

# bibliography

This bibliography lists the works cited specifically in the report as well as additional works which were used as reference materials.

Academy of Pharmaceutical Sciences: *Drug Product Quality*. Washington, 1969.

American Pharmaceutical Association: The Pharmacist's Role In Product Selection. *APhA White Paper*. Washington, 1968.

American Pharmaceutical Association: *The Bioavailability of Drug Products*. (The APhA Bioavailability Pilot Project), Washington, 1973.

American Pharmaceutical Association Ad hoc Committee: Report of the ad hoc committee on drug product selection of the academy of general practice of pharmacy and the academy of pharmaceutical sciences. *J. Am. Pharm. Assoc.* NS13 (NO. 6), 1973.

Anon.: Tetracycline and salicylamide as model drugs to illustrate methods and problems in assessing systemic availability. *Drug Information Bulletin* pp. 30-35, (Jan./Jun.) 1969.

Anon.: Erythromycin estolate versus erythromycin stearate. *Med. J. Aust.* 2:1203-1204, (May 28) 1971.

Apple, W.S. : Statement before the Subcommittee on Health, Committee on Labor and Public Welfare, United States Senate, (Jan.) 1974.

Arnold, K., Gerber, N., and Levy, G.: Absorption and dissolution studies on sodium diphenylhydantoin capsules. *Canadian Journal of Pharmaceutical Science* 5 (No. 4):89-92, 1970.

- Barr, W.H., Gerbracht, L.M., Letchen, K., Plaut, M., and Strahl, N.: Assessment of the biologic availability of tetracycline products in man. *Clin. Pharmacol. Ther.* 13 (No. 1):97-108, (Jan./Feb.) 1972.
- Bell, S.M.: A comparison of absorption after oral administration of erythromycin estolate and erythromycin stearate. *Med. J. Aust.* -:1280-1283, (Dec. 18) 1971.
- Blair, D.C., Barnes, R.W., Wildner, E.L., and Murray, W.J.: Biological availability of oxytetracycline HCl capsules: a comparison of all manufacturing sources supplying the United States market. *JAMA* 215 (No. 2):251-254, (Jan. 11) 1971.
- Brice, G.W., and Hammer, H.F.: Therapeutic non-equivalency of oxytetracycline capsules. *Drug Information Bulletin* pp. 112-114, (Jan./June) 1969.
- Brodie, B.B., and Heller, W.M. (eds.): *Bioavailability of Drugs*. New York, Karger, 1972.
- Cadwallader, D.E.: Nitrofurantoin. *J. Am. Pharm. Assoc.* NS13 (July) 1973.
- Canadian Food and Drug Directorate: Papers from the Symposium on The Physiological Equivalence of Drug Dosage Forms. Ottawa, Queens Printer for Canada. (Catalogue #H 44-2969), 1970.
- Catz, B., Ginsburg, E., and Salenger, S.: Clinically inactive thyroid, U.S.P. a preliminary report. *New Eng. J. Med.* 266:136-137, (January 18) 1962.
- Chapman, D.G., Crisafio, R., and Campbell, J.A.: The relation between in vitro disintegration time of sugar-coated tablets and physiological availability of riboflavin. *J. Am. Pharm. Assoc.* XLIII (No. 5):297-304, (May) 1954.
- Chasseaud, L.F., and Taylor, T.: Bioavailability of drugs from formulations after oral administration. *Annu. Rev. Pharmacol.* 14:35-46, 1974.
- Chiou, W.L.: "Determination of physiological availability of commercial phenylbutazone preparations. *J. Clin. Pharmacol.* 12:296-299, (July) 1972.

