

LEON SHARGEL, Ph.D., R.Ph.

Adjunct Professor, School of Pharmacy 1995 -
UNIVERSITY OF MARYLAND, Baltimore, MD

PREVIOUS EXPERIENCE

Vice President and Technical Director 1997 - 2001
NATIONAL ASSOCIATION OF PHARMACEUTICAL MANUFACTURERS
Ronkonkoma, New York 11779

Senior Research Pharmacist 1996 -1997
JOHNS HOPKINS BAYVIEW MEDICAL CENTER, Baltimore, MD 21224

Adjunct Visiting Associate Professor of Pharmacy 1995 - 1996
School of Pharmacy and Pharmacal Sciences
HOWARD UNIVERSITY, Washington, DC

Vice President, Scientific Affairs 1995
PHARMAKINETICS LABORATORIES, INC., Baltimore, MD

Director of Biochemistry and Pharmacokinetics 1993 - 1994
FOREST LABORATORIES, INC., New York, NY

Director of Pharmacokinetics 1991- 1993
CHELSEA LABORATORIES, INC., West Hempstead, NY

Associate Professor, Pharmacy and Pharmacology 1982-1991
Director of Pfeiffer Pharmaceutical Sciences Laboratory, Inc.,
MASSACHUSETTS COLLEGE OF PHARMACY AND ALLIED HEALTH SCIENCES,
Boston, MA

Section Leader, Pharmaceutics 1975-1982
Associate Professor of Pharmacy and Pharmacology
NORTHEASTERN UNIVERSITY, College of Pharmacy and Allied Health Professions,
Boston, MA

Associate Research Biologist and Group Leader,
Drug Metabolism and Disposition, 1969-1975
STERLING-WINTHROP RESEARCH INSTITUTE, Rensselaer, NY

EDUCATION

Ph.D. Major: Pharmacology, Minors: Physiology, Biochemistry, Drug Metabolism
The George Washington University, Medical Center, Washington, DC

B.S. (Cum laude) Pharmacy, University of Maryland, Baltimore, Maryland

REGISTERED PHARMACIST

District of Columbia, Massachusetts, Maryland

TEXTBOOKS AND CHAPTERS

- | | |
|---|--|
| Shargel L and Yu ABC
<i>Applied Biopharmaceutics and Pharmacokinetics</i>
McGraw-Hill
New York, NY | First Edition 1980
Italian Edition 1984
Second Edition 1985
Third Edition 1993
Fourth Edition 1999
Chinese Edition 2002 |
| Shargel L, Wu-Pong S and Yu ABC
<i>Applied Biopharmaceutics and Pharmacokinetics</i>
McGraw-Hill, New York, NY | Fifth Edition 2005 |
| Shargel L
Editor, <i>Comprehensive Pharmacy Review</i>
Lippincott William & Wilkins
Baltimore, MD | First Edition 1989
First Canadian Edition 1992
Second Edition 1994
Third Edition 1997
Fourth Edition, 2001
Fifth Edition 2004 |
| Shargel L
Associate Editor
<i>Study Guide and Board Review. Pharmacy Practice Exam</i>
Lippincott Williams & Wilkins
Baltimore, MD | First Edition 1989
Second Edition 1994
Third Edition 1998
Fourth Edition, 2001
Fifth Edition 2004 |
| Shargel L, Editor
<i>Comprehensive Pharmacy Review</i> , CD-ROM
Lippincott William & Wilkins, Baltimore, MD | First Edition 2003
Second Edition 2004 |
| Shargel L and Kanfer I (eds)
<i>Development of Generic Drug Products: Solid Oral Dosage Forms</i>
Marcel Dekker, Inc., New York, NY, 2005 | |

CHAPTERS

- Shargel L, Yu ABC: "Biopharmaceutics" In: Encyclopedia of Pharmaceutical Technology, 2nd edition, J. Swarbrick and J.C. Boylan (Ed), Marcel Dekker, Inc., 2002, pp 156-176 Also in: Encyclopedia of Clinical Pharmacy, J. DiPiro (ed), Marcel Dekker, Inc., 2003
- Amann AH, Shargel L: "Drug Product Development in the Pharmaceutical Industry," in *Comprehensive Pharmacy Review*, L. Shargel (ed), NMS Series, Williams & Wilkins, Baltimore, Second edition, 1993, Chapter 1; Third edition, 1997, Chapter 1, Lippincott Williams & Wilkins, Baltimore, Fourth Edition, 2001, Chapter 1, Fifth Edition, Chapter 1, 2003
- Shargel L: "Pharmacokinetics," in *Comprehensive Pharmacy Review*, L. Shargel (ed), National Medical Series, Williams & Wilkins, Baltimore, First edition, 1989; Second edition, 1993; Third edition, 1996, Chapter 6.

Shargel L: "Basic Pharmacokinetics," in *Comprehensive Pharmacy Review*, L. Shargel (ed Series, Lippincott Williams & Wilkins, Baltimore, Fourth edition, 2001, Chapter 6, Fifth Edition, Chapter 6, 2003

Shargel L: "Bioavailability and Bioequivalence," in *Comprehensive Pharmacy Review*, L. Shargel (ed), NMS Series, Williams & Wilkins, Baltimore, First edition, 1989; Second edition, 1993; Third edition, 1996; Lippincott Williams & Wilkins, Baltimore, Fourth edition, 2001, Chapter 7. Fifth Edition, Chapter 7, 2003

Harrold MW, Yee NS, Shargel L: "Principles of Pharmacodynamics and Medicinal Chemistry," in *Comprehensive Pharmacy Review*, L. Shargel (ed), Lippincott Williams & Wilkins, Baltimore, Fourth edition, 2001, Chapter 12.

