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BP505T · Pharmaceutical Quality Assurance

Unit II — Organization, Personnel, Premises and Materials Management

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From-zero teaching standard: every technical term is defined before use.

Syllabus coverage: Unit II (10 hours)

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CHAPTER 3: ORGANIZATION, PERSONNEL AND PREMISES

Unit II (10 hours)

(Syllabus: Organization and Personnel — responsibilities, training, hygiene, personal records; Premises — design, construction, plant layout, maintenance, sanitation, environmental control, utilities, control of contamination)

1. Learning Objectives

After studying this chapter, you will be able to:

1. Draw and explain the organization chart of a pharmaceutical manufacturing unit and describe the responsibilities of key personnel.
2. Explain why the Quality Assurance (QA) department must work independently of the Production department.
3. Describe the training system for pharmaceutical employees — induction training, on-the-job training, GMP training and refresher training.
4. List the personal hygiene rules that every person entering a manufacturing area must follow.
5. Explain what personal records are maintained for each employee and why.
6. Describe the design and construction requirements of pharmaceutical premises (location, building, floors, walls, drainage, lighting).
7. Explain the principles of a good plant layout, including unidirectional flow of materials and personnel.
8. Describe planned preventive maintenance of premises and utilities.
9. Explain sanitation procedures, cleaning of areas, and rotation of disinfectants.
10. Describe environmental control (temperature, humidity, pressure difference) and the role of HVAC systems.
11. List the utilities used in a pharmaceutical plant (water systems, steam, compressed air, electricity) and their quality requirements.
12. Define contamination and cross-contamination, list their sources, and explain measures to control them.

2. Definitions

1. Organization — The arrangement of people, departments and reporting relationships in a company, showing who reports to whom and who is responsible for what.
2. Personnel — All the people who work in the pharmaceutical unit, from the managing director to the helpers on the shop floor.
3. Quality Assurance (QA) — The total of all planned activities that give confidence that a product will meet quality requirements. QA is about preventing defects.
4. Quality Control (QC) — The part of QA that tests samples of raw materials, in-process materials and finished products in the laboratory to check whether they meet

specifications.

5. Good Manufacturing Practice (GMP) — The set of rules and practices that ensure medicines are consistently produced and controlled to the quality standards required for their intended use.
6. Premises — The land, buildings, rooms and areas where manufacturing, storage, testing and related activities take place.
7. Plant layout — The planned arrangement of rooms, areas, equipment and movement paths inside a factory building.
8. Contamination — The unwanted presence of any foreign material (dust, microbes, another product, chemicals) in or on a starting material, intermediate or finished medicine.
9. Cross-contamination — Contamination of one product or material by another product or material, for example powder of Product A mixing into Product B.
10. Sanitation — All measures taken to keep premises, equipment and personnel clean and free from harmful microbes and dirt, including cleaning procedures and schedules.
11. HVAC — Heating, Ventilation and Air-Conditioning: the system that controls temperature, humidity and cleanliness of air inside manufacturing areas.
12. Utilities — The support services supplied to manufacturing areas, such as water (purified water, water for injection), steam, compressed air, gases and electricity.
13. Quarantine — The status of a material that has been received but not yet tested and released; it is kept separately and marked "UNDER TEST" so that it cannot be used accidentally.
14. Gowning — The procedure of wearing special clean protective clothing (cap, mask, gown or coverall, gloves, shoe covers) before entering a manufacturing area.

3. Terminology (Word Bank)

Term	Simple Meaning
Organogram / Organization chart	A diagram showing departments and who reports to whom
Job description	A written document listing the duties of one post
Delegation	Formally giving your duty to another trained person when you are absent
Induction training	First training given to a new employee on joining
SOP (Standard Operating Procedure)	A written step-by-step instruction for doing a task the same correct way every time
Refresher training	Repeat training given at regular intervals so people do not forget
Health check-up	Medical examination of employees to ensure they are fit to handle medicines
Personal hygiene	Cleanliness habits of a person — washed hands, clean clothes, trimmed nails
Airlock	A small room between two areas of different cleanliness, with two doors that never open together
Change room	Room where workers change from street clothes into factory garments
Differential pressure	Difference in air pressure between two rooms, used to push air (and dust) in one direction
Air changes per hour	How many times the full volume of air in a room is replaced in one hour
Potable water	Drinking-quality water, safe for washing and non-critical uses
Purified water	Water treated to remove impurities, used in manufacturing and final rinsing
Water for Injection (WFI)	Highly pure, sterile, pyrogen-free water used for injectable products
Pest control	Measures to keep rats, cockroaches, flies and birds out of the factory
Preventive maintenance	Planned, regular servicing of building and machines to prevent breakdowns
Breakdown maintenance	Repair work done after something has already broken down
Calibration	Checking a measuring instrument against a known standard and correcting it
Disinfectant	A chemical that kills microbes on surfaces
Cleaning validation	Documented proof that a cleaning procedure removes residues to an acceptable level

Term	Simple Meaning
Status labelling	Labels like UNDER TEST, APPROVED, REJECTED fixed on materials and areas
Mix-up	Using the wrong material or packing the wrong product because of confusion
Recall	Action of withdrawing a defective batch from the market

4. Explanations

4.1 Organization of a Pharmaceutical Unit

Technical concept: A pharmaceutical manufacturing unit must have a clearly defined organization structure in which the Quality Assurance department is independent of the Production department.

Simple explanation: Imagine a cricket match. The players play (that is Production — they make the medicine). But there must also be an umpire who is not a player and who can stop the game if rules are broken (that is Quality Assurance — it checks and can stop production if quality is at risk). If the umpire were also a player, he would never give decisions against his own team. In the same way, QA must be independent of Production so that quality decisions are honest and not influenced by production pressure (targets, deadlines).

The organization chart (top to bottom):

1. Managing Director / Plant Head — Overall responsible for everything, including quality. Gives resources (money, staff, equipment) for quality work.
2. Head of Quality Assurance (QA Manager) — Responsible for the whole quality system: approving documents, batch release decisions, audits, handling deviations and complaints. Reports directly to top management, NOT to the production manager.
3. Head of Quality Control (QC Manager) — Responsible for the laboratory: testing of raw materials, in-process and finished products; approval of specifications and test methods.
4. Head of Production (Production Manager) — Responsible for manufacturing products exactly as per approved documents, keeping areas and equipment clean, and training production staff.
5. Warehouse / Stores Manager — Responsible for receipt, storage and issue of materials under correct conditions.
6. Engineering / Maintenance Head — Responsible for maintenance of building, utilities and equipment, and calibration.
7. Authorized person(s) — Trained, named individuals who are authorized to release batches and sign important quality documents.

Key takeaway: QA and Production are two separate teams. QA can say "stop" to Production. This independence is the backbone of GMP.

4.2 Responsibilities of Key Personnel

Technical concept: Every post must have a written job description, and there must be a sufficient number of qualified people to do the work.

Simple explanation: In a hospital, the doctor, nurse and pharmacist each have fixed duties — the nurse does not do the doctor's job. Similarly, in a pharma company every person must know exactly what they are responsible for, written in a document called the job description. There must also be enough people — one tired person doing the work of three will make mistakes.

Main responsibilities in simple words:

- Top management: Provides money, staff and facilities for quality; reviews quality performance regularly.
- QA Head: Approves master documents and SOPs; approves or rejects batches (batch release); investigates deviations, complaints and recalls; conducts self-inspections (in-house audits); approves vendors and contract manufacturers.
- QC Head: Ensures the laboratory tests are correct; approves specifications, sampling instructions and test methods; ensures instruments are calibrated; approves certificates of analysis.
- Production Head: Manufactures as per the approved batch record; ensures premises and equipment are cleaned and maintained; ensures production staff are trained; investigates production deviations with QA.
- Stores/Warehouse In-charge: Receives materials, checks documents, keeps materials in quarantine/approved/rejected areas, maintains correct storage conditions, issues materials on FIFO/FEFO basis (explained in Chapter 2).
- Engineering Head: Carries out planned maintenance and calibration; keeps maintenance records.

Example: A batch of paracetamol tablets shows low hardness during compression. The Production Head informs QA. The QA Head stops the batch, starts an investigation (deviation), and only after the root cause is found and corrected does QA allow reprocessing or rejection of the batch. Production cannot decide this alone.

Key takeaway: Responsibilities are written down (job descriptions), work is done by trained people in sufficient numbers, and QA has the final word on quality decisions.

4.3 Training of Personnel

Technical concept: All personnel must be trained in GMP, in their specific duties, and in the SOPs they follow. Training must be documented and repeated at regular intervals.

Simple explanation: Giving a new worker a machine without training is like giving car keys to someone who never learned driving — an accident is certain. Training in a pharma company happens in stages:

1. Induction training (on joining): The new employee learns about the company, GMP basics, personal hygiene rules, safety, and where things are. This happens in the first few days.
2. Job-specific / on-the-job training: The employee learns the exact SOPs of their own department — for example, a granulation operator learns the SOP for operating the rapid mixer granulator, supervised by a senior.
3. GMP training: Special training on GMP principles — documentation ("if it is not documented, it is not done"), hygiene, contamination control, data integrity. Given to everyone, including contract and temporary staff.

4. Refresher training: The same important topics are repeated at regular intervals (for example, once a year) because people forget. Also given when an SOP is revised or a new machine is installed.
5. Assessment: After training, the employee is tested (written test or observed performance). Only after passing is the person authorized to work independently.

Training records: For every employee there is a training file containing: training topics, dates, trainer name, assessment results, and the authorization to perform specific jobs. Auditors always ask to see training records.

Example: Before a new analyst is allowed to test samples on the HPLC, she must read the SOP, watch a trained analyst, perform the test under supervision, pass an assessment, and only then is her name added to the list of authorized analysts. Her training record proves this.

Key takeaway: No training = no work. Every training is written down, assessed, and repeated regularly.

4.4 Personal Hygiene

Technical concept: Personnel must follow strict hygiene practices so that they do not become a source of contamination of products.

Simple explanation: Humans are the biggest source of contamination in a factory — we shed skin flakes, hair, and carry microbes on our hands and clothes. That is why every person entering manufacturing areas must follow hygiene rules, just like a surgeon washes up before an operation.

Main hygiene rules:

1. Health check-up: Medical examination at the time of joining and periodically afterwards. Any person with an infectious disease, open wound, skin infection, cold or cough must report it and stay away from manufacturing areas until fit.
2. Hand washing: Hands must be washed with soap and disinfectant before entering production areas, after touching anything dirty, and after using the toilet. Nails must be short and clean.
3. Gowning: Clean, lint-free garments (cap covering full hair, mask, gown/coverall, gloves, shoe covers) must be worn. Street clothes and shoes are never allowed inside.
4. No eating, drinking, chewing or smoking in production and storage areas — food particles and microbes can fall into products.
5. No cosmetics, jewellery, watches in manufacturing areas — they can fall into the product or carry contamination.
6. Illness reporting: Any worker who feels ill must inform the supervisor immediately.

Example: An operator with a cold is sneezing near an open tray of tablet granules. If he does not report his illness and stay out, his germs can contaminate the whole batch. The hygiene SOP requires him to report to the supervisor, who shifts him to non-manufacturing work until he recovers.

Key takeaway: People are the main contamination source — health checks, hand washing, gowning and illness reporting keep products safe.

4.5 Personal Records

Technical concept: Personal records of every employee — qualifications, experience, training, health and job history — must be maintained and kept confidential.

