determined by the Rebinder effect (458). A method of evaluating the size distribution of pores in the 10–300 Å radius range was presented by Haley (459); the mechanism of calcium oxide hydration was studied (460).

The mechanism of micelle formation between anionic surfactants and alkaloids was investigated in extraction processes (461). Hydrodynamic measurements were made on solutions of pure surfactants to determine the size, shape, and hydration of the micelles (462). The critical micelle concentration of several nonionic surfactants was examined in other publications (463, 464). The effect of solvent dielectric constant on micellization by lecithin has been studied by light-scattering, viscosity, and diffusion techniques (465). Schick reported on the effect of urea and electrolytes on micelle formation of some *n*-alkyl sulfates (466). In separate reports, three methods for the estimation of micelle hydration were presented (467–469). Another study evaluated the surface pH of micelles by using solubilized indicator dyes (470). Mysels noted that soap films are a powerful tool for the study of surface and colloidal phenomena (471). Molecular composition of surface-active agents was shown to affect fundamental properties that define surface activity (472).

The utility of the HLB system for some nonionic surfactants in a nonaqueous immiscible system was explored at length (473). One treatise discussed the theoretical and empirical approach to the production or prevention of foams (474); another disclosed the foam properties of various nonionic surfactants (475). Fatty amine oxides were evaluated as foam stabilizers (476). The chemical and mechanical procedures for controlling various foams were reported in another paper (477). Guastalla described a technique for measuring the surface tension of volatile surfactant solutions (478). In a study of aggregation, the function of protective colloids was attributed to their ability to sufficiently coat particles (479). Surface forces and the stability of colloids and disperse systems were topics of another article (480). Phares and Sperandio proposed a method for the preparation of phase diagrams of coacervated systems using physical measurements instead of chemical analysis (481). Several selected variables were examined for their effects on the extractability of oils from coacervate capsules (482), and the coating of pharmaceuticals with a gelatin coacervate system was disclosed (483). Other researchers related the surfactant properties of some synthetic steroids to their bactericidal action (484).

Crystallization.—A detailed review of the theory and practice of crystallization was presented—inorganic materials were emphasized (485). Changes in specific surface area determined by X-ray powder diffraction and electron microscopy were employed to follow crystal changes in amorphous aluminum hydroxide (486). Correlation of polymorphic forms of several long-chain compounds and their long spacings was demonstrated; several triglycerides were studied (487). The mechanism of eutectic crystallization has been ascertained using naphthalene and phenanthrene (488). Mixtures of salol and phenol in the vicinity of their melting points were employed to illustrate the relationship between their temperature and surface tension (489). Another physicochemical study revealed a method for permitting ready discrimination of water of crystallization, sorbed water, and free water (490). The influence of anions on the synthesis of crystalline alumino-silicates (491) and the modification of the crystal habit of sodium chloride by various chemical agents (492) were presented in detail. Inclusion compounds of α-lipoic acid methyl ester with urea and thiourea provided a method of preparing potentially stabilized products (493). Two papers depicted a method for the size reduction of griseofulvin crystals by solvation and desolvation with chloroform (494, 495); another article proposed the use of ultrasonic irradiation for the controlled crystallization of hydrocortisone (496).

Rheology.—Martin *et al.* cited 192 references in a review on rheology (497). A new capillary viscometer was described for measuring the viscosity of non-Newtonian liquids (498). In one study observers made numerical judgments of apparent viscosities of silicone liquids without the use of instruments (499). The yield point and viscoelasticity of concentrated oil-in-water emulsions have been shown to be greatly affected by the cooling rate (500). Schrenzel investigated the effect of alkali, surfactants, and other additives on the viscosity and pH of carboxy vinyl polymer hydrogels (501). Anomalies in the viscosity of polyethlyene glycols and mixtures with

water were studied with the aid of a rotation viscometer (502). In one investigation, a procedure was developed to evaluate the viscoelastic properties of gelatin films (503); a similar evaluation was conducted after plasticization with dimethyl sulfoxide and glycerol (504). A series of papers was concerned with the rheological properties of acacia and tragacanth mucilages in the presence of electrolytes (505–507).