Harrold MW, Engelbrecht AC, Shargel L: "Drug Metabolism and Drug Interactions," in *Comprehensive Pharmacy Review*, L. Shargel (ed), Lippincott Williams & Wilkins, Baltimore, Fourth edition, 2001, Chapter 12.

Yee NS, Shargel L: "Pharmacodynamics," in *Comprehensive Pharmacy Review*, L. Shargel (ed), NMS Series, Williams & Wilkins, Baltimore, Third edition, 1997, Chapter 13.

Shargel L: "Drug Interactions," in *Comprehensive Pharmacy Review*, L. Shargel (ed), NMS Series, Williams & Wilkins, Baltimore, Third edition, 1997, Chapter 20.

Defelice MJ, Grossman S, Shargel L: "Extemporaneous Prescription Compounding," in *Comprehensive Pharmacy Review*, L. Shargel (ed), National Medical Series, Williams & Wilkins, Baltimore, Second edition, 1993, Chapter 5.

Engelbrecht AC, Shargel L: " Drug-Drug and Drug-Nutrient Interactions," in *Comprehensive Pharmacy Review*, L. Shargel (ed), Lippincott Williams & Wilkins, Baltimore, Fifth edition, 2003, Chapter 18.

Shargel L: "Biopharmaceutics" In: *Encyclopedia of Pharmaceutical Technology*, J. Swarbrick and J.C. Boylan (Ed), Marcel Dekker, Inc., New York, 1990.

Shargel L, Kanfer I: Introduction to Generic Drug Product Development, in *Development of Generic Drug Products: Solid Oral Dosage Forms*, Shargel L, Kanfer I (eds), Marcel Dekker, Inc., New York, 2005

Ciganek SM, Mehta AJ, Mellina FJ, Shargel L: *Scale-up, Post-approval Changes and Post-marketing Surveillance*, in *Development of Generic Drug Products: Solid Oral Dosage Forms*, Shargel L, Kanfer I (eds), Marcel Dekker, Inc., New York, 2005

RESEARCH PAPERS

Hurwitz SJ, Coleman NC, Riese N, Loeffler JS, Alexander E, Buswell L, Neben TY, Shargel L, Kramer RK: Distribution of etanidazole into human brain tumors: Implications for treating high grade gliomas, *Int J Rad Onc Biol Phys* 22:573-576, 1992.

Shargel L, Silverman HI, Cohen P, Brisson J, Dennis S. Bioavailability and cardiovascular safety of Dexatrim^R (Phenylpropanolamine Hydrochloride) from a Controlled Release Caplet. *Biopharm Drug Dispos* 11:569-583 (1990).

Chungi VS, Dittert LW, and Shargel L. Pharmacokinetics of sulfasalazine metabolites in rats following concomitant oral administration of riboflavin. *Pharm Res* 6: 1067-1072 (1989).

- Chungi VS, Rekhi GS, and Shargel L. A simple and rapid liquid chromatographic method for the determination of major metabolites of sulfasalazine in biologic fluids. J Pharm Sci 78: 235-238 (1989).
- DiFazio ML, Shargel L: A mathematical utility program to facilitate student comprehension of the pharmacokinetics of the one compartment model. Amer J Pharm Ed 53: 50-53 (1989).
- Wiener B, Melby MJ, Faraci PA, Shargel L, Cleveland, RJ: Cefamandole pharmacokinetics during standard and pulsatile cardiopulmonary bypass. J Clin Pharmacol 28: 655-659 (1988).
- Figge HS, Figge V, Souney PF, Sacks FM, Shargel L, Kaul AF: Comparison of excretion of nicotinic acid after ingestion of two controlled release nicotinic acid preparations in man. J Clin Pharmacology 28: 1136-1140 (1988).
- DePiero D, Rehki GS, Souney PF, Shargel L: Stability of morphine sulfate solutions frozen in polyvinyl chloride intravenous bags. Pharmacy Practice News pp 1, 39, 40, October (1987).
- Yee NS, Shargel L: Effect of cimetidine or ranitidine on hepatic mixed function oxidase activity in the rat. Drug Metab Dispos 14: 580-584, 1986.
- Clarke DF, Werbosky OL, Grodin MLL, Shargel L: Conversion from intravenous to sustained release oral theophylline in pediatric patients with asthma. Drug Intel Clin Pharm 20: 700-703, 1986.
- Kuttab SH, Nowshed F, Shargel L: Effect of phenobarbital pretreatment on the plasma and urinary levels of l-a-acetylmethadol and its metabolites. J Pharm Sci 74: 331-334 (1985).
- Shargel L, Banijamali AR, Kuttab SH: Relationship between azo dye structure and rat azoreductase activity. J Pharm Sci 73: 161-164 (1984).
- Ameer B, Divoll M, Abernathy DR, Greenblatt DJ, Shargel L: Absolute and relative bioavailability of oral acetaminophen products. J Pharm Sci 72: 955-958 (1983).
- Scheife AH, Grisafe JA, Shargel L: Stability of intravenous nitroglycerin solution. J Pharm Sci 71: 55-59 (1982).
- Shargel L, Masnyj J: Effect of stannous fluoride on hepatic mixed function oxidase activities in the rats. Toxicol Appl Pharmacol 59: 452-456 (1982).
- Ameer B, Greenblatt DJ, Divoll M, Abernathy DR, Shargel L: High pressure liquid chromatographic determination of acetaminophen in plasma: Single dose pharmacokinetic studies. J Chromatog 226: 224-230 (1981).
- Shargel L, Stevens JA, Fuchs JE, Yu ABC: Effect of antacid on the bioavailability of theophylline from rapid and timed-release drug products. J Pharm Sci 70: 599-603: (1981).
- Baker JJ, Benzinger D, Chalecki BW, Clemans S, Fritz A, O'Melia PE, Shargel L, Edelson J: Disposition of trilostane in the rat and monkey. Arch Int Pharmacodyn Therap 243: 4-16 (1980).
- Shargel L, Cheung W, Yu ABC: Analysis of antipyrine in plasma samples by high pressure liquid chromatography. J Pharm Sci 68: 1052-1054 (1979).
- Clarke RL, Heckeler ML, Gambino AJ, Davor SJ, Harding HR, Pierson AK, Tieger DG, Pearl J, Shargel, LD, Goehl, TJ: (exo, exo)-2-aryltropane-3-carboxylic esters, hypoglycemic agents, with accompanying analgesic activity. J Med Chem 31: 1243-1253 (1978).

