

Raw material used in manufacture

Impurities known to be associated with these chemicals may be carried through the manufacturing process and contaminate the final product.



E.g: Rock salt contains CaSO_4 & MgCl_2 . So, NaCl prepared from this will contain Ca & Mg .

Reagents used in the manufacturing process

If reagents used in manufacturing process are not completely removed by washing, these may find entry into the final products.



E.g.: Precipitate of NH_2HgCl contains NH_4OH . If not removed by washing, the final product may contain NH_4OH as impurity.

Method or the process used in the manufacture

Many drugs & chemicals are manufactured from different raw materials & by using different methods or processes. Some impurities are incorporated into materials during the manufacturing process.



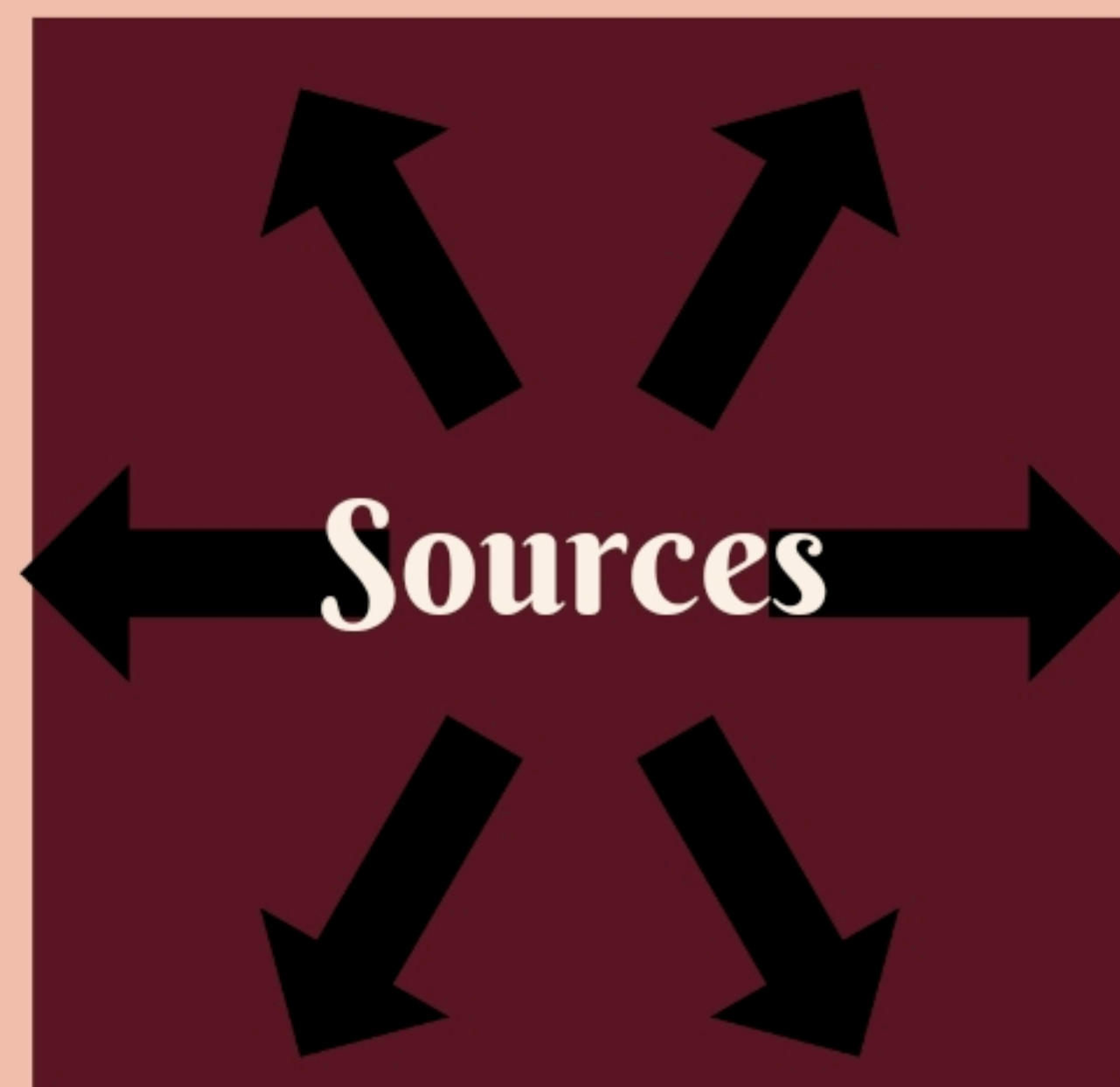
E.g: Reagents employed in the process, reagents added to remove impurities, action of solvents & reagents on reaction vessels.

Chemical process used in the manufacture

For the synthesis of drugs, many chemical reactions such as Nitration, Halogenation, Oxidation, reduction, hydrolysis are involved & different chemicals are used.



E.g: Tap water is used in the various processes & is having Cl^- , Mg^{2+} , Ca^{2+} ions, which are found in the substances being manufactured.



Atmospheric contamination during the manufacturing process

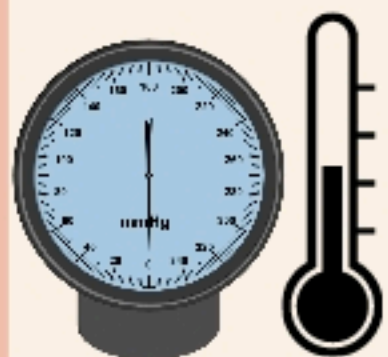
Atmosphere is contaminated with dust particles & gases like H_2S , SO_2 & black smoke. During manufacture/purification, these may enter the final products.



E.g NaOH absorbs atmospheric CO_2 .

Defects in the manufacturing process

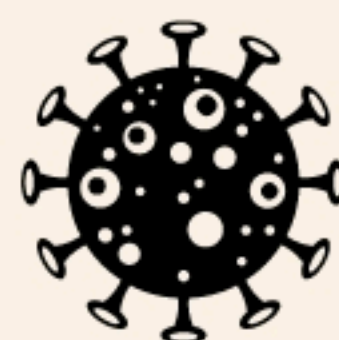
Defects like imperfect mixing, incompleteness, nonadherence to proper temperature, pressure, pH or reaction conditions, which may give chemical compounds with impurities in them.



E.g: ZnO is prepared by heating metallic Zn in current of air. But if there is air, Zn metal is not completely converted to ZnO . Thus it has metallic Zn as impurity.

Manufacturing hazards

Particulate contamination, process errors, cross contamination & microbial contamination



E.g Metal particles which have been found in eye ointments packed in metal tubes.

Intermediate products in the manufacturing process

Some intermediates are produced during manufacturing process & are carried to final product as impurity. E.g: KI is prepared by reacting I_2 with KOH . In this process if the intermediate product (KIO_3) is not completely converted into KI & becomes an impurity.



Storage conditions

Filth, Chemical instability, Reactions with container materials, Physical changes & Temperature effect.



E.g: Contamination with dust, bodies of insects & excreta. Decomposed by light, acid/alkali, air, water vapour & traces of metal ions. Physical changes occur if not stored at proper temperature.

Decomposition of the product during storage

Separation of a chemical compound into elements or simpler compounds. It is often an undesired chemical reaction.



E.g: Deliquescent substances, absorb water from the atmosphere and get liquefied.

Accidental substitution/deliberate adulteration with spurious/useless materials

Pharmaceutical chemicals are adulterated with cheaper substances.



E.g The expensive potassium may be adulterated with sodium bromide.