Zacek designed a new method for the rheological control of pharmaceutical suspensions (508). Rheological factors for the physical and chemical characterization of thixotropic flow of bentonite suspensions in water, glycerin, and mineral oil were also discussed (509). Other workers reported on the quantification of pseudoplastic viscosity as a second-order function of the rheogram and the relationship of this parameter to concentration (510); the suspension activity of pseudoplastic polymers at fixed apparent viscosities was compared (511). An examination of the rheological properties of four natural vaselines revealed they were not thixotropic (512). Schulte and Kassem determined the viscosities of polyethylene glycol gels (513). In other studies, the flow properties of creams and ointments were similarly investigated (514, 515).

PHARMACOCHEMICAL ASPECTS

This section of the review considers many of the papers on polymers, antibiotics, and radioisotopes which might be of interest to the pharmaceutical scientist. It is not intended to encompass the vast area of pharmaceutical chemistry concerned with synthesis, structure-activity studies, reaction mechanisms, analysis, etc. These related disciplines are reviewed annually in other publications and are, therefore, omitted from this report.

Polymers.—Mark reviewed the current status for macromolecules and forecasted their future (516). In a series of six articles, the medical importance of synthetic polymers has been thoroughly surveyed by Auber (517–522). A summary with 140 references included the toxicity, untoward reactions, and related considerations on the medical use of plastics (523). The theory of dielectric crystalline dispersion which is observed at high temperatures in highly crystallized polymers was discussed in detail (524). The effects of pH, concentration, chain length, and electrolytes on the photolysis of polymethacrylic acid were examined in a treatise by Chou and Jellinek (525). The distribution of vinyl groups in vinyl starch (526) and the polymerization mechanisms of drying oils were also reported (527). In another investigation, a plastograph was used to evaluate several peroxides as cross-linking agents for high-density polyethylene (528). The interaction of various weak organic acids with nylon was studied in two publications by the same authors (529, 530). Several theories have been tested by comparing the calculated and experimental viscosities of branched polymers produced by high-energy radiation (531). In a water-vapor-permeation study of cellulose ester films, the permeability constant was shown to decrease with increasing chain length of the acid moiety (532); equations were established to predict penetration of polymer films by water, organic solvents, or surfactants (533).

The application of polyvinyl alcohol in cosmetology was reviewed by Vitez (534). Other publications included the preparation and properties of polyvinylpyrrolidinone iodide (535) and other iodine-containing high polymers (536). A screening procedure for the evaluation of polymeric materials as film-coating agents was presented by Munden *et al.* (537). Denatured polyvinyl alcohol acid phthalates were compared to cellulose acetate phthalate as enteric coatings (538); vinyl and acrylic polymers were screened for their potential use as prolonged-action coatings in another study (539). Also revealed was the effect of various plasticizers on the water vapor transmission of cellulose acetate phthalate films (540).

Antibiotics.—Changing approaches to antibiotic production by submerged-culture techniques were commented upon by Hockenhull (541), and the use of ion exchangers in antibiotics technology was surveyed by Kotula (542). Other reviews reported results from cephalosporin studies over the last 2 years (543) and concentrations and determinations of old and new antibiotics in blood (544). The properties of new antibiotics, cephalothin (545) and ruticulomycins (546), were disclosed. Tylosin, at 2.5 p.p.m., was found to prevent sporulation of the putrefactive anaerobe, 3679; nisin, at the same concentration, was ineffective (547). Gramicidin C demonstrated greater bactericidal activity in cottonseed oil than in fish oil or petrolatum (548). Brown and Garrett conducted a study on the reproducibility of *Escherichia coli* growth curves and their dependence upon tetracycline concentration (549). Two other publications were concerned with the effect of penicillinase on the activity of penicillins (550) and the relationship between penicillinase activity and penicillin structure (551).

Data were published on the water solubility and activity of 226 commercial samples of erythromycin (552). The physical and chemical properties of colimycin, mycerin, neomycin (553), janthinellin (554), levorin (555), and olivomycin (556) were presented in other papers. Tetracycline and formaldehyde were combined to form a water-soluble derivative that provided higher blood levels than tetracycline hydrochloride after oral or parenteral administration (557). Stable and biologically active water-soluble derivatives of nystatin have also been prepared (558).