- Chodos, D.J., and DiSanto, A.R.: *Basics of Bioavailability and Description of Upjohn Single-Dose Study Design*. Kalamazoo, Upjohn, 1973.
- Committee of Revision: *The Pharmacopoeia of the United States of America XVIII*. Bethesda, United States Pharmacopoeial Convention, Inc. , 1970.
- Cook, D.: Canadian experience. Panel discussion on case histories in bioavailability of drugs, the Proceedings of the Conference on Bioavailability of Drugs, Washington, United States Pharmacopoeia Convention, Inc., pp. 190-195, 1971.
- Davis, C.M., Vandersarl, J.V., and Kraus, E.W.: Tetracycline inequivalence: the importance of 96-hour testing. *Am. J. Med. Sci.* 265 (No. 1): 69-74, (Jan.) 1973.
- Division of Medical Sciences, National Research Council: *Drug Efficacy Study*. Washington, D.C., National Academy of Sciences, 1969.
- Drug Quality and Therapeutics Committee: *PARCOST Comparative Drug Index*. Ontario, Canada, 1974.
- Dyer, A.E. : Ontario experience in selecting quality drugs. Paper presented to the American Association for the Advancement of Science, 1974.
- Edwards, C.C. , Statement before the Subcommittee on Health, Committee on Labor and Public Welfare, United States Senate, (Jan.) 1974.
- Feldman, E.G.: Brand name system--an intrusion upon the profession. *J. Am. Pharm. Assoc.* NS11 (No. 7) :376-379, 390, (July) 1971.
- Feldman, E.G., Brand versus generic drugs. *J. Am. Pharm. Assoc.* NS9 (No. 1):8-13, (Jan.) 1969.
- Feldman, E.G., Drug product selection--freedom with responsibility. *J. Am. Pharm. Assoc.* NS12 (No. 7), (July) 1972.
- Francke, D.E.: The pharmacist's dilemma: drug product selection using bioavailability data. *Drug Intelligence and Clinical Pharmacy* ~:443-450; (Oct.) 1973.

- Geekie, D.A.: Bioavailability: report of the special advisory committee to the health protection branch, DNH&W. *Can. Med. Assoc. J.* 109:920-921, (Nov. 3) 1973.
- Glazko, A.J.: Diphenylhydantoin. Panel Discussion on Case Histories in Bioavailability of Drugs, the Proceedings of the Conference on the Bioavailability of Drugs, Washington, United States Pharmacopeial Convention, Inc., pp. 163-177, 1971.
- Glazko, A.J., Kinkel, A.W., Alegnani, W.C., and Holmes, E.L.: An evaluation of the absorption characteristics of different chloramphenicol preparations in normal human subjects. *Clin. Pharmacol. Ther.* 9' (No. 4):472-483, 1968.
- Griffith, R.S. and Black, H.R., Comparison of blood levels following pediatric suspensions of erythromycin estolate and erythromycin ethyl succinate. *Clinical Medicine*, pp. 16-18, (June) 1969.
- Harris, R.: *The Real Voice*. New York, MacMillan, 1964.
- Hayden-Stone, Inc.: *The Health Care Industry*. Washington, Hayden-Stone, Inc., 1974.
- Leeson, L.J., Phenylbutazone. Panel Discussion on Case Histories in Bioavailability of Drugs, the Proceedings of the Conference on Bioavailability of Drugs, Washington, United States Pharmacopeial Convention, Inc., pp. 154-163, 1971.
- Levy, G.: Bioavailability of drugs: focus on digoxin. *Circulation* XLIX:391-400, (March) 1974.
- Levy, G. and Nelson, E. : United States Pharmacopoeia and National Formulary standards, Food and Drug Administration regulations, and the quality of drugs. *N.Y. State J. Med.* 61 (No. 23):4003-4008, (Dec. 1) 1961.
- Lindenbaum, J., et al: Variations in biological availability of digoxin from four preparations. *N. Eng. J. Med.* 285:1344, 1971.
- MacDonald, H., Pisano, F., Burger, J., Dornbush, A., and Pelcak, E.: Physiological availability of various tetracyclines. *Clinical Medicine* pp. 30-33, (Dec.) 1969.