Simple explanation: Just as a school keeps a file for every student (admission form, marks, attendance), a pharma company keeps a personal file for every employee. This file proves to auditors that the right, trained, healthy person did each job.

A personal record file normally contains:

- Bio-data, educational certificates and experience letters
- Appointment letter and job description
- Medical fitness certificates (joining and periodic health check-ups)
- Training records (topics, dates, assessments, authorizations)
- Any disciplinary or appreciation notes

Confidentiality: Personal records contain private information (health, salary history), so they are kept securely and shown only to authorized persons.

Key takeaway: Personal records = proof that qualified, trained, healthy people performed the work. They are confidential documents.

4.6 Premises — Design and Construction

Technical concept: Premises must be designed, constructed and located so that they are suitable for the operations carried out, allow effective cleaning, and prevent contamination.

Simple explanation: You would not cook food in a garage full of dust and oil. In the same way, medicines cannot be made in any ordinary building. The factory building itself must be designed for medicine-making — smooth, cleanable, and protective.

Location: The factory should be located away from sources of pollution and contamination — away from open drains, garbage dumps, chemical factories releasing fumes, heavy traffic dust, and areas prone to flooding or pests.

Building design and construction requirements:

1. Smooth, cleanable surfaces: Floors, walls and ceilings should be smooth, without cracks or crevices where dust and microbes can hide. Floors are usually of seamless, chemical-resistant material (like epoxy); wall–floor junctions are coved (curved, not sharp corners) so mopping is easy.
2. No ledges and open pipes: No unnecessary horizontal ledges where dust can settle. Pipes and ducts are preferably concealed or easily cleanable.
3. Proper drainage: Drains should be of adequate size, trapped (to stop back-flow of foul air), covered, and easy to clean. Open drains are avoided inside manufacturing areas.
4. Lighting: Adequate, glare-free lighting so workers can see clearly; light fittings are flush with the ceiling and covered so glass cannot fall into products.
5. Ventilation: Fresh, filtered air; no uncontrolled entry of outside dust.
6. Separate defined areas: Receiving, quarantine, storage (approved/rejected), dispensing, manufacturing, packaging, quality control laboratory, utilities, offices, canteen and toilets — each in its own place. Toilets and canteens must NOT open directly into manufacturing areas.

7. Protection against entry of pests: Doors, windows and ventilators are screened; gaps under doors are sealed.

Example: In a tablet manufacturing hall, the floor is seamless epoxy with coved corners. At the end of the day, the whole floor is mopped with disinfectant — because there are no cracks or sharp corners, dirt has nowhere to hide. If the floor were ordinary cracked concrete, powder would collect in the cracks and contaminate the next product.

Key takeaway: The building itself is the first shield — smooth, crack-free, well-drained, well-lit, and with every activity in its own separate area.

4.7 Plant Layout

Technical concept: The layout must follow a logical sequence of operations with unidirectional flow of materials and personnel, and with segregation of incompatible operations.

Simple explanation: In a good kitchen, raw vegetables enter from one side, move through washing → cutting → cooking → serving in one direction, and never go backwards. A pharma plant works the same way: materials and people move in one direction (unidirectional flow), so that dirty/raw things never cross paths with clean/finished things.

Principles of a good plant layout:

1. Logical sequence: Rooms are arranged in the order of manufacture — e.g., raw material store → dispensing → granulation → compression → coating → packing → finished goods store. No back-tracking.
2. Unidirectional flow: Materials move forward only; personnel enter through change rooms and exit by a separate route where needed. This prevents mix-ups and cross-contamination.
3. Segregation: Operations that can harm each other are separated — for example, a highly potent or dusty product (like hormones or antibiotics) is made in a dedicated separate area or building; washing areas are separate from clean manufacturing areas.
4. Airlocks and change rooms: Between areas of different cleanliness, small buffer rooms (airlocks for materials, change rooms for people) prevent direct mixing of air.
5. Quarantine areas: Clearly marked separate areas for materials "under test" and for rejected materials, so they can never be mixed with approved stock.
6. Sufficient space: Enough room for equipment, movement of people and trolleys, cleaning, and maintenance — overcrowding causes errors and contamination.

Example of flow in a tablet plant:

Receiving bay → Quarantine store → Sampling room → Approved raw material store → Dispensing (weighing) room → Granulation → Drying → Blending → Compression → Coating → Blister packing → Finished goods store → Dispatch. Each arrow moves forward; rejected material goes backward only into a locked rejected cage, never into the forward line.

Key takeaway: Good layout = one-way traffic. Materials and people flow forward in logical order; incompatible operations are kept apart.

4.8 Maintenance of Premises

Technical concept: Premises must be maintained in a good state of repair through a planned maintenance programme, and all maintenance work must be recorded.

Simple explanation: A house needs regular repair — leaking taps, cracked tiles, peeling paint. A pharma factory needs the same, but with written plans and records, because a cracked floor or a leaking pipe can contaminate medicines.

Types of maintenance (details in Classifications):

- Planned preventive maintenance: Regular, scheduled servicing — e.g., repainting walls every year, checking drains every month, servicing HVAC filters as per schedule. Done before anything breaks.
- Breakdown (corrective) maintenance: Repair after a failure — e.g., fixing a burst water pipe. Recorded with details of the breakdown and corrective action.
- Maintenance inside manufacturing areas is done carefully — no debris or lubricant should contaminate products; areas are cleaned after maintenance.

Maintenance records include: what was done, when, by whom, spare parts used, and verification that the area/equipment is fit for use again.

Key takeaway: Maintain before it breaks (preventive), repair quickly when it breaks (breakdown), and write down everything.

4.9 Sanitation

Technical concept: Written sanitation programmes must specify which areas and equipment are cleaned, how, how often, with which agents, and by whom; cleaning must be recorded and supervised.

Simple explanation: Cleaning a pharma factory is not like casual home cleaning — it is a written, scheduled, supervised operation. Every room has a cleaning SOP: what to clean, with which detergent/disinfectant, in which dilution, how often (daily, weekly, monthly), and who signs the record.

Elements of a sanitation programme:

1. Cleaning procedures (SOPs): Step-by-step method for floors, walls, ceilings, drains, change rooms.
2. Cleaning agents: Detergents for removing dirt/grease; disinfectants for killing microbes. Different areas may need different agents.
3. Rotation of disinfectants: Using the same disinfectant for months can allow resistant microbes to survive. So two or more disinfectants are used in rotation (e.g., alternate every month or quarter).
4. Frequency: Defined schedules — e.g., floors of manufacturing areas cleaned daily, walls weekly, ceilings monthly, drains daily.
5. Records: Cleaning logbooks signed by the cleaner and checked by the supervisor; QA may verify.
6. Pest control: Regular, documented pest control by trained operators using methods that cannot contaminate products (no spraying inside manufacturing areas during operations; use of traps and sealed bait stations outside).

Example — daily floor cleaning SOP (simplified): Remove loose powder with a vacuum → mop with detergent solution → rinse-mop with purified water → mop with disinfectant solution (correct dilution, correct contact time) → allow to dry → enter in the cleaning logbook with date, time, area, agent used and signature.

Key takeaway: Sanitation = written cleaning SOPs + correct agents in rotation + fixed schedules + signed records + pest control.

4.10 Environmental Control

Technical concept: Temperature, humidity, air cleanliness and pressure differences in manufacturing areas must be controlled and monitored to suit the operations and protect products.

Simple explanation: Many medicines are sensitive — heat, moisture or dust can spoil them. So the factory air itself is controlled like the climate inside a greenhouse: temperature, humidity and dust levels are kept within fixed limits and continuously watched.

Parameters controlled:

1. Temperature: Kept within limits suitable for the product and comfort of workers (commonly controlled room temperature ranges are defined in SOPs; sensitive areas may need cooler conditions). Monitored with calibrated thermometers/data loggers.
2. Relative humidity: High moisture can spoil tablets (they absorb water, become soft) and help microbes grow. Humidity is controlled, commonly within defined limits, and monitored.
3. Air cleanliness (particulate control): Air is filtered through high-efficiency filters; the number of dust particles is kept low, especially in critical areas like sterile manufacturing.
4. Differential pressure: Clean areas are kept at higher air pressure than less-clean areas, so air always flows from clean → less clean, pushing dust outward, never inward. This is called a pressure cascade. Monitored with pressure gauges with alarms.
5. Air changes: The HVAC system replaces room air many times per hour to sweep away dust and heat.

HVAC system: The Heating, Ventilation and Air-Conditioning system supplies filtered, temperature- and humidity-controlled air. Filters are checked and replaced as per schedule; temperature/humidity/pressure readings are recorded daily and reviewed.

Example: In a tablet coating area, the SOP fixes temperature and humidity limits. If humidity rises above the limit, tablets may stick together. The monitoring system sounds an alarm, production is paused, engineering corrects the HVAC, and QA decides whether the batch is still acceptable.

Key takeaway: Control the air — temperature, humidity, dust and pressure direction — monitor it daily, and act immediately on alarms.

4.11 Utilities

Technical concept: Utilities (water systems, steam, compressed air, gases, electricity) that come into contact with products or affect their quality must be of suitable quality, qualified, and routinely monitored.

Simple explanation: Utilities are the invisible services of the factory — like water, electricity and gas in a house. But in a pharma plant, even the water must be special, because ordinary tap water contains microbes and minerals that can spoil medicines.

Main utilities:

1. Water systems:

- Potable water (drinking quality): for washing, toilets, cooling — not for manufacturing.
- Purified water: specially treated (by purification systems) to remove impurities and microbes; used for manufacturing non-sterile products and final rinsing of equipment.
- Water for Injection (WFI): the purest grade — sterile and free from pyrogens (fever-causing substances); used for injectable products and their final rinsing. Stored and circulated hot or with continuous circulation to prevent microbial growth.
- Water systems are qualified and tested regularly for chemical purity and microbial counts; results are trended.

2. Steam: Pure (clean) steam generated from purified water is used for sterilization; ordinary boiler steam (which may contain boiler chemicals) must never contact products.
3. Compressed air / gases: Air or nitrogen that contacts products must be dry, oil-free and filtered (often through sterile filters for sterile areas). Tested for oil, moisture and particles.
4. Electricity: Stable power supply with backup (generators/UPS) so that HVAC, water systems and critical equipment never stop suddenly.

Example: A parenteral (injection) plant uses WFI for the final rinse of vials. If the WFI system shows high microbial counts, vial washing is stopped immediately, the water system is sanitized, and QA investigates before any batch is released.

Key takeaway: Utilities are ingredients too — water, steam and air that touch products must be pure, qualified and tested regularly.

4.12 Control of Contamination

Technical concept: Measures must be in place to prevent contamination and cross-contamination of products during manufacturing and storage.

Simple explanation: Contamination means "something unwanted got into the medicine." It can make the medicine unsafe or ineffective. Controlling it is like protecting food in a kitchen — covered vessels, clean hands, separate chopping boards for veg and non-veg.

Types of contamination (see Classifications): cross-contamination (one product into another), microbial contamination (bacteria/fungi), particulate contamination (dust, fibres, glass), and mix-ups (wrong material/product due to confusion).

Sources of contamination: people (skin, hair, clothes, breath), air (dust, microbes), water, equipment (residues of previous product, lubricants), raw materials, pests, packaging materials.

Control measures:

1. Dedicated areas/equipment for highly sensitizing or highly potent products (e.g., penicillins, hormones) — or campaign manufacturing with validated cleaning between products.
2. Closed systems where possible (powder transfers through closed pipes, not open trays).
3. Pressure cascades and airlocks so dust flows away from clean areas.
4. Gowning and hygiene (Section 4.4).
5. Validated cleaning between products (cleaning validation proves residues are removed).

