

## J. MICHAEL GRINDEL, Ph.D.

### PUBLICATIONS

1. J. M. Grindel. "The Role of Charge Transfer Interactions of Adrenergic Sites: Non-Aromatic Analogs of Phenylethanamines." Dissertation Abstracts International, 34B, 5860B (1974).
2. G. L. Grunewald, J. M. Grindel, W. C. Vincek and R. T. Borchardt. "Importance of the Aromatic Ring in Adrenergic Amines. Non-Aromatic Analogs of Phenyl-ethanolamine as Substrates for Phenylethanolamine-N-Methyltransferase." Molecular Pharmacology, 11, 684-699 (1975).
3. G. L. Grunewald, J. M. Grindel, P. N. Patil and K. N. Salman. "Importance of the Aromatic Ring in Adrenergic Amines. 2. Synthesis and Adrenergic Activity of Some Non-Aromatic Six- and Eight-membered Ring Analogs of B-Phenylethanolamine." Journal of Medicinal Chemistry, 19, 10-16 (1976).
4. J. M. Grindel, R. S. Rozman, D. M. Leahy, N. A. Molek and H. H. Gillum. "The Absorption, Distribution and Excretion of a Quinolinemethanol Antimalarial, 2,8-Bis(trifluoromethyl)-4-[1-Hydroxy-3-(N-t-butylamino)propyl] Quinoline Phosphate (WR 184,806)." Drug Metabolism and Disposition, 4, 133-139 (1976).
5. J. M. Grindel, P. F. Tilton, and R. D. Shaffer. "Quantitation of the Antimalarial Agent, Mefloquine, in Blood, Plasma and Urine Using High Pressure Liquid Chromatography." Journal of Pharmaceutical Sciences, 66, 834-837 (1977).
6. B. H. Migdalof, J. M. Grindel, J. J. P. Heykants and P. A. J. Janssen. "Penfluridol: A Neuroleptic Drug Designed for Long Duration of Action." Proceedings of the Symposium on Drug Disposition in Man. Drug Metabolism Reviews, 9, 281-299 (1979).
7. J. M. Grindel, B. H. Migdalof and J. Plostnieks. "Absorption and Excretion of Tolmetin in Arthritic Patients." Clinical Pharmacology and Therapeutics, 26, 122-128 (1979).
8. J. M. Grindel, B. H. Migdalof and W. A. Cressman. "The Comparative Metabolism and Disposition of Penfluridol-3H in Rat, Rabbit, Dog and Man." Drug Metabolism and Disposition, 7, 325 (1979).

## J. MICHAEL GRINDEL, Ph.D.

9. J. M. Grindel, B. H. Migdalof and J. F. Hills. "Characterization of a New Urinary Metabolite of Penfluridol in Rat, Rabbit, Dog and Man." Drug Metabolism and Disposition, 7, 448 (1979).
10. J. M. Grindel, P. J. O'Neill, K. A. Yorgey, M. H. Schwartz, L. A. McKown, B. H. Migdalof and W. N. Wu. "The Metabolism of Zomepirac Sodium I. Disposition in Laboratory Animals and Man." Drug Metabolism and Disposition, 8, 343, (1980).
11. W. N. Wu, L. E. Weaner, J. Kalbron, P. J. O'Neill and J. M. Grindel. "The Metabolism of Zomepirac Sodium II. Isolation and Identification of the Urinary Metabolites in Mouse, Rat, Monkey and Man." Drug Metabolism and Disposition, 8, 346 (1980).
12. J. M. Grindel, B. H. Migdalof, K. A. Yorgey and J. F. Pritchard. "Pharmacokinetics and Metabolism of Tolmetin in Normal and Adjuvant Arthritic Lewis Rats." European Journal of Drug Metabolism and Pharmacokinetics, Vol. 7, 299-306 (1982).
13. J. M. Grindel, J. F. Hills and N. L. Renzi. "Reversed-Phase HPLC Assay for Zomepirac in Urine." Journal of Chromatography, 272, 210-215 (1983).
14. J. M. Grindel. "The Pharmacokinetic and Metabolic Profile of the Anti-inflammatory Agent Tolmetin in Laboratory Animals and Man." Drug Metabolism Reviews, 12, 363-377 (1981).
15. L. D. Muschek, J. M. Grindel. "Farmacocinetica y metabolism de zomepirac en el animal y en el hombre." La nouvelle Presse Medicale, 13-18 (November 1982).
16. W. Meuldermans, J. Hendrickx, F. Knaeps, W. Lauwers, J. M. Grindel, J. Heykants. "Plasma Levels, Biotrans-formation and Excretion of Oxatomide (R35443) in Rats, Dogs and Man." Xenobiotica, 14, 445-462 (1984).
17. J. M. Grindel, T. J. Musick, Z. Jiang, A. Roskey, and S. Agrawal. "Pharmacokinetics and metabolism of an oligodeoxynucleotide phosphorothioate (GEM 91) in cynomolgus monkeys following intravenous infusion." Antisense Nucleic Acid Drug Dev., 8, 43-52 (1998).
18. J. K. Marquis, J. M. Grindel. "Toxicological Evaluation of Oligonucleotide Therapeutics", Current Opinion in Molecular Therapeutics, 2 (3), 258-263 (2000).

