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UNIT - III

GMP

ESSAYS

1) Write about GMP and CGMP.

Ans

GMP: Good Manufacturing practices

GMP is a part of Quality assurance which ensures that the products are consistently manufactured and controlled according to the quality requirements

- GMP is a set of principles, when followed by the manufactures, produce the products with the required quality

GMP Guidelines include,

1) Buildings & facilities:

- Buildings used are of suitable size, design and construction with proper cleaning & maintainance
- Floors, walls & cielings are constructed smoothly without any cracks
- Lighting and ventilation must be sufficient
- Water supply, floor drianage and sewage system must be properly maintained

2) Equipments

- The Equipments used must be well sanitized & well-maintained.
- The Equipments used in the processing & manufacturing must be handled by trained person to avoid any corossion

3) personnel:

- The personnel perform the operation must

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have enough training and experience to perform the function
- consumption of food / drink / smoking must be avoided.

4) Raw Materials:
- The raw materials must be stored and handled very carefully to prevent any mix-ups and contamination with micro-organisms
- The raw materials must be stored in the ware-house alphabetically labelled for easy identification

5) production,
- The production operations includes formulation, filling, in-process control methods etc
- The equipments used in the production must be properly maintained & Calibrated
- weighing during production is done separately

6) Laboratory Controls:
- All the Raw materials, in-process samples & finished products are tested to determine their physical & chemical properties and to determine any kind of errors / Microbial Contamination
- Sampling must be done according to the specifications.

7) Records:
- All the processing functions must be documented for future processings and stored as an evidence
- Individual laboratory controls, test results, must be documented.
- Documenting the disposition of rejected materials is essential.

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8) Labelling:

- The labelling must include warning signs - like 'keep reach out of children', 'stored in a cool place' etc
- It also includes the direction for use of that product i.e, 'for External use only' etc

9) Complaints:

- Handling of complaints is essential aspect in the pharmaceutical industry
- The product name, the date & time of purchase, description of the complaint must be clearly stated for proper investigation

CGMP: Current good Manufacturing practices.

- It was given by USFDA in Aug 2002
- The CGMP guidelines assures the quality, purity, strength of the drug products
- CGMP gives proper design, control for the manufacturing operations and facilities.

CGMP includes:

1) Personnel:

- The personnel must have enough knowledge about the particular operation that he has to perform and must be properly trained.
- He must follow the suitable safety precautions in the laboratory which include use of safety clothing, masks, gloves etc

2) premises:
- The premises of the plant-layout should be away from the living areas
- The plant-lay out must be big enough for the proper placement of all the equipment & to perform the intended operation
- The walls & floors must be smooth with out any cracks
- The plant layout must be equipped with proper water & drianage facilities

3) Equipments:
- The equipments used in the processing areas must be properly maintained
- The equipments must be calibrated before use.
- The equipment must be santized after every batch to prevent any mix-up's and contamination

4) Sanitation:
- The working areas, equipments must be sanitized at regular intervals of time
- The most commonly used disinfectants for sanitation include IPA, methanol etc

5) SOPs: SOP's are the step-by-step written procedu to perform any operation in the Industry
- It must be written in a clear & understandable language

6) Raw materials: All the raw materials procured from the supplier must be stored in a ware-house
- The raw materials are arranged alphabetically for easy identification

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(5) Write about ICH Guidelines

Ans: International Council on Harmonisation

- It was given in the year 1990 by US, EU & Japan
- The ICH brings the regulatory authorities and pharmaceutical industries together to discuss about the scientific and technical aspects of drugs registration.

ICH Guidelines include.

Q1A - Stability testing of New Drug substances & products
Q2B - photostability testing of " " "
Q1C - Stability testing of new dosage forms
Q1D - Bracketing & matrixing designs for stability testing
Q1E - Evaluation of stability date
Q1F - Climatic Zones III and IV

Q1A: Stability testing of (NDS) & (NDP) → New Drug substances / products

It includes:

i) Stress testing:

The stability of the New drug products & substances can be determined by stress testing of the active substances.

- various types of stress testing include
  - ✓ photo-stability
  - ✓ ↑ Temp
  - ✓ ↓ Temp
  - ✓ oxidation → done by placing substance in H_2O_2 solution
  - ✓ pH extremes → " " adding " to buffers of pH (1-10)
  - ✓ water

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2) Selection of batches:
- Stability studies must be done for at least three primary batches
- The batches should be manufactured by the similar methods of manufacture and procedures of the final products

3) Containers & Closures
- The stability studies should be conducted on the active substances packaged in a container that is same as the container used for storage and distribution.