Das and Dutta published a general review of the stability of antibiotics (559), and Pinyazhko surveyed the stability of penicillin G (560). Sodium citrate and ethyl-*p*-hydroxybenzoate were shown to stabilize aqueous solutions of penicillin for use as eye drops (561). The effect of catechol derivatives on the hydrolysis of penicillin was communicated (562); a similar study of the influence of pH, temperature, moisture, and metals was also reported (563). The stability of polymixin M was followed over a pH range of 1 to 10 (564). Crevar and Slotnick noted the stability of actinomycin D in relation to temperature (565). The stability of erythromycin (566) and erythromycin glucoheptanate (567) in aqueous solution has been considered in detail. In a similar study on the hydrolysis of cycloserine, the pH-rate profile revealed apparent pseudo first-order degradation (568). Other authors offered a formulation which provided 1 week stability for oxytetracycline eye drops (569). The thermal stability of nystatin (570) and antiphage activity of fumagillin after 1 year of storage were delineated (571).

Radioisotopes.—The use of radioactive compounds in pharmacy was reviewed in five publications by Spaander (572–576). Radiation-protective drugs were discussed and classified according to their pharmacological action (577). Another review considered the use of whole-body counters in radiological protection (578). Schifferdecker *et al.* claimed that whole-body radioactivity measurement opened up new areas of research for the pharmaceutical sciences (579); a new high-level whole-body counter for γ-emitting radioisotopes was also described (580). Other investigators employed the whole-body counter to measure absorption and degradation rates of ^{131}I-labeled thyroxine (581) and triiodothyronine (582). Current techniques for α and β counting by liquid scintillation were the subject of a review by Rapkin (583). A procedure for dual-channel scintillation counting permitted study of the *in vitro* release of two labeled drugs from sustained-release tablets (584). The use of siliconized glass vials was advocated to prevent wall adsorption of some inorganic radioactive compounds in liquid scintillation counting (585). A correlation was made between counting efficiency and water content of the liquid scintillation solvent system (586).

A procedure was developed for the determination of the thickness of walls of hard gelatin capsules by radioisotopic means (587). The use of radioelements as an approach to problems of general pharmacodynamics was reviewed and interpreted (588); a method was proposed for the long-term daily administration of radioisotopes in metabolic studies (589).

Methods for the tritiation of steroids (590) and an antigammaglobulin (591) were discussed at length. Samuel and Wasserman observed the effect of structure and stereochemistry of the organic compound on the isotopic exchange of oxygen with alumina (592). A simplified procedure was given for making ^{131}I-labeled hippuran with high specific activity (593). Independent investigators also described the preparation of ^{131}I-labeled serum albumin (594, 595) and triolein (595) for clinical use. Methods were proposed for the synthesis of ^{131}I-labeled iodobenzoic acids (596). Precautions in the use of ^{125}I as a radioactive tracer were the topic of another paper (597).

BIOPHARMACEUTICS

Biopharmaceutics comprises the research effort directed toward studying the influence of pharmaceutical formulations on the biological activity of drugs. A review of the gastrointestinal absorption aspects of biopharmaceutics was published by Wagner (598). Two different *in vitro* models have been proposed to test pH and drug partitioning on the rate and extent of drug absorption (599, 600). Levy and Miller suggested a novel method for the determination of drug absorption rates across biologic membranes without chemical assay (601). Another topic of study was the binding of sulfonamides in serum albumin (602).

The *in vitro* reaction rate of several proprietary antacid preparations was evaluated with 0.1 *N* hydrochloric acid (603); the neutralizing capacity of various antacids using a pH stat to pH 3 under constant agitation and various temperatures and volumes was also studied (604). Other researchers found that various proteins, polypeptides, and amino acids inhibited the neutralization rate of aluminum hydroxide gel (605). The capacity of sodium malonate to neutralize gastric acidity was similar to that of sodium citrate, acetate, or lactate (606). Preparations with sodium bicarbonate and insoluble antacids had the highest amyl-

ase activity in a study of enzyme preparations (607).

