Quality control and quality assurance test in laboratories of API's

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- **Abstract** : API's (Active Pharmaceutical Ingredients) are the active substance in pharmaceutical products that provide the therapeutic effect and this are core components of medication. For this API the quality control and quality assurance test perfoming is important. The fundamental principle of the given experiment is to ensure the efficacy and the efficiency of the experimental API's. In this experiment researcher can gain the knowledge about the technological equipment used to perform the process. In that the various equipment can be used.

- **Keywords :** API's , Quality Control test , Quality Assurance, Laboratory Equipment

- **Introduction :**

Objectives :

1. To assess the current state of QC/QA practices in pharmaceuticals companies/labs, identifying strength , opportunities.
2. To identify the best practices in QC/QA , including innovative technologies, methods, and strategies.
3. Ensuring patient safety, efficacy and the products quality.

➢ ***Quality Control And Quality Assurance :***

❖ *Quality Control* : It is a process that helps a company make sure it creates quality products and that staff and management alike make minimal mistakes.

❖ *Quality Assurance* : Quality assurance in the pharmaceutical industry is a set of process+ that the safety, efficacy, and purity of medications. Primary goal of QA is to prevent issues and ensure that the final product meets predetermined specifications. QA also aims to build and maintain customer confidence in the product.

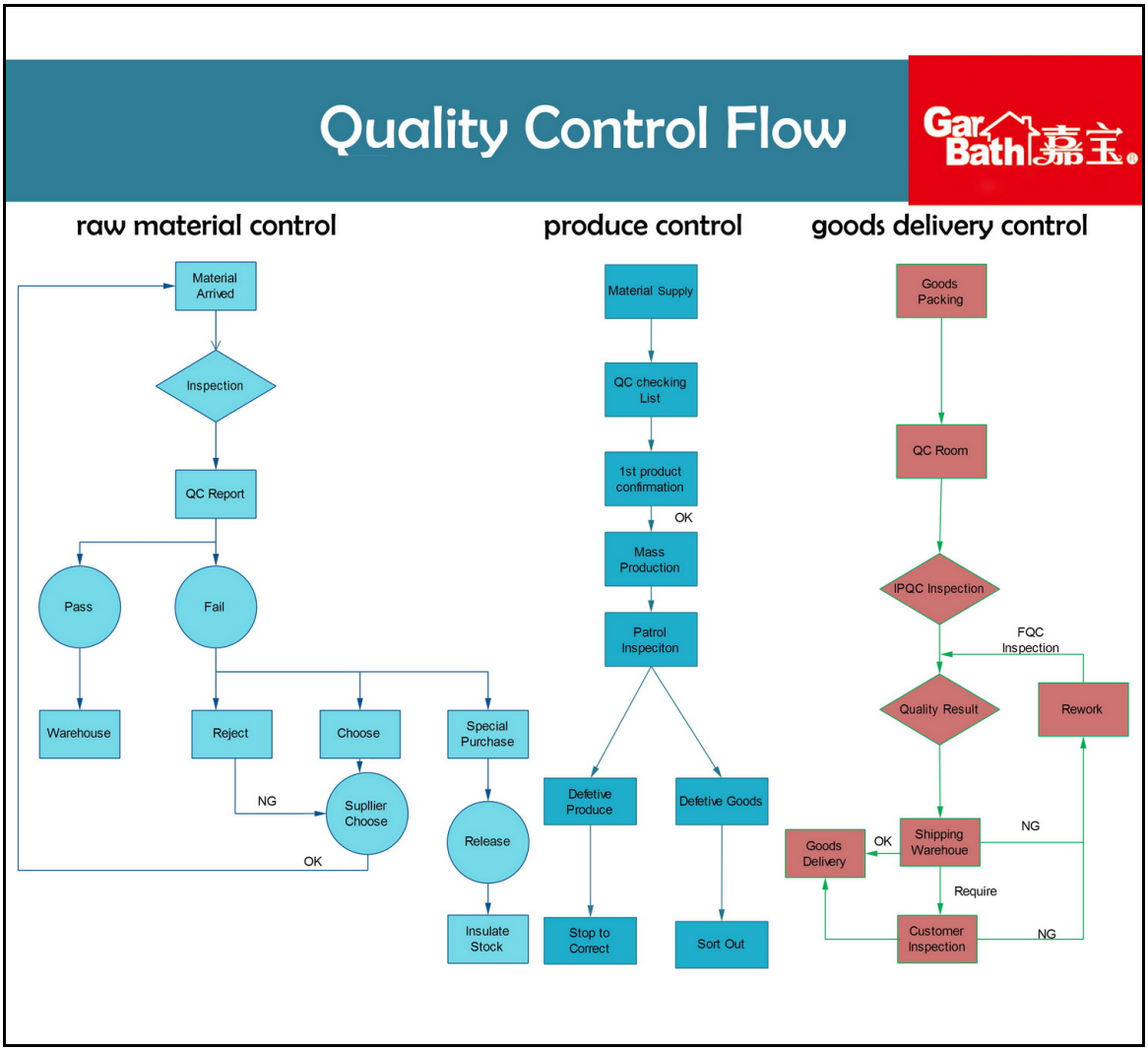
➢ ***Key aspects of QA*** –

- Quality assurance plan
- Good Manufacturing Practices
- Adverse event investigation
- Corrective and preventive actions plans.

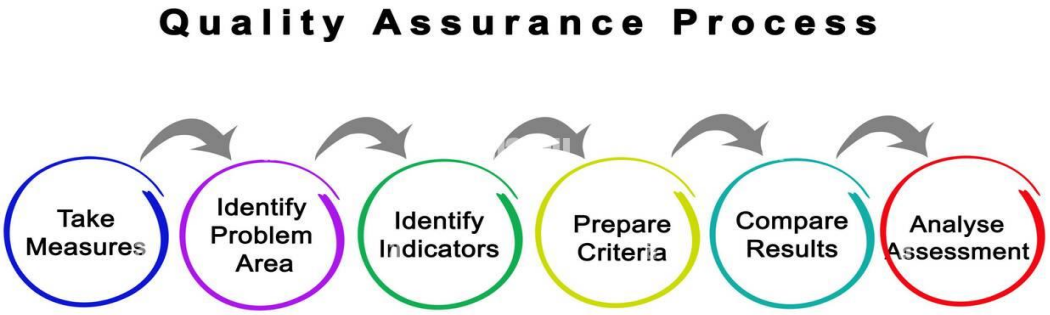
➢ *API's :* Active pharmaceutical ingredient is the substance in a drug that produces the desired medical effect. API's can be Synthetic or Natural.

Quality Control	Quality Assurance
Reactive	Proactive
Narrow process	Broad process
Goals is to detect mistakes or errors in a product	Goal is to prevent quality failures
Takes place after development	Takes place through the development process
Line function	Staff function

