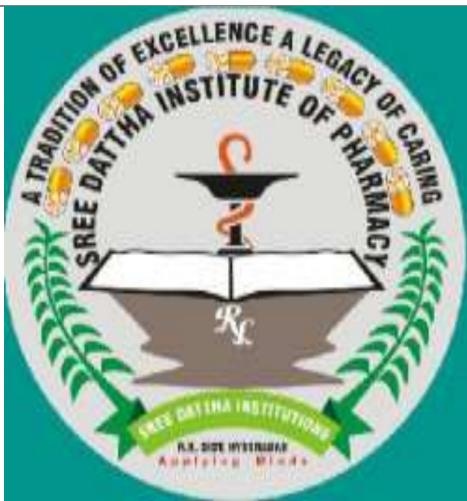
IMPURITIES



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Ph.D

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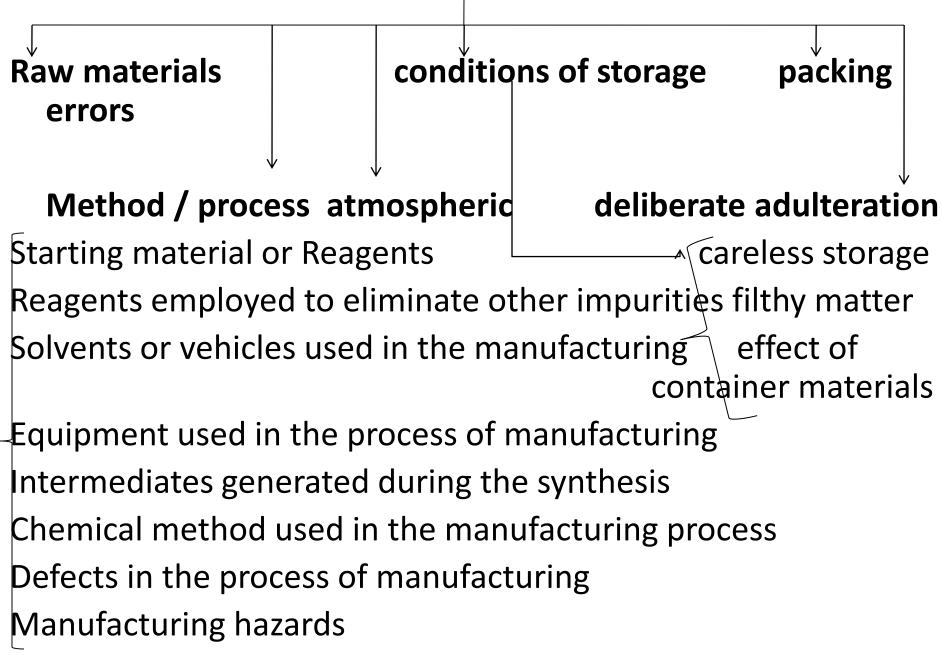
- Impurities defined as a foreign particle that affects the purity of a substance. Usually, impurities occurring in many pharmaceutical or medicinal preparations may be of the following types.
- •Foreign particle that bring about adverse or toxic reactions when present in excess beyond their limits.
- 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 KIO₃ 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.





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

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.