Effects of Physicochemical Properties.—The effects of release rate, solubility, particle size, crystal changes, polymorphism, and various derivatives were discussed in relation to drug absorption (608). Sokolski *et al.* examined the influence of various chemical and physical factors on the biological responses to neomycins B and C (609). In a communication, the *in vitro* metabolism rate of some sulfonamides was correlated with their ionization constant and extent of plasma protein binding (610). Another study related the form and pharmacobiochemical properties of parenteral iron preparations (611). The effects of surfactant and particle size of griseofulvin were evaluated in terms of oral absorption (612); available surface area of tolbutamide on rates of metabolism was also explored (613). Complexes of salicylic acid were used to modify its absorption characteristics (614). Differences in oral absorption of quinalbarbitone and its sodium salt were attributed to drug particle size after gastric precipitation (615); in the evaluation of chloroquine base and sulfate, there were no differences in the blood or urine concentrations (616). A rat perfusion study indicated thiourea enhanced the uptake of quinine from the intestine but had no effect on quinidine (617). The water solubility, turbidity point, distribution coefficient, and surface activity of several procaine analogs were claimed to affect their local anesthetic action (618).

Effects of Formulation.—The importance of the formulation was illustrated in a paper describing certain pharmaceutical compositions with phenylephrine (619). Acetylsalicylic acid served as a model drug to demonstrate a quantitative correlation of human absorption-rate data with the results of an *in vitro* dissolution test (620). In publications by Lieberman *et al.* protocols for study of the *in vivo* absorption process of acetylsalicylic acid were first established (621)—the influence of tablets, antacids, and solutions on serum salicylate levels was also examined (622). Another study on absorption from ointments revealed thiamine was well absorbed from a hydrophilic base (623). The effect of various ointment bases on absorption of salicylic acid (624) and the influence of a nonionic surfactant on the percutaneous penetration of diethylamine salicylate were discussed in separate papers (625).

Plasma level studies on the oral absorption of spironolactone indicated variations with different tablet compositions (626). Other workers noted that the smaller particle size of griseofulvin produced a longer urinary excretion time (627). Several authors were concerned with the relationship between availability and dissolution time of prednisone (628), tolbutamide (629), and riboflavin tablets (630). A new vehicle for long-lasting troches was demonstrated to be effective in a clinical evaluation (631). Cohen observed fewer side effects while collecting data on the acute bronchodilator properties of a steroid microaerosol (632). Other studies have been conducted on absorption from different suppository bases by the vaginal (633) and rectal (634) routes; the release of salicylates from fatty suppository bases both *in vitro* and *in vivo* was also reported (635).

Absorption Control.—Lin *et al.* designed a radiofrequency generator for release of drugs in known areas of the gastrointestinal tract. Absorption of trimeprazine-^{35}S and penicillin G was noted in dogs (636). Polyvinyl alcohol was evaluated as a new vehicle for antibiotics in general practice (637). In recommended doses, cholestyramine had no effect on vitamin K_1 absorption; larger doses demonstrated delayed and decreased absorption (638). Molecular compounds of long-acting sulfa drugs were prepared by Chae; 26 binary systems were revealed (639). In separate studies the intestinal absorption of enteric-coated iron (640) and chymotrypsin (641) was investigated. Blood levels indicated enteric-coated ethionamide tablets were lower and more variable in relation to the uncoated control (642). Paksy and Ecsery prepared a new enteric coating from phenylacetic acid and formaldehyde (643). The *in vivo* effectiveness of enteric-coated tablets prepared by a programmed automated process has also been discussed (644).

The development and design of prolonged-action pharmaceuticals was reviewed in several publications (645–648). Bogner and Walsh evaluated the sustained-release principle in humans utilizing radioactive techniques (649). A phenoxyacetic acid–formaldehyde resin was complexed with propantheline bromide to produce a prolonged-action pharmaceutical (650). The absorption efficiency and excretion profile of chlorpromazine were determined in a comparative study of prolonged-action and tablet forms (651). Other researchers conducted a similar investigation with a sustained-release multivitamin preparation (652), and the absorption of creatinine from regular and sustained-release tablets was also noted (653). In a study of drug release from a matrix-type dosage form, the most significant factors controlling its rate were concentration and crystal size (654). A polyvinyl chloride matrix

was used to produce a sustained-release aspirin tablet (655). Various enteric polymers were examined as potential sustained-release coatings for granules (656) and pellets (657).

