D.PHARM • FIRST YEAR

फार्मास्यूटिक्स

अध्याय 6

औषधि निर्माण संयंत्र



हिंदी अध्याय नोट्स

PHARMACEUTICAL MANUFACTURING PLANTS

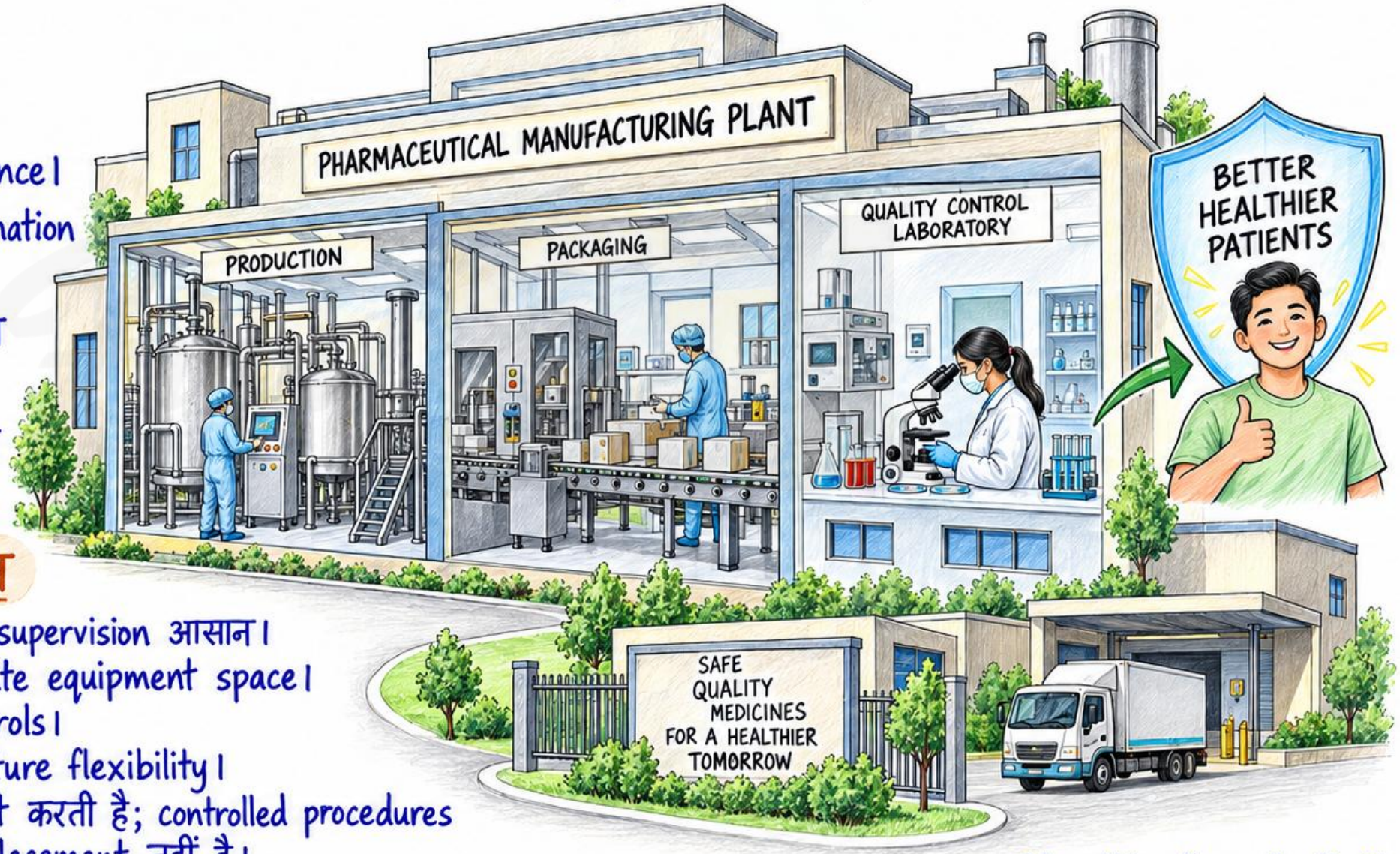
Pharmaceutical products के controlled industrial-scale production के specialized facilities।

MAIN OBJECTIVES

- Consistent product quality तथा applicable GMP compliance।
- Contamination, cross-contamination और mix-ups रोकें।
- Materials तथा personnel का efficient movement रखें।
- Safe working conditions और waste management दें।

