



Industrial Pharmacy/Fifth Stage

Lecture:5

Dr Yasir Qasim Al-Majidi

PhD in Pharmaceutics

Al-Nahrain University/Collage of Pharmacy



Oral Solid Dosage Forms(Tablets)



Tablets Preparation Techniques

- Materials intended for compaction into tablets must have two characteristics:
 - 1) Fluidity
 - 2) Compressibility

Therefore tablet materials should be in physical form that flow smoothly and uniformly, besides being compressible.

Tablets Preparation Techniques

- Accordingly three established based preparation techniques have been introduced which are :
 - 1) Direct Compression
 - 2) Compression Granulation (dry granulation)
 - 3) Wet Granulation

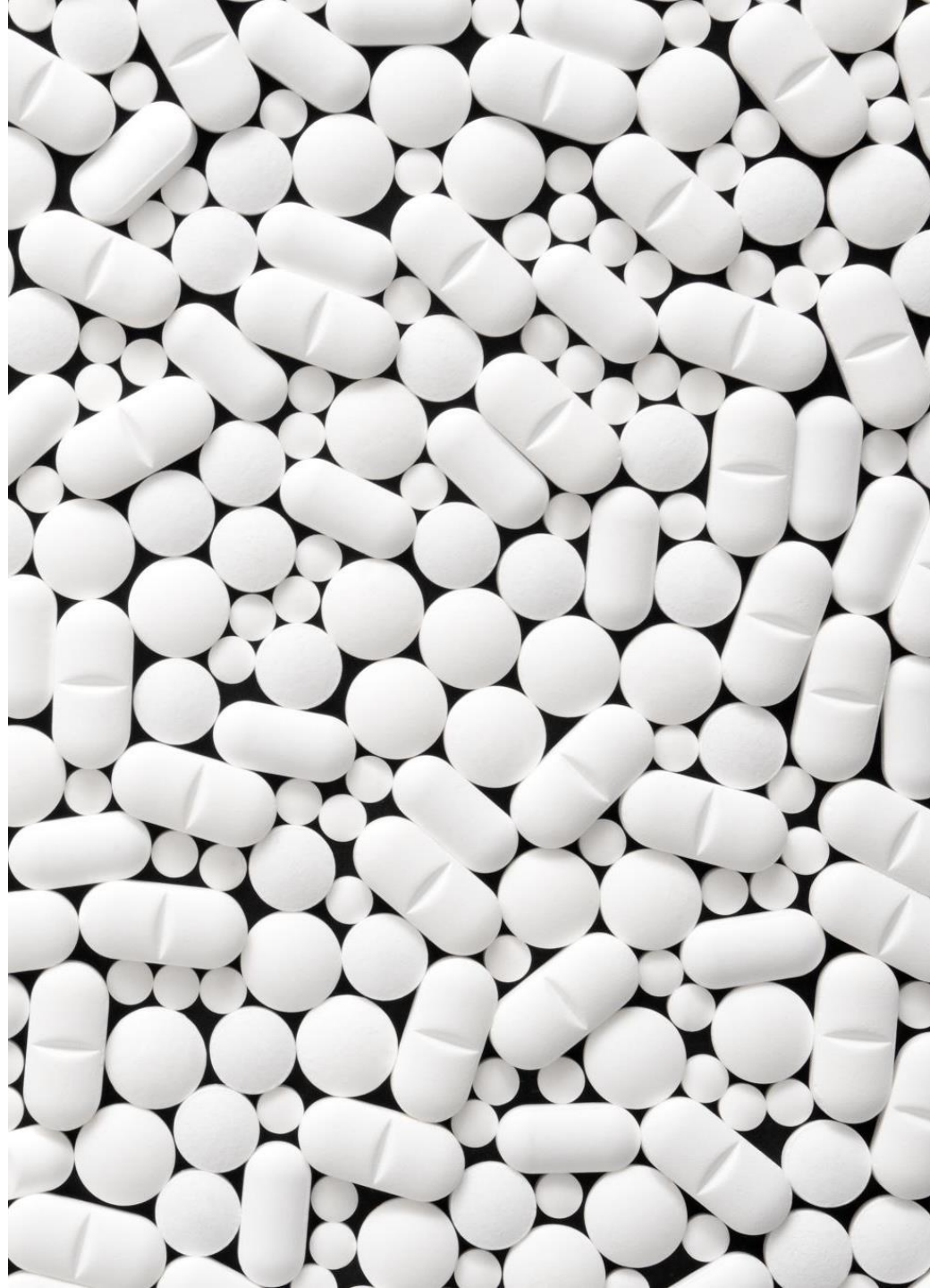


Direct Compression

- The processing of drug with excipients can be achieved without any need of granulation and related unit operations.
- By simply mixing in a blender, formulation ingredients can be processed and compressed into tablets without any of the ingredients having to be changed.
- This procedure is called direct compression and it is used in the manufacture of tablet when formulation ingredients can flow uniformly into a die cavity