- Macek, T.J.: Influence of product formulation on therapeutic activity. *Minnesota Pharmacist* pp" 17 ff., (Nov.) 1963.
- MacLeod, C., Rabin, H. , Reudy, J., Caron, M. , Zaroway, D., Davies, R.O.: Comparative bioavailability of three brands of ampicillin. *Can. Med. Assoc. J.* 107:203-209, 1972.
- Mattock, G.L. , Hossie, R.D., McGilveray, I.J.: In vivo-in vitro studies of nitrofurantoin tablets. *Canadian Journal of Pharmaceutical Sciences* 7 (No. 3):84-87, 1972.
- Middleton, E.J., Davies, J.M. , and Morrison, A.B.: Relationship between rate of dissolution, disintegration time and physiological availability of riboflavin in sugar-coated tablets. *J. Pharm. Sci.* 53 (No. 11):1378-1380, (Nov.) 1964.
- Morrison, A.B. and Campbell, J.A.: The relationship between physiological availability of salicylates and riboflavin and in vitro disintegration time of enteric coated tablets. *J. Am. Pharm. Assoc.* 49 (No. 7):473-478, (July) 1960.
- Nadel, M.V.: *The Politics of Consumer Protection.* New York, Bobbs-Merrill, 1971.
- "National Formulary Board: *National Formulary XIII.* Washington, American Pharmaceutical Association, 1970.
- Olson, T.N.T. and Lee, I.: Application of statistical methodology in quality control functions of the pharmaceutical industry. *J. Pharm. Sci.* 55 (No. 1):1-14, (Jan.) 1966.
- O'Reilly, R.A.: Sodium warfarin. Panel Discussion on Case Histories In Bioavailability of Drugs, the Proceedings of the Conference on Bioavailability of Drugs, Washington, United States Pharmacopoeia Convention, Inc. pp. 181-190.
- Pentikainen, P., Wan, S.H., and Azarnoff, D.L.: Bioavailability studies on p-aminosalicylic acid and its various salts in man. *Am. Rev. Respir. Dis.* 108:1340-1347, 1973.
- Pernarowski, M. : Bioavailability in drug therapy. *Canadian Pharmaceutical Journal* (Feb.) 1971.

- Pharmaceutical Manufacturers Association: *Brands, Generics, Prices and Quality*. Washington, Pharmaceutical Manufacturers Association, 1971.
- Poole, J.W., Owen, G., Silverio, J., Freyhof, J.N., and Rosenman, S.B.: Physiochemical factors influencing the absorption of the anhydrous and trihydrate forms of ampicillin. *C u r r . Ther. Res.* **10**(No. 6):292-303, (June) 1968.
- Proposed Bioavailability Requirements*. 'Federal Register 38 (No. 3), (Jan. 5) 1973.
- Ritschel, W.A.: Bioavailability in the clinical evaluation of drugs. *Drug Intelligence and Clinical Pharmacy* **6**:-:246-256, (July) 1972.
- Schirmer, R.E., Kleber, J.W., and Black, H.R.: Correlation of dissolution, disintegration, and bioavailability of aminosalicyclic acid tablets. *J. Pharm. Sci.* **62** (No. 8):1270-1274, (Aug.) 1973.
- Schneller, G.H.: The hazard of therapeutic non-equivalency of drug products. *Drug Information Bulletin* pp. 100-104, (Jan./June) 1969.
- Schumaker, G.E.: Biopharmaceutics and dosage form design, keeping bioavailability in perspective. *Am. J. Hosp. Pharm.* **30**:150-154, (Feb.) 1973.
- Silverio, J., and Poole, J.W.: Serum concentrations of ampicillin in newborn infants after oral administration. *Pediatrics* **51** (No. 3):578-580, (Mar.) 1973.
- Slessor, A.E.: The myth of drug product "equivalency." Presented at the meeting of the Hillsboro County Medical Association, (June 1) 1965.
- Stetler, C.J., Statement before the Subcommittee on Health, Committee on Labor and Public Welfare, United States Senate, (Jan.) 1974.
- Stoll, R.G., Bates, T.R., and Swarbrick, J.: In vitro dissolution and in vivo absorption of nitrofurantoin from deoxycholic acid coprecipitates. *J. Pharm. Sci.* **62** (No. 1):65-68, (Jan.) 1973.