- Levitt N, Cumiskey WR, McGrath MB, Shargel L: A rapid procedure for the assessment of compounds which modify the uptake and release of tritiated norepinephrine. J Pharm Sci 65: 1165-1588 (1976).
- Shargel L, Dorrbecker SA: Physiological Disposition and metabolism of (3H) Bitolterol in man and dog. Drug Metab Dispos 4: 72-78 (1976).
- Shargel L, Dorrbecker SA, Levitt M: Physiological disposition and metabolism of N-t-butylarterenol and its di-p-toluato ester (Bitolterol) in the rat. Drug Metab Dispos 4: 65-71 (1976).
- Shargel L, McGrath MB: Effect of racemic mephobarbital and d-mephobarbital on hepatic microsomal enzyme induction in rat and monkey. Toxicol Appl Pharmacol 34: 248-257 (1975).
- Spilker B, Shargel L, Koss RF, Minotoya H: Cardiovascular effects and blood concentrations of ajmaline and its 17-monochloro-acetate ester in cats. Arch Int Pharmacodyn Therap 216: 63-78 (1975).
- Levitt M, Cumiskey WR, Shargel L, Studies on the physiologic disposition and the activity of phenylpropanolamines in the mouse. Drug Metab Dispos 2: 187-192 (1974).
- Shargel L, Koss RF, Crain AVR, Boyle, VJ: Analysis of nalidixic acid and hydroxynalidixic acid in human plasma and urine by liquid chromatography. J Pharm Sci 62: 1452-1454 (1973).
- Shargel L, Mazel P: The effect of riboflavin deficiency on phenobarbital and 3-methylcholanthrene induction of microsomal drug-metabolizing enzymes of the rat. Biochem Pharmacol 22: 2365-2373 (1973).
- Shargel L, Akov S, Mazel P: The reduction of nitro and azo compounds by housefly microsomes. J Agr Food Chem 20: 27-29 (1972).
- Shargel L, Mazel P: Influence of 2,4-dichloro-6-phenoxyethylamine (DPEA) and B-diethylaminoethyl diphenylpropylacetate (SKF 525A) on hepatic microsomal azoreductase activity from phenobarbital or 3-methylcholanthrene rats. Biochem Pharmacol 20: 69-75 (1972).
- Shargel L, Koss R: Determination of fluorinated hydrocarbon propellants in blood of dogs after aerosol administration. J Pharm Sci 61: 1445-1449 (1972).

MISCELLANEOUS PAPERS

- Milanese, RS, Shargel, L: Covering the cost of prescriptions under Medicare: The case for generic substitution, Health Care Distributor, May, 1999, pp 16-17
- Shargel L, Foster T: USP advisory panels on the USP performance test, Pharmacopeial Forum, 31(6), 1742-1744, 2005.

ABSTRACTS

- Lambiris K, Zurek T, Dimitrious G, Getek T, Hariharan S, Shargel L, Albert KS, Sista S: Urine Analysis of Monurol by GC/NPD and GC/MS, Eastern Analytical Symposium, Somerset, NJ, November, 1994.
- Shargel L, Amann AH: The dissolution test as a predictor of *in vivo* bioequivalence, Pharm Res 9:S214, 1992.