Direct Compression

- The manufacture of tablets by direct compression involves comparatively few steps and they include
 - 1)Pre-milling of formulation ingredients (active drug substance and excipients)
 - 2)Mixing of active drug substance with the powdered excipients (including the lubricant)
 - 3)Compression of the mixed powders into tablets.



DIRECT COMPRESSION

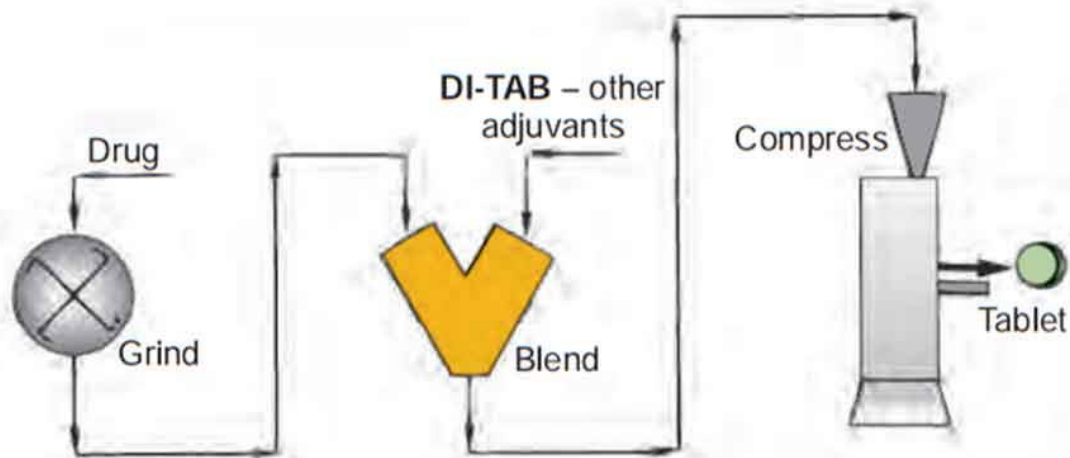
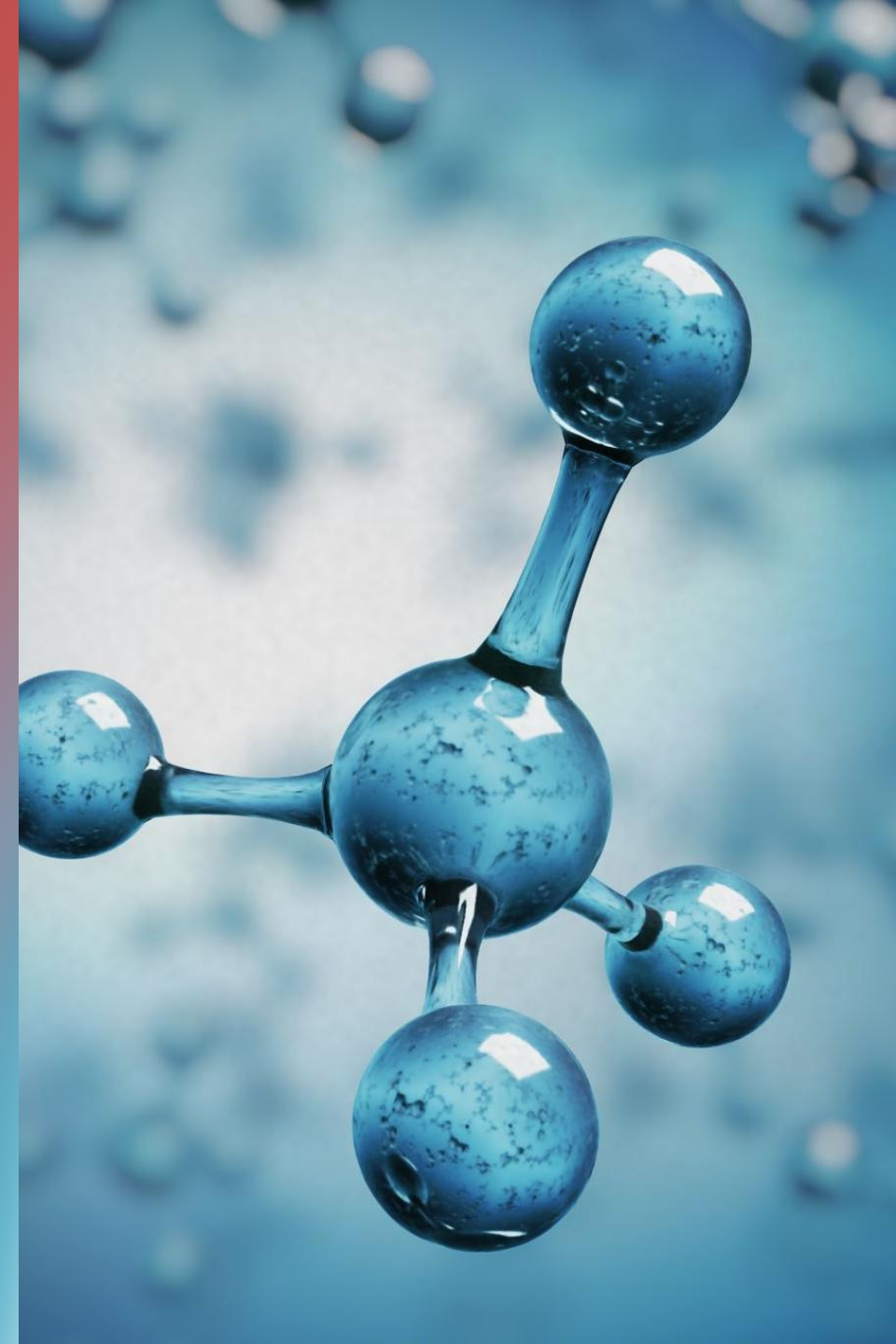
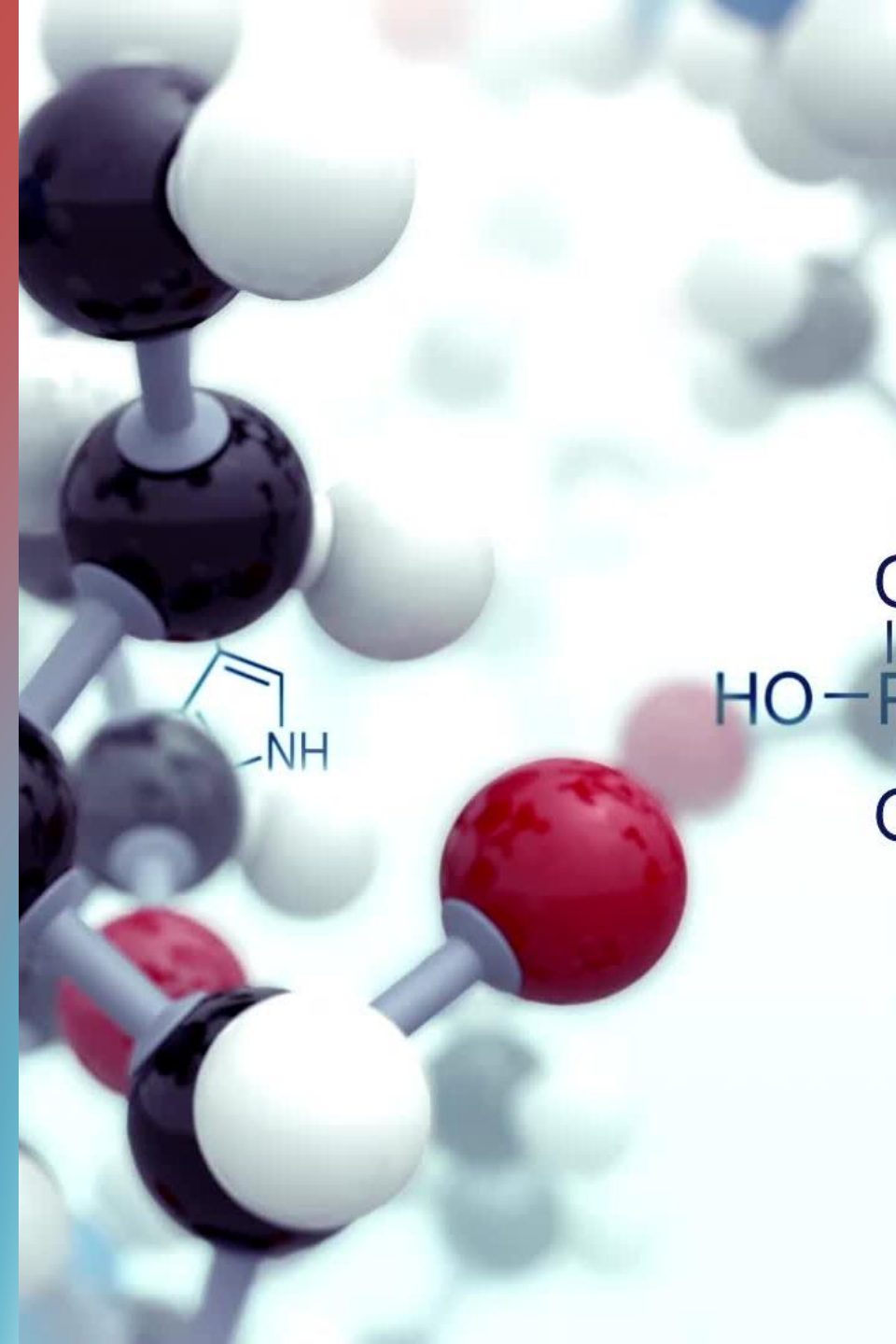