6. Status labelling — every container and area labelled UNDER TEST / APPROVED / REJECTED so nothing is used by mistake.
7. Line clearance — before starting a new product on a line, QA/production verify that no material, label or document of the previous product remains.
8. Segregation of materials and separate air handling for dusty operations.

Example: A factory makes both penicillin tablets and general tablets. Penicillin dust can cause severe allergy in sensitive patients, so penicillin is made in a completely separate, dedicated building with its own air system — never on the same line as other products.

Key takeaway: Keep every product away from everything that does not belong in it — by separation, closed systems, cleaning, air control, gowning and correct labelling.

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5. Classifications

5.1 Types of Contamination

Type	Meaning	Example
Cross-contamination	One product/material contaminates another product/material	Powder of an antibiotic found in vitamin tablets made on the same line
Microbial contamination	Bacteria, fungi or their toxins present in the product	High bacterial count in a cough syrup due to contaminated water
Particulate contamination	Visible foreign particles (dust, fibre, glass, metal) in the product	A glass particle in an injection vial; fibre in an ointment
Mix-up	Wrong material or product used because of confusion or wrong labelling	Salt (sodium chloride) bags used instead of sugar bags; wrong labels on bottles

5.2 Types of Maintenance

Type	When done	Example
Preventive (planned) maintenance	Regular schedule, before breakdown	Repainting walls yearly, replacing HVAC filters as per schedule, monthly drain checks
Breakdown (corrective) maintenance	After something fails	Repairing a burst water pipe, fixing a fused light
Predictive maintenance	Based on monitoring signs of wear (advanced plants)	Replacing a pump bearing when vibration monitoring shows wear

5.3 Types of Water Used in a Pharma Plant

Type	Quality	Used for
Potable water	Drinking-water quality	Washing, toilets, cooling towers, gardening
Purified water	Treated to remove chemical and microbial impurities	Manufacturing of non-sterile products, final rinsing of equipment
Water for Injection (WFI)	Sterile, pyrogen-free, highest purity	Manufacturing of injections, final rinse of sterile product contact parts

5.4 Types of Training

Type	When	Purpose
Induction training	At joining	Company rules, GMP basics, hygiene, safety
On-the-job (job-specific) training	Before starting a new task	Exact SOPs of the person's own work
GMP training	For all staff, including temporary	Principles of GMP, documentation, contamination control
Refresher training	At regular intervals	Revision so knowledge does not fade; also after SOP changes

5.5 Cleanroom Grades (Qualitative Concept)

Manufacturing areas are classified by air cleanliness. As per current guidelines, grades run from the cleanest to the least clean:

Grade	Cleanliness	Typical use (qualitative)
Grade A	Cleanest — critical zone	Filling/sealing of sterile products, usually under unidirectional (laminar) airflow
Grade B	Background to Grade A	Background area surrounding Grade A operations
Grade C	Less clean	Preparation of solutions, washing of components for sterile products
Grade D	Least clean of classified areas	Washing, component preparation, handling of raw materials for sterile products

Air always flows from cleaner grades to less-clean grades (pressure cascade).

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6. Diagrams (How to Draw Them)

Diagram 1 — Organization chart of a pharmaceutical manufacturing unit.

Draw boxes in a pyramid. Top box: "Managing Director / Plant Head". Second row, three boxes side by side: "Head – Quality Assurance", "Head – Quality Control", "Head – Production". Below QA: "QA Executives (documentation, audits, batch release)". Below QC: "QC Analysts (laboratory)". Below Production: "Production Officers/Operators (manufacturing, packing)". Side boxes at the same level: "Warehouse/Stores In-charge" and "Engineering/Maintenance Head". Draw a bold line showing QA reporting directly to top management (independent of Production). Label the diagram: "QA is independent of Production".

Diagram 2 — Plant layout with unidirectional flow.

Draw a long horizontal arrow from left to right. Place boxes along it in order: Receiving Bay → Quarantine Store → Sampling Room → Approved RM Store → Dispensing Room → Granulation → Drying → Blending → Compression → Coating → Packing → Finished Goods Store → Dispatch. Draw a separate small locked box below labelled "Rejected Materials Cage (locked)". Add people-icons entering through "Change Room" at the manufacturing block. Title: "One-way flow of materials; rejected material never re-enters the line".

Diagram 3 — Pressure cascade (cross-section view).

Draw four rooms side by side: Grade D | Grade C | Grade B | Grade A (filling zone). Between each pair draw a small "Airlock" box. Draw arrows of airflow pointing from Grade A → B → C → D → outside (clean to less clean). Write "+ + +" under Grade A and fewer "+" marks towards D to show decreasing pressure. Title: "Air always flows from clean to less-clean areas".

Diagram 4 — Gowning procedure (step boxes).

Draw six boxes in sequence with arrows: 1. Enter change room → 2. Remove street clothes, shoes, jewellery → 3. Wash and disinfect hands → 4. Wear cap, mask, coverall/gown → 5. Wear gloves and shoe covers → 6. Pass through airlock/air-shower into manufacturing area. Title: "Correct gowning order — head to toe, dirty to clean".

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7. Flowcharts

Flowchart 1 — Training and authorization of a new employee.

```
New employee joins
|
Induction training (company, GMP basics, hygiene, safety)
|
Job-specific training (read SOPs of own department)
|
On-the-job training under supervision of senior
|
Assessment (written test / observed performance)
|
Pass? ---- No ----> Re-train
|
Yes
|
Name added to list of authorized persons → Works independently
|
Refresher training at regular intervals / when SOP changes
```

Flowchart 2 — Entry of personnel into a manufacturing area.

```
Reach the change room
|
Remove street clothes, shoes, watch, jewellery
|
Wash hands with soap; disinfect
|
Wear fresh cap (cover full hair) → mask → gown/coverall
|
Wear gloves and shoe covers
|
Pass through airlock / air-shower
|
Enter manufacturing area (do not touch face, hair or outer surfaces)
```

Flowchart 3 — Daily sanitation of a manufacturing room.

```
Identify the room and read its cleaning SOP
|
Remove loose powder/debris (vacuum, dry mop)
|
Wash floor/walls with detergent solution
|
Rinse with purified water (mop)
|
Apply disinfectant at correct dilution; keep correct contact time
|
Allow to dry
|
Record in cleaning logbook (date, time, area, agent, signature)
|
Supervisor checks and signs
```

Flowchart 4 — Handling a contamination risk (deviation).

```
Contamination risk noticed (e.g., alarm, visible dust, failed test)
|
Stop the operation; contain the area/batch (quarantine)
|
Inform QA immediately
|
Investigation: find the source and root cause
|
Corrective and preventive action (CAPA)
|
QA verifies effectiveness → batch disposition decision (release/reprocess/reject)
```

8. Infographic Concept Box

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+=================================================================+
| THE 5 PILLARS OF GMP PREMISES & PEOPLE |
+=================================================================+
| |
| 1. RIGHT PEOPLE Trained, healthy, hygienic staff; |
| clear job descriptions; QA independent. |
| |
| 2. RIGHT BUILDING Smooth, crack-free, coved corners; |
| proper drainage, lighting, ventilation. |
| |
| 3. RIGHT LAYOUT One-way flow of men and materials; |
| incompatible operations segregated. |
| |
| 4. RIGHT AIR & HVAC controls temperature, humidity, |
| WATER dust and pressure; pure water grades |
| for manufacturing. |
| |
| 5. RIGHT CLEANING Written sanitation SOPs, disinfectant |
| rotation, pest control, signed records. |
| |
| RESULT: Every tablet, capsule and injection is made in a |
| place — and by people — that cannot contaminate it. |
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9. Comparison Tables

Table 1 — QA vs QC vs Production

Point	Quality Assurance (QA)	Quality Control (QC)	Production
Main role	Prevents defects through systems	Detects defects by testing	Makes the product
Works in	Whole factory (documents, audits)	Laboratory	Manufacturing areas
Typical activities	Approves SOPs, batch release, audits, deviations, complaints	Tests raw materials, in-process and finished products	Operates machines, fills batch records, cleans areas
Relation	Independent; can stop production	Supports QA with test data	Must follow QA-approved documents

Table 2 — Preventive vs Breakdown Maintenance

Point	Preventive Maintenance	Breakdown Maintenance
Timing	Planned, on schedule, before failure	After failure has occurred
Cost & disruption	Low; no sudden stoppage	High; sudden stoppage, possible batch loss
Example	Monthly HVAC filter check	Repairing a burst pipe
GMP preference	Preferred and required by schedule	Kept to a minimum; fully recorded when it happens

Table 3 — Cleaning vs Disinfection vs Sterilization

Point	Cleaning	Disinfection	Sterilization
Purpose	Remove visible dirt, dust, residues	Kill microbes on surfaces	Destroy ALL microbes including spores
Agent	Detergent + water	Disinfectant chemical	Steam under pressure, dry heat, filtration
Where	All areas, equipment	Manufacturing surfaces, floors, walls	Sterile product contact parts, media

Table 4 — Quarantine vs Approved vs Rejected Status

Status	Label colour (common practice)	Meaning
Quarantine / Under test	Yellow	Received but not yet tested; must NOT be used
Approved / Released	Green	Tested and meets specifications; may be used
Rejected	Red	Failed testing; kept in locked area; must never be used

10. Examples

1. Organization: In a medium-size tablet factory, the QA Manager reports directly to the Plant Head. One day the Production Manager wants to release a batch quickly to meet a dispatch deadline, but the QC results are still pending. The QA Manager refuses release until results arrive — this is QA independence in action.
2. Training: A newly joined packing operator first attends induction (GMP, hygiene), then reads the packing SOPs, then works for two weeks under a senior operator, then passes a short assessment. Only then is he authorized to run the blister packing machine alone.
3. Hygiene: An analyst with a skin infection on her hand is shifted by her supervisor to documentation work until a doctor declares her fit — she is not allowed to handle open products.
4. Premises design: A new ointment plant is built with epoxy flooring, coved wall–floor junctions, flush ceiling lights and trapped, covered drains — so every surface can be washed and no dirt can hide.
5. Plant layout: Raw material drums enter through the receiving bay on the east side and move forward through dispensing → manufacturing → packing, exiting as finished goods from the west side. They never travel backwards through the clean corridor.
6. Maintenance: The engineering team replaces HVAC filters every three months as per the preventive maintenance schedule, even though the old filters "still look fine" — because waiting for failure would risk dust in products.
7. Sanitation: The granulation room floor is mopped daily with detergent, then with disinfectant A in January and disinfectant B in February (rotation), and every cleaning is signed in the logbook.
8. Environmental control: The capsule filling room has a temperature and humidity display. When humidity crosses the upper limit, an alarm rings, filling stops, and QA is informed before work restarts.

9. Utilities: The injection plant's WFI storage tank is kept in continuous hot circulation. Daily samples are tested for microbes; a rising trend triggers sanitization of the loop before limits are crossed.
10. Contamination control: Before starting a new product on a tablet press, two operators perform line clearance — they check and sign that no tablets, labels or documents of the previous product remain on or around the machine.

