

IMPURITIES



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IMPURITIES

Impurities defined as a foreign particle that affects the purity of a substance. Usually, impurities occurring in many pharmaceutical or medicinal preparations may be of the following types.

- Foreign particle that bring about adverse or toxic reactions when present in excess beyond their limits.

Example: lead, heavy metals, arsenic etc.

- Impurities which may not cause toxic effects but bring about deterioration of the activity of chemical.

Example: hard soap containing excess of water.

- Impurities that cause incompatibility of active ingredient with other substance or which reduce the properties of active ingredient.

- Impurities which may lead to technical problems in the applications of the substance.
- Example: presence of carbonate in ammonia solution, presence of KIO_3 in KI solution.
- Impurities arising due to humidity temperature.
- Example: presence of very low amount of moisture may enable substance to get oxidized easily or may reduce its free flowing characteristics.
- Impurities arising due to colouring and flavoring substances. These impurities can be detected by changes in colour, odour, taste and appearance.

Examples: Presences of phenolic compounds decolourize sodium salicylate, presence of minute quantities of magnesium salt causes dampening of sodium chloride.

- Impurities which may alter the physical and chemical properties of the substance.
- Impurities which decrease the shelf – life.

Source of impurities

Raw materials errors

conditions of storage

packing

Method / process

atmospheric

deliberate adulteration

Starting material or Reagents

Reagents employed to eliminate other impurities

Solvents or vehicles used in the manufacturing

Equipment used in the process of manufacturing

Intermediates generated during the synthesis

Chemical method used in the manufacturing process

Defects in the process of manufacturing

Manufacturing hazards

careless storage

filthy matter

effect of

container materials

Pharmaceutical preparation	Raw materials	Impurities present
Sodium compounds	Sodium chloride rock salt	Chlorides, Ca and Mg
Bismuth compounds	Bismuth salts	Lead, copper, and silver
Copper compounds	Copper turnings	Arsenic and iron
Zinc compound	Zinc metal or zinc oxide	Aluminum, copper, manganese, Mg, arsenic, iron and nickel.

Method / process of manufacture:

Manufacturing process involves various reactions carried out in single or multiple steps. Starting from the raw materials used, equipment, reactions, intermediates produced, solvents employed to the status of completion of the reaction, every aspect serves as the source of impurity.

Starting materials or reagents used:

Many reagents are used in the process of manufacturing a product. If the products are not washed properly to remove excess reagents, then these reagents are liable to be carried as impurities to the final preparation.

Reagents employed to eliminate other impurities:

In some manufacture process certain reagents are used to remove impurities present in the final product, these reagents if not carefully used are liable to get carried to the end product

Solvents or vehicles used in the manufacturing

Type of water	Impurities present
Tap water	Calcium, magnesium, sulphates, chlorides, sodium and carbonates
Softened water	Sodium and chloride
Demineralized water	Organic impurities
Distilled water	No impurities

Equipment used in the process of manufacturing

Material of the equipment	Impurity
Iron	Arsenic
Galvanized iron	Zinc
Soda glass	Alkali
Stream or waste pipe	lead

Intermediates generated during the synthesis

Most of the preparations involve generation of intermediates. If these intermediate products are not completely converted into the final product, they get incorporated as impurities.

Chemical methods used in the manufacturing process:

A substance or a reagent is subjected to a variety of chemical reactions during the manufacturing process. The type of chemical reactions like halogenations, oxidation, reduction, nitration, hydrolysis etc., employed may also contribute to the presence of impurities in the final preparation.

Defects in the process of manufacturing

Synthesis of a compound should be carried out under appropriate conditions along with correct measures of preparation. Improper mixing, incompleteness of the reaction, inappropriate temperature, pressure and pH conditions yield compounds with impurities.

Manufacturing hazards:

Hazardous and toxic substance such as dust, paints, fuel or chemicals present in the work place are capable of causing harm to the pharmaceutical products. The manufacturer should provide analytical procedure to limit such impurities. The manufacturing errors may go unnoticed. These are typical errors that occur due to microbial contamination, particulate contamination etc. specifications and analytical procedures are employed to estimate the identified or unidentified impurities and also to include limits for impurities.