



## Drug Formula – Tablet & Capsule

### Tablet Drug Formula

--A tablet contains:

- \*Active Pharmaceutical \*Ingredient (API) – therapeutic effect
- \*Excipients – aid manufacturing, stability, and drug release

### Typical Tablet Formula:

- \*API : 5–50%
- \*Diluent (Lactose, MCC) : \*20–80%
- \*Binder (PVP, starch) : 2–10%
- \*Disintegrant (SSG, CCS) : 2–8%
- \*Lubricant (Mg stearate) : 0.5–2%
- \*Glidant (Talc) : 0.2–1%

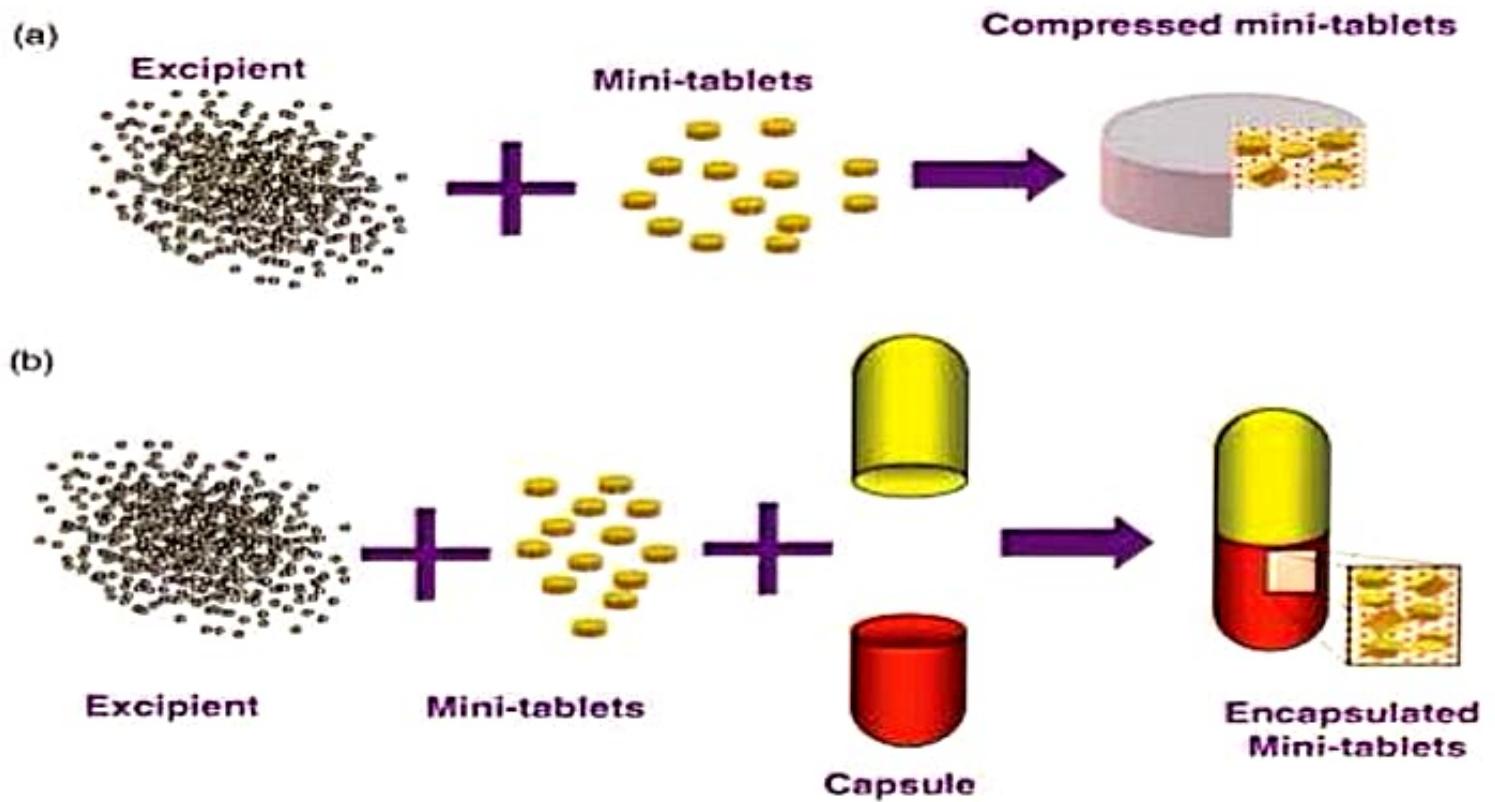


### Capsule Drug Formula:

\*Capsules may be hard gelatin or soft gelatin.

### Typical Capsule Formula:

- \*API
- \*Diluent (Lactose, MCC)
- \*Disintegrant
- \*Lubricant
- \*Capsule shell (Gelatin + water + plasticizer)



## 2: ☺ Formulation Process & Excipients Used

### Tablet Formulation Process--

1. Weighing of API & excipients
2. Mixing/blending
3. Granulation (Wet or Dry)
4. Drying
5. Compression
6. Coating (optional)

### Common Tablet Excipients

- a. Diluent: Lactose, Microcrystalline cellulose
- b.. Binder: PVP, starch paste
- C.. Disintegrant: Sodium starch glycolate
- D.. Lubricant: Magnesium stearate
- E.. Glidant: Talc

### Capsule Formulation Process

1. Blending of API with excipients
2. Capsule shell preparation
3. Filling of powder/granules
4. Sealing and polishing

### Capsule Excipients

Diluent: Lactose, MCC

A.. Lubricant: Magnesium stearate

B. Shell: Gelatin, HPMC (vegetarian)

### 3: Stability Factors Affecting : Tablet and capsule

#### Major Stability Factors--

1. Moisture – causes hydrolysis, shell softening
2. Temperature – accelerates degradation
3. Light – photodegradation of drugs
4. pH – affects chemical stability
5. Oxygen – oxidation reactions

#### Stability Protection Methods

- Use of antioxidants (BHT, sodium metabisulfite)
- Proper packaging (blister packs, HDPE bottles)
- Desiccants for moisture-sensitive drugs
- Coating of tablets

#### Stability Diagram

Drug + Heat + Moisture → Degradation



Proper Excipients & Packaging



Stable Product

# Challenges in Tablet & Capsule Formulation

## Tablet Formulation Challenges

- Poor flow properties
- Capping and lamination
- Weight variation
- Hardness vs disintegration balance
- Content uniformity

## Capsule Formulation Challenges

- Moisture sensitivity of gelatin shell
- API-shell interaction
- Capsule brittleness
- Leakage in soft gelatin capsules
- Dose uniformity

## Key Solutions

- 1\* Selection of suitable excipients
- 2\* Optimized granulation method
- 3\* Stability testing (ICH guidelines)
- 4\* Controlled manufacturing environment