GOOD DESIGN से लाभ

- Cleaning, maintenance तथा supervision आसान।
- Logical workflow और adequate equipment space।
- Suitable environmental controls।
- Process control खोए बिना future flexibility।
- Good building, quality support करती है; controlled procedures तथा trained people का replacement नहीं है।



TYPES OF MANUFACTURING FACILITIES

Facility requirements, product तथा process risks पर निर्भर हैं।

1. FORMULATION FACILITIES



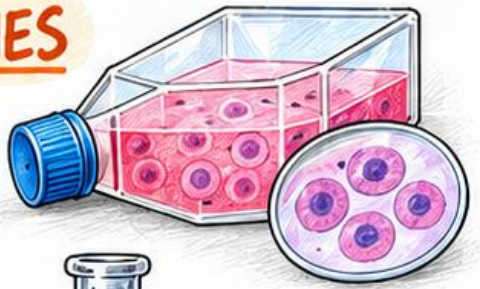
- Oral solids: tablets, capsules, powders और granules।
- Liquids: oral या topical solutions तथा dispersions।
- Semisolids: ointments, creams और gels।
- Sterile products: injections तथा ophthalmic preparations।



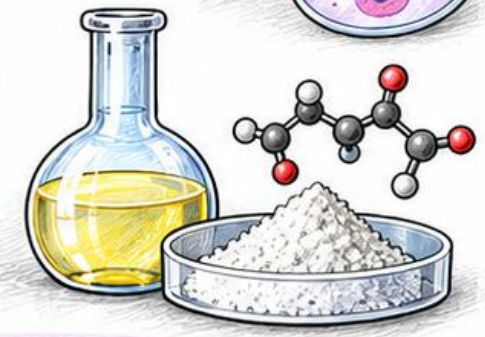




2. SPECIALIZED FACILITIES



- Biologics: biological systems से बने products।
- API manufacture: active drug substances का production।



3. IMPORTANT DISTINCTION

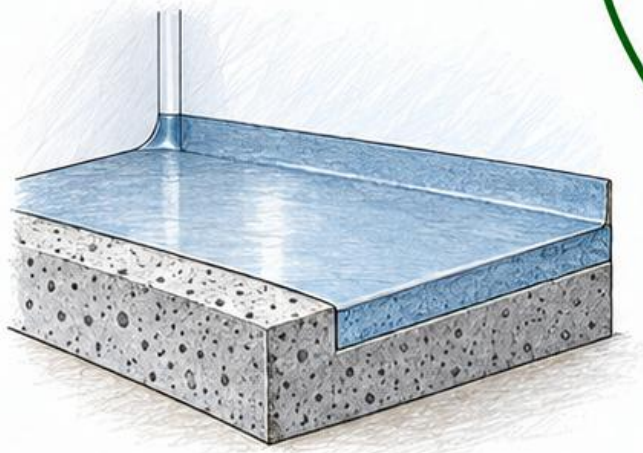
- Containment तथा segregation requirements, risk-based हैं।
- Sterile production में suitable sterility-assurance route चाहिए; हर product में aseptic filling जरुरी नहीं।
- एक layout तथा environmental standard, हर pharmaceutical facility के लिए नहीं हैं।

