Metin Çelik, Ph.D.

22 Durham Road, Skillman, New Jersey 08558, USA Voice: + 1 908-864 0555 ; +90 548 853 0550 e-mail: <u>Metin.Celik@pt-int.com</u> metin.celik@neu.edu.tr

CURRICULUM VITAE

Current/Recent Position(s) and Affiliation(s):

9/97 - present:President, Pharmaceutical Technologies International, Inc. (PTI), Skillman, NJ.08/08 - presentPart-time faculty member, Department of Pharmaceutical Technology, Faculty of
Pharmacy, Near East University, Nicosia, Turkish Republic of Northern Cyprus

Fields and Areas of Specialization:

Dr. Çelik's recent areas of interests include:

- QbD and PAT;
- Development of solid dosage formulation and processing (including milling, mixing, granulation, tabletting, and film coating) using SUPAC guidelines, QbD and PAT approach
- Process assessment of pharmaceutical manufacturing process for solid dosage forms
- Evaluation of novel drug delivery technologies;
- Development of artificial intelligence based pharmaceutical expert systems, excipient databases (for tableting, spray drying, film coating, and novel dosage forms), and management tools for FDA inspection preparations (PAI, API, Validation, Technology Transfer, etc)
- Utilization of compaction simulators in the product development; pharmaceutical compaction; excipient functionality;

Education:

B.S. (Hons.): Faculty of Pharmacy, Hacettepe University, Ankara, Turkey (1979).

Ph.D.: Department of Pharmaceutical Technology, School of Pharmacy, De Montfort University (formerly known as Leicester Polytechnic), UK (1984).

Previous Positions Held:

1/04 – 08/08	Faculty, Departm NJ	nent of Industrial & Systems Engineering, Rutgers University, Piscataway,
	1/04 – 9/04	Part-time Faculty
	9/05 – 5/08	(Visiting) Research Professor of Pharmaceutical Processing
9/1988 - 7/1997: Assistant Professor of Pharmaceutics, and Director of Pharmaceutical Compaction Research		
Laboratory & Information Center, College of Pharmacy, Rutgers University, Piscataway, NJ.		
6/1986 - 9/1988: Post Doctoral Scientist, Pharmaceutical Research & Technologies, SK & F Labs, Swedeland, PA.		
11/1985 - 3/1986: Military Service.		
5/1985 - 10/1985: Development Coordinator, Galenical R & D, Sandoz, Istanbul, Turkey.		
7/1984 - 5/1985: Special Trainee, Galenical R & D, Sandoz Ltd., Basel, Switzerland.		

Professional Licensure:

Pharmacy License (Turkey)

RM

DOCKE

Find authenticated court documents without watermarks at docketalarm.com.

Honors, Awards, Promotions, and Recognitions:

Faculty Academic Service Increment Program Award (1991, 1993, 1994) Who is who in science and engineering (1995) Commission of Science & Technology of New Jersey Award (1996).

THE PORTFOLIO OF ACCOMPLISHMENTS

1. Publications:

Book:

M. Çelik "Pharmaceutical Powder Compaction Technology", 2nd Edition, Informa Healthcare (2011).

Book Chapters:

M. Çelik*, M. Mollan and N. Chang, "The reworkability of microcrystalline cellulose formulations" in "Tableting technology Volume 2 (Compression), Edited by J.I. Wells and M.H. Rubinstein, Ellis Horwood, Chapter 5, 44-61 (1993).

M. Çelik, "Compaction of multiparticulate oral dosage forms", in "Multiparticulate oral drug delivery" (Edited by I. Ghebre-Sellassie), Marcel Dekker, Inc., Chapter 9, 181-216 (1994).

M. Çelik* and L. Maganti, "An overview of the compaction of microspheres" in "Minutes: 9th Int. Symposium on Microencapsulation", 157-168, Edited by S. Kal and A.A. Hincal, Editions de Santé, Paris (1994).

M.J. Mollan, Jr. and M. Çelik*, "Maltodextrin", in "Analytical profiles of drug substances and excipients", Edited by H.G. Brittain, Vol. 24, Chapter 8, 307-350, Academic Press (1996).

M. Çelik and S.C. Wendel "Spray drying", in "Handbook of Granulation Technology", Edited by Dilip Parikh, 2nd Edition, Taylor & Francis, Chapter 5, 129-157 (2005).

M. Çelik and S.C. Wendel "Spray drying and pharmaceutical applications", in "Handbook of Granulation Technology", Edited by Dilip Parikh, 3nd Edition, Informa Healthcare, Chapter 5, 98-126 (2009).

M. Çelik and S.C. Wendel "Expert systems and their pharmaceutical applications", in "Handbook of Granulation Technology", Edited by Dilip Parikh, 3nd Edition, Informa Healthcare, Chapter 5, 579-597 (2009).

C. Ruegger and M. Çelik, "Advanced compaction research equipment, Compaction simulators", in Pharmaceutical Powder Technology, Edited by M. Çelik, 2nd Edition, Informa Healthcare, Chapter 6, (2011).

