Unit - I

Solubility of drugs

Introduction:

- ✓ In general terms, solubility is the maximum amount of substance (solute) dissolve in the given amount of the solvent at the specific temperature.
- ✓ **In quantitative term, Solubility is defined as** "Maximal amount of solute that can be dissolve in an amount of solute at specified temperature".
- ✓ **In qualitative term, it can be defines as** "When solute (solid, liquid or gaseous) is to be dissolved in solvent(solid, liquid or gaseous), it form a homogenous solution of solute in the solvent".
- ✓ **IUPAC defines the solubility as** "An analytical composition of saturated solution expressed as a proportion of a designated solute in a designated solvent."
- ✓ It is expressed as ppm (parts per million) according to BP in mg/ml (moles/litre).
- ✓ **The thermodynamic solubility of a drug in a solvent is** "Under equilibrium condition, at a given temperature and pressure, the maximum amount stable crystalline form that stay in solution in a given volume of the solvent."
- ✓ Thermodynamic equilibrium is obtained when the lowest overall energy state of the system is obtained.
- ✓ The solubility is an intrensic property of material that can be altered only by the chemical modificaton of a molecule.

- ✓ **Dependency**: The solubility of a compound depends on the physical and chemical properties of the solute and the solvent as well as on such factors as
    - ✓ Temperature

- ✓ Pressure
- ✓ pH of the solution
- ✓ To a lesser extent, the state of subdivision of the solute.

Key terms:

1. Solution: A mixture of two or more components that form a homogenous mixture. The components are referred to the solute and/or solutes and solvents and/or solvents.

2. Solute: A dissolved agent. (less abundant part of the solution)

3. Solvent: A component in which a solute is dissolved. (more abundant part of solution)

4. Saturated Solution: A saturated in which an equilibrium is established between dissolved and undissolved solute at a definite temperature.

(OR)

A solution that contains the maximum amount of solute at a definite temperature.

5. Unsaturated Solution: An unsaturated or subsaturated solution is one containing the dissolve solute in concentration below that necessary for a complete saturation at a definite temperature.

6. Supersaturated Solution: A solution that contain more of a dissolved solute that it would normally contain at a definite temperature.

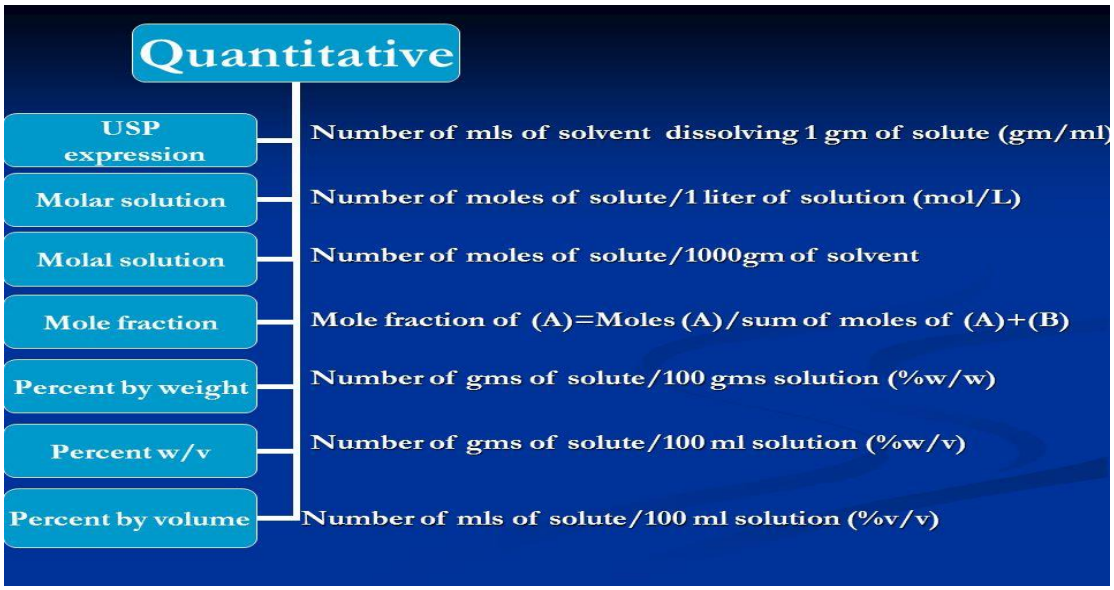
Solubility expression:

1. US Pharmacopeia and NF:

The United States Pharmacopeia (USP) describes the solubility of drugs as parts of solvent required for one part solute.

Definition	Parts of solvent required for one part of solute
Very soluble	< 1
Freely soluble	1 - 10
Soluble	10 - 30
Sparingly soluble	30 - 100
Slightly soluble	100 - 1000
Very slightly soluble	1000 - 10,000
Insoluble	> 10,000

2. Quantitative Expression



3. BCS classification: