PHARMACEUTICAL QUALITY ASSURANCE

UNIT 2 NOTES

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Organization & Personnel

- The pharmaceutical industry has a well-defined organization to ensure quality, safety & smooth production of medicines.
- Personnel in the pharmaceutical industry are the people who work in different departments such as production, quality control, quality assurance,
- R&D of a pharma company & help in manufacturing, testing, development & sales of medicine.

Organization Chart

① Board Of Directors

- Responsible for framing company policies & long-term goals.
- They've overall control on the pharmaceutical organization.

② Managing Director / CEO

- Manages day-to-day operations of the company.
- Coordinates activities of all departments.

③ Production Department

- Production manager responsible for manufacturing of pharmaceutical products.
- Ensures smooth production as per GMP guidelines.
- Under production managers:

@ Production Supervisors

- Supervise day-to-day manufacturing activities.
- Monitor workers & production processes.

ⓑ Pharmacist (Production)

- Involved in formulation & manufacturing operations.
- Ensure proper use of raw materials & compliance with SOPs.

ⓒ Operators / Technicians

- Operate machines & equipment.
- Assist in tablet, capsule, liquid & injection manufacturing.

④ QUALITY DEPARTMENT

- Quality manager ensures quality, safety & efficacy of pharmaceutical products.
- Maintains compliance with regulatory standards.
- Under Quality manager:

ⓐ Quality Control (QC) Head

- Conducts testing of raw materials, in-process samples & finished products.
- Maintain laboratory records & analytical reports.

ⓑ Quality Assurance (QA) Head

- Ensures implementation of GMP & SOPs.
- Handles documentation, audits & product release.

⑤ RESEARCH AND DEVELOPMENT (R&D) DEPARTMENT

- R&D manager responsible for development & improvement of new drugs & existing formulation.
- Under R&D manager:

ⓐ Research scientists

- Carry out research on new drug molecules.
- Study safety, efficacy & stability of drugs.

ⓑ Formulation scitist

- Develop dosage forms like tablets, capsules & injections.
- Work on bioavailability & stability improvement.

⑥ MARKETING DEPARTMENT

- Marketing manager plans marketing strategies for pharmaceutical products.
- Manages product promotion & sales growth.
- Under marketing manager:

ⓐ Medical Representatives (MRs)

- Promote products to doctors & healthcare professionals.
- Provide scientific information & samples.