- Thirucote R, Shargel L, Dempsey D, Dasse K: Development of a transdermal drug delivery device utilizing an ultraviolet cured polyurethane matrix Pharmacy World Congress, Washington, DC, September, 1991.
- Dempsey D, Thirucote R, Dasse K, Shargel L. Release kinetics of chlorhexidine gluconate from antimicrobial wound dressing, in vitro. Proceedings, RTEC Medical Plastics Conference, Anaheim, January, 1990.
- Dempsey D, Thirucote R, Shargel L, Dasse K. Development of a novel UV curable polyurethane drug delivery matrix: Characterization of chlorhexidine gluconate wound dressing. Proc Int Symp Control Rel Bioact Mater 17, Controlled Release Society Inc., 1990.
- Dempsey D, Thirucote R, Dasse K, Shargel, L. Direct HPLC method for total gentamicin sulfate in vitro using size exclusion chromatography and electrochemical detection. Pharm Res 6:S-20, 1989.
- Thirucote R, Dempsey D, Dasse K, Shargel L. Release kinetics of gentamicin sulfate from an antimicrobial dermal wound dressing, in vitro. Pharm Res 6:S-167, 1989.
- Labarquilla L, Tabibi SE, Shargel L. Freeze-drying of emulsions in the presence of cryoprotectants. Pharm Res 6:S-68, 1989.
- Hurwitz SJ, Coleman CN, Loeffler JS, Noll L, Zakher J, Shargel L. and Kramer, RA, Human brain tumor pharmacokinetics of SO (Etanidazole), a 2-nitroimidazole hypoxic tumor radiation sensitizer. Pharm Res 6:218, 1989
- Chungi VS, Rekhi GS, Shargel, L. A simple, rapid and sensitive HPLC method for the determination of major metabolites of sulfasalazine. Pharm Res 5:S-8 (1988).
- Shargel L, Silverman, HI, Cohen P, Brissom J, Dennis S. Bioavailability of phenylpropanolamine from a controlled release caplet. Pharm Res 5:S-173 (1988).
- Chungi VS, Dittert LW, Shargel L. Pharmacokinetics of sulfasalazine metabolites in rats following concomitant oral administration of riboflavin. Pharm Res 5:S-194 (1988).
- Oza B, Philbrook M, Huang MC, Shargel L. HPLC analysis of nicotinic acid (Niacin) and dissolution profile from controlled release dosage forms. J Pharm Sci 76: 5290 (1987).
- Bhagat H, Shargel L. HPLC method of analysis of nicotinic acid and its metabolites in water and in human urine. J Pharm Sci 76: 56 (1987).
- Biswas M, Shargel L. Effect of nicotinic acid pretreatment on mixed function oxidase (MFO) activity in the rat. Pharmacologist 28: 116 (1986).
- Breen PJ, Shargel L. Effect of azathioprine and 6-mercaptopurine on hepatic mixed function oxidase activity in the rat. Pharmacologist 28: 116 (1986).
- DePiero D, Rekhi GS, Souney PF, Shargel L. Stability of morphine sulfate solution frozen in polyvinyl chloride minibags. Presented to the Midyear Clinical Meeting of the American Society of Hospital Pharmacists, December (1986).
- Breen PJ, Jambhekar S, Shargel, L. Relationship of drug protein binding constants derived from the Scatchard equation to the fraction drug bound. Pharmacologist 27: 271 (1985).
- Yee N, Lam D, Shargel L. Effect of cimetidine and ranitidine pretreatment on hepatic mixed function oxidase (MFO) activities in the rat. Pharmacologist 27: 147 (1985).

Mundawarara MA, DiFazio M, Shargel L,. Interactive computer program describing the clinical pharmacokinetics of theophylline. American Association of Colleges of Pharmacy, July (1984).

Wiener B, Faraci PA, Shargel L. Cefamandole pharmacokinetics during standard and pulsatile cardiopulmonary by-pass. American College of Clinical Pharmacology, October (1984). J Clin Pharmacol 24: 411 (1984).

Shargel L, Breen PJ, Panichpol S. Analysis of phenylbutazone and oxyphenbutazone in human serum. Single dose pharmacokinetic study. American Pharmaceutical Association, Academy of Pharmaceutical Sciences, November (1983).

Panichpol P, Breen PJ, Shargel L. Effect of dimethyl sulfoxide on phenylbutazone pharmacokinetics in rabbits. American Pharmaceutical Association, Academy of Pharmaceutical Sciences, November (1983).

Brown D, Ng J, Bogdanffy M, Krull I, Kuttab S, Shargel L. Alcohol-stress inhibition of mixed function oxidase metabolism in the rat. Society of Toxicology, March (1982).

Roberge DM, Engelbrecht A, Scheife AH, Shargel L. "Computer Assisted Pharmacokinetics for Drug Level Monitoring", Massachusetts State Hospital Pharmacist, Framingham, MA, April, 1982.

Shargel L, Banijamali AR, Kuttab SH. Reduction of azo dyes by hepatic azoreductase, Fed Proc 40: 735 (1981).

Ameer B, Divoll M, Abernathy DR, Greenblatt DJ, Shargel L. Acetaminophen bioavailability. American College of Clinical Pharmacology, April 1981.

Banijamali AR, Kuttab SH, Shargel L. "Reduction of Azo Dyes by Rat Hepatic Azoreductase", New England Pharmacologist, Boston, MA, February, 1981.

Nowshad F, Kuttab S, Shargel L. "Effect of Phenobarbital on the Metabolism of 1-2-Acetylmethadol in the Rat", New England Pharmacologist, Boston, MA, February, 1981.