Photo credit: Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems, Philadelphia: Lipincott Williams and Wilkins



Direct Compression

- The term direct compression was reserved for a small group of granular chemicals having all the physical characteristics that enable them to be directly compressed into tablets without an intermediate granulating step.
- As most of medicinal agent have weak intermolecular attraction or covered with film of adsorbed gas that hinder compaction



Direct Compression

- As such, direct compression was restricted for chemicals, such as potassium salts (chlorate, chloride, bromide, iodide, nitrate, and permanganate), ammonium chloride

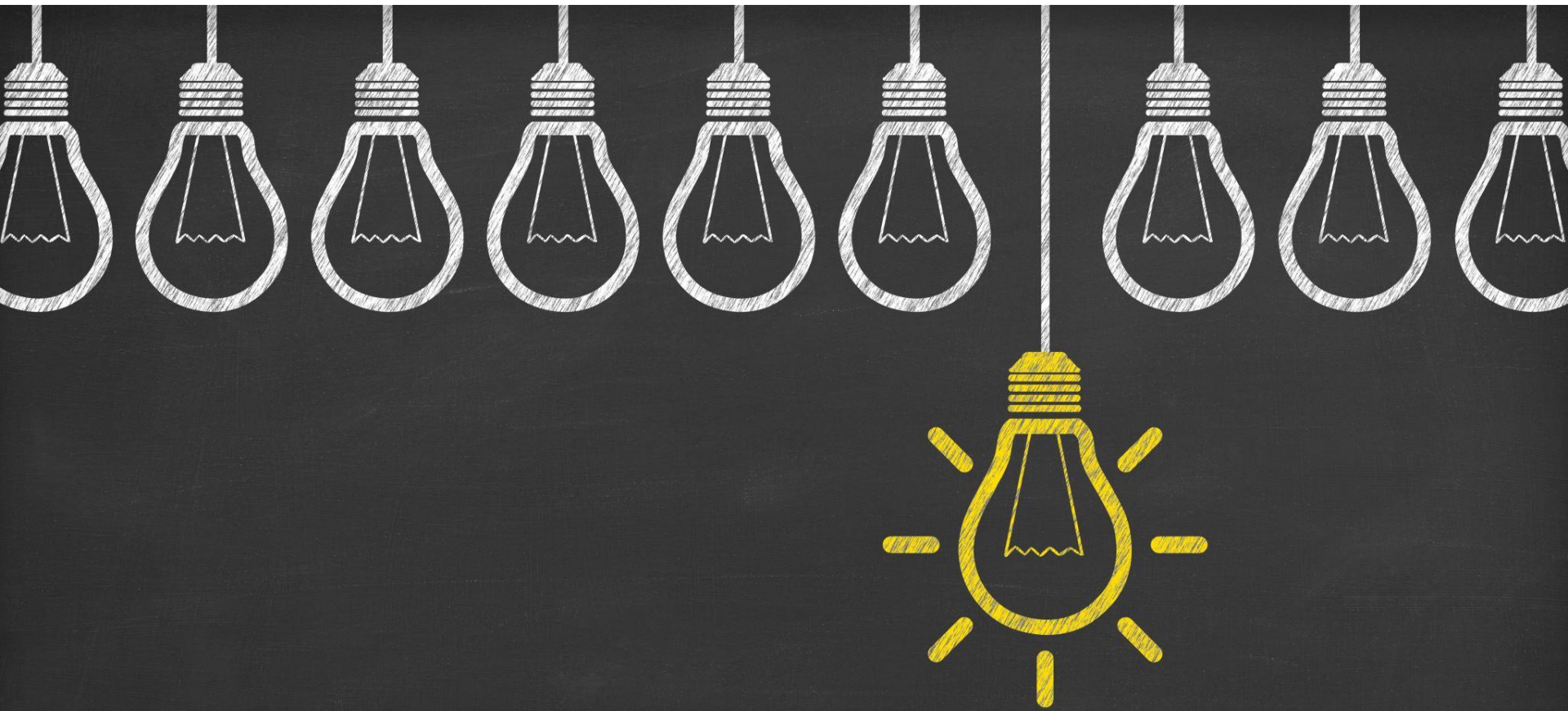
Direct Compression

- Today, the term direct compression is used to define the process by which tablets are compressed directly from powdered active drug substance and suitable excipients into a firm compact without employing the process of granulation