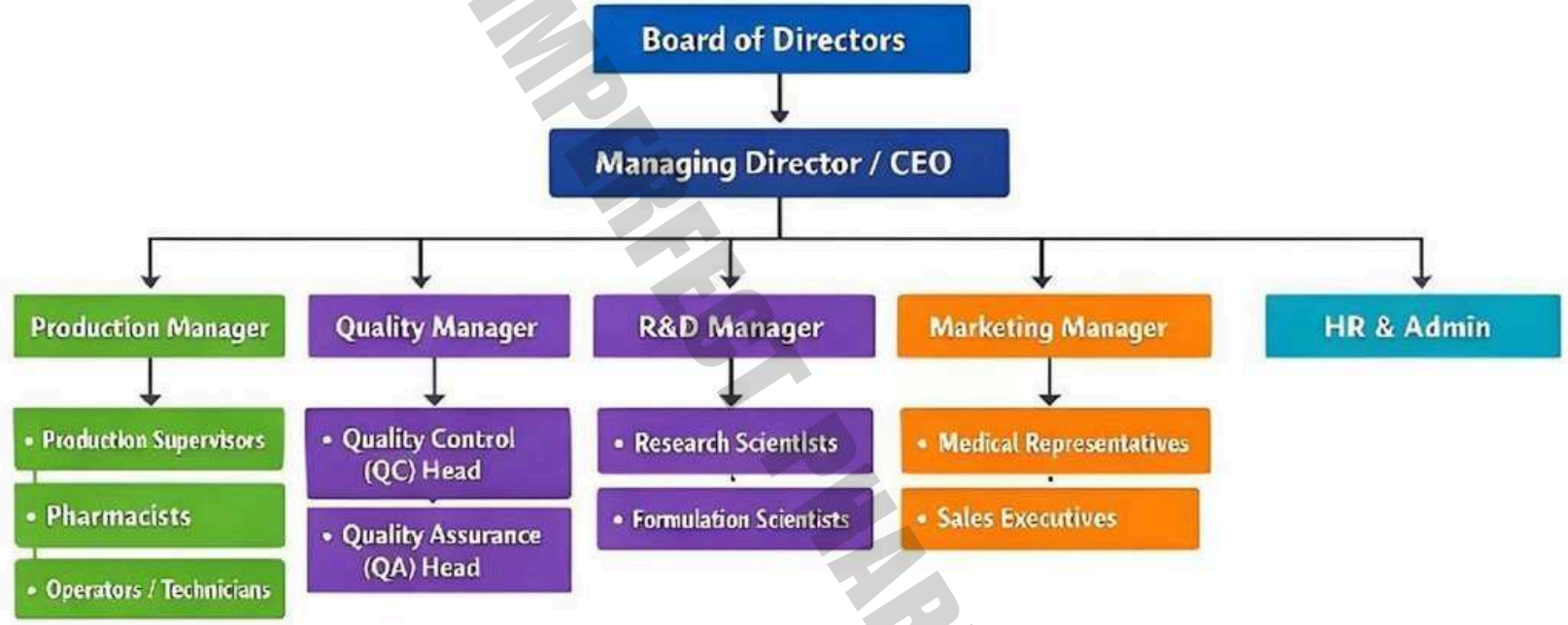
ⓑ Sales Executives

- Handle product sales & distribution.
- Maintain market presence & achieve sales targets.

⑦ HR & ADMINISTRATION DEPARTMENT

- Manages recruitment, training & employee welfare.
- Handle administrative work, records & office management.

Organization Chart of Personnel in Pharmaceutical Industry



PERSONNEL

- Personnel in the pharmaceutical industry are all trained people working in different departments like production, quality control, quality assurance, research, marketing & administration.
- They help in manufacturing, testing, ensuring quality & distribution of medicines.

KEY PERSONNEL

- Key personnel are important persons who hold major responsibilities & ensure that medicines are safe, effective & of good quality.

① HEAD OF PRODUCTION

- Responsible for manufacturing of pharmaceutical products.
- Ensures production is carried out as per GMP & approved procedures.

② HEAD OF QUALITY CONTROL

- Responsible for testing of raw materials, in-process samples, & finished products.
- Ensures that products meet required quality standard.

③ HEAD OF QUALITY ASSURANCE

- Ensures implementation of GMP, SOPs & proper documentation.
- Responsible for batch record review & product release.

④ AUTHORISED PERSON

- A qualified person approved by the regulatory authority.
- Authorises release of finished products after ensuring quality & compliance.

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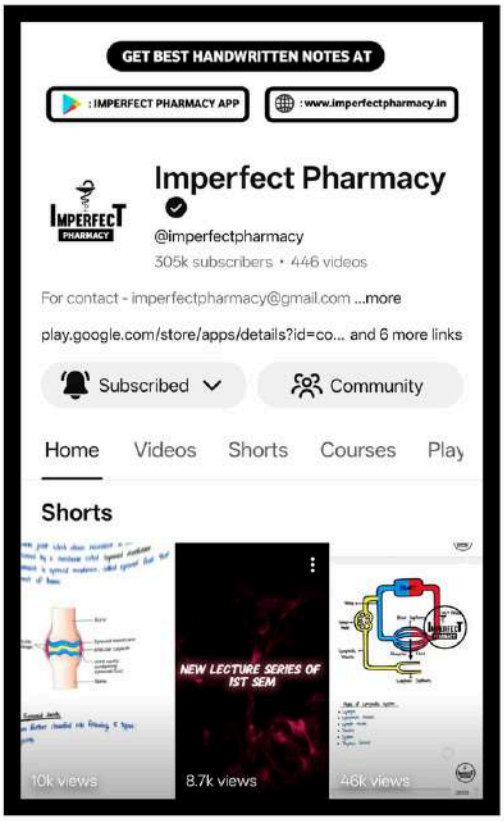