Banijamali AR, Shargel L, Kuttab SH, "Structural Relationship of Azo Dye Reduction by Rat Hepatic Azoreductase", New England Regional Medicinal Chemistry Meeting, Storrs, Connecticut, April, 1981.

Shargel L, Stevens JA, Fuchs JE, Yu ABC. Effect of antacid on the bioavailability of theophylline from rapid and time released drug products. American Pharmaceutical Association, Academy of Pharmaceutical Sciences, April (1980).

Masnyj J, Shargel L. "Effect of Stannous Fluoride and Sodium Fluoride on Hepatic Mixed Function Oxidase Activities in the Rat", New England Pharmacologist, Storrs, Connecticut, January, 1980.

Ning J, Kuttab S, Shargel L, Brown D. "Alcohol and Stress Actions on Mixed Function Oxidase Activity In the Rat", New England Pharmacologist, Storrs, Connecticut, January, 1980.

Yu ABC, Ho J, Shargel L. Pharmacokinetics of cefamandole in rats premedicated with azathioprine. American Pharmaceutical Association, Academy of Pharmaceutical Sciences, April (1979).

Shargel L, Stevens J, Yu ABC. Effect of azathioprine on theophylline elimination in the rat. Pharmacologist 21: 169 (1979).

Scheife AH, Grisafe JA, Shargel L. Stability of intravenous nitroglycerin solution. American Society of Hospital Pharmacists, December (1979).

Shargel L, Masnyj J, Kim E, Yu ABC. Effects of stannous fluoride (SnF₂) pretreatment of hepatic drug metabolism capacity in the rat. Pharmacologist 19: 211 (1977).

Shargel L, Levitt M, Dorrbecker SA. Physiological disposition and metabolism of (3H) N-t-butylarterenol (tBA) and its di-p-toluate ester (ester) in rat, dog and man. Pharmacologist 17: 194 (1975).

Shargel L, Mazel P. Influence of 2, 4, dichloro-6-phenoxethylamine (DPEA) and B-diethylaminoethyl diphenyl propylacetate, (SKF 525A) on the induced cytochrome P450 pathway of microsomal azoreductase. Fed Proc 30: 282 (1971).

Shargel L, Akov S, Mazel P. The reduction of nitro and azo compounds by housefly microsomes. Toxicol Appl Pharmacol 14: 645 (1969).

Mazel P, Katzen J, Skolnick P, Shargel L. Reduction of sulfoxides in hepatic enzymes. Fed Proc 28: 456 (1969).

Hernandez P, Pittman KA, Shargel L. Stabilization and preservation of hepatic drug metabolizing systems. Pharmacologist 11: 260 (1969).

Shargel L, Mazel P. The effect of flavin on purified and microsomal azoreductase. Toxicol Appl Pharmacol 11: 317 (1968).

Shargel L, Mazel P. Phenobarbital and 3-methylcholanthrene induction of microsomal azoreductase in riboflavin deficient rats. Fed Proc 27: 302 (1968).

Shargel L. The mechanism of flavin stimulation of microsomal and purified azoreductase. Fed Proc 26: 461 (1967).

LETTERS TO THE EDITOR

Silverman HI and Shargel L. Phenylpropanolamine Amer Family Physician 34:39-40 (1986).

Shargel, L. Safe Drug? Proper use the key. Pharmacy Times pp 20-21 October (1987).

CLASSROOM AND LABORATORY MANUALS

Shargel L, McGrath MB, Pittman KA. "A Procedural Manual for Routine Assessment of Hepatic Mixed Function Oxidase". Sterling-Winthrop Research Institute, Rensselaer, New York, 1973.

Shargel L, Chryzanowski, FA, Smith PF. "Pharmaceutics Laboratory Manual". Northeastern University Press, 1977, Revised 1979.

Shargel L, Yu ABC. "Applied Biopharmaceutics and Pharmacokinetics". Northeastern University Press, 1978, Revised 1979.

BOOK REVIEWS

Shargel L. "The Fate of Drugs in the Organism. A Bibliographic Survey". Vol. 3, by J. Hirtz, Marcel Dekker, in J Med Chem 10: 862 (1977).

Shargel L. "Annual Review of Pharmacology and Toxicology", Vol. 16, H.W. Elliott et al (Ed) Annual Reviews, Inc. in J Med Chem 20 615 (1977).

Shargel L. "A Guide to Vitamins: Their Role in Health and Disease", by J. Marks, University Park Press in Amer J Pharm Ed 41: 147, (1977).

Shargel L. "The Fate of Drugs in the Organism. A Bibliographic Survey", Vol. 4, by J. Hirtz in J Med Chem 20: 1537 (1977).

Shargel L. "Annual Review of Pharmacology and Toxicology", Vol. 17, by H.W. Elliott et al (Ed) in J Med Chem 21: 315 (1978).

Shargel L, Yu ABC. "Drug and Metabolism, Methods and Techniques", Vol. 2, Marcel Dekker in Amer J Pharm Ed 42 (1978).

Shargel L. "Drug Level Monitoring. Analytical Techniques, Metabolism and Pharmacokinetics", W. Sadee and G.C.M. Beeler, Wiley, New York, 1980 in J Med Chem 23: 1271 (1980).

Shargel L. "Extrahepatic Metabolism of Drugs and Other Foreign Compounds", T.E. Gram (Ed) Spectrum, New York 1980 Amer J Pharm Ed 45: 223 (1981).

