New Jersey Institute of Technology
Otto H. York Department of Chemical Engineering

Course: PhEn 606 Pharmaceutical Unit Operations: Solids Processing (3 credits)

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Course description: The course focuses on fundamentals of particulate processing, such as the particle characterization, blending, milling, granulation, tableting, and coating. The emphasis is on the application of macro- and micro-scale models of granular materials to quantify and scale up manufacturing pharmaceutical processes.

The course combines lectures, problem-solving, and project assignment to provide students with

- Fundamentals of particulate processing in pharmaceutical technology
- Societal and economic impacts of pharmaceutical powder technologies
- Ability to communicate effectively the acquired knowledge in written & verbal form

The course objectives

- Identify the fundamental macro- and micro-scale phenomena underlying particulate processing
- Introduce the basic operating principles of solids processing units
- Apply basic concepts to analyze and scale up manufacturing pharmaceutical processes

Course outline

• Introduction		Pharmaceutical Powder Technology Main Challenges of Pharmaceutical Technologies FDA Process Analytical Technology Initiative
• Particle & Granule Micrometrics		Particle Size Characterization Static and Dynamic Powder Sampling Particle Size Measurement Characterization of the Powder Bed Density, Porosity, Permeability, and Surface Area
• Continuum Mechanics of Particulate Solids	Flow of Powders	Flow of Granular Materials Mohr's Circle for Normal and Shear Stresses The Mohr-Coulomb Failure Criterion Active and Passive Rankine States Angle of Repose The Effective Wall Yield Locus Shear Testing Equipment Cohesionless and Cohesive Materials Stress-Strain Diagram Jenike's Method for Flow of Cohesive Powders Mass Flow Rate of Free-Flowing Materials Discharge Devices Janssen's Analysis of Stresses and Forces in Silos
	Powder	Basic Methods of Tablet Manufacturing

	Compaction	Diagram of Forces in a Punch-Die Assembly Characterization of Powder Compressibility Densification Behavior of Soft Powders Work Involved in Compression of Powders Optimization of Force-Displacement Diagram Mechanical Tests of Formed Compacts Indentation Hardness
• Micromechanics of Particulate Solids	Interparticle Forces	Dry Vs. Wet Granular Materials Van der Waals Intermolecular Forces Interaction of Elastically and Plastically Deformed Spherical Particles Adhesion Model for Particle Friction Types of Electrostatic Forces Two Spheres Joined by a Liquid Bridge Liquid Bridge Between a Cone and a Plane Viscous Force Between Two Colliding Spheres Impact and Rebound of Particles Classification of Interparticle Forces Particle Assembly Elasticity
	Wet and Dry Granulation	Wetting and Nucleation Drop Controlled Regime Granule Consolidation and Growth Characteristic Dimensionless Parameters Operating Regime Map Breakage of Wet and Dried Granules Measurements of Fracture Properties High and Low Shear Mixer Granulators Scale-Up, Endpoint Determination and Control Fluid Bed Granulation Geldart's Diagram of Fluidization Behavior Scale-up and Granulation Endpoint Dry Granulation Roller Compaction Pressure Distribution Between Rolls
	Mixing of Granular Materials	Mixing and Segregation Characterization of Powder Mixture Mixing Mechanisms Powder Mixers
	Particle Size Reduction	Mechanisms of Size Reduction Properties Affecting Size Reduction Classification of Mills Low- and High-Energy Mills

Tentative weekly listing of topics (15-week schedule)

Week	Topic	Subtopic
1	Introduction	
2	Particle & Granule Micrometrics Continuum Mechanics of Particulate Solids	
3, 4		Flow of Powders
4, 5		Powder Compaction
6	Midterm Micromechanics of Particulate Solids	
7, 8		Interparticle Forces
9, 10		Wet and Dry Granulation
11, 12		Mixing of Granular Materials
13		Particle Size Reduction
14	Project Presentations	
15	Final Exam	

Midterm and final exam

- There will be a midterm exam. Exact date of the midterm exam will be announced a week before.
- There will be a final exam during Finals' week, covering all of the course materials.
- The midterm and final exams must be completed individually, in accordance with the NJIT Honor Code.
- Each problem will be graded independently.