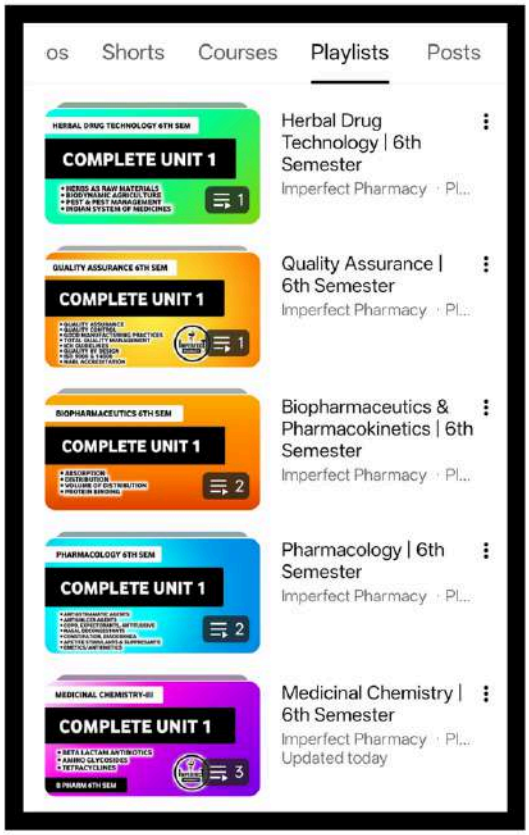

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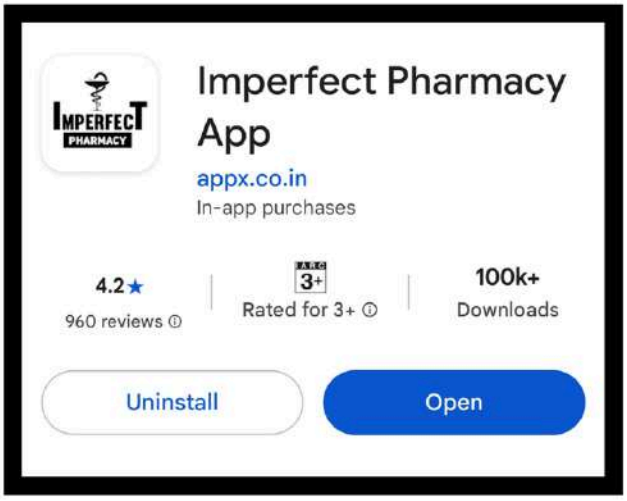


PERSONNEL RESPONSIBILITIES

Every person working in pharmaceutical industry has specific responsebilities to ensure product quality & safety.

- Personnel must follow Good Manufacturing Practices (GMP) at all times.
- They should work strictly according to Standard Operating Procedures (SOPs).
- Employees must report any deviation, error or abnormality immediately to their supervisor.
- Personnel should avoid any activity that may cause contamination or mix-up of products.
- Each worker is responsible for maintaining cleanliness & discipline in the working area.
- Supervisors are responsible for guiding workers & ensuring proper execution of work.

PERSONNEL TRAINING

Training is essential to ensure that employees are competent & aware of their duties.

- All personnel should recieve initial training before starting work.
- Training should include GMP, SOPs, safety procedures & hygiene products.
- Regular fresher training should be conducted to update knowledge.
- Specialized training is required for working in sterile areas, QC labs, & production labs.
- Training programs should be documented & evaluated for effectiveness.

PERSONNEL HYGIENE

Good personnel hygiene is necessary to prevent contamination of pharmaceutical products.