Shargel L. "Basic Clinical Pharmacokinetics", M.E. Winter, Applied Pharmaceutics Inc., San Francisco, 1980 in Pharmaceutical Technology (1982).

Shargel L, Breen PJ. "Graphic Approach to Clinical Pharmacokinetic", Drug Intelligence Publications, 1983 in Amer J Pharm Ed 48: 456 (1984).

Shargel L. "Bioactivation of Foreign Compounds", M.W. Anders (Ed) Academic Press, New York, 1985 in J Med Chem 29: 592 (1986).

Shargel L, Breen PJ. "Drug Fate and Metabolism. Methods and Techniques", E.R. Garrett, J.L. Hirtz (Ed) Marcel Dekker, New York, 1985 in J Med Chem 29: 1555-1556 (1986).

Shargel L. "Dictionary of Pharmacy", J.H. Fincher, University of South Carolina Press. in Amer J Pharm Ed 51: 107 (1987).

Shargel L. "Pharmacokinetics: Regulatory, Industrial, Academic Perspectives", P.G. Welling; F.L.S. Tse (Ed), Marcel Dekker, New York, 1988, in J Pharm Sci, 1990.

ORAL PRESENTATIONS AND INVITED LECTURES

"Analysis of Drugs in Biological Tissue" Presented before the Boston Bacteriological Club, February 25, 1976.

"Are All Drugs Created Equal?" A discussion of bioavailability and bioequivalence of drug products. Presented to the U.S. Naval Research Company 1-1, March 29, 1976.

"Career Opportunities Discussion" Presented to SPhA and Rho Chi Meeting, May 3, 1976.

Research Seminar presented to the Department of Medicinal Chemistry and Pharmacology Colloquia, May 10, 1976.

"Problems of Human Drug Research" Presented before the Boston Association of Retail Druggists, July 17, 1976.

"Inhibition of Hepatic Microsomal Enzymes by Chloramphenicol", J.P.E.T., 203:338 (1977).
Presented before the Pharmacology Journal Club, April, 1977.

"Toxicity of Fluorinated Hydrocarbons (Freons)" Presented to the Naval Reserve, NR VTU
Research 0103, Boston, MA, June, 1977.

"Brand Name vs. Generic Name Drug/Does Price Make the Difference?" Presented to the Boston
Association of Retail Druggists, July, 1978.

"Where this College should be in 1984" Retreat, College of Pharmacy and Allied Health Professions,
Northeastern University, September, 1978.

"Interdisciplinary Research" Retreat, College of Pharmacy and Allied Health Professions,
Northeastern University, December, 1978.

"Problems of Human Studies" Seminar, Pharmacology Section Northeastern University, June, 1979.

"Product Selection on Bioavailability" Maine Pharmaceutical Association Meeting, September, 1979
(sponsored by the Upjohn Company).

"Considerations in Human Drug Research" Presented to the Northeastern University Health Care
Faculty, Northeastern University, April, 1980.

"Bioavailability and Biopharmaceutics" Continuing Education Program on Drug Product selection,
Northeastern University, June, 1980.

"Bridging the Gap Between Basic Sciences and Clinical Practice: Teaching, Research and Service"
Opportunities in Pharmaceutics". NABP/AACP District I Annual Meeting, Providence, Rhode
Island, October, 1980.

"Drug Interaction for the Health Practitioner" Continuing Education Program Northeastern
University, November, 1980.

"Therapeutic Drug Monitoring" Guest Lectures for Advanced Clinical Chemistry Course,
Northeastern University, December, 1981-1983.

"Pharmacokinetic Principles in Clinical Medicine" Veteran's Administration Hospital, Boston, MA,
February, 1982.

"Effect of Antacid on Theophylline Pharmacokinetics" Presented to the Department of Pharmacology
and Experimental Therapeutics, Boston, University Medical Center, March, 1983.

"Biopharmaceutic/Pharmacokinetic Study Procedures and Laboratory Practices" Associates of
Clinical Pharmacology, Annual Meeting, Boston, October 1984.

Breen PJ, Jambhekar S, Shargel L. "Relationship of Drug Protein Binding Constants Derived from
the Scatchard Equation to the Fraction of Drug Bound", Society of Toxicology, New England
Chapter, Cambridge, MA, June, 1985.

DeFelice M, Shargel L, "Pharmacy Prescription Survey", American Association of Colleges of
Pharmacy (AACP/NAPB), District I, September, 1985, Burlington, VT.

"Effect of Cimetidine or Ranitidine on Hepatic Mixed Function Oxidase Activity in the Rat"
Presented to the School of Pharmacy, University of Connecticut, March, 1986

Shargel L: Toxicokinetics - Practical Pharmacokinetics: Applications to Toxicology, Chemical Carcinogenesis Branch, National Institute of Environmental Health Sciences (NIEHS), Research Triangle Park, NC, April, 1991

"The FDA's Orange Book Coding System" Continuing Education Seminar, North Carolina Mutual Wholesale Company, Durham, NC, October, 1991

Shargel L: Strategies and Problems in the Development of Generic Drug Products, Fourth Phoenix International Symposium, Montreal, Canada. May, 1993

Shargel L: Pharmacokinetics of Hydromorphone (Dilaudid), National Institutes of Drug Abuse, Division of Intramural Research, Baltimore, MD, September, 1996.