## **J. MICHAEL GRINDEL, Ph.D.**

19. E. P. Orringer, J. F. Casella, M. Koshy, P. Adams-Graves, L. Lori Luchtman-Jones, M. Watanabe, F. Shafer, A. Kutlar, M. Abboud, M. Steinberg, B. Adler, P. Swerdlow, C. Terregino, S. Saccente, B. Files, K. Ataga, R. Brown, S. Wojtowicz-Praga, J. M. Grindel. "Purified Poloxamer 188 for Treatment of Acute Vaso-occlusive Crisis of Sickle Cell Disease." JAMA 2001; 286: 2099-2106.
20. J. M. Grindel, T. Jaworski, R. M. Emanuele, P. Culbreth. "Pharmacokinetics of a Novel Surface-Active Agent, Purified Poloxamer 188, in Rat, Rabbit, Dog and Man." Biopharm Drug Dispos 2002; 23: 87-103.
21. J. M. Grindel, T. Jaworski, O. Piraner, R. M. Emanuele, M. Balasubramanian. "Distribution, Metabolism and Excretion of a Novel Surface-Active Agent, Purified Poloxamer 188 in Rats, Dogs and Humans." J Pharm Sci 2002; 91: 1936-1947.
22. S. K. Ballas, B. Files, L. Luchtman-Jones, L. Benjamin, P. Swerdlow, L. Hilliard, T. Coates, M. Abboud, S. Wojtowicz-Praga, J. M. Grindel. "Purified Poloxamer 188 and Sickle Cell Disease: Evaluation of a Nonionic Surfactant in the Management of Acute Chest Syndrome." Hemoglobin 2003; (in press)
23. S. Mani, S. Goel, R. R. Martin, J. M. Grindel, M. L. Rothenberg, R. Zhang, G. Tortora, Y. S. Cho-Chung. "Clinical Studies in Patients with Solid Tumors Using a Second-Generation Oligonucleotide (GEM231) Targeting the Type I Protein Kinase A mRNA." NY Acad Sci 2003; (submitted)
24. S. Goel, K. Desai, A. Bulgaru, A. Fields, G. Goldberg, S. Agrawal, R. Martin, M. Grindel, S. Mani. "A Safety Study of a Mixed-Backbone Oligonucleotide (GEM231) Targeting PKA R1 $\alpha$  Using a Continuous Infusion Schedule in Patients with Refractory Solid Tumors." J Clin Oncol 2003; (in press)

## **BOOK CHAPTERS**

1. G. L. Grunewald and J. M. Grindel. "Carbomethoxy-cyclooctatetraene." Organic Photochemical Syntheses, vol. II, ed. by R. Srinivasan; John Wiley and Sons; NY, NY; 1976, p. 19-22.
2. J. M. Grindel. "Going Global: Establishing R&D Project Management Teams", Technology Management: Case Studies in Innovation, Vol I, edited by Robert Szakonyi, Auerbach, New York, NY, 1992, p. 219-231.