Direct Compression

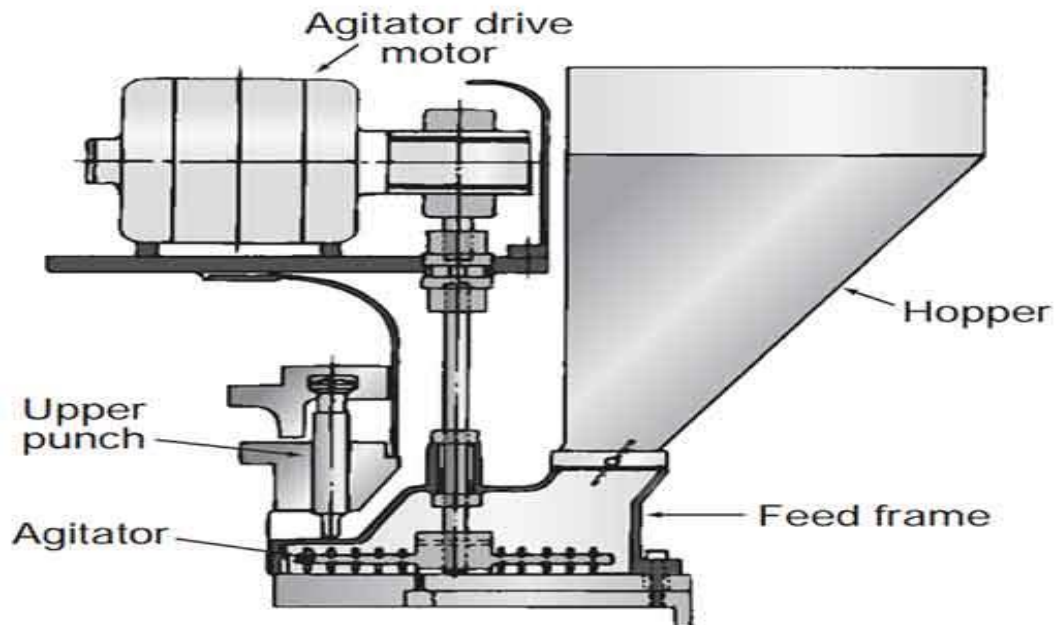
- The successful application of direct compression technique in tablet manufacture especially for low and medium dosage range of drugs can be attributed to the availability of new excipients, modified form of old excipients, and the invention and utilization of new tablet machinery



Direct Compression

➤ Direct compression technique using induced die feeders

This involves the use of a special feeding device which prevents segregation and enhances the flow of powders from the hopper into the die cavity of a tablet machine.



Direct Compression

Direct compression technique using direct compression excipients

also referred to as direct compressible excipients
filler/binders are inert, non-medicinal substances with good tableting properties.

Microcrystalline cellulose, spray dried lactose, are example on such excipients.