Absorption Mechanism.—The physicochemical and pharmaceutical factors influencing gastrointestinal absorption were outlined by Delgado and Cosgrove (658). In another presentation, intestinal drug transfer was investigated *in vitro* by perfusion through guinea pig small intestine (659). Intestinal absorption of hexoses was studied in the dog (660); the intestinal transport of tryptophane, its derivatives (661), and other amino acids (662) have also been explored. Cholate was observed to possess a specific transport mechanism, but several organic dyes were absorbed by a passive process (663). Nogami *et al.* published a paper on the *in vitro* intestinal transfer mechanism of sulfisomezole (664). Experimentation with thiamine revealed optimal absorption occurred in the duodenal section of the intestine (665). Of interest was an article which correlated the partition coefficient with the rate of permeation across the blood-brain-barrier (666).

Reviews concerned with the chemical basis of emollient function (667) and the roles of hydration (668) and cutaneous lipids (669) on emollient action in the skin were presented by investigators in the dermatological field. The Furey apparatus was used by Appeldoorn and Barnett to determine the "slip" characteristics of raw materials and formulated products for topical application (670). Tillman and Higuchi examined the effects of some electrolytes and nonelectrolytes on callus tissue by stress-relaxation studies (671). A method was developed for testing percutaneous absorption in animals (672), and the influence of an organo-silicon complex of potassium salicylate on percutaneous absorption was also evaluated (673). The absorption of salicylic acid (674) and methyl- and glycol-salicylate (675) from various types of bases was explored. Siebert observed the percutaneous absorption of radioactive camphors from ointments (676). Benzalkonium chloride was demonstrated to penetrate the epidermis only if the barrier layer was damaged by alkalies, lipid solvents, or stripping with pressure-sensitive tape (677).

Kinetic Studies.—The interaction of one or more drugs with different receptors was reviewed as a molecular basis for drug action (678). A different review discussed the simultaneous use of two drugs which may involve changes in potency (679). Another worker commented on the relationship between elimination rate of drugs and rate of decline of their pharmacologic effects (680). Absorption rates from drug implants have been found to be dependent upon body temperature (681). Cummings *et al.* analyzed the kinetics of elimination for simultaneous first-order and zero-order processes (682). Other investigators suggested a statistical method of fitting theoretical equations to blood level data (683) and the use of per cent absorbed *versus* time plots to analyze blood and urine data during the absorptive phase after single doses of drug (684). The analog computor was employed to predict multiple-dose serum levels of an antibiotic from single-dose data when administered by constant rate intravenous infusion (685). A digital computer also indicated that unexpected deviations in absorption data were clinically important when considering drug action and dosage (686).

Nelson published a review on the kinetics of acetylation and excretion of sulfonamides (687); other aspects on the absorption of sulfonamides from the stomach (688) and intestine (689) along with excretion from the kidney (690) were disclosed by Koizumi *et al.* Long-term excretion studies with labeled vitamin B_{12} were conducted clinically (691). Vitamin A was found to accumulate in the intestinal wall with a kinetic process analogous to the Michaelis-Menton kinetics (692). Salicylic acid was used to study the inter- and intrasubject variations in drug absorption kinetics (693). These authors recommended individual adjustment of the dosage schedule based on elimination rate to prevent drug accumulation or gradual decline to subtherapeutic levels (694). A mathematical model involving three consecutive first-order reactions expressed hourly variations in serum levels after varying repeated doses in humans (695). The effect of site and pathologic state on the rate of absorption of cortisol was published (696).

