D.PHARM • FIRST YEAR

फार्मास्यूटिक्स

अध्याय 5.7

जीवाणुरहित फॉर्मुलेशन

हिंदी अध्याय नोट्स

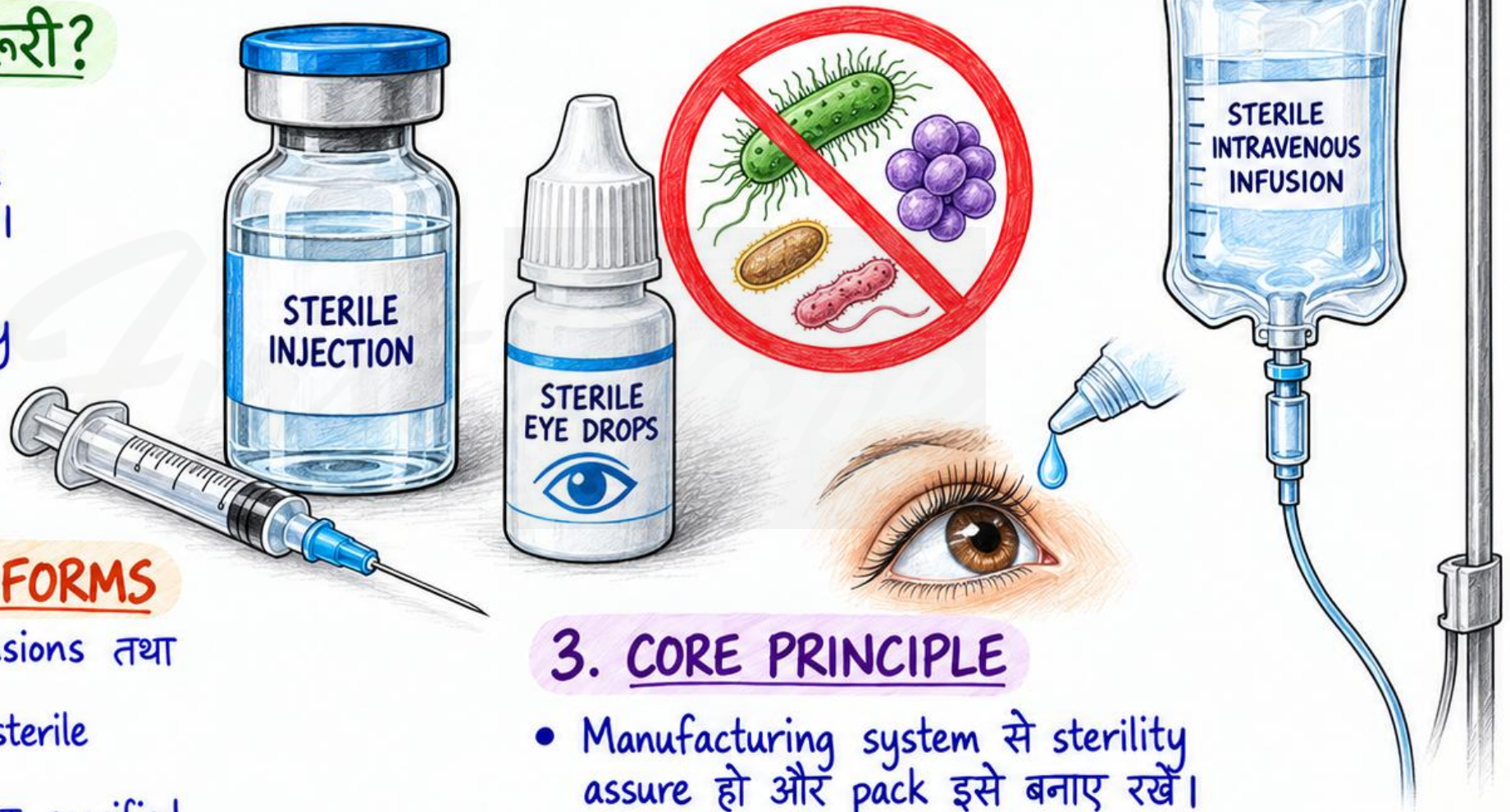


STERILE FORMULATIONS

Preparations में viable microorganisms, including bacterial spores, नहीं होने चाहिए।