4) Specifications
- The stability studies should be done on drug substances that are more likely to change during storage.
- The testing should include physical, chemical, biological & micro-biological qualities

5) Testing frequency
*) For long-term studies
1st year - Every 3 months
2nd - " 6 "
*) For accerlerated storage conditions
Minimum 3 points
Eg: 0 3 6
*) For intermediate-storage condition (12 months) → 4 points
Eg. 0 6 9 12

6) Storage conditions:

Study	Condition	Time period
long term	25 ± 2°c	12 months
Intermediate	30 ± 2°c	6 "
Accelerated	40 ± 2°c	6 "

Q2B Photo-stability testing studies include:

1) Testing on drug substance
2) " " " outside the immediate pack
3) " " " in immediate pack
4) " " " in marketed "

Light source:

Option 1: Artificial day light lamp D65 & ID65
2: Cool white flouroscent lamp.

procedure:

10ml solution in 20ml colourless ampule (Sample)

10ml solution in 20ml ampule wrapped in aluminium foil (Standard)

↓ Exposed to light

↓ Determine absorbance

↓ Change in absorbance is calculated

$$\Delta A = A_T - A_0$$

Q1C A New Dosage form is defined as the drug product which is a different pharmaceutical product type but contains same active ingredient in the existing drug product.

Q1D Bracketing:
It includes testing of only samples on the extremes such as strength, package size

Matrixing:
It includes testing of selected subset of total no. of samples.
After sometime, another subset of samples are tested

Q1E: The evaluated data should be presented in an appropriate format like tabular (or) graphical etc

Q1F: As per the survey of WHO, 30°C/65%RH is considered as long-term storage conditions

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SHORTS:

1) GMP (Essay)
2) TQM

Essays:

1) First Aid
2) Hazadrous chemicals
3) Safety rules at work place

Shorts:

1) PPE
2) Fire Extinguisher
3) Safety Signals & Signs

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SHORTS:

1) TQM

TQM means Total Quality Management.

→ TQM is a system developed in the pharmaceutical Industry inorder to improve the customer satisfaction regarding the products (Drugs)

→ TQM leads to the continous improvement in the quality of the pharmaceutical products

→ TQM is an approach in the pharmaceutical manufacturers to ensure the pharmaceutical products meets the required quality, safety, purity and efficacy.

Benefits:

→ Improving quality

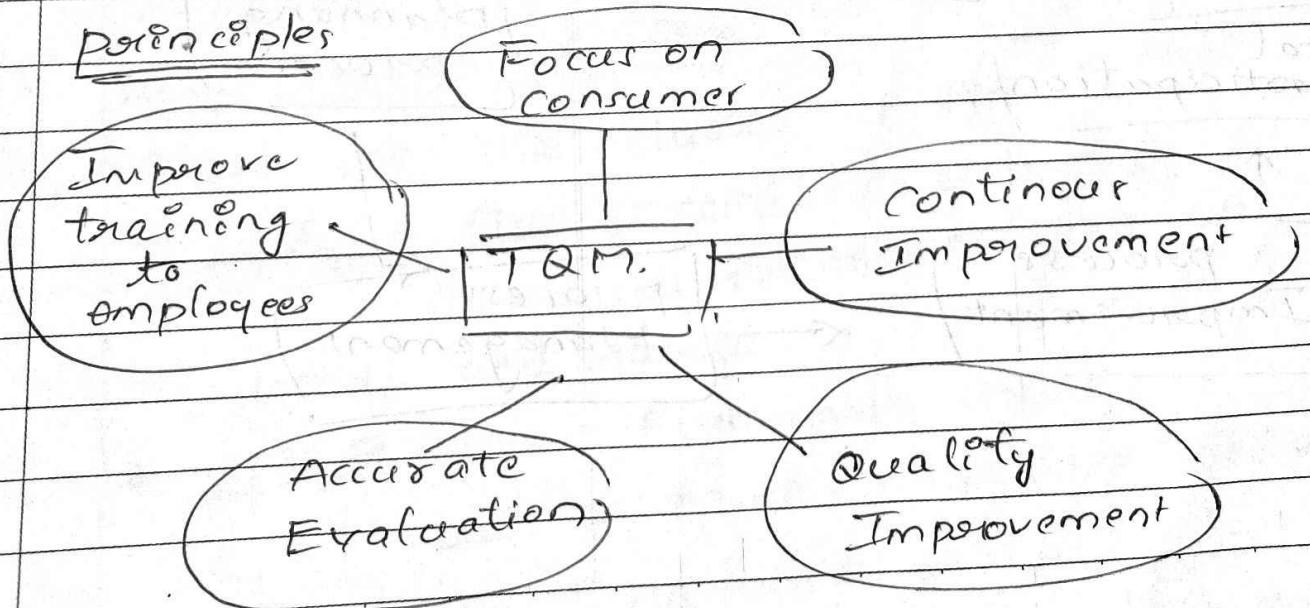
→ Lower production cost.

→ Increase product quality

→ Increased sales & profits

→ Development of New Innovations

Principles



Teacher's Signature :

Categories of TQM

TQM can be divided into 4 categories.

- ✓ plan
- ✓ Do
- ✓ check
- ✓ Act

It is called as PDCA cycle

① Planning phase - Most crucial in TQM
- Employees have to come up with their problem and doubts and challanges they face

② Doing phase - In this phase, employees develop a solution for the problems with strategies to overcome the challenges

③ Checking phase It is the stage, where there is a comparsion and analysis of results

④ Acting phase: In this phase, document the results

TQM Model