Drug Absorption.—Studies with labeled vitamins concluded that maximum absorption of riboflavin occurred in the lower ileum in 2–4 hr., and optimal absorption of thiamine took place in the small intestine in 1 hr. (697). Data were presented to demonstrate magnesium and calcium as regulators of intestinal permeability (698). Blood levels of isopropylantipyrine, when administered concurrently with several other drugs, were measured by Naito (699). Beal evaluated some of the factors influencing binding of radioactive vitamin B_{12} to plasma protein (700). A method for adjusting rates of absorption with fused conglomerates of urea and chloramphenicol has been suggested (701). Triamcinolone was studied clinically for its effectiveness in a once-a-day dosage regimen (702). α-Ethylcaproic acid

was reported as increasing the absorption of ^{14}C-cholesterol *in vivo* (703). A different absorption study compared the eosinopenic effect after oral and rectal doses of prednisone (704). Dawson *et al.*, in a comparative study on absorption of short-chain fatty acids, found that the longer-chain acids were absorbed more rapidly—this was attributed to their greater lipid solubility (705). The effect of ascorbic acid on the excretion of the potassium salt of penicillin V was reported (706); another publication reviewed the factors affecting the renal excretion of unmetabolized drugs (707). The application of silicones and quaternary ammonium compounds in dermatological formulations was discussed (708).

Cummings and Martin investigated some of the factors influencing plasma salicylate concentration and urinary salicylate excretion after oral dosage with aspirin (709). Other researchers studied the effect of gastric emptying time, dissolution rates, and gastric pH on the rate of aspirin absorption (710). The complexation of aspirin with a silicone antacid depicted prolonged blood levels in the dog (711). The biochemical mechanism of gastric erosion caused by aspirin and certain other salicylates has been reported in separate papers (712, 713). In a similar study, erosive gastritis was reported to occur after oral adminstration of plain aspirin, buffered aspirin, or sodium salicylate; oral administration of effervescent buffered aspirin or intravenous administration of sodium salicylate did not exhibit erosion (714). Davenport claimed that diffusion of the fat-soluble form of fatty and acetylsalicylic acids through the mucosa causes the changes responsible for gastric injury (715).

PHARMACOGNOSY[1]

Scheindlin published a review on new developments in plant drugs (716), and Nordal listed more than 400 medicinal plants and crude drugs of Burma (717). Other reviews were concerned with the source of several chemical constituents such as polyacetylenes (718), coumarins (719), pseudoquinone, and yohimbin alkaloids (720), and anticancer alkaloids of *Vinca rosea* (721). Another survey revealed the structure-activity relationship and pharmaceutical applications of anthracene derivatives found in medicinal plants (722). The tumorous phenomena in plants and their relationship to the problem of cancer have been examined (723). Sorm discovered evidence of olefins in plant waxes (724); Wahba and Sinsheimer found coniferyl aldehyde as a constituent of oils containing eugenol (725). In a study with alloxan-diabetic rats, several types of plants were demonstrated to possess antidiabetic effects (726).

Pharmacognostic Investigations.—This section of the review is primarily concerned with those references pertaining to isolation and identification of plant constituents. Table I lists alphabetically each plant studied, followed by the appropriate references to the bibliography.

Methodology.—The effect of deuterium oxide on the growth of *Mentha piperita* was discussed in three different articles (986–988). Bennett and Sciuchetti studied the effects of various growth regulators on the alkaloid content of *Datura meteloides* (989). A factorial experimental design with 320 plants was used by the latter author to investigate the effect of various concentrations and frequency of application of gibberellic acid on *Datura stramonium* (990). Radioactive proline was utilized to study its role in the biosynthesis of tropane alkaloids in *Datura stramonium* and *Datura innoxia* (991). Research on the biosynthesis of sterols tagged with ^{14}C-mevalonic acid in *Solanum tuberosum* has also been conducted (992). The alkaloid content of *Stramonium* species was improved by generative hybridization (993). Another paper was concerned with the desiccation and stabilization of medicinal plants containing flavonic heterosides (994). In a comparative study, the best method of drying for conversion of primary glucosides of *Digitalis purpurea* to readily absorbed glucosides has been proposed (995). The presence of sulfur dioxide prevented complete extraction of vanillin, but this difficulty was overcome by first removing the sulfur dioxide in a current of air (996). Several papers reported the use of ultrasound in the extraction of plants: preparations from the cortex of *Rhamni frangulae* were noted (997); the increase of the alkaloid yield from *Datura stramonium* (998) and of belladonna alkaloids (999) was observed; it was also utilized in the extraction of morphine (1000). In another paper on isolation methods, Steiger-Trippi recommended turboextraction for removal of alkaloids from cinchona bark (1001). Separation of certain phenols from alfalfa was accomplished by countercurrent distribution (1002), and the extraction of several alkaloids from *Salsola richleri* was conducted by ion exchange (1003). Extraction of alkaloids by electrodialysis was discovered to be an effective procedure (1004). Another publication suggested a new method to improve the antimicrobial spectrum of biflorin extracted from *Capraria biflora* (1005).