11. Analogies

1. QA vs Production = Umpire vs Players. Players (Production) play to win; the umpire (QA) enforces the rules and can stop play. The umpire cannot be a player.
2. Premises = Human body. Walls are the skin (first barrier), HVAC is the lungs (breathing clean air in and out), water systems are the blood (must be pure), and drains are the excretory system (waste must leave without coming back).
3. Unidirectional flow = One-way traffic. Just as one-way roads prevent head-on collisions, one-way material flow prevents raw and finished materials from colliding and mixing.
4. Pressure cascade = Water flowing downhill. Air, like water, flows from high to low. Clean rooms are kept at "high ground" (high pressure) so dust flows downhill, away from them.
5. Training records = Driving licence. You cannot drive without learning, passing a test and holding a licence; similarly, you cannot operate a pharma machine without training, assessment and authorization.
6. Disinfectant rotation = Changing passwords. Using the same password forever is risky; using the same disinfectant forever lets resistant microbes survive. Rotation keeps both safe.
7. Gowning = Surgeon's scrub-up. A surgeon covers everything before an operation; a pharma worker covers everything before entering manufacturing — both protect something precious from human contamination.

12. Pharmacy Relevance

- You will work in these roles: Most B.Pharm graduates join as QA officers, QC analysts, production officers or warehouse officers. This chapter describes your future workplace and your future duties.
- Audits: When auditors (regulatory or customer) visit a plant, they first ask for the organization chart, job descriptions, training records and cleaning records. Knowing this chapter helps you face audits confidently.
- Batch release: As a QA pharmacist, you may one day sign the batch release decision — the concepts of QA independence and documentation make that signature meaningful and legally serious.
- Deviation handling: When something goes wrong (temperature excursion, contamination alarm), the pharmacist leads the investigation. Understanding premises, HVAC and contamination control lets you find root causes scientifically.
- Career growth: Knowledge of premises and utilities design is essential for roles in validation, engineering coordination and new plant projects — high-growth areas for pharmacists.

13. India Context

- In India, GMP requirements for manufacturing premises, plant and equipment are laid down in Schedule M of the Drugs and Cosmetics Rules (as per current notifications) — every licensed manufacturing unit must comply with it, and state licensing authorities inspect against it.
- The OPPI Quality Assurance Guide (Organisation of Pharmaceutical Producers of India) is a widely used Indian reference that explains GMP expectations for organization, premises, sanitation and contamination control in practical terms.
- India has a very large pharmaceutical manufacturing base supplying both domestic and export markets; therefore Indian plants commonly maintain separate, dedicated areas for sensitive products (such as penicillins) and strong HVAC and water systems to satisfy both Indian and international auditors.
- Training and personal records receive special attention during Indian regulatory inspections — inspectors routinely verify that operators are trained on the current version of SOPs before being allowed to work independently.
- Pest control, drainage and location requirements of Schedule M reflect Indian conditions — for example, protection against monsoon flooding, dust, and tropical pests is a practical part of premises design here.

14. Key Points

1. QA must be independent of Production; QA can stop production on quality grounds.
2. Every post needs a written job description; work needs sufficient, qualified, trained people.
3. Training has four stages: induction → job-specific → GMP → refresher, all documented and assessed.
4. People are the biggest contamination source: health checks, hand washing, gowning, illness reporting.
5. Premises must be smooth, crack-free, coved, well-drained, well-lit, with separate areas for each activity.
6. Plant layout follows unidirectional flow; incompatible operations are segregated.
7. Preventive maintenance is planned and preferred; every maintenance is recorded.
8. Sanitation = written SOPs + disinfectant rotation + schedules + signed records + pest control.
9. Control temperature, humidity, air cleanliness and differential pressure; air flows from clean to less clean.
10. Utilities that contact products (purified water, WFI, pure steam, oil-free air) must be qualified and routinely tested.
11. Prevent contamination by dedication/segregation, closed systems, airlocks, gowning, validated cleaning, status labelling and line clearance.

15. Common Confusions

1. QA vs QC: QA prevents defects through systems (documents, audits, release); QC detects defects by laboratory testing. QC is a part of the overall QA system.

2. Quarantine vs Rejected: Quarantine = "not yet tested, wait"; Rejected = "tested and failed, never use". Both are kept separate from approved stock, but rejected material is locked away.
3. Cleaning vs Disinfection: Cleaning removes dirt (detergent); disinfection kills microbes (disinfectant). Disinfection without prior cleaning is less effective because dirt protects microbes.
4. Preventive vs Breakdown maintenance: Preventive is planned before failure; breakdown is repair after failure. Exams often ask which is preferred — preventive.
5. Airlock vs Change room: An airlock is a buffer room for materials/air between areas of different cleanliness; a change room is where people change garments. Both have interlocked doors.
6. Purified water vs Water for Injection: Both are treated waters, but WFI is sterile and pyrogen-free — the highest grade, reserved for injectables.
7. Cross-contamination vs Mix-up: Cross-contamination is physical mixing of one product into another; mix-up is using the wrong material/product due to confusion or wrong labelling.

16. Common Mistakes (in exams and in practice)

1. Writing that the QA Head reports to the Production Manager — wrong; QA is independent and reports to top management.
2. Forgetting training records — training without documentation is treated as "not done" in GMP.
3. Drawing plant layout with materials moving backwards — always show unidirectional (one-way) flow.
4. Showing air flowing from dirty to clean areas — air must flow from clean to less-clean (pressure cascade).
5. Using the same disinfectant forever — rotation is required to prevent resistant microbes.
6. Confusing quarantine (yellow/under test) with approved (green) status — never use quarantined material.
7. Forgetting line clearance before starting a new product — a classic cause of mix-ups.
8. Writing "cleaning" when the question asks about killing microbes — the correct term is disinfection (or sterilization, as applicable).

17. Mnemonics

1. "Q-P" — QA is the Umpire, Production are the Players. (QA independence)
2. "I-J-G-R" — Induction, Job-specific, GMP, Refresher. (Four stages of training — "I Join, Get Ready")
3. "H-G-H-I" — Health check, Gowning, Hand wash, Illness reporting. (Four hygiene pillars — "Healthy Garments, Hygienic Individuals")
4. "S-C-D-L-V" — Smooth surfaces, Coved corners, Drainage, Lighting, Ventilation. (Premises design — "Smart Construction Defeats Lurking Viruses")
5. "U-S-A" — Unidirectional flow, Segregation, Airlocks. (Layout principles — "Use Safe Arrangement")

6. "T-H-P" — Temperature, Humidity, Pressure difference. (Environmental parameters — "The Healthy Plant")
7. "P-W-S-A" — Purified water, WFI, Steam, Air. (Critical utilities — "Pure Water, Safe Air")
8. "D-C-A-G-L-S" — Dedicated areas, Closed systems, Airlocks, Gowning, Line clearance, Status labelling. (Contamination controls — "Dedicated Cleaning Always Guards Life Safety")

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18. Exam Summary

- Organization: Pyramid structure; QA independent of Production; key posts — QA Head, QC Head, Production Head, Warehouse In-charge, Engineering Head; every post has a written job description.
- Personnel: Sufficient number of qualified people; duties delegated only to trained persons.
- Training: Induction → job-specific → GMP → refresher; assessment before authorization; all training documented in personal training files.
- Hygiene: Medical check-ups, illness reporting, hand washing, gowning (cap-mask-gown-gloves-shoe covers), no eating/drinking/smoking/cosmetics/jewellery in manufacturing areas.
- Personal records: Bio-data, certificates, job description, health records, training records — confidential.
- Premises design: Suitable location; smooth crack-free floors/walls, coved junctions, no ledges, trapped covered drains, adequate lighting and ventilation, separate areas, pest-proofing.
- Plant layout: Logical sequence, unidirectional flow of materials and personnel, segregation of incompatible operations, airlocks/change rooms, quarantine and rejected areas, adequate space.
- Maintenance: Planned preventive maintenance preferred; breakdown maintenance recorded; area cleaned after maintenance.
- Sanitation: Written cleaning SOPs, correct detergents/disinfectants, disinfectant rotation, fixed frequencies, signed cleaning records, documented pest control.
- Environmental control: Temperature, humidity, air cleanliness and differential pressure controlled by HVAC; pressure cascade from clean to less-clean; daily monitoring with alarms.
- Utilities: Potable water (general use), purified water (manufacturing), WFI (injectables, sterile and pyrogen-free); pure steam for sterilization; dry oil-free compressed air/gases; stable power with backup. All qualified and routinely tested.
- Contamination control: Types — cross-contamination, microbial, particulate, mix-up. Controls — dedicated areas, closed systems, pressure cascade, airlocks, gowning, validated cleaning, status labelling, line clearance.

19. One-Minute Revision

NOTE

QA is the umpire, Production the players — independent. People need job descriptions, four-stage training (I-J-G-R), hygiene (H-G-H-I) and confidential personal records. The building must be smooth, coved, well-drained, well-lit (S-C-D-L-V) with one-way flow (U-S-A). Maintain before breakdown, clean by SOP with disinfectant rotation, control temperature-humidity-pressure (T-H-P), keep pure utilities (P-W-S-A), and block contamination with dedicated areas, closed systems, airlocks, gowning, line clearance, status labels (D-C-A-G-L-S).

20. Exam Questions

A. Short Answer Questions (2–3 marks each)

1. Why must the QA department be independent of the Production department?
2. List the responsibilities of the Head of Quality Assurance.
3. Name the four stages of training in a pharmaceutical unit.
4. What details are maintained in an employee's personal (training) record?
5. List any four personal hygiene rules for workers entering manufacturing areas.
6. What is an airlock? What is its purpose?
7. Define cross-contamination and give one example.
8. What is disinfectant rotation? Why is it done?
9. What is a pressure cascade? In which direction should air flow?
10. Differentiate between purified water and water for injection.
11. What is line clearance? When is it performed?
12. List four measures to prevent mix-ups in a manufacturing area.

B. Long Answer Questions (5–10 marks each)

1. Draw the organization chart of a pharmaceutical manufacturing unit and explain the responsibilities of key personnel. Why is QA independence essential?
2. Describe the training system for pharmaceutical personnel. What records prove that training is effective?
3. Explain the design and construction requirements of pharmaceutical premises with respect to location, floors, walls, drainage, lighting and ventilation.
4. What are the principles of a good plant layout? Explain unidirectional flow and segregation with a neat labelled diagram.
5. Describe the sanitation programme of a pharmaceutical manufacturing area, including cleaning SOPs, disinfectant rotation and pest control.
6. Explain environmental control in manufacturing areas — temperature, humidity, air cleanliness and differential pressure — and the role of the HVAC system.
7. What are pharmaceutical utilities? Describe the different grades of water and their uses, and the quality requirements of steam and compressed air.
8. Define contamination. Classify its types and explain the measures used to control contamination and cross-contamination in a manufacturing plant.

C. Multiple Choice Questions (10)

1. The department that can stop production on quality grounds and works independently of production is:

a) Production b) Quality Assurance c) Warehouse d) Engineering

2. The first training given to a newly joined employee is called:

a) Refresher training b) Induction training c) On-the-job training d) GMP training

3. "If it is not documented, it is not done" is a principle most closely associated with:

a) Marketing b) GMP documentation and training c) Recruitment d) Pest control

4. Wall–floor junctions in manufacturing areas are made curved (coved) mainly to:

a) Look beautiful b) Make cleaning easy and prevent dirt accumulation c) Save paint d) Reduce room size

5. In a good plant layout, materials should move:

a) In any direction b) Backwards for checking c) In one direction only (unidirectional flow) d) Only vertically

6. Air in classified areas should flow:

a) From less-clean to clean areas b) From clean to less-clean areas c) In circles d) Only at night

7. Rotation of disinfectants is done to:

a) Save money b) Prevent development of resistant microbes c) Change the smell d) Reduce cleaning time

8. Water for Injection (WFI) differs from purified water in that WFI is:

a) Cheaper b) Sterile and pyrogen-free c) Used for gardening d) Not tested

9. A material kept separately with "UNDER TEST" status and not to be used is in:

a) Approved store b) Quarantine c) Dispatch area d) Canteen

10. Line clearance is performed:

a) After packing is over b) Before starting a new product/batch on a line, to remove traces of the previous product c) Only once a year d) By the canteen staff

Answer Key: 1-b, 2-b, 3-b, 4-b, 5-c, 6-b, 7-b, 8-b, 9-b, 10-b

D. Viva Questions

1. Who is the umpire in a pharma factory — QA or Production? Why?
2. What is a job description?
3. Name the four stages of training.
4. Why are cosmetics and jewellery not allowed in manufacturing areas?
5. What should a worker do if he has a cold and works near open products?
6. Why are wall–floor junctions coved?
7. What is unidirectional flow?
8. Preventive or breakdown maintenance — which is preferred in GMP?
9. Why do we rotate disinfectants?
10. Which way does air flow in a pressure cascade?