1. STERILITY क्यों जरूरी?

- Injection तथा ophthalmic routes, important natural defences bypass करती हैं।
- Contamination से serious infection या tissue injury हो सकती है।
- Vulnerable patients में risk अधिक है।



2. COMMON STERILE FORMS

- Injectable solutions, suspensions तथा selected emulsions।
- Intravenous infusions और sterile injection powders।
- Ophthalmic preparations तथा specified irrigation fluids।
- Selected implants और aqueous oral-inhalation products।

3. CORE PRINCIPLE

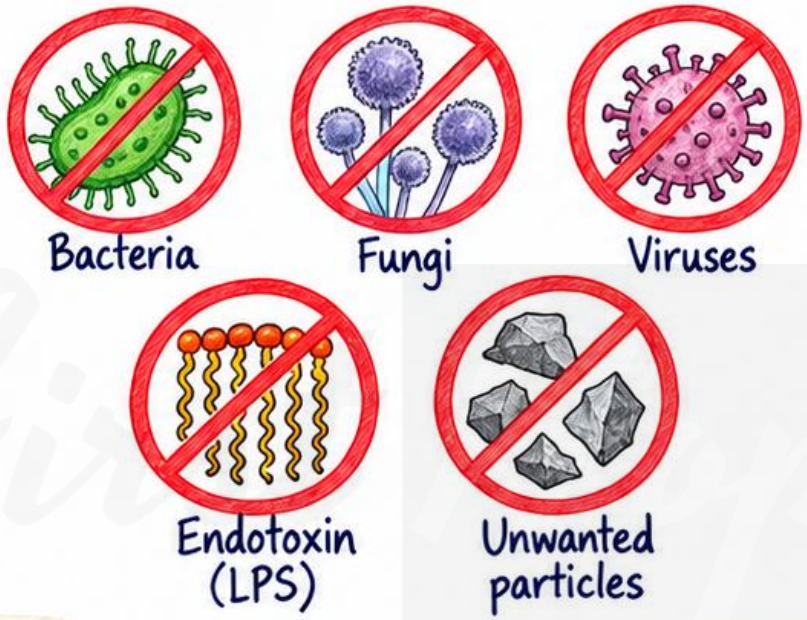
- Manufacturing system से sterility assure हो और pack इसे बनाए रखे।
- हर skin product या dry inhalation powder sterile नहीं होता।

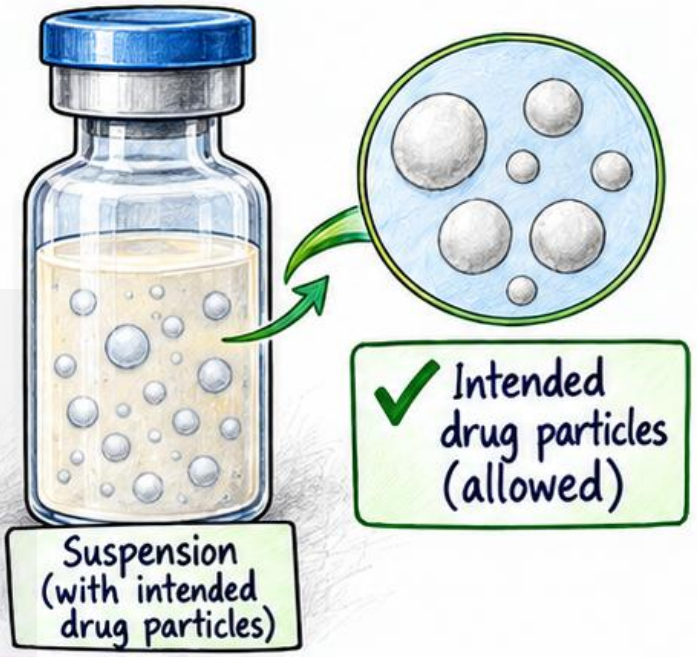
STERILE PRODUCT QUALITY ATTRIBUTES

अलग quality hazards के लिए अलग controls चाहिए।

1. ESSENTIAL CONTROLS

- Sterility: viable microorganisms का absence।
- Required pyrogen या bacterial-endotoxin control।
- Unwanted visible तथा subvisible particles control करें।
- Correct drug content, stability और container integrity।