## **PRESENTATIONS**

## J. MICHAEL GRINDEL, Ph.D.

1. J. M. Grindel, D. B. Mirth and G. L. Grunewald. "Non-Aromatic Analogs of Phenethylamines." **10th Medicinal Chemistry Meeting-in-Miniature**, University of Minnesota, June 1972.
2. G. L. Grunewald and J. M. Grindel. "Importance of the Aromatic Ring in Adrenergic Amines. Some Non-Aromatic Analogs of Phenethanolamines." **169th ACS National Meeting**. Philadelphia, PA, April 1975.
3. J. M. Grindel, D. M. Leahy, N. A. Molek and R. S. Rozman. "The Absorption, Distribution and Excretion of 2,8-Bis(trifluoromethyl)-4-[1-Hydroxy-3-(N-t-butylamino)Propyl-1-14C] Quinoline Phosphate (WR 184,806-14C) in the Mouse." **Federation Proceedings**, 34, 734 (1975).
4. J. M. Grindel, P. J. O'Neill, K. A. Yorgey, J. E. Epps, M. Schwartz, L. E. Weaner and B. H. Migdalof. "The Comparative Disposition of Zomepirac-14C Sodium in Man, Monkey, Rat and Mouse". **Federation Proceedings**, 37, 691 (1978).
5. P. J. O'Neill, J. M. Grindel, M. Schwartz and L. A. McKown. "The Comparative Disposition of McN-3495 in Rat, Dog, Monkey and Man." **Federation Proceedings**, 37, 691 (1978).
6. J. M. Grindel, B. H. Migdalof and K. A. Yorgey. "Comparative Disposition of Tolmetin-14C in Normal vs Adjuvant Arthritic Lewis Rats." **Federation Proceedings**, 38,264 (1979).
7. W. N. Wu, L. E. Weaner, J. Kalbron, P. J. O'Neill and J. M. Grindel. "CI and EI Mass Spectral Identification of the Urinary Metabolites of Zomepirac." **American Society for Mass Spectrometry**, Seattle, Washington, June 3-8, 1979.
8. J. M. Grindel and R. K. Nayak. "Recent Developments in Understanding the Pharmacokinetics of Zomepirac." **Presented at ZOMAX Oxford Symposium**, April 8, 1982.
9. W. N. Wu, J. F. Hills, R. S. Egan, K. T. Ng, J. M. Grindel and P. J. O'Neill. "Isolation and Identification of Xilobam Metabolites in Plasma (Man) and Urine (Mouse, Rat, Dog and Man)." **Presented at ASPET Meeting**, August 1983.
10. J. M. Grindel. "R&D Project Planning: International Interface." **1983 Management Conference For the Pharmaceutical Industry**, Purdue University, September 1983.
11. J. M. Grindel. "Quality in Project Management." **Project Management Institute Annual Meeting**, Philadelphia, PA (March 15, 1986).

## J. MICHAEL GRINDEL, Ph.D.

12. J. M. Grindel. "Management of Quality in Pharmaceutical R&D Drug Development Projects", **Project Management Institute Annual Meeting**, Milwaukee, WI (October 4-7, 1987).
13. J. M. Grindel. "Project Management in the Pharmaceutical Industry - 1988", **Project Management Institute Annual Meeting**, Atlanta, GA (October, 1989).
14. J. M. Grindel. "Project Management as a Profession in the Pharmaceutical/ Biotechnology Industry", **PMA Project Management & Finance Subsection Annual Meeting**, Fort Lauderdale, FL., May 11, 1993.
15. J. M. Grindel. "Pharmacokinetics and Disposition of Antisense Oligonucleotides", **Fifteenth Annual Robert S. Rozman Symposium, Delaware Valley Drug Metabolism Discussion Group**, Langhorne, PA, May 16, 1996.
16. R. R. Martin, P. J. Schechter and J. M. Grindel. "Clinical Trials with Systemic Antisense Oligonucleotides". **Oligonucleotide & Gene Therapy-Based Antisense Therapeutics**. San Diego, CA, February 6-7, 1997
17. J. M. Grindel. "Pharmacokinetics and Disposition of Oligonucleotides", **Society of Toxicology Annual Meeting**, Cincinnati, OH, March 9-12, 1997.
18. R. R. Martin, J. M. Grindel and P. Guinot. "From Concept to Execution: Clinical Studies with Antisense Oligonucleotides". **Antisense 97: Targeting the Molecular Basis of Disease**. Boston, MA, May 1-2, 1997.
19. J. M. Grindel, A. Bourque, A. Cohen and S. Agrawal. "Disposition and Pharmacokinetics of Trecovirsen Sodium (GEM®91) in Primates". **Antisense 97: Targeting the Molecular Basis of Disease**. Boston, MA, May 1-2, 1997.
20. J. M. Grindel. "Integration of Line Function and Project Team Management: Keys to Success." **IBC Meeting Secrets of Successful Drug Development Project Management**, Philadelphia, PA, October 30-31, 1997.
21. J. M. Grindel, J. K. Marquis and D. W. Dalgard. "One Week Continuous Infusion Toxicity Study on GEM 91 in Cynomolgus Monkeys with a 2-Week Recovery Period", **Society of Toxicology Annual Meeting**, Seattle, WA, March 1-5, 1998.
22. T. J. Jaworski, J. M. Grindel, and R. M. Emanuele. "Interaction of Purified Poloxamer 188 (FLOCOR) with Normal and Damaged Red Blood Cells", **Blood**, 92, 6b (1998).

