

Pharmaceutical Chemistry - I.Impurities and Their Source.Pharmaceutical Impurities

The impurities in P'ceuticals are unwanted/undesired chemicals that remain with the active P'ceutical ingredients (APIs) or develop during formulation or upon aging of both API and formulation.

- (i) Presence of these impurities may influence the efficacy and safety of P'ceutical product.

27/11

Sources of impurities

According to the ICH (International Conference of Harmonisation) impurities in the new drug substance are classified as :-

- (i) Organic Impurities.
- (ii) Inorganic Impurities.
- (iii) Residual Solvent.

Sources of Organic Impurities.

→ Impurities originating from drug substance synthetic process.

- Starting material and intermediate.
- Reagent, ligands and catalyst.
- By-Product of the synthesis.
- Product of over reaction.
- Product of side chain.

Source of Inorganic Impurities

May be derived from manufacturing process and they are identified as reagent, ligand, catalyst, inorganic salt, heavy metals, filter aids, charcoal.

Residual solvent are impurities which are introduced / added with solvent in Pharmaceutical formulation.

Various Source of Impurities

Various source of impurities in Pharmaceutical substances are follows :-

(1) Raw material

(2) Method of Manufacturing

- (i) Reagents used.
- (ii) Intermediate products.
- (iii) Reagents used to eliminate impurities.
- (iv) Solvent used.

(3) Manufacturing Hazard.

- (i) Contamination from matter.
- (ii) Cross contamination.
- (iii) Contamination of microbes.
- (iv) Errors in manufacturing.
- (v) Error in storage and packaging.

(4) Instability of Product.

- (i) Chemical Instability.
- (ii) Physical Instability.
- (iii) Reaction with container.
- (iv) Temperature.

30.11

Effects of Impurities on Pharmaceutical formation.

- (i) Impurities may bring about incompatibility with other substances.
- (ii) Impurities may lower the self-life of the substances.
- (iii) Impurities may lower decrease therapeutic effects of pharmaceutical product.

- (iv) Some impurities may change the physical, chemical properties of the substance.
- (v) Impurities may show toxic effect after certain period.
- (vi) Impurities may change odour, colour, taste of substance.