M. Çelik, "Expert systems and their use in pharmaceutical applications", in Pharmaceutical Powder Technology, Edited by M. Çelik, 2nd Edition, Informa Healthcare, Chapter 13, (2011).

Refereed Journal Articles:

DOCKET

D.N. Travers*, M. Çelik and T.C. Buttery, "A computer aided investigation on strain movements in compacts under constant stress within the die", Drug Dev. & Ind. Pharm., 9, 139 - 157 (1983).

DOCKE.

M. Çelik, D.N. Travers* and T.C. Buttery, "Computer logged changes of strain movements in compacts of direct compression bases and granules produced by wet massing techniques", Labo-Pharma, 32, 22 - 27 (1984).

M. Çelik and D.N. Travers*, "The use of an elastic recovery index as a criterion of compactional behavior of some direct compression bases", Drug Dev. & Ind. Pharm., 11, 299 - 314 (1985).

M. Çelik and K. Marshall, "Use of a compaction simulator system in tabletting research, I. Introduction to and initial experiments with the system", Drug Dev. & Ind. Pharm., 15(5), 759 - 800 (1989).

M. Çelik* and N. G. Lordi, "The Pharmaceutical Compaction Research Laboratory & Information Center", Pharm. Technol., 15(3), 112 - 116 (1991).

M. Çelik, "Overview of compaction data analysis techniques", Drug Dev. & Ind. Pharm., 18(6&7) 767 - 810 (1992).

L. Maganti and M. Çelik* "Compaction studies on pellets Part I: Uncoated pellets", Int. J. Pharmaceutics, 95, 29 - 42 (1993).

M. Çelik* and C.E. Driscoll, "An overview of the effects of some physico-chemical and mechanical characteristics of particulates on the compaction and post-compaction properties of compacts", Drug Dev. & Ind Pharm., <u>19(17-18)</u>, 2119 - 2141 (1993).

M. Çelik* and E. Okutgen, "A feasibility study for the development of a perspective compaction functionality testing and the establishment of a compaction data bank", Drug Dev. & Ind Pharm., 19(17-18), 2309 - 2334 (1993).

M.J. Mollan, Jr. and M. Çelik*, "Characterization of directly compressible maltodextrins manufactured by three different processes", Drug Dev. & Ind Pharm., 19(17-18), 2335 - 2358 (1993).

L. Maganti and M. Çelik*, "Compaction studies on pellets Part II: Coated pellets", Int. J. Pharmaceutics, 103, 55 - 67 (1994).

M.J. Mollan, Jr., and M. Çelik*, "Tabletability of maltodextrins and acetaminophen mixtures", Drug Dev. & Ind. Pharm. 20(20), 3139 - 3149 (1994).

M. Çelik* and L. Maganti, "Formulation and compaction of microspheres", Drug Dev. & Ind. Pharm., 20(20), 3151 - 3173 (1994).

M.J. Mollan, Jr., and M. Çelik*, "The effects of humidity and storage time on the behavior of maltodextrins for direct compression", Int. J. Pharmaceutics, 114(1), 23-32 (1995).

M.J. Mollan, Jr., N. Chang and M. Çelik*, "The effect of reworking on post-compaction properties of microcrystalline cellulose formulations", Pharm. Technol. 19(10), 2-14 (1995).

M. Çelik, "The past, present and future of tableting technology", Drug Dev. & Ind. Pharm., 22(1), 1-10 (1996).

M. Çelik* and M.E. Aulton, "The viscoelastic deformation of some tableting materials as assessed by indentation rheology", Drug Dev. & Ind. Pharm., 22(1), 67-75, (1996).

M. Çelik*, J.T.H. Ong, Z.T. Chowhan and G.J. Samuels, "Compaction simulator studies of a new drug substance: Effect of particle size and shape, and its binary mixtures with microcrystalline cellulose", Pharmaceutical Development & Technology, 1(2), 119-126 (1996).

M. Çelik* and C.E. Ruegger, "An overview of tableting technology - Part I: Tablet presses and instrumentation", Pharm. Technol., Vol. 20, Suppl. 20-39(1996).

M.J. Mollan, Jr. and M. Çelik*, "The effects of lubrication on the compaction and post-compaction properties of directly compressible maltodextrins". Int. J. Pharmaceutics, 144(1), 1-9 (1996).

S. A. Sharpe, H. G. Brittain*, A. W. Newman, and M. Çelik, "Physical characterization of the polymorphic variations of magnesium stearate and magnesium palmitate species". Structural Chemistry, 8, 73-84 (1997).

S.C. Wendel & M. Çelik*, "An overview of spray drying applications", Pharm. Technol., 21(10), 124-156 (1997).

C. E. Ruegger & M. Çelik*, "The effect of compression and decompression speed on the mechanical strength of the compacts", Pharmaceutical Development & Technology, 5(4), 485-494 (2000).