11. Name the three grades of water used in a pharma plant.
12. What does a red "REJECTED" label mean?

E. Application-Based Questions

1. Scenario: During an audit, the auditor finds that an operator has been running the tablet press for two months but his training file has no assessment record for that machine. What is the GMP problem here, and what corrective action would you suggest?
2. Scenario: The humidity alarm rings in the capsule filling room and the display shows humidity above the specified limit. As the QA officer on the floor, list the immediate steps you will take.
3. Scenario: A factory wants to manufacture penicillin tablets and multivitamin tablets. Advise the management on premises and contamination-control requirements for this plan.
4. Scenario: You notice the same disinfectant has been used for floor mopping for the last eight months. Identify the risk and explain the correct practice.
5. Scenario: Draw a simple block diagram showing how you would arrange receiving → storage → manufacturing → packing → dispatch in a new oral-dosage plant to satisfy unidirectional flow.

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21. References

1. Godfrey, A. B. and Juran, J. M. Juran's Quality Handbook. McGraw-Hill Education. (Preferably latest edition.)
2. Organisation of Pharmaceutical Producers of India. Quality Assurance Guide. OPPI. (Preferably latest edition.)
3. Weinberg, S. Good Laboratory Practice Regulations. Marcel Dekker. (Preferably latest edition.)
4. World Health Organization. Quality Assurance of Pharmaceuticals: A Compendium of Guidelines and Related Materials. World Health Organization. (Preferably latest edition.)

CHAPTER 4: EQUIPMENT, RAW MATERIALS AND WAREHOUSING

Unit II (10 hours)

(Syllabus: Equipment and Raw Materials — equipment selection, User Requirement Specifications (URS), handling and maintenance of raw materials; Warehousing — good warehousing practices and materials management)

1. Learning Objectives

After studying this chapter, you will be able to:

1. List the criteria for selection of pharmaceutical equipment.
2. Define User Requirement Specifications (URS) and explain its contents and importance.
3. Explain the link between URS and equipment qualification (DQ, IQ, OQ, PQ).
4. Describe the procedure for receipt, quarantine, sampling, testing and approval of raw materials.
5. Explain the correct handling, storage and dispensing of raw materials.
6. Describe the design and zones of a pharmaceutical warehouse.
7. Explain good warehousing practices — storage conditions, FIFO/FEFO, stock records, pest control.
8. Describe materials management, including inventory control and ABC analysis.
9. Explain the handling of rejected, expired and returned materials.

2. Definitions

1. Equipment — Any machine, apparatus or instrument used in manufacturing, packing, testing or storage, e.g., tablet press, mixer, autoclave, refrigerator.
2. User Requirement Specifications (URS) — A written document in which the user (the pharma company) describes exactly what it wants a new equipment or system to do — capacity, materials, functions, safety and compliance needs. It is the "wish list" given to the vendor.
3. Qualification — Documented proof that equipment or a system works correctly and consistently for its intended purpose. Its four stages are DQ, IQ, OQ and PQ.
4. Raw material — Any starting material used to make a medicine, including the active ingredient (API), excipients (helpers like binders, fillers) and packaging materials.
5. API (Active Pharmaceutical Ingredient) — The part of the medicine that actually treats the disease (e.g., paracetamol in a paracetamol tablet).
6. Excipient — An inactive helper ingredient that helps make, stabilize or deliver the medicine (e.g., starch as binder, lactose as filler).
7. Sampling — Taking a small, representative portion from a bulk consignment for testing in the QC laboratory.
8. Quarantine — Keeping received materials separately under "UNDER TEST" status until QC testing is complete and QA releases them.

9. Batch / Lot — A defined quantity of material produced or received in one operation, given one batch number for traceability.
10. Retest date — The date by which a stored raw material must be tested again to confirm it is still good for use.
11. Expiry date — The date after which a material or product must not be used.
12. Warehouse — The building or area designed for the receipt, quarantine, storage and issue of raw materials, packaging materials and finished products under controlled conditions.
13. Inventory — The stock of materials held in the warehouse, with records of quantities received, issued and balance.
14. FIFO (First In, First Out) — The rule that the material received first is used first.
15. FEFO (First Expiry, First Out) — The rule that the material which expires first is used first.

3. Terminology (Word Bank)

Term	Simple Meaning
Vendor / Supplier	The company that sells equipment or materials
Purchase order (PO)	The official order document sent to a vendor
FAT (Factory Acceptance Test)	Testing the equipment at the vendor's factory before delivery
SAT (Site Acceptance Test)	Testing the equipment after installation at our site
DQ (Design Qualification)	Proof that the design of the equipment meets the URS
IQ (Installation Qualification)	Proof that the equipment is installed correctly
OQ (Operational Qualification)	Proof that the equipment operates correctly across its working range
PQ (Performance Qualification)	Proof that the equipment performs consistently under real production conditions
Certificate of Analysis (CoA)	The vendor's test report showing the material meets specifications
Goods Receipt Note (GRN)	The warehouse document recording what was received
Bin card	A card kept with each stored material showing receipts, issues and balance
Stock register / ledger	The master record of all materials and their quantities
Temperature mapping	Study proving that temperature is uniform in all parts of a warehouse/room
Segregation	Keeping different materials physically apart to avoid mix-ups
Spill kit	Ready-kept materials (absorbent, gloves, scoop) for cleaning spilled material safely
Dispensing	Weighing/measuring the exact quantities of raw materials needed for one batch
Reconciliation	Comparing actual stock with recorded stock to find differences
ABC analysis	Classifying inventory by value/usage: A = high value, B = medium, C = low
EOQ (Economic Order Quantity)	The order quantity that balances ordering cost and holding cost
Lead time	The time between placing an order and receiving the material
Safety stock	Extra stock kept to avoid running out during delays
Recall (materials)	Withdrawing issued material back to the warehouse on quality grounds

4. Explanations

4.1 Equipment Selection

Technical concept: Equipment must be selected so that it is suitable for its intended purpose, easy to clean and maintain, made of non-reactive materials, and capable of consistently producing quality products.

Simple explanation: Buying a pharma machine is like buying a school bus — you check safety, capacity, mileage, service support and price before buying, not after. A wrong machine gives wrong products for years. Selection criteria:

1. Suitability for purpose: The machine must do the required job at the required capacity — e.g., a tablet press that can compress the tablet size and output (tablets per hour) you need.
2. Material of construction: Product-contact parts must be of non-reactive, non-additive, non-absorptive material — commonly stainless steel of suitable grade — so the machine does not contaminate the product or get corroded by it.
3. Cleanability: Smooth surfaces, easy to dismantle, no dead spots where powder can hide — because the machine must be cleaned between products (remember cleaning validation from Chapter 1).
4. Accuracy and control: Instruments and controls (speed, temperature, pressure) must be accurate and, where needed, calibrated.
5. Safety: Guards on moving parts, emergency stops, protection for operators.
6. Utilities needed: Check what the machine needs — power load, water, steam, compressed air — and whether your plant can supply them.
7. Automation and data integrity: Modern machines record data automatically; this reduces human error and supports data integrity.
8. Vendor support: Availability of spare parts, service engineers, manuals and training.
9. Regulatory compliance: The machine and its documentation must satisfy GMP expectations (calibration certificates, material certificates).
10. Cost: Purchase price plus running cost (power, spares, maintenance) — the total cost of ownership.

Example: A company choosing between two mixers picks the one with stainless-steel contact parts, a documented cleaning procedure, calibrated load cells, and a local service centre — even though it costs slightly more — because breakdowns and contamination would cost far more.

Key takeaway: Select equipment like a long-term partner — suitable, cleanable, accurate, safe, serviceable and GMP-compliant. The selection starts with a written URS.

4.2 User Requirement Specifications (URS)

Technical concept: The URS is the foundation document of equipment qualification — it states what the user needs, and every later qualification step (DQ, IQ, OQ, PQ) is checked against it.

Simple explanation: Before a tailor stitches your clothes, you tell him your measurements, the cloth, the style — that instruction is the URS. If you don't tell him clearly, you can't complain later that the shirt doesn't fit. Similarly, before buying equipment, the pharma company writes down exactly what it wants. The vendor builds/supplies accordingly, and later we verify "did

we get what we asked for?"

Contents of a URS (what it normally includes):

1. Purpose and scope: What the equipment is for, which products/processes it will handle.
2. Capacity and performance: e.g., "mix 200 kg per batch", "fill 100 vials per minute".
3. Materials of construction: e.g., product-contact parts of stainless steel of suitable grade.
4. Functions and features: Operating ranges (speed, temperature), controls, alarms, automation level.
5. Utilities required: Electrical load, water, steam, compressed air needs.
6. Safety requirements: Guards, emergency stops, noise limits.
7. Cleaning and maintenance: Easy dismantling, cleaning procedure support, access for maintenance.
8. Documentation: Manuals, drawings, calibration certificates, material certificates to be supplied.
9. Compliance: Must meet GMP expectations; data integrity requirements for electronic records.
10. Acceptance criteria: How the company will test and accept the equipment (FAT/SAT).

Who prepares it: The user department (e.g., Production) with inputs from QA, Engineering and QC; QA approves it.

Key takeaway: URS = the company's written wish list. Everything purchased and qualified afterwards is judged against it — "no URS, no proof that the machine is right."

4.3 Link Between URS and Qualification (DQ, IQ, OQ, PQ)

Technical concept: Qualification proves, step by step, that the equipment designed, installed, operated and performing as per the URS is fit for its intended use.

Simple explanation: Think of buying a new scooter: (1) you check the brochure/design matches what you asked (DQ); (2) you check it was assembled/delivered correctly (IQ); (3) you take a test ride at different speeds (OQ); (4) you ride it daily for a month to confirm it performs reliably (PQ). Each step is documented.

Stage	Full form	Simple meaning	Checked against
DQ	Design Qualification	The design (drawings, specifications) meets the URS	URS
IQ	Installation Qualification	Installed correctly — right place, utilities connected, as per drawings	Design/drawings
OQ	Operational Qualification	Works correctly across its operating range (min to max speed, temperature)	Operating ranges
PQ	Performance Qualification	Performs consistently under actual production conditions	Real batches

Flow: URS → vendor selection → purchase → FAT (at vendor) → delivery → installation → IQ → OQ → PQ → release for routine use. QA approves each stage.

Key takeaway: URS is the question paper; DQ/IQ/OQ/PQ are the step-by-step answers proving the equipment passes.

4.4 Raw Materials — Receipt to Approval

Technical concept: Every incoming raw material must be checked, quarantined, sampled, tested and formally approved before use. Nothing enters production on trust alone.