Shargel L: Economic Impact of Current Legislative and Regulatory Issues on the Generic Drug Industry: Overview of Issues, presented at the NAPM Workshop on Current Regulatory and Legislative Issues for API Manufacturers, New York, NY, March, 1998

Shargel L: Generic Drug Substitution and Narrow Therapeutic Index Drugs, NAPM Mid-Year Meeting and Educational Conference, Washington, D.C., June, 1998

Shargel L: Scientific, Regulatory and Legislative Aspects of Generic Pharmaceutical Development and Sale, The National Congress on the Future of Pharmaceuticals in Medicare. Innovation and Cost Management, Arlington, VA, December 9, 1999.

Shargel L: Current Issues and Challenges in Generic Drug Development, Academy of Pharmaceutical Sciences, 21st Annual Congress, Rhodes University, Grahamstown, South Africa, September 12, 2000

Shargel L: The Generic Drug Industry: Current Issues and Challenges, Andrew J. Bartilucci 42nd Pharmacy Congress, St. John's University College of Pharmacy and Allied Health Professions, Jamaica, NY, November 1, 2000

Shargel L: Dissolution – A Generic Perspective, AAPS Workshop, Dissolution: Current and Emerging Practices – Methodology, Technology and Regulatory Issues, Arlington, VA, May7, 2001.

Shargel L: In Vitro and In Vivo Correlation in Drug Product Development, FDA/OGD Regulatory Training Workshop, Gaithersburg, MD, September 24, 2002.

Shargel L: Update from PQRI Biopharmaceutics Technical Committee, Fall Technical Workshop, Generic Pharmaceutical Association, Bethesda, MD, October 16, 2002.

Shargel, L: Generic Drug Industry in the United States, Legislative, Regulatory and Scientific Issues, The Pharmacological and Therapeutic Society of Thailand and the Faculty of Science, Mahidol University, Bangkok, Thailand, September 22, 2003.

Shargel L: Generic Drug Industry Product Development – Regulatory and Scientific Issues, School of Pharmacy, MCV-Virginia Commonwealth University, Richmond, VA, February, 2004

Shargel L: Bioavailability and Bioequivalence, Guest Lecturer, Undergraduate Pharmacy Program, School of Pharmacy, MCV-Virginia Commonwealth University, Richmond, VA, 2004, 2005

Shargel L: Generic Drug Product Development: Regulatory and Scientific Issues, School of Pharmacy, Campbell University, Buis Creek, NC, April 15, 2004

Shargel L: Design and conduct of bioavailability and bioequivalence studies, Febrafarma-USP Discussion Forum, Sao Paulo, Brazil, August 23, 2004

Shargel L: Bioavailability and bioequivalence studies: Issues and concerns, Febrafarma-USP Discussion Forum, Sao Paulo, Brazil, August 23, 2004

Shargel L: Generic Drug Industry In The United States: Legislative, Regulatory and Scientific Issues 25th Congress of the Academy of Pharmaceutical Sciences, Rhodes University, Grahamstown, South Africa, September, 2004

Shargel L: Introduction To Generic Drug Development, SFBC Anapharm Symposium, Newark, NJ, March, 2005.

Shargel L: Generic Drug Development – Legislative, Regulatory and Scientific Issues, North Carolina Regulatory affairs Forum, Research Triangle Park, NC February, 2006.

Shargel L: Challenges in the Development of Generic Drug Products, Eino Nelson Conference, Coral Gables, FL, March 2006

Shargel L: Generic Drug Development – Scientific issues and Regulatory Policy, Seminar lecture series on Drug Discovery and Product Development, US Food and Drug Administration, Center for Devices and Radiological Health, Rockville, MS, March 2006

RELATED PROFESSIONAL ACTIVITIES

PMA Coordinated Industry Program for Pharmacy Faculty, Visitation to Endo Laboratories, Inc., Subsidiary of I.E. duPont de Nemours and Co., Inc., 1980.

Visiting Scientist for Minority Institutions (Sponsored by NIGMS, National Institutes of Health, 1982-1991.

National Institutes of Health Special Study Section for Grant Reviews, 1982.

National Institute of Environmental Health Sciences Special Study Section for Grant Reviews, Bioanalytical Chemistry Support, 1991

Member, Controlled Substances Advisory Board, The Commonwealth of Massachusetts, Department of Public Health, 1982-1984.

Member, Drug Formulary Commission, Commonwealth of Massachusetts, 1987 - 1991 (Member, Subcommittee for Public Comment)

Reviewer, Chapter 19, "Weight Control Products" in Handbook of Nonprescription Drugs, 9th edition, American Pharmaceutical Association, Washington, DC, 1990, 1993

Organizer and Founder, "Graduate Research Day" Annual event at MCP/AHS, 1983-1990.

Advisor, Chinese Student Organization, MCP/AHS, 1985-1991.