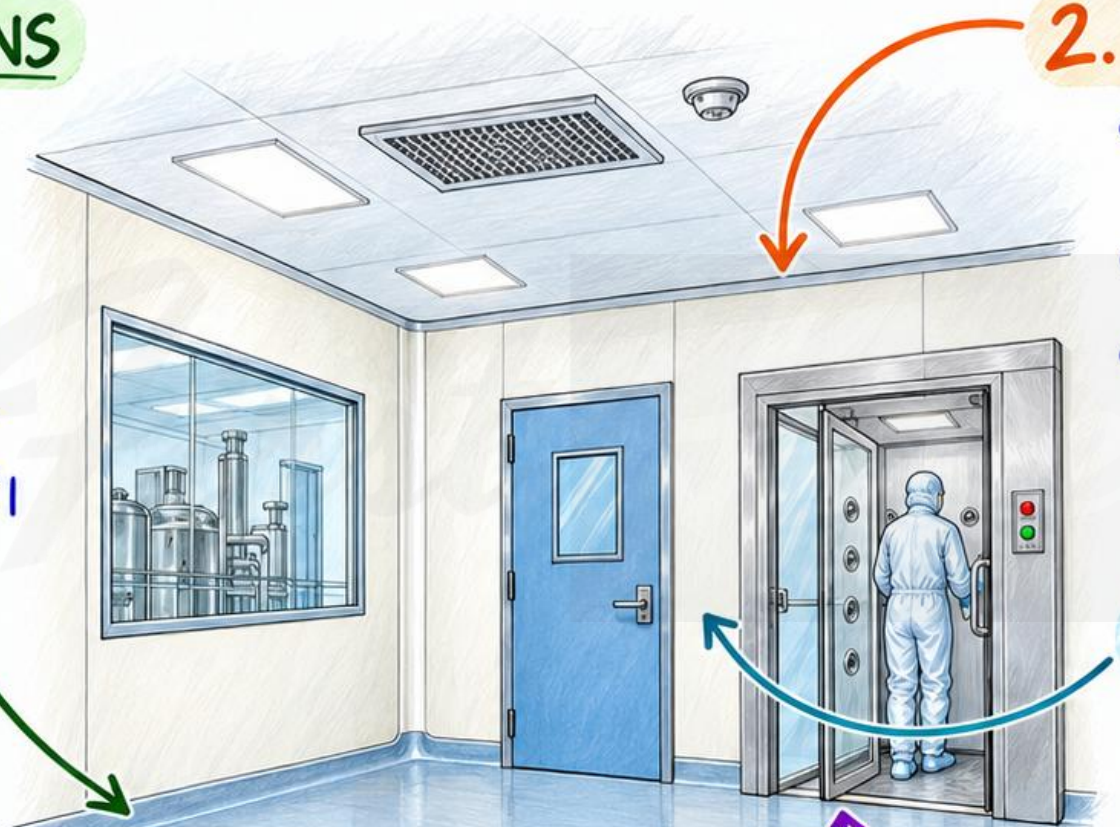
PLANT STRUCTURE और FINISHES

Construction से cleaning, durability तथा contamination control support होना चाहिए।

1. FLOORS और FOUNDATIONS

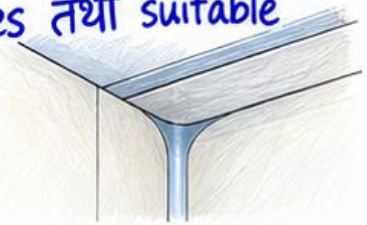
- Intended equipment loads support करें।
- Suitable smooth, non-shedding तथा cleanable surfaces।
- Chemical resistance और अन्य properties, area के अनुसार हों।





2. WALLS और CEILINGS

- Unnecessary dust-trapping gaps के बिना cleanable surfaces।
- Appropriate coved junctions।
- Sealed services तथा suitable lighting।



3. DOORS और WINDOWS

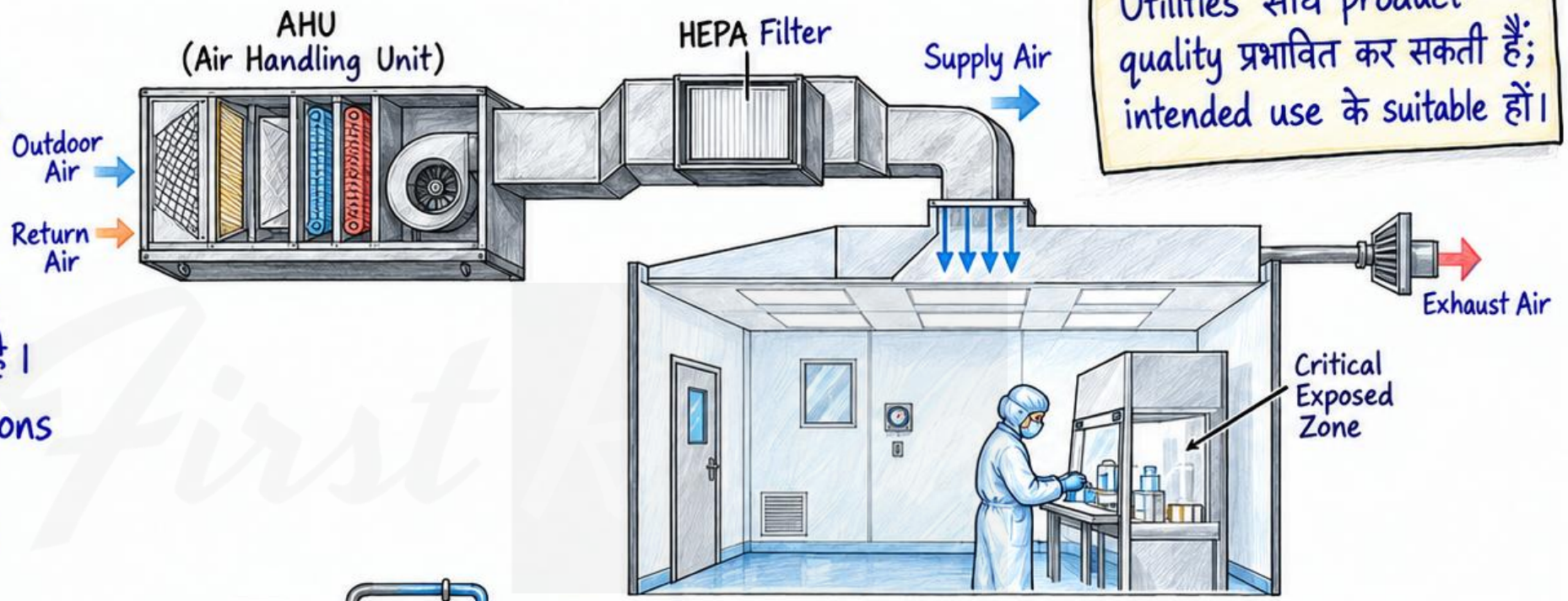
- Production areas में controlled access।
- Suitable flush observation windows।
- Required airlocks, interlocks या pass-through arrangements।