- Personnel must wear clean protective clothing, caps, masks, gloves & footwear.
- Hands should be washed & sanitized before entering production area.
- Eating, drinking, smoking or chewing gum is strictly prohibited in production areas.
- Personnel suffering from infectious diseases, skin problems, or wounds should not enter manufacturing areas.
- Jwelery, cosmetics & strong perfumes should not worn inside production areas.

PERSONNEL RECORDS

Personnel records are maintained to ensure accountability & regulatory compliance.

- Records of qualification, experience & job responsibilities of employees should be maintained.
- Training records including date, topic & trainer details must be documented.
- Health records of personnel should be regularly updated.
- Attendance & shift records should be properly maintained.
- All personnel records should be accurate, up to date, & easily retrievable for inspection.

PREMISES

- Premises means the building & sorrounding area where pharmaceutical activities, like manufacturing, testing, packing, storage & distribution are carried out.
- Proper designing & construction of premises are essential to maintain quality, safety, hygiene & contamination control.

DESIGN, CONSTRUCTION & PLANT LAYOUT

- The pharmaceutical building should be of suitable size, proper construction, & good location to allow easy cleaning, maintenance & smooth manufacturing operations.
- The factory should be located away from open drains, sewage, public toilets, smoke, dust, fumes chemical or biological pollution to avoid contamination.
- The premises must be designed to allow hygeinic production of drugs.
- The building should comply with the Factories Act, 1948
- Manufacturing, packaging, testing & storage areas should be compatible with the operations performed.
- Adequate space should be provided for proper placement of equipment & free movement of staff to avoid mix-ups & cross-contamination.
- The design should prevent the entry of insects, rodents, birds & pets.
- HVAC design should be provided where environmental control is required.
- Proper drainage & waste disposal systems should be available to prevent back-flow & pest entry.
- Floors & walls should be smooth, crack-free, non-porous & washable to avoid dust contamination.

- Premises should be regularly maintained & repair work should not affect product quality.
- Cleaning & disinfection should be done as per written SOPs.
- Electricity, lighting, ventilation, temperature & humidity should be suitable & should not adversely affect the product or equipment.

SOME PRINCIPLE AREAS OF PREMISES INCLUDES

(a) ANCILLARY AREAS

- These are support areas for workers, not directly used for production.
- They include rest rooms, toilets, changing rooms, & clothes storage.
- These areas must be separate from production & storage areas to maintain hygiene.

(b) WAREHOUSING AREAS

- These areas are used for storage of materials & products like raw materials, packaging materials, intermediates & finished products.
- Different materials should be stored separately & under proper temperature & humidity conditions.

(c) PRODUCTION AREAS

- These are the main areas where drug manufacturing takes place.
- They should've adequate space, proper ventilation, & logical flow of materials to avoid mix-ups & contamination.

ⓓ Quality Control Areas

- QC areas are used for testing & analysis of raw materials & finished products.
- They must be separate from production areas & properly designed for chemical & microbiological testing.

② MAINTENANCE

- Premises should always be kept in a good state of repair.
- Maintenance includes checking:
  - Roof leakage
  - Pipeline leakage
  - Plumbing issues
  - Broken tiles
  - Faulty doors & windows
  - Electrical wiring & fittings
- Defects should be corrected immediately.
- Cracks & damage can allow pests & micro-organisms, affecting product quality.
- Regular inspections & maintenance records must be maintained.

③ SANITATION

- Sanitation means keeping the premises, equipment & working areas clean & hygienic to prevent contamination of pharmaceutical products.
- The premises must be free from rodents, insects, birds & other pests.
- Cleaning & sanitation should be done according to Written Standard Operating Procedures (SOPs).
- Only approved disinfectants, insectisides & cleaning agents should be used to avoid product contaminations.
- Regular cleaning helps to remove dust, dirt & micro-organisms.
- Good sanitation reduces the risk of cross-contamination & ensures product quality & safety.