A missed midterm exam will be averaged into the final grade as *zero*, unless an excuse is obtained in advance. Excuses are granted only for very serious circumstances attested to by the NJIT administration, verifiable and significant medical problems, religious holidays, and also serious personal situations, such as deaths in the family. A student who has been excused will be required to take a makeup exam.

Project assignment

Students will work as a team by cooperating in a group to carry out a short research project on specific applications of solids processing and prepare a written report and a verbal presentation at the seminar. Topics for research projects may include but are not limited to:

- Particle size analysis and control for process quality
- Powder processing equipment
- Pharmaceutical powder mixing, compaction, fluidization
- Pharmaceutical powder testing
- Pharmaceutical powder blends
- Properties of pharmaceutical powders (adhesion, wetting, flowability, etc) and their effects on powder processing
- Powder coating for pharmaceutical applications

Project grading

Evaluation of an the written report and oral presentation will be based on

- Mastery of the subject
- Quality of the write-up
- Presentation of the subject matter
- Quality of visuals
- Capture of the audience's attention

Assessment criteria and grading

This course has been designed so that lectures, problem-solving, project assignment, and laboratory work are integral and essential parts of the learning process. Final grades will be determined from scores as follows:

- Project 40%
- Homework 15%
- Midterm exam 15%
- Final exam 30%

The final grade will be assigned on the basis of "*a curve*".

Course Materials

Lecture notes, relevant publications and websites:

- Chemical Engineering in Pharmaceutical Industry: R & D to Manufacturing, Ed. D.J. am Ende, Wiley, 2011
- Introduction to Particle Technology, 2nd Edition, Martin J. Rhodes (Editor), Wiley, 2008
- L.V. Allen, H.C. Ansel, Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems, 10th Edition, Wolters Kluwer Health, 2013
- Pharmaceutical Online http://www.pharmaceuticalonline.com
- FDA Process Analytical Technology (PAT) Initiative http://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/ucm088828.htm
- Introduction to Solids Processing and Particle Technology, AIChE Webinar, 2010 http://www.aiche.org/resources/chemeondemand/webinars/introduction-solids-processing-and-particle-technology
- Pay Attention to Mixing For Successful Process Development and Scale-up, AIChE Webinar, 2011 http://www.aiche.org/resources/chemeondemand/webinars/pay-attention-mixing-successful-process-development-and-scale
- Mixing and Blending of Solids, AIChE Webinar, 2013 http://www.aiche.org/resources/chemeondemand/webinars/mixing-and-blending-solids
- Strategies for the Design and Production of Particulate Materials, AIChE Webinar, 2014 http://www.aiche.org/resources/chemeondemand/webinars/strategies-design-and-production-particulate-materials
- J.N. Israelachvili, Intermolecular and Surface Forces, 3rd Edition, Elsevier, 2011
- E. Ortega-Rivas, Unit Operations of Particulate Solids: Theory and Practice, CRC Press, 2011
- L.L. Augsburger, S.W. Hoag, Pharmaceutical Dosage Forms: Tablets, 3rd Edition, Volume 1, Unit Operations and Mechanical Properties, Informa Healthcare, 2008
- J.P.K. Seville, U. Tuzun, R. Clift, Processing of Particulate Solids, Particle Technology Series, Volume 9, Springer, 1997
- R. Weinekötter, H. Gericke Mixing of Solids, Particle Technology Series, Volume 12, Springer 2000
- R. Xu, Particle Characterization: Light Scattering Methods, Particle Technology Series, Volume 13, Springer, 2002
- J. Litster, B. Ennis, The Science and Engineering of Granulation Processes, Particle Technology Series, Volume 15, Springer, 2004
- J.M. Valverde Millán, Fluidization of Fine Powders: Cohesive versus Dynamical Aggregation, Particle Technology Series, Volume 18, Springer, 2013
- H.G. Merkus, G.M.H. Meesters, Tailoring Properties for Optimal Performance, Particle Technology Series, Volume 19, Springer, 2014

Accommodations due to disability

If you need accommodations due to a disability please contact Chantonette Lyles, Associate Director of Disability Support Services, Fenster Hall Room 260 to discuss your specific needs. A Letter of Accommodation Eligibility from the Disability Support Services office authorizing your accommodations will be required.