- Tyrer, J. H., Eadie, M. J., Sutherland, J. M.,  
and Hooper, W.D. : Outbreak of anticonvulsant  
intoxication in an Australian city. *Br. Med. J.*  
4:271-274, (Oct. 31) 1970.
- United States: *Code of Federal Regulations*,  
Title 21, April 1973.
- U.S. Department of Health, Education, and Welfare:  
*Final Report of the Task Force on Prescription  
Drugs.* Task Force on Prescription Drugs,  
Washington, Government Printing Office, 1969.
- US. Department of Health, Education, and Welfare:  
Guidelines: manufacturing and controls for  
IND's and NDA's. *FDA Papers*, Food and Drug  
Administration, Washington, Government Printing  
Office, 1971.
- Us. Department of Health, Education, and Welfare:  
*Report of the Secretary 's Review Committee  
of the Task Force on Prescription Drugs.* Office  
of the Secretary, Washington, Government Printing  
Office, 1969.
- Us. Department of Health, Education, and Welfare:  
*Significant Dates in Food and Drug Law History*,  
Food and Drug Administration, Washington,  
Government Printing Office, 1968.
- VanPetten, G.R., Becking, G.C., Withey, R.J., and  
Lettau, H.F.: Studies on the physiological  
availability and metabolism of sulfonamides.  
*J. Clin. Pharmacol.* pp. 27-34, (Jan./Feb.) 1971.
- VanPetten, G.R., Feng, H., Withey, R.J., and Lettau,  
H.F.: The physiological availability of solid  
dosage forms of phenylbutazone. *J. Clin.  
Pharmacol.* 11:177-196, (May/June) 1971.
- Wagner, J.G.: *Biopharmaceutics and Relevant  
Pharmacokinetics.* Hamilton, Ill., Drug  
Intelligence Publications, 1971.
- Wagner, J.G., Welling, P.G., Kwang, P.L., and  
Walker, J.E.: In vivo and in vitro availability  
of commercial warfarin tablets. *J. Pharm. Sci.*  
60 (No. 5):666-677, (May) 1971.
- Wagner, J.G., et al: Equivalence lack in digoxin  
plasma levels. *JAMA* 224:199, 1973.

- Wagner, J.G., Wilkinson, P.K. , Sedman, A.J. ,  
and Stoll, R.G.: Failure of USP tablet  
disintegration test to predict performance in  
man. *J. Pharm. Sci.* 62 (No. 5):859-860,  
(May) 1973.
- Weinberger, C.W.: Statement before the Subcommittee  
on Health, Committee on Labor and Public Welfare,  
United States Senate (Dec.) 1973.
- Westlake, W.J.: Use of confidence intervals in  
analysis of comparative bioavailability trials.  
*J. Pharm. Sci.* 61 (No. 8):1340-1341, (Aug.)  
1972.
- Wiener, Harry: *Generic Drugs: Safety and Effective-  
ness.* New York, Pfizer, Inc. 1973.
- World Health Organization: *Bioavailability of  
Drugs.* World Health Organization Technical  
Report Series No. 536, Geneva, 1974.

#### CONFIDENTIAL DOCUMENTS

Documents and communications for confidential  
review by the Panel and staff were received from:

American Pharmaceutical Association

Bureau of Drugs, Food and Drug Administration, U.S.  
Department of Health, Education, and Welfare.

Health Protection Branch, Department of National  
Health and Welfare, Canada

Lederle Laboratories Division, American Cyanamid  
Company

National Association of Pharmaceutical Manufacturers

National Formulary Board

Pfizer, inc.

Pharmaceutical Manufacturers Association

Softcon Products Division, Warner-Lambert Laboratories

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