④ ENVIRONMENTAL CONTROL

- Environmental control means maintaining clean air, proper temperature, humidity & pressure inside pharmaceutical premises.
- Proper ventilation & HVAC system should be provided to control air quality.
- Temperature should be maintained as required so that drug quality & stability are not affected.
- Humidity must be controlled because excess moisture can cause drug degradation & microbial growth.
- Sterile & aseptic areas require strict environment control with filtered air supply using HEPA filters.
- Regular monitoring & recording of temperature, humidity, air pressure & microbial count is neccessary.
- Proper environmental control helps in GMP compliance, ensures products safety & improves overall quality of pharmaceutical products.

⑤ UTILITIES

- Utilities are the basic support systems required for smooth & safe functioning of pharmaceutical premises.
- Proper utilities are essential to maintain product quality, hygiene & GMP compliance.
- Water supply should be adequate, clean and of required quality (potable, purified or WFI as applicable).
- Electrical supply should be continuous & sufficient for machines, lighting & HVAC systems.
- HVAC systems is an important utility used to control temperature, humidity, air quality & ventilation.

- Steam supply should be properly maintainted for sterilization & heating purposes.
- Drainage system should be properly well designed to avoid backflow, water logging & contamination.

⑥ MAINTENANCE OF STERILE AREAS

- Sterile areas are very sensitive & require strict control to maintain aseptic conditions.
- Floors, walls & ceilings of sterile areas should be smooth, hard, crack-free, & easy to clean.
- Temperature & humidity should be properly controlled according to the operation being performed.
- Sterile areas should have HEPA-filtered air supply to remove dust particles & micro-organisms.
- An effective environmental monitoring system should be in place to check air quality, pressure, temperature & humidity.
- Regular cleaning & disinfection of sterile areas, equipment & facilities is essential.
- Cleaning & disinfecting procedures should be validated to ensure effective removal of contaminants.
- HEPA filters should be tested & maintained at regular intervals.
- Proper maintenance helps in preventing microbial contamination, ensures GMP compliance & maintains the quality & safety of sterile pharmaceutical products.

⑦ CONTROL OF CONTAMINATION

- Control of contamination means preventing entry & spread of dust, microorganisms, chemicals & foriegn particles in pharmaceutical premises.
- Contamination can be controlled by implemeting following measures :

ⓐ AREA & FACILITY CONTROL

- Positive air pressure & HEPA filtration should be used.
- Surfaces should be smooth & crack-free.
- Entry into sterile areas should be restricted & controlled.

ⓑ PERSONNEL CONTROLLED

- Personnel should maintain high personal hygiene.
- Illness should be reported immediately.
- Cosmetics, jewellery, eating, smoking, & unneceessary talking are prohibited.
- Proper glowing & glove disinfection should be followed.

ⓒ CLEANING & DISINFECTION

- Cleaning SOPs should be followed strictly.
- Cleaning should be done before disinfection.
- Correct disinfectant at correct concentration should be used.

EQUIPMENTS

- Equipments in the pharmaceutical industry are the machines & tools used for manufacturing, processing, testing & packing of drugs.
- While selecting & purchasing equipments following things must be considered to select the best equipment according to need.

EQUIPMENT SELECTION

① QUALITY

- Choose equipment that meets the highest industry standards for precision, accuracy & reliability.
- This is important for maintaining product quality & consistency.

② SUITABILITY OF EQUIPMENT

- Equipment should be suitable for the type of the product.
- It should match the batch size & production need.
- It should give uniform & consistent output.

③ MATERIAL OF CONSTRUCTION

- Equipment should be made of non-toxic material
- It should not react with the product.
- Stainless steel is prefferred in pharma industry.

④ Design & Construction

- Equipment should've smooth surfaces.
- There should be no sharp corners or joints
- Design should prevent dust & contamination.

⑤ Ease Of Cleaning & Operation

- Equipment should be easy to clean.
- It should be simple to operate.
- Less time should be required for cleaning.