Simple explanation: When you order groceries online, you check the packet at the door — correct item? sealed? expiry date OK? A pharma warehouse does the same, but much more strictly, because a wrong or poor-quality raw material can spoil lakhs of tablets.

Step-by-step procedure:

1. Receipt: The truck/container arrives at the receiving bay. Warehouse staff check the delivery documents — purchase order, invoice, vendor's Certificate of Analysis (CoA) — and check for damage, correct labels, batch numbers and quantities. A Goods Receipt Note (GRN) is prepared.
2. Quarantine: The material is moved to the quarantine area with a yellow "UNDER TEST" label. It is entered in the stock records as "under test". It must not be used yet.
3. Sampling: The QC department takes samples using clean, dedicated sampling tools (e.g., a sampling thief for powders), following a written sampling plan. Sampling is preferably done in a dedicated sampling room/booth to avoid contaminating the warehouse air. Sample containers are labelled with material name, batch, date and sampler's signature.
4. Testing: QC tests the sample against the approved specification (identity, purity, assay and other tests as per the specification). Results are recorded and reviewed.
5. Approval or rejection:
    - If it passes → QA/QC approves; the material moves to the approved store with a green "APPROVED" label; stock records are updated.
    - If it fails → it moves to the rejected area (locked cage) with a red "REJECTED" label; the vendor is informed; the material is returned or destroyed as per SOP.
6. Documentation: GRN, CoA, sampling record, test report, approval/rejection note — all filed and traceable to the batch number.

Example: 25 drums of lactose arrive. The warehouse checks documents and moves them to quarantine (yellow labels). QC samples a defined number of drums, tests identity and purity. All pass → green "APPROVED" labels, drums shifted to the approved raw material store. One drum of a different material fails identity → red "REJECTED", locked cage, vendor complaint raised.

Key takeaway: Receive → check documents → quarantine (yellow) → sample → test → approve (green) or reject (red). No approval, no use — ever.

4.5 Handling, Storage and Dispensing of Raw Materials

Technical concept: Raw materials must be stored under the conditions stated on their labels/specifications, protected from contamination, and dispensed accurately against the batch manufacturing record.

Simple explanation: Raw materials are like precious groceries — each needs its own storage rule (fridge, cool dry shelf, away from sunlight), must stay sealed and labelled, and must be weighed exactly as the recipe says.

Storage rules:

1. Follow label conditions: Store as per the manufacturer's storage instructions — e.g., "store in a cool, dry place", "store at 2–8°C" (refrigerator), "protect from light", "protect from moisture".
2. Segregation: Different materials kept apart; potent/toxic materials (e.g., hormones, cytotoxic) in separate, locked areas; flammable solvents in flame-proof stores away from the main building.
3. Off the floor: Drums and bags kept on pallets/racks, away from walls — for cleaning, air circulation and pest inspection.
4. Containers closed and labelled: Every container carries material name, batch number, status label (under test/approved/rejected), retest/expiry date.
5. Spill control: Spill kits kept ready; spills cleaned immediately as per SOP so one material never contaminates another.
6. Stock rotation — FIFO/FEFO: Use older stock (or stock expiring first) before newer stock, to avoid expiry on the shelf.
7. Environmental monitoring: Temperature and humidity of stores recorded daily; cold rooms and refrigerators monitored continuously with alarms.

Dispensing (weighing for a batch):

1. Dispensing is done in a dedicated dispensing room/booth (often with controlled dust extraction), based on the batch manufacturing record.
2. The operator weighs each material on a calibrated balance, counter-checked by a second person.
3. Each weighed material is labelled (material name, batch number of RM, quantity, batch number of the product, date, signatures) and kept ready for manufacture.
4. Left-over material is resealed, relabelled and returned to stock; records updated.

Retest and expiry: Materials with a retest date are re-tested by QC before the date passes; expired materials are never used — they are rejected and destroyed as per SOP.

Key takeaway: Store each material as its label demands, keep everything labelled and segregated, rotate stock (FIFO/FEFO), and dispense exact quantities with double-checking.

4.6 Warehouse Design and Zones

Technical concept: The warehouse must be designed with separate, clearly marked zones for each status and activity, with controlled environment and easy material movement.

Simple explanation: A warehouse is like a well-organized kitchen store-room — raw items, ready items and spoilt items each have their own shelf, nothing is on the floor, and everything is labelled. A pharma warehouse has fixed zones:

1. Receiving bay: Where trucks unload; documents checked here.
2. Quarantine area: For "UNDER TEST" materials (yellow labels).
3. Sampling room/booth: Clean, dedicated area for taking QC samples.

4. Approved storage: Separate sections for raw materials, packaging materials and finished products (green labels); often racks with labelled locations.
5. Rejected area: Locked cage/room for rejected materials (red labels).
6. Cold room / refrigerated storage: For materials needing 2–8°C or freezer conditions, with continuous monitoring and alarms.
7. Flammable/ hazardous store: Separate, flame-proof, ventilated area for solvents — away from main stores.
8. Dispatch area: Where finished goods are packed for transport and loaded.

Design features: Adequate space for movement of trolleys/forklifts; smooth cleanable floors; good ventilation; protection from sunlight, moisture and pests; fire-fighting equipment; security (locked rejected area, controlled entry).

Key takeaway: Every status has its own zone — receiving, quarantine, approved, rejected, cold, hazardous, dispatch — each clearly marked, so materials can never be confused.

4.7 Good Warehousing Practices (GWP)

Technical concept: Good warehousing practices are the set of procedures that keep materials safe, uncontaminated and traceable from receipt to issue.

Simple explanation: GWP is "good housekeeping with records" for the warehouse. The checklist:

1. Cleanliness and order: Floors swept/mopped regularly; no cobwebs; aisles clear.
2. Correct storage conditions: Temperature and humidity as per material labels; daily monitoring records.
3. Status labelling: Every container/rack labelled — UNDER TEST (yellow), APPROVED (green), REJECTED (red).
4. FIFO/FEFO: Older or earlier-expiring stock issued first.
5. Stock records: Bin cards with each material + stock register; every receipt and issue recorded with date, quantity, balance and signature.
6. Periodic stock verification: Physical counting at defined intervals; differences investigated (reconciliation).
7. Pest control: Regular, documented; no food or waste attracting pests.
8. Security: Locked rejected area; controlled entry; no unauthorized persons.
9. Handling equipment: Clean trolleys, forklifts, pallets; no damaged containers used.
10. Returned/recalled goods: Stored separately, clearly marked, never mixed with normal stock.

Key takeaway: GWP = right conditions + clear labels + FIFO/FEFO + accurate records + cleanliness + security. The warehouse must be able to tell, at any moment, what is where, how much, and what status.

4.8 Materials Management

Technical concept: Materials management ensures the right materials are available in the right quantity at the right time — without overstocking (money blocked, expiry risk) or understocking (production stops).

Simple explanation: It is like managing a home kitchen — you don't want the atta dabba to run out suddenly (production stops), but you also don't want to buy a year's atta that gets spoilt (money blocked, expiry). Materials management balances this scientifically.

Tools used:

1. Inventory records: Bin cards and stock ledgers showing receipts, issues and balances for every material.
2. ABC analysis: Materials classified by annual consumption value —
    - A items: few items, high value (e.g., costly APIs) — tight control, frequent review;
    - B items: medium value — moderate control;
    - C items: many items, low value (e.g., labels, minor excipients) — simple control.

This focuses attention and money where it matters most.

3. Reorder level / safety stock: A minimum level is fixed; when stock falls to it, a new order is placed. Extra safety stock covers delivery delays (lead time).
4. EOQ (Economic Order Quantity): The order size that balances ordering cost (placing many small orders is costly) against holding cost (storing huge stock is costly).
5. Vendor management: Approved vendor list; vendor performance reviewed (quality, delivery time); poor vendors removed.
6. Reconciliation: Physical stock compared with records; shortages/excess investigated — this also detects theft, spillage or recording errors.

Key takeaway: Materials management = right material, right quantity, right time — using ABC analysis, reorder levels, safety stock and accurate records, so production never stops and money is never wasted.

4.9 Handling of Rejected, Expired and Returned Materials

Technical concept: Non-conforming materials must be identified, segregated under lock, and dispositioned (return to vendor or destroy) through documented procedures so they can never re-enter production.

Simple explanation: Spoilt milk is thrown away, never poured back into the fresh milk vessel. Similarly:

- Rejected materials: Red-labelled, locked cage, entered in records; QA decides — return to vendor or destroy (e.g., by incineration through authorized agencies, with certificates).
- Expired materials: Treated like rejected — never used, destroyed as per SOP with records.
- Returned goods (from market): Kept in a separate marked area; QC re-tests if needed; QA decides — reprocess, repack or destroy. Never mixed with fresh stock without QA approval.

Key takeaway: Red label + locked area + QA decision + documented destruction/return. Rejected or expired material must never find its way back into manufacturing.

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5. Classifications

5.1 Types of Raw Materials

Type	Meaning	Example
API (Active Pharmaceutical Ingredient)	The ingredient that treats the disease	Paracetamol, amoxicillin
Excipient	Inactive helper ingredient	Starch (binder), lactose (filler), magnesium stearate (lubricant)
Packaging material (primary)	Touches the product directly	Blister foil, glass vial, bottle cap
Packaging material (secondary)	Does not touch the product	Carton, label, leaflet

5.2 Stages of Equipment Qualification

Stage	Question it answers
DQ — Design Qualification	"Is the design as per our URS?"
IQ — Installation Qualification	"Is it installed correctly?"
OQ — Operational Qualification	"Does it operate correctly at all settings?"
PQ — Performance Qualification	"Does it perform consistently in real production?"

5.3 Material Status Labels

Status	Common label colour	Meaning	Location
Under test / Quarantine	Yellow	Received, QC testing pending — DO NOT USE	Quarantine area
Approved / Released	Green	Passed testing — may be used	Approved store
Rejected	Red	Failed testing — NEVER use	Locked rejected cage

5.4 Common Storage Conditions (as per label/specification)

Condition	Meaning	Example of material
Store at room temperature	Normal warehouse conditions, protected from excessive heat	Most tablets' raw materials
Store in a cool place	Below room temperature, away from heat	Some syrups, suppositories
Refrigerate (2–8°C)	In refrigerator/cold room	Certain antibiotics, vaccines, biologicals
Protect from light	In opaque containers / dark area	Light-sensitive vitamins, nifedipine
Protect from moisture	Airtight containers, dry area, desiccants	Effervescent granules, hygroscopic powders

5.5 ABC Analysis of Inventory

Class	Share of items (typical pattern)	Share of value (typical pattern)	Control level
A	Few items	High value	Tight — frequent review, low safety stock
B	Medium items	Medium value	Moderate control
C	Many items	Low value	Simple control, larger safety stock OK

5.6 Zones of a Pharmaceutical Warehouse

Zone	Purpose
Receiving bay	Unloading and document checking
Quarantine area	"Under test" materials (yellow)
Sampling room/booth	Clean area for QC sampling
Approved RM store	Released raw materials (green)
Approved PM store	Released packaging materials
Finished goods store	Released packed products awaiting dispatch
Rejected area (locked)	Failed materials (red)
Cold room	2–8°C storage with alarms
Hazardous/flammable store	Separate, flame-proof, ventilated
Dispatch area	Packing for transport and loading

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6. Diagrams (How to Draw Them)

Diagram 1 — From URS to routine use (qualification chain).

