SOLUTIONS :-

①

→

	Quality Control	Quality Assurance
Definition	• It is the process to ensure the identity and purity of a pharmaceutical products.	• It is the process to assure the quality of of any manufactured products..
	• Control & manage quality throughout manufacturing	• Check & Assure the quality after QC is completed.
Objectives	• to established the desired quality standards which are acceptable to the consumer..	• Assured the quality of raw material and of finished product.
	• to find flaws & variations	• Also manage GLP & GMP
② Responsibilities	• Responsible for day-to-day control of quality	• Ensure proper warehousing practices, manufacturing process and process check
	• Responsible for analytical testing of raw materials, packaging components etc..	• Responsible for making master plan, stability testing, shelf life evaluation etc.

(3)

→ Quality →

It is defined as the product with zero defects [OR] product that nuts "customer satisfaction".

- It refers to the degree of excellence.

(4)

→ GMP →

Good Manufacturing Practics

- It is the part of QA which ensure that the products are consistently produced and controlled according to quality standard for their indended use
- It is a set principles and procedures which followed by manufactures for the therapeutic goods.

(5)

→ Quality Audit/monitoring →

It is the process of systemic examination of a quality system carried out by an internal or external auditor or an audit team. It is a key element in the ISO quality system std.

(6)

→ TQM → Total Quality Management

It is the art of handling the whole to achieve perfection.

The main focus of TQM is to continuous quality improvement in the area of product / services, Employee - Employee relation and customer business relations.. — elements

(7)

→ ICH → International Conferance on Hormonization.

It is a joint association which involves pvt. industry and govt. regulatory bodies together as equal partner in scientific and technical discussion of testing procedure which is required to ensure the quality, safety and efficacy of medicines..

- purpose →

the main purpose to organise ICH is thalidomide tragedy in 1960's in Europe, thus It organised in rapid increase in law and guidlines for evaluating the data on quality, safety & efficacy

of new medicinal products..

- stability guidlines - Imq II

(8)

→ QSEM →

It is the part of ICH which includs guidlines

Q → Quality

S → Safety

E → Efficacy

M → Multidisciplinary

(9)

→ QBD →

Quality by Design

. It is a strategic process for development and manufacturing of pharmaceutical products..

. A systematic approach to development that begins with predefined objectives and emphasizes product and process understanding and process control, based on sound science and quality risk management.

(10) International organisation of standardization

→ ISO 9000 →

It is family of standards that are related to the quality management system.

- ISO 9000 certify the company about its quality.
- It helps a company to satisfy its customers
- It provides base level of quality system, not a complete guarantee of quality.

ISO 14000 →

It is family of standards that are related to the Environmental management system.

- It's main focus on environment thus encouraging a cleaner, Safer, healthier world for all of us.

(11)

→ NABL →

National Accrediation Board for testing and Calibration laboratories

It specifies the general requirement for the competence to carry out test and calibration including sampling.

- It provide national and international recognisation.
- It certify the laboratories..

(12)

→ Sterile areas →

It is a premise in a clean area, designed, constructed, serviced and used with an intention to prevent the microbial contamination of the product.

- It is also free from all types of catamination.

(13)

→ Environmental control →

(1) indicates the entire surrounding. It includes the biological, physical & social things present on the earth

- Pharmaceutical manufacturing plants produces large amount of waste material that pollute the environment.

It should take appropite step to reduce waste material, to reduce the consumption of raw material and control the pollution.

- It can be treatment by - Physical, Chemical and Biological treatment.. etc.

- Contamination control →

Contamination is the presence of any foreign substance in the product such as dirt, dust, Pollens, spores, bacteria etc..

- to control the contamination in steile area is necessary.
- It can be control by :-
  - Use proper tools designed
  - prevent cross contamination..

(14)

→ Personnel →

A person who is responsible for manufacturing, processing, packaging and handling of drug products should be provided with adequati education, training and experience is defined as personnel.

Organization →

An organisation, is an entity such as company, an institution or an association comprising one or more people and having a particular purpose

(eg.) Company, Institute, ISO, etc..