Advantages of Direct Compression

Direct compression method requires fewer processing steps (unit operations) and less equipment. Therefore, the method is potentially less expensive than other methods used in tablet manufacture

Tablet manufacture can be carried out without the involvement of moisture and heat. Hence, product stability is almost guaranteed

Advantages of Direct Compression



Some direct compressible excipients possess inherent disintegration properties e.g., microcrystalline cellulose.



Tablets produced by direct compression method generally show faster dissolution times than those prepared by wet granulation.



Changes in dissolution profile are less likely to occur in tablets manufactured by direct compression (if stored for a long time) than in those prepared by wet granulation

Advantages of Direct Compression

- Because direct compression excipients have a relatively high binding capacity, the pressure required to manufacture the desired hardness is, in general, less with direct compression vehicles than with conventional granulations, resulting in both higher production rates and longer machine life.



Drawbacks of Direct Compression Technology

High-dose drugs may present problems with direct compression if it is not easily compressible by itself



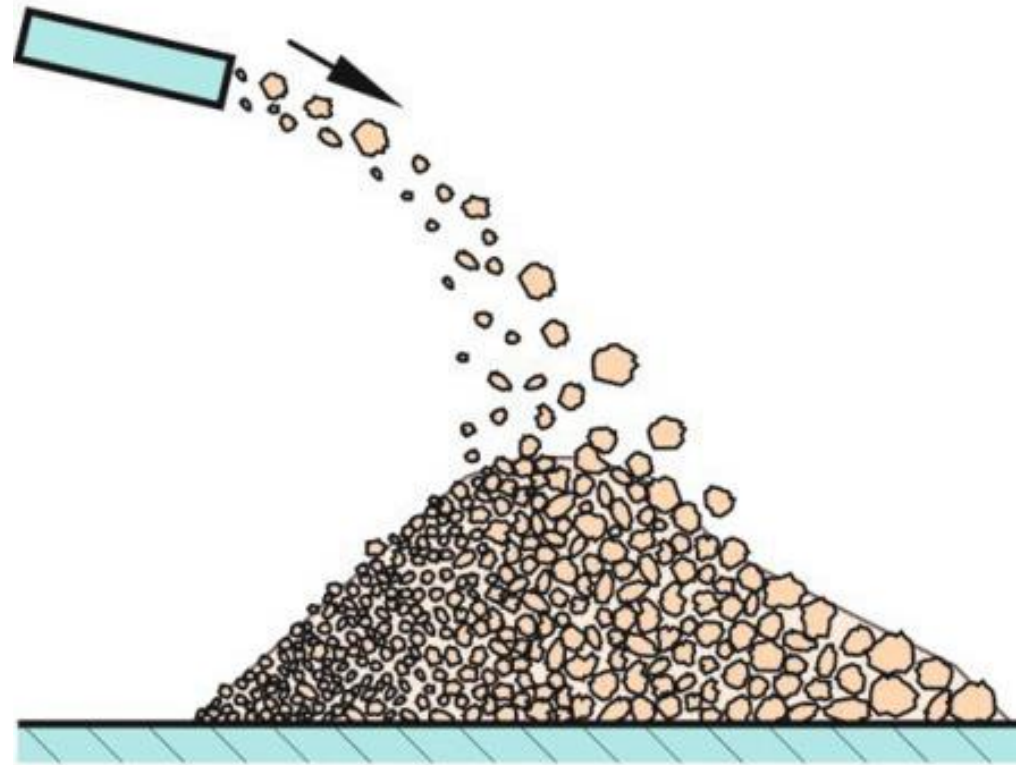
Low-dose drugs may not be uniformly blended



Direct compression excipients are often more expensive than other tablet excipients used in other granulation methods

Drawbacks of Direct Compression Technology

- Direct compression blends are subject to un-blending/segregation in post-blending handling steps which lead to poor content uniformity.



a)

Drawbacks of Direct Compression Technology

- This arises from lack of moisture in the blends (which may give rise to static charges leading to un-blending) or variations in particle size or density of formulation ingredients. This problem can be solved by applying the concept of ordered blending and/or use of excipients of narrow particle size ranges



Drawbacks of Direct Compression Technology

- In some instances, direct compression excipients may interact with the drug substance. A good example of such reaction is that which occurs between amine compounds and spray-dried lactose and this results in a yellow discoloration of the tablets.



Drawbacks of Direct Compression Technology

- Coloring of tablets is difficult to achieve when the colorant in dry particulate form.
- Tablet defects such as sticking, capping and lamination are usually pronounced in tablets manufactured by direct compression method





Thanks for
Listening