## J. MICHAEL GRINDEL, Ph.D.

23. B. A. Files, S. K. Ballas, L. J. Benjamin, S. Wojtowicz-Praga, J. M. Grindel, T. J. Jaworski, C. A. Cobb and M. Emanuele. "Multicenter Trial of FLOCOR in Patients with Sickle Cell Disease and Acute Chest Syndrome", **Blood**, 92, 30b (1998).
24. M. Koshy for Investigators of the Multicenter Study of FLOCOR, S. Wojtowicz-Praga, and J. M. Grindel. "A Phase III Multicenter Randomized, Double-Blind, Placebo-Controlled Study of FLOCOR (Purified Poloxamer 188) in Patients with Sickle Cell Disease in Acute Vaso-Occlusive Crisis", **Blood**, 94, 25b (1999).
25. L. Luchtman-Jones, B. A. Files, S. K. Ballas, P. Swerdlow, L. Benjamin, L. Hilliard, T. D. Coates, M. Abboud, S. Wojtowicz-Praga and J. M. Grindel. "Phase I Study of FLOCOR in Patients with Acute Chest Syndrome of Sickle Cell Disease", **Blood**, 94, 25b (1999).
26. L. Luchtman-Jones, B. A. Files, S. K. Ballas, P. Swerdlow, L. Benjamin, L. Hilliard, T. D. Coates, M. Abboud, S. Wojtowicz-Praga and J. M. Grindel. "Phase I Study of FLOCOR in Patients with Acute Chest Syndrome of Sickle Cell Disease", **National Sickle Cell Disease Meeting**, Philadelphia, PA, April 9 -12, 2000.
27. J. F. Casella for Investigators of the Multicenter Study of FLOCOR, S. Wojtowicz-Praga, and J. M. Grindel. "A Phase III Multicenter Randomized, Double-Blind, Placebo-Controlled Study of FLOCOR (Purified Poloxamer 188) in Patients with Sickle Cell Disease in Acute Vaso-Occlusive Crisis", **National Sickle Cell Disease Meeting**, Philadelphia, PA, April 9 -12, 2000.
28. J. F. Casella, M. Watanabe, B. Files, F. Shafer, L. Luchtman-Jones, T. Wun, R. M. Emanuele, J. M. Grindel. "FLOCOR's Efficacy and Safety in Pediatric Sickle Cell Patients Experiencing Acute Vaso-occlusive Crisis: A Subgroup Analysis." **Blood**, 96, 9a, 2000.
29. A. C. Lockhart, C. Rudin, J. D. Berlin, B. J. Roth, K. R. Hande, R. R. Martin, T. M. Sullivan, J. M. Grindel, R. Zhang, M. L. Rothenberg. "GEM231, a Second Generation Anti-PKA Oligonucleotide, Administered with Weekly CPT-11: a Phase I Trial." ASCO Meeting, Chicago, IL, May 31-June 3, 2003.