⑥ GMP & Safety Requirements

- Equipment should follow GMP guidelines.
- It should be safe for workers to use.

⑦ Capacity

- Consider your production scale & future growth potential when selecting equipment.
- Choose equipment that can handle your current needs & allows for future expansion.

PURCHASE SPECIFICATIONS

① TECHNICAL SPECIFICATIONS

- Mention equipment name, type & model clearly.
- Specify capacity & performance details.
- Define technical parameters before purchase.

② MATERIAL & QUALITY REQUIREMENTS

- Specify material of construction clearly.
- Follow pharmaceutical quality standards.
- Ensure proper surface finish for hygiene.

③ UTILITY REQUIREMENTS

- Mention power requirement clearly.
- Specify water, air & utility needs.
- Allocate proper space for installation.

④ SUPPLIER & DOCUMENTATION

- Select approved & reliable suppliers.
- Collect operating & maintenance manuals.
- Ask for validation & test documents.

⑤ WARRANTY & AFTER-SALE SERVICE

- Check warranty period before purchase.
- Ensure availability of service support.
- Confirm easy availability of spare parts.

Maintenance Of Equipments

① Routine Maintenance

- Equipment should be clean regularly.
- Lubrication should be done when required.
- Visual inspection should be carried out daily.

② Prevetive Maintenance

- Maintenance should be done at fixed intervals.
- It helps in avoiding sudden breakdowns.
- It increases the life of equipment.

③ Calibration

- Instruments should be calibrated regularly.
- Calibration ensures accurate readings.
- Calibration schedule should be followed.

④ Breakdown Maintenance

- Faulty equipment should be repaired immediately.
- Only approved spare parts should be used.
- Production should stop during major faults.

⑤ Records & Documentation

- All maintenance activities should be recorded.
- Dates & details should be properly mentioned.
- Records help during audits & inspections.

RAW MATERIALS

- Raw materials are the basic substances used to manufacture medicines in the pharmaceutical industry.
- The quality of raw materials directly affects the safety, quality & effectiveness of the final product.
- Raw materials should be purchased only from approved suppliers & must follow pharmacopoeial standards such as IP, BP or USP.

TYPES OF RAW MATERIALS

- Active Pharmaceutical Ingredients (APIs): Provide therapeutic effects
- Excipients: Inactive substances aiding formulation stability, taste or delivery.
- Solvents & Reagents: Used in synthesis or purification.
- Packging Materials: Ensure product protection & stability.

PURCHASE SPECIFICATION OF RAW MATERIALS

- Purchase specifications are written guidelines that describes the quality & requirements of raw materials before they're purchased.
- These specifications ensure that only safe, standard & good-quality materials are procured.
- It includes following specifications:

① NAME OF RAW MATERIAL

- The correct & official name of the raw materials should be mentioned to avoid confusion or mix-up.

② Grade & Quality

- The required grade (pharmaceutical grade, analytical grade, etc.) must be specified to ensure suitability for medicinal use.

③ Pharmacopoeial Standards

- The raw material should comply with recognized standards such as IP, BP or USP.

④ Description Of Material

- Physical appearance like color, odor & form (powder, liquid, crystals) should be clearly stated.

⑤ Identification Tests

- Tests used to confirm the identity of the raw material must be mentioned.

⑥ Microbial Limits

- For materials prone to contamination, microbial limits must be specified.

⑦ Packaging Requirements

- Type of container, pack size, & protection from moisture, light, or air should be mentioned.

⑧ **STORAGE CONDITIONS**

Required storage conditions such as temperature, humidity & light protection should be clearly tested.

