

PME-628 - Pharmaceutical Finishing and Packaging Systems – Solid Dosage

Overview

The course covers finishing and packaging systems in the pharmaceutical industry, concentrating on the oral solid dosage forms. Finishing unit operations include blending, granulating, size reduction, drying, compressing, and coating for tablets, as well as blending and filling for capsules. Design of typical packaging line for solid dosage products, including equipment specifications and selection, line layout, material flow, operator needs will be discussed. Design and operation of packaging equipment for tablet and capsule counting, capping, security sealing, labeling, cartoning, and case packing will be considered. Approach for development of project documentation, such as equipment specifications, capital expenditure request, purchase orders, test plans, and validation documents, will be presented. Term project will require students to design a manufacturing plant and/or packaging line, considering material flow, space constraints, operator needs, and equipment selection.

Prerequisites: PME530.

Cross-listed with ME628, CHE628.

Learning Goals

- To learn solid dosage manufacturing and packaging technology
- To learn about the facility design, specification and procurement of process and packaging equipment
- To gain an understanding of the challenges associated with quality in solid dosage manufacturing and packaging

Pedagogy

The course employs lectures, online discussions, quizzes, homework, and term project.

Required Text(s)

Pharmaceutical Dosage Forms: Tablets, Second Edition, -- Volume 2, Herbert Lieberman, Leon Lachman, & Joseph Schwartz, Marcel Dekker, 1990, ISBN 0824782895.

Required Readings

Readings will be assigned for each week.

Assignments

The assignments and their weights are as shown below:

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| • Weekly assignments (discussions): 12 weeks x 20 points each | 240 points |
| • Self-check quizzes: 12 quizzes x 10 points each | 120 points |
| • Midterm | 100 points |

- Term paper/ project 150 points
- Final exam 150 points

Please note that assignments in this class may be submitted to www.turnitin.com, a web-based anti-plagiarism system, for an evaluation of their originality.

Course Schedule

Week	Topic Covered
0	Orientation week
1	Introduction and overview of product and dosage forms, process flow, finishing & packaging unit operations.
2	Mixing and granulation
3	Size reduction and roller compaction.
4	Drying of solid dosage products.
5	Tablet compression.
6	Coating of tablets.
7	Midterm Exam. Deadline for the term project topic selection.
8	Design of tablet manufacturing plant.
9	Primary packaging operations: container feeding, cleaning, filling, capping, tamper-evident sealing
10	Packaging operations: coding/labeling, vision inspection.
11	Secondary packaging operations: cartoning, bundling, shelf pack, and case packing, palletizing; auxiliary equipment
12	Packaging line performance issues. Simulation of packaging operations. Term Projects due.
13	Packaging line design, acquisition, commissioning and qualification.
14	Final Exam