Draw seven boxes in a horizontal chain with arrows: URS → Vendor selection & Purchase → FAT (at vendor) → Installation → IQ → OQ → PQ → Released for routine use. Below the chain write: "URS is the question paper; DQ/IQ/OQ/PQ are the step-by-step proof." Add a small box above Installation labelled "DQ: design checked against URS".

Diagram 2 — Warehouse layout (top view).

Draw a large rectangle (the warehouse). Divide it into labelled zones: top-left "Receiving Bay" with a truck icon; next to it "Quarantine Area (yellow)"; a small square "Sampling Booth"; a large central block "Approved RM Store (green)" with rack rows; beside it "Approved PM Store"; bottom-right "Finished Goods Store"; a small locked square with a lock icon "Rejected Cage (red, locked)"; a separate small building outside the main rectangle "Flammable Store"; a strip at the bottom "Dispatch Area". Draw arrows: Receiving → Quarantine → Approved stores → Dispatch.

Diagram 3 — Raw material journey (flow of one consignment).

Draw boxes in sequence: Truck arrives → Documents checked (PO, invoice, CoA) → GRN prepared → Moved to Quarantine (yellow label) → QC sampling (sampling booth) → Laboratory

testing → Decision diamond: "Pass?" → Yes: Approved store (green label) → Dispensing for batch; No: Rejected cage (red label) → Return to vendor / destroy.

Diagram 4 — Bin card (how it looks).

Draw a card with columns: Date | Received (qty) | Issued (qty) | Balance | Signature. Fill two sample rows: "04-10 | 500 kg | — | 500 kg | R.S." and "06-10 | — | 100 kg | 400 kg | R.S.". Title: "One bin card per material — balance always up to date".

---

7. Flowcharts

Flowchart 1 — Equipment procurement and qualification.

```
Need identified (new product / capacity increase)
|
Prepare URS (user dept + QA + Engineering + QC inputs; QA approves)
|
Invite quotations; evaluate vendors (technical + commercial)
|
Place purchase order
|
FAT – test at vendor's factory
|
Deliver, install at site (as per drawings)
|
DQ (design vs URS) → IQ (installation) → OQ (operation range) → PQ (real batches)
|
QA approves each stage
|
Release equipment for routine use; SOPs and training completed
```

Flowchart 2 — Raw material receipt to release.

```
Material arrives at receiving bay
|
Check documents (PO, invoice, vendor CoA), labels, quantity, damage
|
Prepare GRN; move to QUARANTINE with yellow "UNDER TEST" label
|
QC draws samples in sampling booth (as per sampling plan)
|
Laboratory testing against approved specification
|
Pass? ---- No ----> Move to locked REJECTED area (red label)
| Vendor informed; return or destroy as per SOP
Yes
|
Move to APPROVED store (green label); update stock records
|
Available for dispensing against batch manufacturing record
```

Flowchart 3 — Dispensing for a batch.

```
Receive batch manufacturing record (recipe with quantities)
|
Go to approved store; pick materials (FIFO/FEFO)
|
Weigh each material on calibrated balance in dispensing booth
|
Second person counter-checks weights
|
Label each weighed container (material, qty, product batch no., date, signatures)
|
Reseal and return leftovers to stock; update bin cards
|
Send labelled materials to manufacturing
```

Flowchart 4 — Handling a temperature excursion in the cold room.

```
Alarm: cold room temperature above limit
|
Inform warehouse in-charge and QA immediately
|
Do NOT issue materials until QA decides
|
Shift materials to backup cold storage if needed
|
Engineering corrects the fault; record the breakdown
|
QA assesses impact on material quality (stability data, duration of excursion)
|
Decision: release / retest / reject — all documented
```

8. Infographic Concept Box

```
+=====================================================================+
| FROM WISH LIST TO WAREHOUSE: THE MATERIAL JOURNEY |
+=====================================================================+
| |
| STEP 1: WISH LIST (URS) |
| Write exactly what the machine must do — capacity, steel, |
| safety, documents. No URS = no proof later. |
| |
| STEP 2: PROOF (DQ -> IQ -> OQ -> PQ) |
| Design OK? Installed OK? Operates OK? Performs OK in real |
| batches? QA signs each stage. |
| |
| STEP 3: GATE CHECK (Receipt) |
| Documents + labels + quantity + damage checked; GRN made. |
| |
| STEP 4: WAITING ROOM (Quarantine - YELLOW) |
| Under test. Nobody touches it for production. |
| |
| STEP 5: HEALTH CHECK (Sampling + Testing) |
| QC samples in a clean booth; lab tests against specification. |
| |
| STEP 6: GREEN OR RED |
| Pass = GREEN, approved store. Fail = RED, locked cage. |
| |
| STEP 7: SMART STORAGE (Warehouse) |
| Right temperature, labelled racks, FIFO/FEFO, bin cards, |
| pest control, locked rejects. |
| |
| GOLDEN RULE: Nothing enters production without QA approval. |
+=====================================================================+
```

9. Comparison Tables

Table 1 — URS vs Purchase Order

Point	URS (User Requirement Specifications)	Purchase Order (PO)
Nature	Technical "wish list" of what is needed	Commercial order document
Prepared by	User department with QA/Engineering/QC	Purchase department
Contents	Capacity, materials, functions, safety, documents, acceptance criteria	Item, quantity, price, delivery date, terms
Purpose	Defines what is needed and how it will be accepted	Formally orders it from the vendor

Table 2 — DQ vs IQ vs OQ vs PQ (one-line each)

Stage	Focus	Typical question
DQ	Design	Does the design meet the URS?
IQ	Installation	Is it installed as per drawings, with utilities connected?

Stage	Focus	Typical question
OQ	Operation	Does it work correctly from minimum to maximum settings?
PQ	Performance	Does it consistently perform in real production batches?

Table 3 — FIFO vs FEFO

Point	FIFO (First In, First Out)	FEFO (First Expiry, First Out)
Rule	Use the oldest received stock first	Use the stock expiring first first
Based on	Receipt date	Expiry/retest date
Best for	Materials without expiry dates	Materials with expiry dates
Goal of both	Avoid old/expired stock remaining on shelves	Avoid old/expired stock remaining on shelves

Table 4 — Quarantine Area vs Approved Store vs Rejected Area

Point	Quarantine	Approved store	Rejected area
Label	Yellow — UNDER TEST	Green — APPROVED	Red — REJECTED
Access	Restricted	Normal (authorized staff)	Locked; QA-controlled
Material may be used?	Never	Yes	Never

Table 5 — ABC Analysis: A vs B vs C Items

Point	A items	B items	C items
Examples	Costly APIs	Medium-cost excipients	Labels, cartons, minor items
Control	Very tight, frequent review	Moderate	Simple
Stock kept	Minimum (money blocked)	Moderate	Can be liberal

10. Examples

1. Equipment selection: A company needs a tablet press for 5 lakh tablets per shift. It prepares a URS (output, tablet size range, stainless-steel contact parts, 21 CFR-style data recording, safety guards) and selects the vendor whose machine meets the URS with local service support — not merely the cheapest quote.
2. URS: The URS for a new purified water system states: "capacity 2000 litres/hour, storage and distribution in a continuously circulating loop, all product-contact parts of stainless steel of suitable grade, full documentation including material certificates." The vendor's design is checked against each line in DQ.
3. Qualification: A new autoclave passes IQ (installed as per drawing, utilities connected) and OQ (holds 121°C uniformly in empty-chamber mapping), but in PQ with real loads one corner stays cool — the loading pattern is corrected and PQ is repeated until it passes. The

machine is released only after PQ approval.

4. Receipt: 100 bags of maize starch arrive. The store officer finds the purchase order mentions 100 bags but the truck has 98; he records the shortage on the GRN, informs purchase, and quarantines only the 98 received.
5. Sampling: QC samples 10 drums of lactose out of 50 (as per the sampling plan in the SOP) using a clean sampling thief in the sampling booth, wearing gloves — so the bulk drums are not contaminated during sampling.
6. Approval/rejection: A consignment of gelatin capsules fails the microbial limit test. It is shifted to the locked rejected cage with red labels, the vendor is sent a complaint with the test report, and the batch is returned — it never reaches production.
7. FIFO/FEFO: Two lots of the same excipient are in stock: Lot 1 received in January (expires December), Lot 2 received in March (expires next June). As per FEFO, Lot 1 is issued first even though Lot 2 is also available.
8. Dispensing: For Batch No. P-102, the dispensing officer weighs 25.0 kg of paracetamol API on a calibrated balance; a second officer verifies the weight and both sign the dispensing record. The weighed drum is labelled "Paracetamol 25.0 kg — for Batch P-102".
9. Cold chain: Insulin raw material requiring 2–8°C arrives in a validated cold box with a temperature data logger. The logger shows temperature stayed within 2–8°C during transport — only then is it accepted into the cold room.
10. ABC analysis: The costly anticancer API (A item) is ordered in small quantities with frequent review, while labels and cartons (C items) are ordered in bulk twice a year — attention follows value.

11. Analogies

1. URS = Tailor's measurement slip. You give measurements before stitching; the tailor is judged against them. URS is the measurement slip for machines.
2. DQ/IQ/OQ/PQ = Buying a scooter. Check the brochure (DQ), check delivery and assembly (IQ), test-ride at all speeds (OQ), ride daily for a month (PQ) — then trust it.
3. Quarantine = Airport immigration. Passengers (materials) wait in a holding area until their documents are verified; nobody enters the country (production) without clearance.
4. FIFO/FEFO = Milk packets in a shop. The shopkeeper keeps the earliest-expiring milk in front so it sells first — the warehouse does the same with materials.
5. Bin card = Bank passbook. Every deposit and withdrawal is entered with a running balance — the bin card does the same for material stock.
6. Warehouse zones = Traffic signals. Yellow means wait (quarantine), green means go (approved), red means stop (rejected) — everyone understands instantly.
7. ABC analysis = Exam preparation. You give the most time to high-weightage chapters (A), moderate time to medium ones (B), and quick revision to low-weightage ones (C) — attention follows value.

12. Pharmacy Relevance

- Your first job may be here: Many B.Pharm freshers start as warehouse/QA officers handling GRNs, quarantine, dispensing and bin cards — this chapter is literally your day-one work manual.

- Dispensing accuracy saves lives: A weighing error in a potent drug (e.g., a cardiac or anticancer medicine) can make the medicine toxic or useless. Double-checking during dispensing is a pharmacist's core duty.
- Qualification knowledge = validation career: Understanding URS → DQ → IQ → OQ → PQ opens doors to validation and engineering-QA roles, among the best-paid shop-floor careers for pharmacists.
- Audit focus: Auditors almost always visit the warehouse — they check quarantine discipline, FIFO/FEFO, temperature records and rejected-material control. This chapter prepares you to face those questions.
- Materials management saves crores: Poor inventory control blocks money and causes expiries; pharmacists who understand ABC analysis and reorder systems become valuable to management.

13. India Context

- In India, GMP requirements for equipment, materials and warehousing are covered under Schedule M of the Drugs and Cosmetics Rules (as per current notifications), which inspectors from state licensing authorities verify during licensing and renewal inspections.
- The OPPI Quality Assurance Guide gives practical Indian-industry guidance on vendor qualification, warehousing zones, FIFO/FEFO discipline and handling of rejected materials.
- Indian plants commonly face hot and humid conditions and monsoon moisture, so temperature mapping of warehouses, dehumidifiers in stores, and moisture-protective packing are practical necessities here — especially for hygroscopic materials.
- Cold-chain materials (vaccines, insulin, biologicals) need special attention in Indian summers: validated cold boxes during transport, data loggers, and backup power for cold rooms are standard expectations.
- Vendor development is a major Indian QA activity — QA teams regularly audit API and excipient vendors within India and approve them before purchase, because raw material quality decides finished product quality.