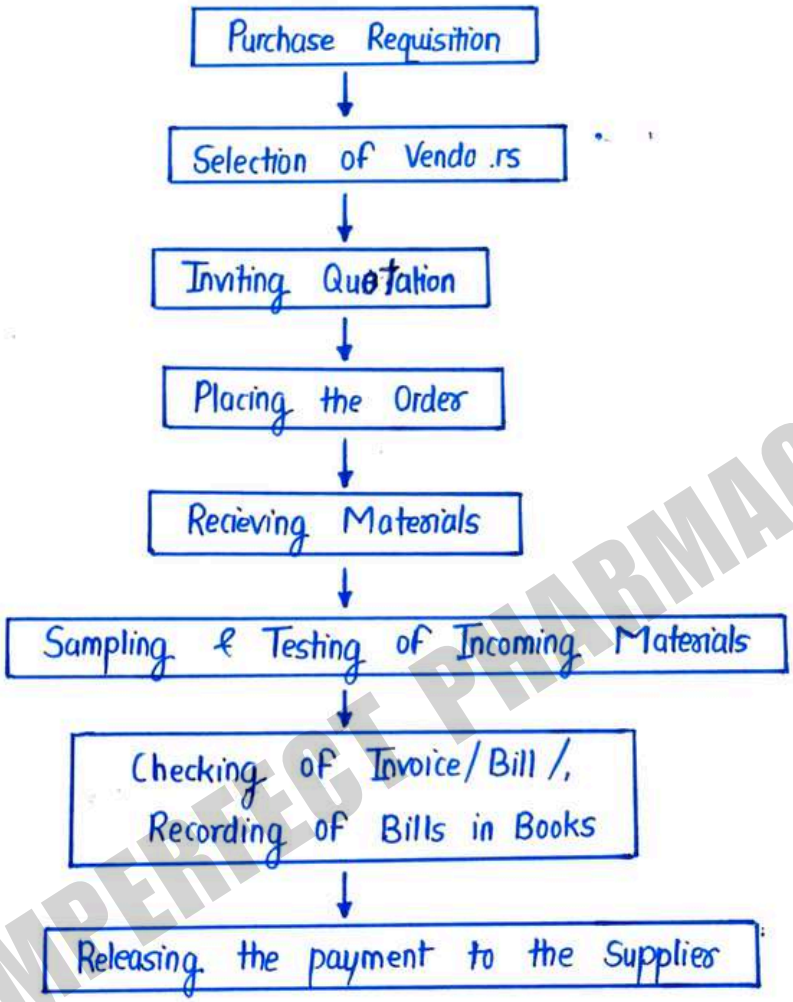
⑨ **LABELLING REQUIREMENTS**

Each container should carry proper labeling like material name, batch number, manufacturing date, expiry date & supplier name.

⑩ **APPROVED SUPPLIER DETAILS**

Raw materials should be purchased only from approved & qualified products.

Steps Of Purchasing Raw Materials



Purchase Records

Points to be check & Recorded :

- Date of reciept
- Name of the product
- Batch no.
- Control no. assigned by the manufacturer
- Quantity recieved
- Name of supplier
- Purchase Order no.
- Excise gate pass
- Date of Manufacture & Expiry

Maintenance Of Raw Materials

① Location Of Stores

- Keep stores near to the manufacturing area.
- Select location based on type & value of raw materials.
- Ensures easy recieving & issuing of materials.

② Storage Area Requirements

- Provide enough space for safe storage.
- Keep store clean, dry & well maintained.
- Control temperature & humidity as required.
- Maintain separate areas for quarantine, approved, & rejected materials.
- Follow FIFO & FEFO systems.

③ Storage Facilities

- Maintain separate inspection area for incoming materials.
- Provide a sampling area for QC testing.
- Use a central weighing area.
- Keep quarantine room for unapproved materials.
- Stored hazardous & narcotic materials in secured areas.

④ Storage Conditions

- Store normal materials at controlled room temperature (around 30°C).
- Store light-sensitive materials in amber containers.
- Store temperature-sensitive materials at 2-8°C when required.

⑤ Labeling Of Raw Materials

- Label every container with material name & internal code.
- Mention batch number, manufacturer name & quantity.
- Clearly show material status like quarantine, approved or rejected.
- Write clearly expiry date on the label.

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