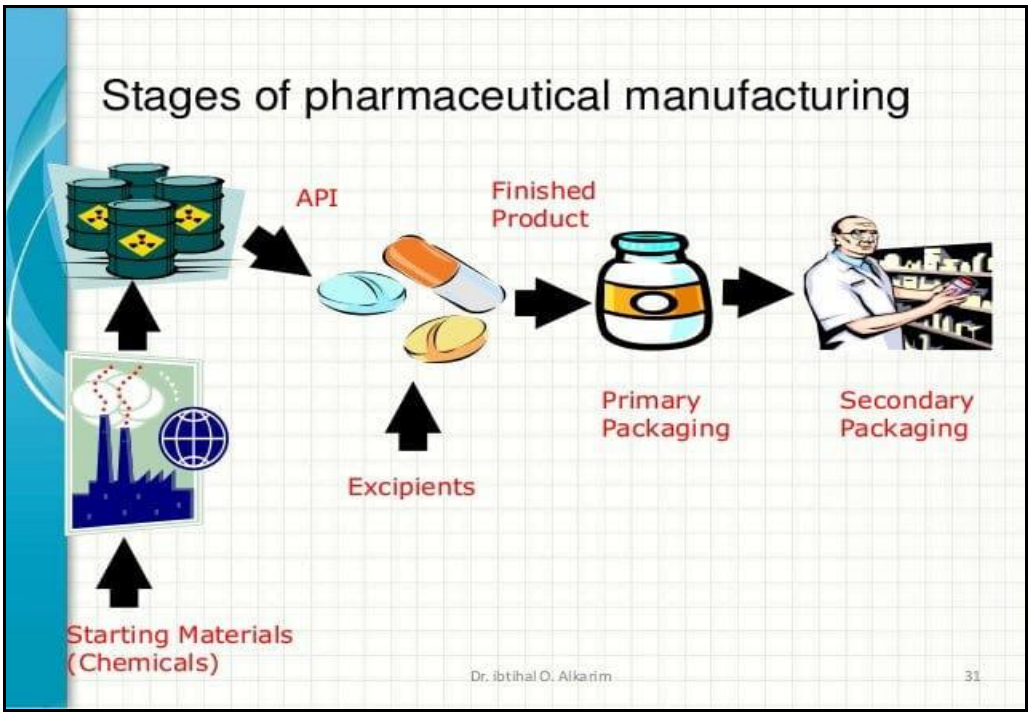
❖ **Quality Control Flow chart :**



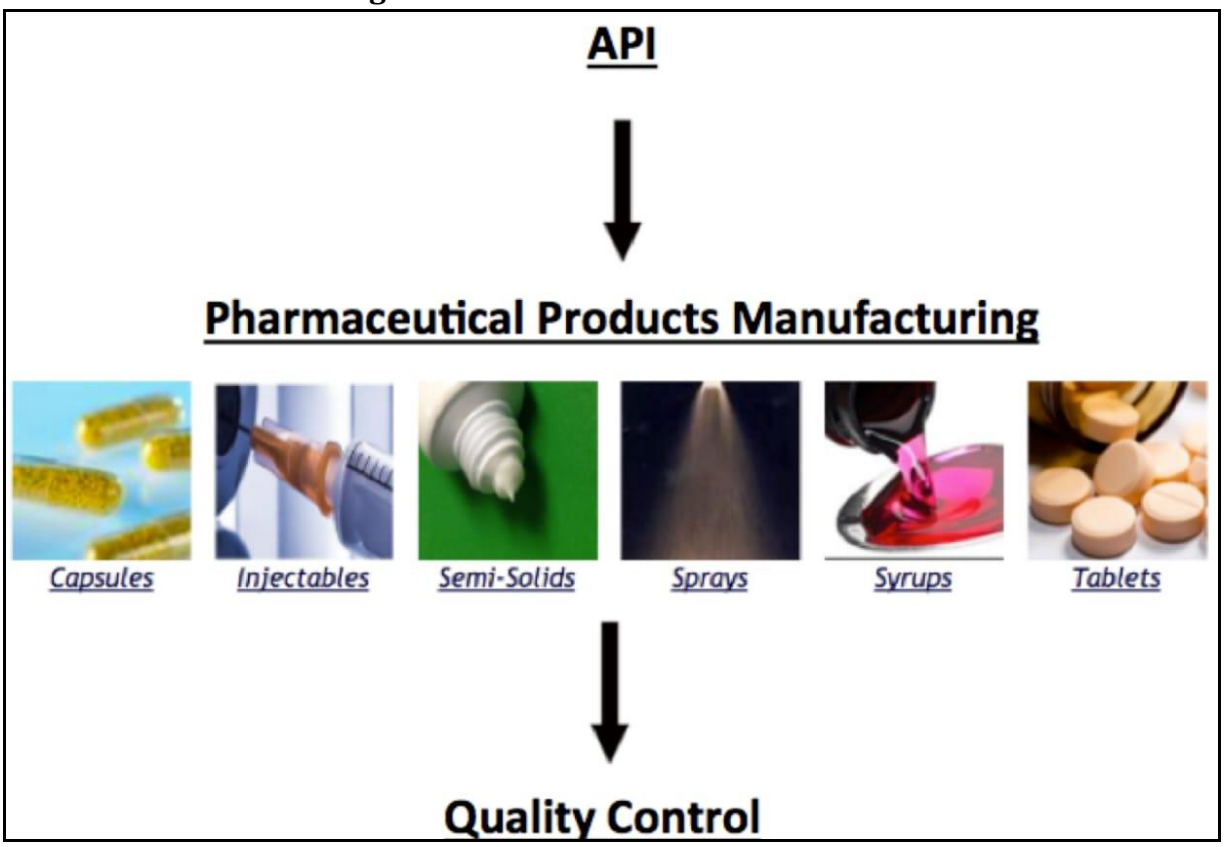
❖ **Quality Assurance Flow Chart :**



- **Stages Of Pharmaceutical manufacturing** :



❖ **Active Pharmaceutical Ingredients :**



- The **API** is the central ingredient. APIs are produced from raw materials with a specified strength and chemical concentration.