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TABLE I.—PHARMACOGNOSTIC INVESTIGATIONS

Plant	Ref.
A	
Acacia melanoxylon	(727)
Acer species	(728)
Achillea fragrantissima	(729, 730)
Achillea millefolium	(731)
Acokanthera spectabilis	(732)
Aconitum bullatifolium	(733)
Aconitum laeve	(734)
Actaea spicata	(735)
Adenocarpus species	(736)
Afrormosia elata	(737)
Agave americana	(738)
Ailanthus altissima	(739)
Albizzia procera	(740)
Aporphine alkaloids	(741)
Aquilegia species	(742, 743)
Argyrolobium megarhizum	(744)
Artemisia species	(745)
Aspidosperma species	(746–748)
Atherosperma moschatum	(749)
Atractylis gummifera	(750)
B	
Berberis serrata	(751)
Bryonia dioica	(752)
Bupleurum plantagineum	(753)
Butea frondosa	(754)
Buxus sempervirens	(755)
C	
Calendula officinalis	(756)
Calumba species	(757)
Calvatia species	(758)
Carum carvi	(759)
Carya illinoensis	(760)
Cassia angustifolia	(761)
Cassia excelsa	(762)
Catharanthus lanceus	(763)
Centrosema plumari	(764)
Chamaecyparis obtusa	(765)
Chimaphila japonica	(766)
Christisonia bicolor	(767)
Chrysanthemum cinerariaefolium	(768)
Cimicifuga racemosa	(769)
Cinnamomum camphora	(770)
Claviceps gigantea	(771)
Codium fragile	(772)
Colchicum autumnale	(773)
Conopharyngia durissima	(774)
Convallaria keiskei	(775)
Convallaria majalis	(776)
Corydalis species	(777–781)
Crataegus species	(782, 783)
Crotalaria species	(784–786)
Cymbopogon citratus	(787)
Cyperus articulatus	(788)
Cytisus austriacus	(789)
D	
Datura species	(790–795)
Daucus carota	(796)
Delphinium consolida	(797)
Desmodium pulchellum	(798)
Dichapetalum toxicarium	(799)
Dictamnus albus	(800)
Digitalis grandiflora	(801, 802)
Digitalis thapsi	(803)
Dryopteris felix-mas	(804)
E	
Ecballium elaterium	(805)
Ergot alkaloids	(806)
Erythroxylon monogynum	(807)
Eucalyptus species	(808)
Euptelea polyandra	(809)
F	
Fagraea fragrans	(810)
Ferula communis	(811)
Festuca elatior	(812)
Ficus carica	(813)
Filipendula species	(814)
Firmiana platanifolia	(815)
Foeniculum dulce	(816)
Furcraea gigantea	(817)
G	
Galanthus nivalis	(818)
Galium ruthenicum	(819)
Gardenia jasminoides	(820)
Genista pilosa	(821)
Gentiana bellidifolia	(822)
Geranium species	(823)
Ginseng species	(824)
Girardinia heterophylla	(825)
Gnaphalium affine	(826)
Gymnema sylvestre	(827)
H	
Harungana madagascariensis	(828)
Heimia species	(829–831)
Helenium amarum	(832)
Heliotropium strigosum	(833)
Helleborus cyclophyllus	(834)
Helleborus odorus	(835)
Heracleum species	(836–839)
Herpestis monnieria	(840)
Hunteria eburnea	(841)
Hypericum species	(842–845)
I, K	
Illicium verum	(846)
Inocybe species	(847)
Ipomea rubrocoerulea	(848)
Iriartea ventricosa	(849)
Kaempferria pandurata	(850)
L	
Laburnum alpinum	(851)
Lagochiline species	(852)
Lampteromyces japonicus	(853)
Lecidea pantherina	(854)
Leonotis leonurus	(855)
Leucojum aestivum	(856)
Libanotis intermedia	(857)
Lithospermum officinale	(858)
Lobelia species	(859, 860)
Lolium perenne	(861)
Lupinus luteus	(862)
Lycopodium species	(863–866)
M	
Magnolia acuminata	(867)
Marrubium vulgare	(868)
Mechilus thunbergii	(869)
Menispermum dauricum	(870)
Mentha species	(871–873)
Morina longifolia	(874)
Morinda citrifolia	(875)
N	
Nardostachys jatamansi	(876)
Nelumbo nucifera	(877)
Nerium oleander	(878)
Nigella sativa	(879)
Nuphar luteum	(880)
O, P	
Ocimum species	(881)
Ocotea species	(882–884)
Pachysandra terminalis	(885, 886)