4. Anti-static flooring तथा airtight doors जैसे features, relevant risks के लिए चुने जाते हैं; हर जगह नहीं।

HVAC और UTILITIES

1. HVAC

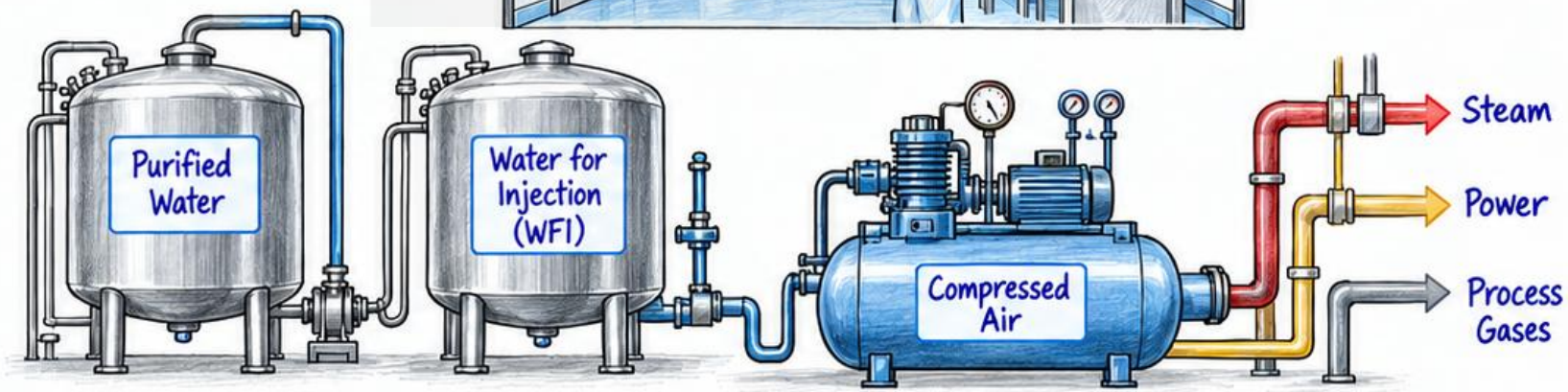
- Suitable temperature, humidity तथा air movement control करता है।
- Contamination control और containment के लिए pressure relationships manage करता है।
- Relevant cleanroom applications में HEPA filtration होती है।
- Cleanroom grades, operation तथा applicable system पर निर्भर हैं।



Utilities सीधे product quality प्रभावित कर सकती हैं; intended use के suitable हों।

2. OTHER UTILITIES

- Required qualified Purified Water या Water for Injection।
- Suitable compressed air तथा process gases।
- Steam, power और supporting services।
- Effluent treatment तथा safe waste handling।



★ हर room में एक जैसा filter, pressure या environmental classification जरूरी नहीं।

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