How Do APIs Work?

APIs work by interacting with cells within your body to produce their intended effects. For example, painkillers like ibuprofen and aspirin contain APIs that interact with your body's cells to reduce inflammation and relieve pain. Other types of drugs may contain APIs that interact with different parts of your body to produce different results – antibiotics may kill bacteria while antidepressants may help regulate moods by affecting brain chemicals like serotonin and dopamine levels

➢ **In the quality control test there are various equipments are used :**

1. Ph meter
2. Hardness tester
3. Dissolution apparatus
4. Disintegration apparatus
5. Spectrophotometer
6. Friability tester
7. HPLC

8. TLC
9. Incubator
10. Autoclave,etc.

1) PH meter :

A pH meter is a scientific instrument used to measure the acidity or alkalinity (pH) of a solution.

ranges of pH is from 0-14

- pH 0-1 being strongly acidic (e.g., hydrochloric acid)

- pH 7 being neutral (e.g., pure water)

- pH 13-14 being strongly alkaline (e.g., sodium hydroxide)

- ***Procedure :*** 1. Prepare pH meter

2. Calibration

3. Measurement (prepare sample ,take reading)

4. Post – Measurement (clean electrode , maintain meter)

2) Dissolution Apparatus :

A dissolution apparatus, also known as a dissolution tester, is a laboratory device used to measure the dissolution rate of pharmaceutical dosage forms, such as tablets, capsules, and injectables.

- ***Procedure :***

1. Prepare sample and dissolution medium.

2. Set apparatus parameters (temperature, agitation rate, sampling times).

3. Add sample to vessel.

4. Start test.

5. Collect and analyze samples.

- ***Application :***

1. Pharmaceutical development: Formulation optimization and quality control.

2. Bioequivalence studies: Comparing generic drugs to innovator products.

3. Quality control: Ensuring product consistency and stability.

3) Disintegration apparatus :

A disintegration tester is a laboratory device used to evaluate the disintegration time of pharmaceutical dosage forms, such as tablets, capsules, and suppositories.

- ***Procedure :***

1. Prepare sample (tablet, capsule, or suppository)

2. Fill disintegration tube with water (or specified medium)

3. Add sample to tube

4. Place tube in tester

5. Set temperature (37°C ± 0.5°C) and timing device

6. Observe and record disintegration time

- ***Application :*** 1. Tablets (immediate/controlled release)

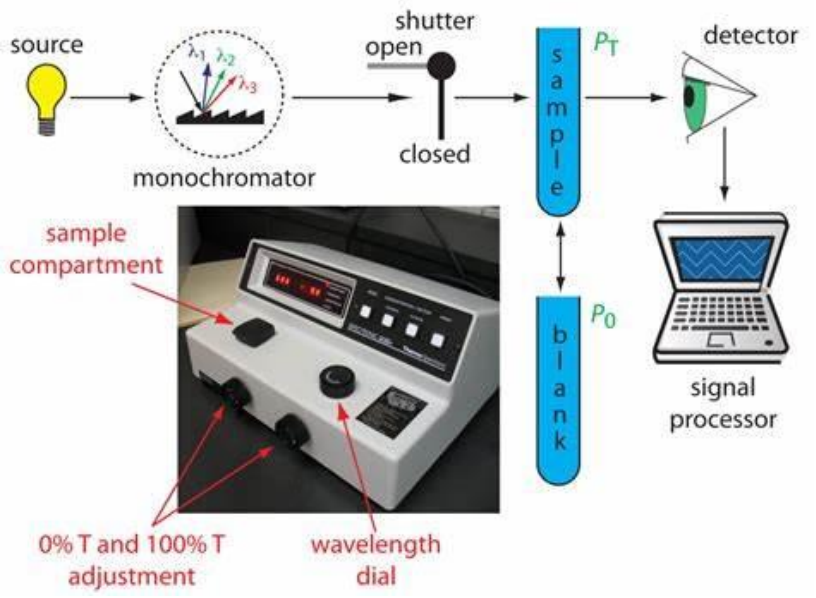
2. Capsules (hard/soft gelatin)

3. Suppositories

4. Buccal tablets

5. Sublingual tablets

4) Spectrophotometer :



A spectrophotometer is an analytical instrument used to measure the interaction between light and matter, detecting and quantifying the absorption, transmission, or reflection of light by molecules.

