



**Course Outline**  
***Introduction to Solid Dosage Forms***  
***for Production Operators***

**1) Introduction**

- a) Definition of a solid dosage form
- b) Manufacturing overview - raw material → finished product
  - i) Process flow

**2) Raw Materials**

- a) List
  - i) Active
  - ii) Dry binder
  - iii) Wet binder
  - iv) Filler/diluent
  - v) Disintegrant
  - vi) Surfactant
  - vii) Glidant
  - viii) Lubricant
  - ix) Flavor, Color, Coating, Carrier
- b) Active-What the dosage form “delivers”
  - i) Therapeutic response
  - ii) -Examples
- c) Dry binder- How the dosage form is held together
  - i) Compaction
  - ii) -Examples
- d) Wet Binder-Used to glue particles together
  - i) Usually dispersed in a wet granulation
  - ii) -Examples
- e) Fillers/diluents-makes dosage form user friendly
  - i) Dilute low dose drugs
  - ii) -Examples
- f) Disintegrant- Breaks the tablet back into particles
  - i) Draws fluid into the tablet, helps it explode
  - ii) -Examples
- g) Surfactant-wetting agent
  - i) Help solubilize tablet particulates
  - ii) -Examples
- h) Lubricant-keeps the formula from sticking to equipment
  - i) Coats sticky powder
  - ii) -Examples
- i) Glident-increases flow
  - i) -Examples
- j) Flavors/Colors/Carriers/Coating-customer appeal

- i) Marketing
- ii) –Examples
- 3) Exercise I**
  - a) Groups of 3-5 people
    - i) “Invent” (formulate) a prototype product
      - (1) Name your product
      - (2) What is the therapeutic response desired?
      - (3) Who is the target patient/customer?
      - (4) Lay out the formula
        - (a) Functionality, ingredient, quantity/dose
  - b) Review all prototypes
  - c) Define the “ideal” dosage form
- 4) Solids-Properties**
  - i) Chemistry
  - ii) Physics
  - iii) Mechanics (functionality)
- 5) Preparing a BLEND**
  - a) Mixture of actives and excipients
  - b) The ideal
  - c) Goal→Homogeneity Demonstrations
  - d) Types of blends
    - i) Distribution (dry blend)
    - ii) Dispersion (granulation)
- 6) Process Overview (Flow Chart)**
- 7) Processing**
  - a) Dispensing
    - i) Measuring components
  - b) Delumping/screening/milling
  - c) Granulation (dispersion blending)
    - i) Conventional granulation oven/tray dry
    - ii) Fluid bed granulation
    - iii) Dry compaction/granulation
  - d) Blending - Distribution (dry blending)
    - (1) Defraction blending
      - (a) High shear
      - (b) Low shear
    - (2) Diffusion blending
- 8) Measuring the Success of a Blend**
  - a) Demonstration
- 9) Physical Measurement Blend Classification (Fingerprinting)**
  - a) Particle size distribution
  - b) Density
  - c) Surface area
  - d) Porosity
  - e) Flow
- 10) Dosage Form Preparation**
  - a) Pill
  - b) Tablet

- c) Capsule
- d) Pouch
- e) Can

**11) Tablets**

- a) Basic principles of tableting
  - i) Compaction vs. compression
- b) Tablet press parts - schematic
- c) In-process monitoring
  - i) Physical measurements
    - (1) Weight/weight variation
    - (2) Thickness
    - (3) Hardness

**12) Encapsulation (Two Piece Hard-Shell)**

- a) Differences (vs. soft-shell)
- b) Basic principles
- c) Encapsulating machines (type, description, parts and operating principle)
  - i) Gravity (feed rings)
  - ii) Tamping
  - iii) Dosator
- d) In-process monitoring

**13) Post Dosage Form Operations**

- a) Tablet coating
- b) Capsule polishing
- c) Tablet/capsule printing
- d) Capsule banding
- e) Sorting

**14) Tablet Coating**

- a) Sugar coating
- b) Film coating
- c) Functional coating

**15) Other Unique Dosage Forms**

- a) Soft gelatin capsules
- b) Geltabs
- c) Gelcaps
  - i) Conventional
  - ii) Dipped
  - iii) Enrobed
  - iv) Pressfit
- d) Quick dissolving tablets
- e) Lozenges
- f) Gum

**16) Exercise 3 (time permitting) - Redevelop Your Product or Develop a New One**

**17) Conclusion**