C. E. Ruegger & M. Çelik*, "The influence of varying pre- & main compaction profile parameters on the mechanical strength of the compacts", Pharmaceutical Development & Technology, 5(4), 495-505 (2000).

R. Sirihorachai, S.C. Wendel & M. Çelik*, "Evaluation of a novel portable instrumented punch system", stp Pharma Pratiques, (10) 27-31, 2000

M. Çelik, "Catching up with Expert Systems", Pharm. Technol., 25(7), 122-124 (2001)

M. Çelik, "Excipient selection: Practical advice on using SUPAC", Tablets & Capsules, 6(6), PP. , 2008

M. Çelik, Eye on Excipients: "Compactability testing of excipients", Tablets & Capsules, 7(3), 37-40, 2009

M. Çelik, Eye on excipients: "Compactability testing of excipients, Part 2", Tablets & Capsules 7(4), 33-37, 2009

M. Çelik, Eye on Excipients: "Tools for risk-based product development", Tablets & Capsules, 7(6), 55-59, 2009

Non-Refereed Journal Articles:

M. Çelik, "A new method for characterizing the compression process", IPP (Information for Pharmaceutical Production), 2(March), 23 - 29 (1985).

Book Reviews:

M. Çelik, "Excipient and delivery systems for pharmaceutical formulations", Journal of American Chemical Society, 118(21), 5160 (1996).

Abstracts:

DOCKE.

M. Çelik and D.N. Travers, "Tablet compression studies using a 5 channel computer linked data processor", Pharm. Research, 4(2), S69 (1987).

E. Okutgen, P. Wray and M. Çelik, "The effect of crystal surface history on post- compaction properties of sodium chloride tablets", Pharm. Research, 9(10), S115 (1992).

M. Çelik, D. Goldman, E. Okutgen, R. Pinal and A.W. Malick, "Simulation of an F-3 single station press using an integrated compaction research system", Pharm. Research, 9(10), S134 (1992).

DOCKE.

M.J. Mollan, Jr. and M. Çelik, "Direct compression of maltodextrins and acetaminophen", Pharm. Research, 9(10), S134 (1992).

M. Çelik, E. Okutgen and C. Driscoll, "Compaction functionality testing", Pharm. Research, 10(10), S138 (1993).

E. Okutgen, C. Driscoll and M. Çelik, "Introduction to a compaction data bank", Pharm. Research, 10(10), S138 (1993).

M.J. Mollan, Jr. and M. Çelik, "Lubrication effects on the properties of maltodextrins", Pharm. Research, 10(10), S146 (1993).

M.J. Mollan, Jr. and M. Çelik, "The effect of humidity on the properties of maltodextrins", Pharm. Research, 10(10), S146 (1993).

M. Çelik and M.E. Aulton, "The viscoelastic deformation of some tableting materials as assessed by indentation rheology", Pharm. Research, 11(10), S131 (1994).

C.E. Driscoll, E. Okutgen and M. Çelik, "A new approach to the use of pre- & main compaction cycles", Pharm. Research, 11(10), S132 (1994).

A. Ayman, M. Çelik, H. Brittain, A. Newman and G. Young, "Physicochemical properties of the pure magnesium stearate pseudopolymorphs", Pharm. Research, 11(10), S152 (1994).

C. Driscoll-Ruegger and M. Çelik, "The effect of compression and decompression speed on the mechanical strength of compacts", Pharm. Research, 12(9), S179 (1995).

M. Çelik, "The use of Force-Time Curves to evaluate the compaction behavior of pharmaceutical materials", Pharm. Research, 12(9), S185 (1995).

M. Çelik and E. Okutgen, "An electronic tablet compaction data bank - I: Microcrystalline cellulose", Pharm. Research, 12(9), S185 (1995).

M. Çelik and E. Okutgen, "An electronic tablet compaction data bank - I: Microcrystalline cellulose", European Journal of Pharmaceutics and Biopharmaceutics, Suppl. 5S (1996).

M. Çelik, A.W. Newman, R. Mueller, C. Kiesnowski, I. Vitez, S.A. Sharpe, R.C. Moreton, "Pre-compaction and lubrication properties of Pruv", Pharm. Research, 13(9), S200 (1996).

M. Çelik, R.C. Moreton, B.E. Sherwood, J.D. Cobb, D.J. Schaible, and J.A. Zeleznik, "The effects of moisture content and particle size on the functional properties of microcrystalline cellulose for use in direct compression", Pharm. Research, 13(9), S209 (1996).

C. Driscoll-Ruegger, M. Çelik and S.D. Bateman, "Simulation of an instrumented manesty betapress using an integrated compaction research system", Pharm. Research, 13(9), S209 (1996).

M. Çelik and R.L. Schmitt, "A Study on the compaction properties of three water soluble polymers", Pharm. Research, 14(11), 1 (1997).

S. Wendel and M. Çelik, "Limitations of applying artificial neural networks to a small spray drying data set and methods for overcoming limitations", Pharm. Research, 14(11), 88 (1997).

DOCKET A L A R M



Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.