- ***Principle***

1. Light passes through the sample.

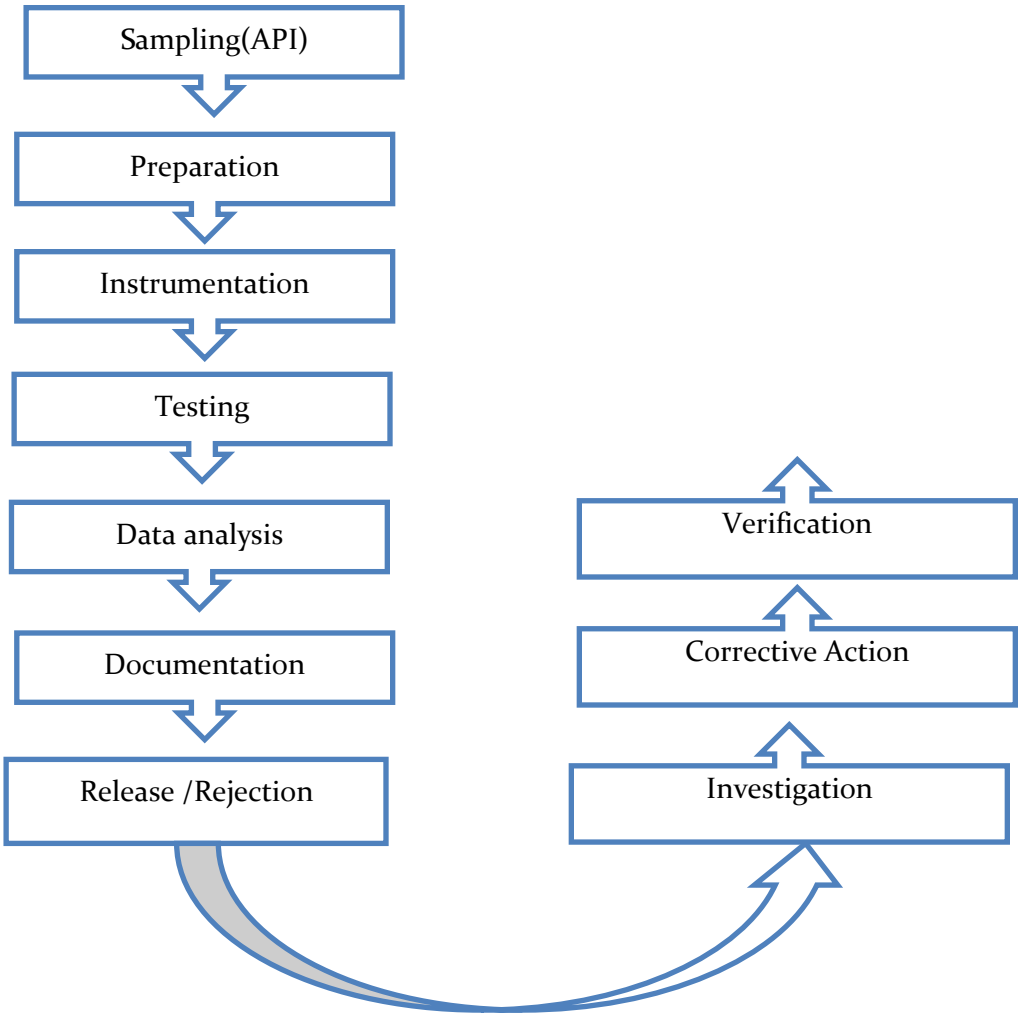
2. Molecules absorb specific wavelengths.

3. Detector measures transmitted or reflected light.
4. Absorbance (A) or transmittance (T) calculated.

❖ ***Applications:***

1. Pharmaceutical analysis (drug concentration, purity)
2. Biotechnology (protein quantification, DNA/RNA analysis)
3. Environmental monitoring (water, soil, air quality)
4. Food and beverage analysis (nutrient content, contamination)
5. Clinical diagnostics (blood analysis, medical research)

❖ *Methodology :*



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