PMA Pharmaceutical Industry Visiting Scientist
University of Minnesota, College of Pharmacy, January, 1992
University of Kentucky, College of Pharmacy, April, 1993

External Examiner, Rhodes University, Grahamstown, South Africa, February, 1992, 2001

American Association of Pharmaceutical Sciences, Charter Member, Pharmacokinetics, Pharmacodynamics and Drug Metabolism (PPDM) Section, Member, 1994, Co-Chair, 1997, Chair, 1998 - 1999 - Eastern Regional Meeting; Program Chair, Eastern Regional Meeting, June, 2000

Member, Institutional Review Board (IRB), National Institutes of Health, National Institute on Drug Abuse, Division of Intramural Research, Baltimore, MD, 1996 - 1997

Moderator: Pharmaceutical Equivalents of Biological Drugs: Regulatory/Scientific Hurdles and Policy Issues, NAPM Annual Meeting and Educational Conference, Rio Grande, PR, February, 1998

Moderator, Drug Abuse, AAPS Eastern Regional Meeting, Parsippany, NJ, June, 1998

Moderator: Generic Drug Substitution and Narrow Therapeutic Index Drugs, NAPM Mid-Mid-Year Meeting and Educational Conference, Washington, D.C., June, 1998

Moderator, Bioequivalence Issues, Generic Trade Associations/FDA Fall Technical Workshop, The Generic Pharmaceutical Industry: Regulatory and Scientific Challenges," Bethesda, MD, November, 1998

Moderator: Generic Drug Substitution Issues, NAPM Mid-Mid-Year Meeting and Educational Conference, Newark, NJ, May, 1999

Moderator: PPDM Symposium: Bioavailability/Bioequivalence Issues, Eastern Regional Meeting, American Association of Pharmaceutical Scientists, Parsippany, NJ, June, 1999

Product Quality Research Institute (PQRI), Member, Steering Committee, 1998 - 2001, Chair, Biopharmaceutics Technical Committee, 2002 - 2003

Delegate, United States Pharmacopeia Convention, 2000 - 2005

Member, USP Panel of Experts, Biopharmaceutics Expert Committee, United States Pharmacopeia Convention, 2000 - present

Industry Guest Participant, Advisory Committee for Pharmaceutical Science, Center for Drug Evaluation and Research, U.S. Food and Drug Administration, 2001 - 2003

Generic Pharmaceutical Association, Vice-Chair CRO Committee, Member of Technical Advisory Committee, 2002 - 2003

Moderator, Biopharmaceutics Session, Fall Technical Workshop, Generic Pharmaceutical Association, Bethesda, MD, October 16, 2002.

Moderator, Biopharmaceutics Technical Committee and Roundtable Discussion, PQRI Conference, Good Regulation Through Good Science, April 3-4, 2003.

Moderator, Biopharmaceutics and Drug Product Quality: Using performance tests as specifications for drug products, USP Annual Scientific Meeting, Iselin, NJ, September, 27, 2004.

Chair, USP Advisory Panel on Dosage Form Performance – Injectables, 2004 – present.

American Association of Pharmaceutical Scientists, Chair-Elect of the AAPS Focus Group on Bioequivalence, 2004, Chair, 2005.

GRADUATE STUDENT ADVISOR**Ph.D. Dissertations**

Ramachandra R. Thirucote, Ph.D.

Development and Characterization of a Transdermal Drug Delivery System Utilizing an Ultraviolet Curing Polymer Matrix, Massachusetts College of Pharmacy & Allied Health Sciences, 1992

Vinod S. Chungi, Ph.D.

The Effect of Riboflavin on the Pharmacokinetics of AZO Compounds in the Rat, Massachusetts College of Pharmacy & Allied Health Sciences, 1988

Philip J. Breen, Ph.D.

Effect of Azathioprine and 6-Mercaptopurine on Hepatic Metabolism in Rats: In vivo/In vitro Correlation, Massachusetts College of Pharmacy & Allied Health Sciences, 1987

Sompong Panichpol, Ph.D.

A Study of the Effect of Dimethyl Sulfoxide on Phenylbutazone Pharmacokinetics in Rabbits, Massachusetts College of Pharmacy & Allied Health Sciences, 1983

M.S. Theses

Patricia A. Lilagan, M.S.

Biopharmaceutics and Pharmacokinetics of a Novel Controlled Release Dosage Form of Acetaminophen, Massachusetts College of Pharmacy & Allied Health Sciences, 1991

Laura Labarquilla, M.S.

Freeze-Drying of Emulsions in the Presence of Cryoprotectants, Massachusetts College of Pharmacy & Allied Health Sciences, 1990

Ming-Chia Huang, M.S.

Dissolution and Bioavailability of Nicotinic Acid from Controlled Release Dosage Forms, Massachusetts College of Pharmacy & Allied Health Sciences, 1987

Manju Biswas, M.S.

A Study of the Effect of Nicotinic Acid on Hepatic Mixed Function Oxidase in Rats, Massachusetts College of Pharmacy & Allied Health Sciences, 1987

Tsong-Mei Tsai, M.S.

Effect of Oxandrolone on the Elimination of Theophylline, Massachusetts College of Pharmacy & Allied Health Sciences, 1983

Jerry Masnyj, M.S.

Effect of Stannous Fluoride on Hepatic Mixed Function Oxidase Activities in Rats, College of Pharmacy & Allied Health Professions, Northeastern University, 1981

Andrea H. Scheife, M.S.

Stability of Intravenous Nitroglycerin, College of Pharmacy & Allied Health Professions, Northeastern University, 1981