Plant	Ref.
Panax ginseng	(887, 888)
Pancratium species	(889, 890)
Papaver species	(891–893)
Pausinystalia yohimbe	(894)
Phaeanthus ebracteolatus	(895)
Phaeolus schweinitzii	(896)
Phaseolus coccineus	(897)
Phylica rogersii	(898)
Phyllanthus discoides	(899, 900)
Picralima nitida	(901)
Piper chaba	(902)
Platydesma campanulata	(903)
Polyporos umbellatus	(904)
Poncirus trifolialata	(905)
Populus nigra	(906)
Populus trichocarpa	(907)
Premna integrifolia	(908)
Primula officinalis	(909)
R	
Ranunculaceae septentrionales	(910)
Rauwolfia perakensis	(911)
Rauwolfia serpentina	(912)
Retama duriaei	(913)
Rhamnus purshiana	(914)
Rheum species	(915–917)
Rhododendron maximum	(918)
Rhodotorula graminis	(919)
Rhus javanicus	(920)
Ricinus species	(921)
Rivea corymobosa	(922)
Ruscus alexandrinus	(923)
S	
Salix viminalis	(924)
Salvia divinorum	(925)
Salvia officinalis	(926)
Sanguisorba officinalis	(927)
Sarcococca pruniformis	(928)
Sciadopitys verticillata	(929)
Scutia buxifolia	(930)
Scylla nonscripta	(931)
Secale concentratum	(932)
Securigera securidaca	(933)
Securinega virosa	(934, 935)
Selinum vaginatum	(936)
Sesbania grandiflora	(937)
Silax purpurea	(938)
Solanum species	(939–943)
Sophora species	(944)
Stephania japonica	(945)
Sterculia tragacantha	(946)
Stipa vaseyi	(947)
Streblus asper	(948)
Styrax officinalis	(949)
Succus glycyrrhizae	(950)
Sweetia panamensis	(951)
Symplocos celastrinea	(952)
T	
Tabebeuia avellanedae	(953)
Tagetes minuta	(954)
Tanacetum pseudoachillea	(955)
Teclea grandifolia	(956)
Thalictrum pedunculatum	(957)
Thermopsis fabacea	(958)
Thuja occidentalis	(959)
Trigonella corniculata	(960)
Tropaeolum majus	(961)
Turbina corymbosa	(962)
U	
Uncaria gambier	(963, 964)
Ungernia severtzovii	(965)
Ungernia victoris	(966)
V	
Valencia species	(967)
Valeriana wallichi	(968)
Veratrum species	(969)
Vertiveria zizanioides	(970)
Viburnum opulus	(971)
Vinca species	(972–976)
Virgilia oroboides	(977, 978)
Voacanga globosa	(979)
Voacanga schweinfurthii	(980)
X, Z	
Xanthium italicum	(981)
Xanthorrhiza apiifolia	(982)
Xanthorrhiza simplicissima	(983)
Zephyranthes candida	(984)
Zingiber officinale	(985)

CONCLUSION

The number of references included in this review illustrates the vast amount of recently published information available to the pharmaceutical scientist. It was intended that this survey would present a comprehensive view of the research and development efforts in the various disciplines of pharmaceutical science.

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