14. Key Points

1. Select equipment for suitability, cleanability, accuracy, safety, service support and GMP compliance — starting from a written URS.
2. URS = the user's written wish list (purpose, capacity, materials, functions, safety, documents, acceptance criteria); QA approves it.
3. Qualification chain: URS → DQ → IQ → OQ → PQ; each stage QA-approved before routine use.
4. Raw material flow: receive → check documents → quarantine (yellow) → sample → test → approve (green) or reject (red).
5. Never use quarantined or rejected material; rejected stock stays in a locked area.
6. Store each material as its label demands (temperature, light, moisture); keep containers closed, labelled, off the floor, segregated.
7. FIFO (oldest receipt first) and FEFO (earliest expiry first) prevent expiries on the shelf.
8. Dispensing = exact weighing per batch record in a dedicated booth, double-checked, fully labelled.

9. Warehouse zones: receiving, quarantine, sampling, approved stores, rejected cage (locked), cold room, flammable store, dispatch.
10. Good warehousing = right conditions + status labels + FIFO/FEFO + bin cards/stock records + pest control + security.
11. Materials management = ABC analysis + reorder levels + safety stock + vendor control + reconciliation — right material, right quantity, right time.

15. Common Confusions

1. URS vs Purchase Order: URS is the technical wish list (what the machine must do); the purchase order is the commercial order (price, quantity, delivery). URS comes first.
2. DQ vs IQ vs OQ vs PQ: DQ = design OK? IQ = installed OK? OQ = operates OK at all settings? PQ = performs OK in real batches? Remember the scooter analogy.
3. FAT vs SAT: FAT = tested at the vendor's factory before delivery; SAT = tested at our site after installation.
4. Quarantine vs Approved: Quarantine (yellow) = waiting for test results, cannot use; Approved (green) = passed, can use.
5. FIFO vs FEFO: FIFO uses oldest receipt first; FEFO uses earliest expiry first. For materials with expiry dates, FEFO is the smarter rule.
6. Retest date vs Expiry date: Retest date = test again to extend use; expiry date = do not use after this date, full stop.
7. API vs Excipient: API treats the disease; excipient is the inactive helper. Both are raw materials and both are tested.
8. Bin card vs Stock register: Bin card = card kept with the material showing its balance; stock register = the master book for all materials.

16. Common Mistakes (in exams and in practice)

1. Writing that materials can be used directly after receipt — wrong; they must pass quarantine → sampling → testing → approval.
2. Confusing the order of qualification — it is always DQ → IQ → OQ → PQ, never jumbled.
3. Saying URS is prepared by the vendor — wrong; the user (pharma company) prepares it; the vendor responds to it.
4. Forgetting status labels — every container must show under test / approved / rejected; unlabelled stock is a GMP failure.
5. Issuing the newest stock first — violates FIFO/FEFO and risks expiry.
6. Storing flammable solvents in the general store — they need a separate flame-proof area.
7. Using expired material "because it looks fine" — never allowed; expired = reject and destroy.
8. Doing dispensing without a second check — weighing errors are caught only by independent verification.

17. Mnemonics

1. "U-D-I-O-P" — URS, DQ, IQ, OQ, PQ. (Qualification chain — "User Demands, Inspectors Observe Proof")

2. "R-Q-S-T-A" — Receive, Quarantine, Sample, Test, Approve. (Raw material flow — "Right Quality Starts Through Approval")
3. "Y-G-R" — Yellow = wait, Green = go, Red = stop. (Status labels — traffic-signal memory)
4. "F-F" — FIFO: First in, FEFO: First expiry. ("First Family" — oldest members served first)
5. "C-L-O-S-E-D" — Closed containers, Labelled, Off the floor, Segregated, Environmental conditions, Dated (retest/expiry). (Storage rules — "Keep materials CLOSED")
6. "A-B-C" — A = costly few, tight control; B = medium; C = many cheap, simple control. ("Attention By Cost")
7. "S-C-A-M-P" — Suitability, Cleanability, Accuracy, Material of construction, Price/support. (Equipment selection — "Select Carefully And Manufacture Perfectly")

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18. Exam Summary

- Equipment selection: Suitability, material of construction (stainless steel contact parts), cleanability, accuracy, safety, utilities, automation/data integrity, vendor support, regulatory compliance, total cost.
- URS: User's written wish list — purpose, capacity, materials, functions, utilities, safety, cleaning, documentation, compliance, acceptance criteria; prepared by user dept, approved by QA; basis of all qualification.
- Qualification: DQ (design vs URS) → IQ (installation) → OQ (operating range) → PQ (real production performance); FAT at vendor, SAT at site; QA approves each stage.
- Raw material receipt: Check PO/invoice/CoA, labels, quantity, damage → GRN → quarantine (yellow UNDER TEST).
- Sampling & testing: QC samples in a dedicated booth as per plan → lab tests vs specification → approve (green) or reject (red, locked cage).
- Storage: As per label (temperature, light, moisture); closed labelled containers; off the floor on pallets; segregated; potent/flammable materials in special areas; spill kits ready.
- Dispensing: Dedicated booth, calibrated balance, exact weighing per batch record, second-person check, full labelling, leftovers resealed and recorded.
- Retest/expiry: Re-test before retest date; never use expired material.
- Warehouse zones: Receiving, quarantine, sampling, approved RM/PM stores, finished goods, locked rejected cage, cold room, flammable store, dispatch.
- GWP: Correct conditions, status labelling, FIFO/FEFO, bin cards and stock records, periodic verification, pest control, security.
- Materials management: ABC analysis (A = high value, tight control), reorder levels, safety stock, EOQ concept, approved vendors, reconciliation.
- Rejected/expired/returned: Red label, locked segregation, QA decision — return to vendor or documented destruction; never re-enter production without QA approval.

19. One-Minute Revision

NOTE

Buy machines by a written wish list (URS) and prove them step by step (U-D-I-O-P: URS→DQ→IQ→OQ→PQ). Every raw material travels R-Q-S-T-A: Receive → Quarantine (yellow) → Sample → Test → Approve (green) or Reject (red, locked). Store CLOSED (closed, labelled, off floor, segregated, right environment, dated), issue by FIFO/FEFO, dispense with a double check, and manage stock by ABC — so the right material is always available, traceable, and never expired.

20. Exam Questions

A. Short Answer Questions (2–3 marks each)

1. Define URS. Who prepares it and who approves it?
2. List any five criteria for selection of pharmaceutical equipment.
3. Expand DQ, IQ, OQ, PQ and write one line on each.
4. What is quarantine? Which colour label is used for it?
5. List the documents checked at the time of receipt of raw materials.
6. What is a bin card? What details does it carry?
7. Define FIFO and FEFO. When is FEFO preferred?
8. What is dispensing? Why is a second-person check needed?
9. Differentiate between retest date and expiry date.
10. List the zones of a pharmaceutical warehouse.
11. What is ABC analysis? Give one example each of A, B and C items.
12. How are rejected materials stored and dispositioned?

B. Long Answer Questions (5–10 marks each)

1. Explain the criteria for selection of pharmaceutical equipment. What is URS? Describe its contents and importance.
2. Describe the link between URS and equipment qualification. Explain DQ, IQ, OQ and PQ with a flowchart of equipment procurement.
3. Describe the complete procedure for receipt, quarantine, sampling, testing and approval/rejection of raw materials with a flowchart.
4. Explain the correct handling, storage and dispensing of raw materials in a pharmaceutical unit.
5. Describe the design and zones of a pharmaceutical warehouse. What are good warehousing practices?
6. What is materials management? Explain inventory control with ABC analysis, reorder level and safety stock.
7. How are rejected, expired and returned materials handled? Why is their segregation critical?

C. Multiple Choice Questions (10)

1. URS is prepared by:

a) The equipment vendor b) The user (pharma company), approved by QA c) The transporter d) The auditor

2. The correct order of equipment qualification is:

a) IQ → DQ → PQ → OQ b) DQ → IQ → OQ → PQ c) OQ → PQ → DQ → IQ d) PQ → OQ → IQ → DQ

3. A raw material with a yellow "UNDER TEST" label is kept in:

a) Approved store b) Quarantine area c) Dispatch area d) Canteen

4. Vendor's Certificate of Analysis (CoA) is checked at the stage of:

a) Dispensing b) Receipt of material c) Packing d) Recall

5. FEFO means:

a) First Expiry, First Out b) Fast Entry, Fast Out c) First Entry, First Out d) Final Expiry, Final Out

6. Rejected materials are stored:

a) With approved stock b) In a locked area with red labels c) In the receiving bay d) In the canteen

7. In ABC analysis, 'A' items are:

a) Many items of low value b) Few items of high value needing tight control c) Expired items d) Packing materials only

8. Dispensing of raw materials should be:

a) Done roughly by estimation b) Weighed exactly per batch record with a second-person check c) Done in the warehouse aisle d) Done by any visitor

9. A material past its expiry date should be:

a) Used quickly b) Rejected and destroyed as per SOP c) Mixed with fresh stock d) Kept in quarantine

10. Bin cards are used to:

a) Decorate the warehouse b) Record receipts, issues and balance of each material c) Pack tablets d) Test water quality

Answer Key: 1-b, 2-b, 3-b, 4-b, 5-a, 6-b, 7-b, 8-b, 9-b, 10-b

D. Viva Questions

1. What does URS stand for? Why is it called a "wish list"?
2. Name the four stages of qualification in order.
3. FAT vs SAT — what is the difference?
4. What colour is the quarantine label? The approved label? The rejected label?
5. What is a GRN?
6. Why is sampling done in a dedicated booth?
7. FIFO or FEFO — which do you use for a material with an expiry date?
8. Why are drums kept on pallets, not directly on the floor?
9. What is a spill kit?
10. Where are flammable solvents stored?
11. What is safety stock?
12. What should be done with expired raw materials?

E. Application-Based Questions

1. Scenario: A consignment of starch arrives with the vendor's CoA missing. The production manager is pressuring the warehouse to issue it because production is waiting. As the QA officer, what will you do? Justify with GMP principles.
2. Scenario: During warehouse inspection you find drums of an approved excipient stored directly on a damp floor near a leaking water pipe, with no status labels. List all the GMP violations and the corrective actions.
3. Scenario: A company wants to buy a new rapid mixer granulator. Draft the key points you would include in its URS (at least eight).
4. Scenario: Two lots of the same API are in stock: Lot X received in February (retest due in November), Lot Y received in May (retest due next March). Which lot should be dispensed first for the next batch, and why?
5. Scenario: The cold-room alarm log shows three temperature excursions above 8°C last month, but materials were issued normally each time. Identify the problem and describe the correct procedure (refer to the excursion flowchart).

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21. References

1. Godfrey, A. B. and Juran, J. M. Juran's Quality Handbook. McGraw-Hill Education. (Preferably latest edition.)
2. Organisation of Pharmaceutical Producers of India. Quality Assurance Guide. OPPI. (Preferably latest edition.)
3. Weinberg, S. Good Laboratory Practice Regulations. Marcel Dekker. (Preferably latest edition.)
4. World Health Organization. Quality Assurance of Pharmaceuticals: A Compendium of Guidelines and Related Materials. World Health Organization. (Preferably latest edition.)

UNIT III — QC Tests and Good Laboratory Practice (GLP)
