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المصادر والمراجع	The Theory and Practice of Industrial Pharmacy by Leon Lachman

محتوى المحاضرة

Industrial pharmacy is the science that deal with conversion of raw materials into certain dosage forms.

It deals with the whole processes of manufacturing, development, marketing and distribution of drug.

Steps of pharmaceutical industry:

Research and Development (Preformulation tests)

Production

Quality control

Marketing

Equipment used in industrial pharmacy (production step):

Sieves.

Millers.

Mixers.

Granulators.

Tablet machines.

Coating machines.

Semisolid fillers.

Dry oven.

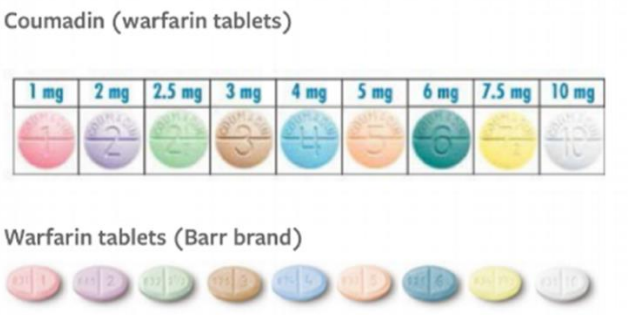
Freeze dryer.

Preformulation tests:

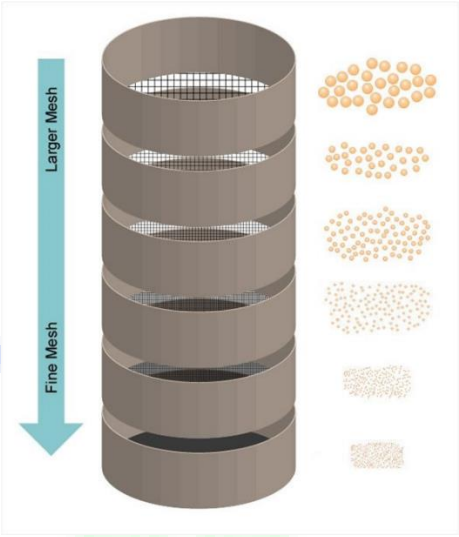
Can be considered as group of tests and studies for characterization of physical and chemical properties of the drug, in order to produce safe, effective and stable dosage forms, as well as economically suitable products.

They have a significant role in anticipating formulation problems and identifying logical development paths for dosage forms.

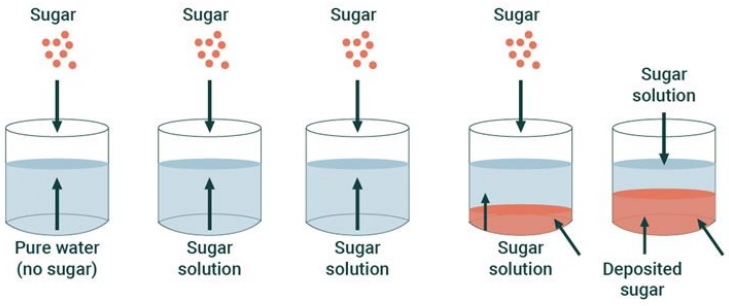
1. **Organoleptic properties:**
   Color: can be considered as stability indicator, also an important factor in pediatric preparations.
   Odor: also, as stability indicator.
   Taste: important in pediatric preparations.



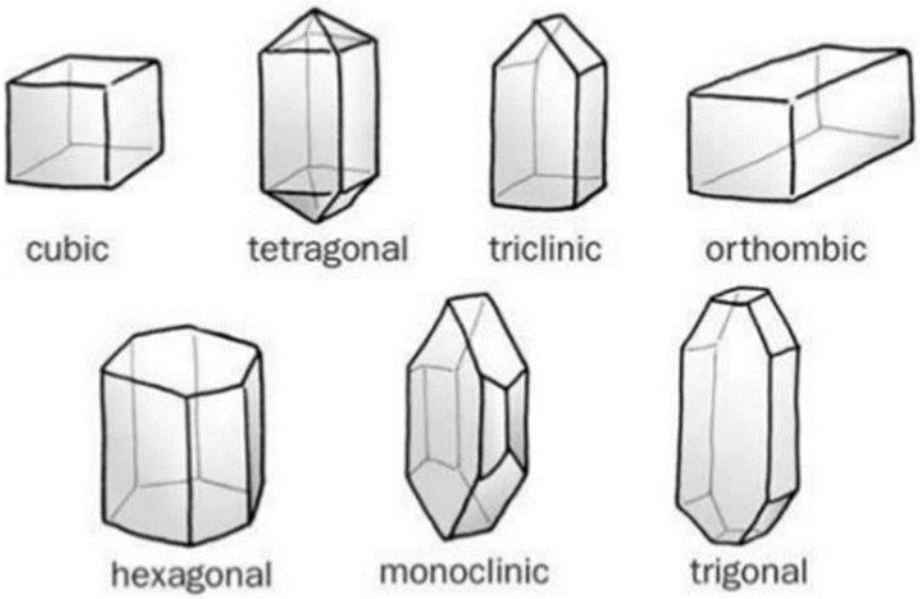
2. **Purity of the drug and excipients:**
   Important for stability and appearance of the final dosage form.
   The impurities even in low concentrations can affect negatively the final product and health of the patient.
3. **Particle size:**
   By means of surface area of particles it affects the rate of dissolution and solubility of the drug.



4. **Partition coefficient:**
   Proportional solubility of the drug between two immiscible liquids.
   Give an idea about solubility in aqueous media then absorption through biological membranes.
5. **Dissolution rate:**
   The rate at which drug goes into solution (amount per unit time).
   It is affected by particle size, porosity, boundary layer thickness, and the difference between solute concentration and solubility.
   It affects absorption and bioavailability of slightly soluble drugs.
6. **Solubility:**
   An expression of maximum concentration for certain compound in certain solvent at certain environment.
   It can be increased by using co-solvent, complexation, pH alteration, salt formation, and surfactants.
   Remember that, no drug will reach its ultimate therapeutic target without first being in solution.
   Measuring solubility at 4, 25, and 37 C^{o}.



7. **Crystallinity and polymorphism:**
   According to spatial arrangement; compounds can be either crystalline or amorphous.
   Polymorphism is the ability of the compound to exist in more than one crystalline form.
   The metastable polymorphs have higher solubility than stable polymorphs.



   Polymorphism can affect some physical properties:
   Solubility
   M.P
   Hardness
   Density
8. **Stability:**
   Checking both physical (hygroscopicity, polymorphism) and chemical (reactions, oxidation, hydrolysis) stability.
   Biological stability (micro-organism growth) is also important for pharmaceutical formulations.
9. **Flowability:**
   ability of powder material to move with relation to neighboring particles and container's wall surface.
   It can be affected by particle size, shape, density, force of friction, and cohesion forces.