(15)

→ Material management →

It is a scientific technique, concerned with planning, organizing and control of flow of material from their initial purchase to destination.

- Components / Elements →
  - Demand estimation
  - Identify the needed items
  - Calculate from the trends in consumption during last 2 year
  - Review with resource constraints.. limitations.

(16)

→ Source of impurities →

Raw materials, Chemical instability, Reaction with container elements, manufacturing hazards, cross contamination ??, microbial catamination.

(17)

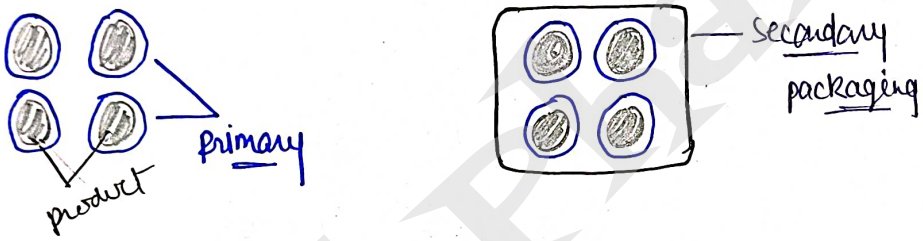
→ Primary packaging →

It is the packaging that's direct contact with the usable or consumable product

you are selling

Secondary packaging →

It is the packaging that pulls together all the primary packaging form of a single product.



(18)

→ Glass → It is strong, rigid, chemically, inert, impermeable and possesses protective qualities.

Classify →

Type -I	Type -II
Neutral or borosilicate glass (Highly) resistant)	Treated soda lime Glass
Type -III	**Type -IV**
Soda lime glass	General purpose soda lime glass

(19)

→ Quality control tests for glass containers

(1) • Chemical Resistant test
  • Powdered glass test — details ??
  • Water attack test — details ??
(2) Hydrolytic Resistance test
(3) Arsenic test
(4) Thermal shock test
(5) Internal bursting pressure test.

(20)

→ Water Attack test →

The principle involved in this test is to determine whether the alkali leached from the surface of a container is within the specified limit or not.

- Inner surface of ampoules is checked.

Container fused with Sulphur dioxide fumes
↓
neutralizes the surface alkali & make chemically more resistant.
↓
Methyl red indicator is used to determine the end point.

(21)

→ Rubber closures →

Also known as Rubber stoppers --

They provides a barrier between the neck of a vial and the vial content thus maintain sterility and prevent contamination.

used to close (or seal) the containers such as vials --

(22)

→ GLP → "Good Laboratory Practice"

It is a quality management system, that provides a frame work within which the laboratory studies are planned, performed, monitored and reported.

(23)

→ control articles → (Test articles)

The identity, strength, purity and composition or other characteristics which will appropriately define the test or control articles.

It shall be determined for each batch and shall be documented.

Test systems →

- It includes physical, chemical and biological test systems..
- Records of source, date of arrival and arrival conditions of test systems.
- Cleaning and sanitization of containers

(24)

→ Non-clinical laboratory study →

these are experiments in which test articles are studied prospectively in test system under laboratory conditions to determine their safety.

excludes field trials in animals

not provide direct diagnosis, treatment or care for the patients...

