

* Source of Impurities :-

any foreign substance moves in a chemical compound. Impurities presence at one substance in another substance in low concentration.

① Raw material Employed in the manufacturing process :

natural source Synthesize

Ex 1: Lead and heavy metals - Sulphide ore
Impurities

2) Barium and Magnesium - Calcium mineral
Impurities

- 3) Aluminium ores usually contain alkali and alkaline earth metals.
- 4) Zinc contains magnesium & iron compounds.
- 5) Cl and SO_4 impurities in HCl and H_2SO_4

② method of manufacture:

a) Reagents Employed in manufacturing process - $CaCl_2 + Na_2CO_3 \rightarrow CaCO_3 + 2NaCl$

b) Reagents Employed to Remove other impurities

c) Solvents

d) Reaction Vessels

↓
potassium
bromide

↓
barium to Remove
Sulphate

Solvents:

1) Tap water: it contains Calcium, magnesium, Sodium, Carbonate (CO_3) Sulphate (SO_4), as impurities

2) Softened water:

it contains Sodium, Chloride as impurities

3) demineralised water:

These water have some bacterial, pyrogens and organic impurities

4) distilled water:

it is free from all the impurities
it is the best solvent.

Reaction Vessels :

The Reaction vessels may be metallic such as Copper, iron, galvanised iron, silver, aluminium, nickel, lead and Zinc.

→ adequate care should be taken to avoid Reaction

③ Chemical process used in the manufacture :

Eg: potassium iodide is prepared from iodine which is obtained from kelp sea weed

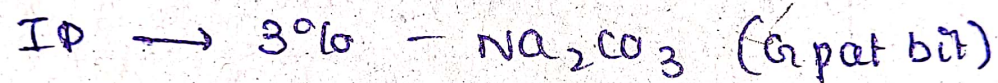
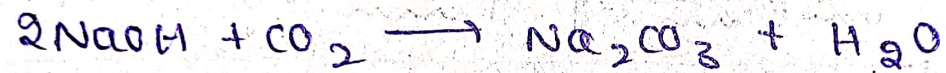
↓
(nitrogenous organic matter)

↓
when we heated we get
Cyanide

* Cyanides tend to get formed when nitrogenous organic matter is burned with alkali. Limit test have been prescribed for cyanides in potassium iodine

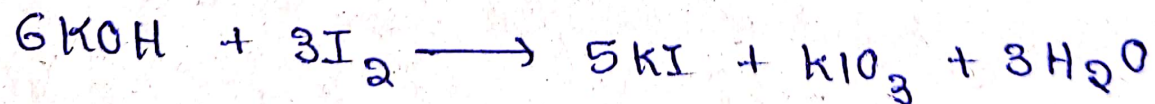
④ atmospheric contamination during the manufacturing process :

In Industrial area atmosphere is contaminated with dust particles like aluminium oxide, silica glass, plastic fragments, black smoke, hydrogen sulphide, sulphuric dioxide



Intermediate products in the manufacturing process:

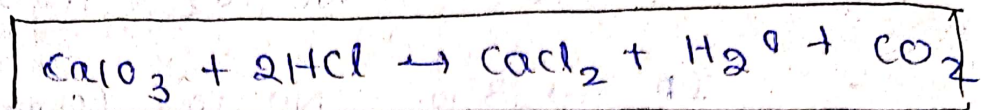
Some Intermediate products are formed in manufacturing process and may be carried to the final product as impurities



potassium iodide



⑥ defects in manufacturing process :



* Defects like Imperfect mixing may yield Chemical Compound with Impurities in them

→ in the given example if Calcium Carbonate and HCl is not completely mixed, that may remain in small quantity.

If prescribed limit test for acidity in Calcium Chloride.

⑦ Manufacturing Hazards :- Hazards means problem

- 1) Microbial Contamination
- 2) particulate Contamination → (dust particles)
- 3) Cross Contamination (we cannot handle all in bulk)
- 4) process errors

↓
eg: Imperfect mixing

5) packaging errors

-
- ① Contamination of product by the microorganisms
 - ② Contamination of product by dust particles
 - ③ bulk Quantity of materials should not handle at a time
 - ④ Imperfect mixing of the product may lead to the source of Impurity
 - ⑤ products of the similar appearance may lead to the confusion it may lead to error.

⑧

Decomposition of product during storage:

All the pharmaceutical products should be stored in their ideal condition

→ Some substances decompose on storing, The rate of decomposition increases in presence of light, air, & oxygen and these appear as impurity.

⑨

Storage Condition:

The Chemical substances are stored in different containers which are made up of plastic, Stainless steel, Aluminium, Copper.

Some substances may undergo Reaction and ~~thus~~ thus, Impurity may be formed.

Eg- Alkali when stored in glass container extract lead from it which is found in final product

⑤ ferrous sulphate slowly get changed into ferric oxide by air and moisture.

→ Inadequate storage condition and their effects are as follows

① filth

② chemical instability

③ Reaction with container material

④ temperature effect

⑤ physical change

→ ① if any material is not stored in their ideal condition it may lead to contamination due to the outer dust particles

- ② If any product is not stored in the Ideal Condition. The product may be contaminated due to the Instable Condition.
- ③ If any product is not stored in the given container, it may Contaminates due to the Chemical Reaction with the container.
- ④ If any product is not stored in a particular Ideal temperature, then the product may Contaminate due to different temperature and Humidity.
- ⑤ If any product is not stored in a correct place, It may Change its appearance like Colour, State.
- ⑥ Accidental substitution with spurious (a) material

There are many pharmaceutical Chemicals which are adulterated with cheaper substances.

KBr is adulterated with NaBr.

So Ip has prescribed a test for Na in KBr.