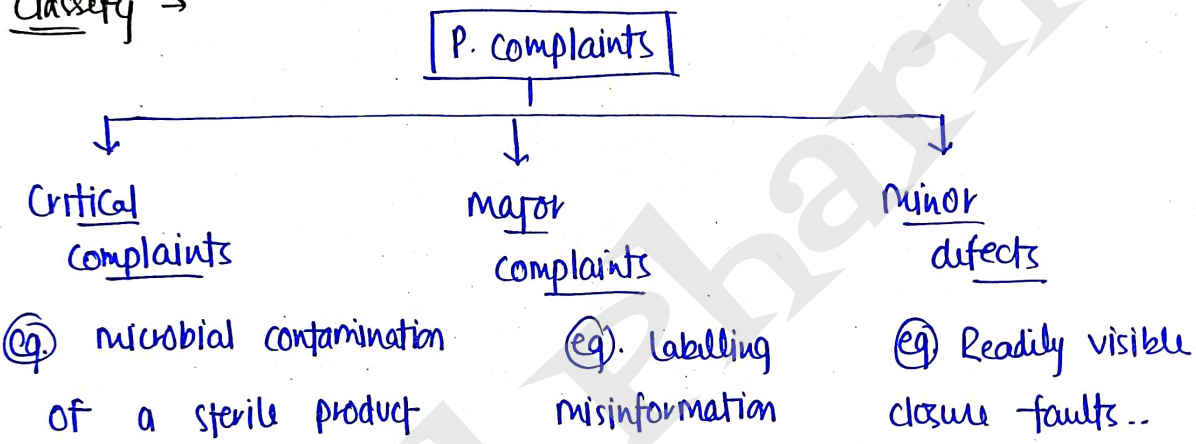
(25)

→ Pharmaceutical complaints →

It is the statement that is

something wrong or not good enough, which shows customer dis-satisfaction about the company and the products..

Classify →



(21)

→ Pharmaceutical products can be returned from market for various reasons :— quality problems, accidental damage of goods..

- After Return →
  - Physically examine the condition of return good & also check the relevant documents
  - Also Q.C department to examine the quality of the good & take a decision
  - Any action taken should be recorded.

(27)

→ Handling of Recalling →

Recall means a firm's removal or correction of a marketed product that the food and drug Administration considered to be in violation of the law its administers & against which the agency would initiate legal activities.

Classify → (Recall)

- Class I → serious adverse health consequences / Death
- Class II → temporary or medically reversible adverse health consequences
- Class III →

foreign objects that pose a physical hazards.

(28)

→ Documentation →

It is a system of information and control, to minimize the risk of mis-interpretation and errors inherent in oral or casually written documentation.

- Objectives →
  - provides necessary working details
  - Reduces the risk of mistake
  - Helps in decreasing batch to batch variations

(29)

→ Batch formula Record →

It is a written record that documents the entire manufacturing process and all the details such as products name, size, no. of batch, etc.

Master formula Record → (MFR)

It is a master document for any pharmaceutical products.

It includes all information about the manufacturing proces process for the product.

It is prepared by R & D department.

Eg.
MFR → Recipe
BPR → activity

(30)

→ SOP → Standard operating procedure

It is a set of written procedure explaining how to safely work with hazardous chemicals.

Its main aim to achieve efficiency, quality, and uniformity of performance

(31) Defins..

→ (1) Calibration → It is the process of determining the accuracy of an instrument/equipment, apparatus etc-

It involves obtaining a reading and measuring it with standards..

(2) Validation →

It is the documentary evidence for determining the consistency of the analytical method and manufacturing process.

- performed for water system, analytical method-

- Scope of Validation →
  - selection of raw materials..
  - process, material and equipment to prove consistent yield of a product of the required quality.

③ Qualification →

It confirm the working capabilities / ability of equipment that it will perform routinely and effectively.

- Qualification shall be performed or related to equipment, instrument, facility and area before use

④ Analytical Method Validation →

It is the process of determining the suitability of a given methodology for providing useful analytical data

manufacturing process.

- Results from Analytical method validation can be used to Judge the quality, reliability & consistency

of analytical results -

(5) Validation Master plan → (VMP)

It is a high-level document that establishes an umbrella validation plan for the entire project and summarizes the (manufacturer's overall philosophy & approach).

[or]

- Outlines the principles involved in the qualification of a facility, defining the areas and system to be validated, and provides a written program for achieving and maintaining a qualified facility

(6) Calibration of pH meter → imp -- ?? (suf)

(32)

→ Warehousing →

When you purchase goods from a manufacture and store them before they are shipped to another location for fulfillment. they are mainly a large plan building in industrial areas --

Good warehousing practics → (GWP)

It means storing supplies so that products are always available, accessible and in good condition

(33)

→ Out of trend →

A result that does not follow the trend based on the data already collected with the same compounds.

Out of specification →

A results that does not comply with stated accepted criteria..