2. FORMULATION COMPATIBILITY

- pH तथा osmolality, drug, route और administration method के suitable हों।
- हर injection exactly isotonic या समान pH वाली नहीं होती।
- Suspensions में controlled drug particles intended होते हैं।



3. महत्वपूर्ण DISTINCTIONS

- Sterile का अर्थ automatically endotoxin-free नहीं।
- Intended drug dispersion तथा foreign contamination अलग हैं।
- Sterility test अकेले पूरे batch की sterility assurance सिद्ध नहीं करता।

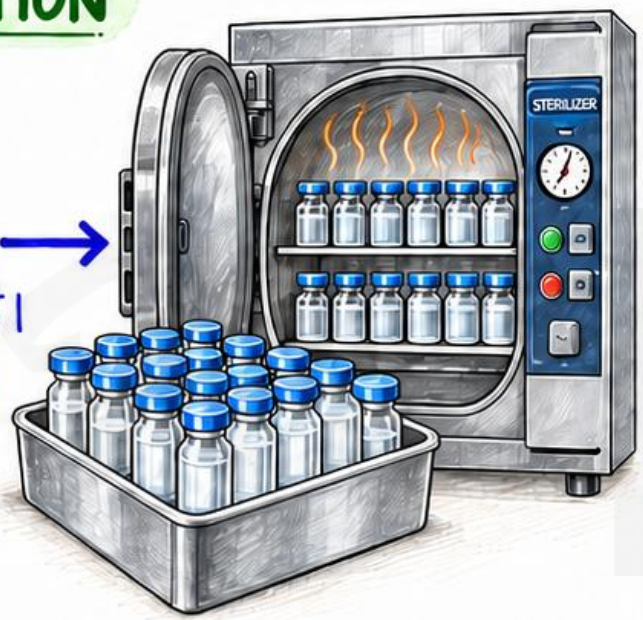


TERMINAL STERILIZATION VS ASEPTIC PROCESSING

Product तथा container के suitable validated approach चुनें।

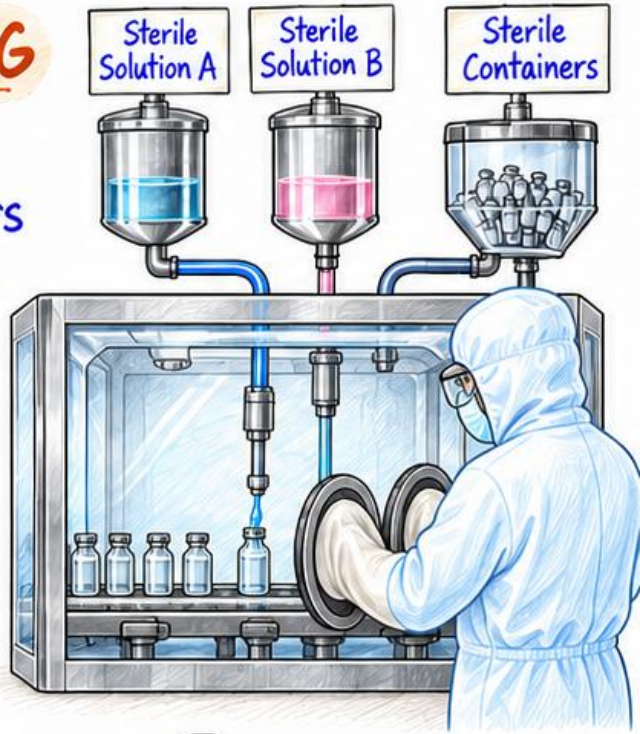
TERMINAL STERILIZATION

- Final sealed container में product sterilize करें।
- Product और pack tolerate करें तो preferred approach है।
- Actual load तथा cycle control करें; केवल memorized temperature नहीं।



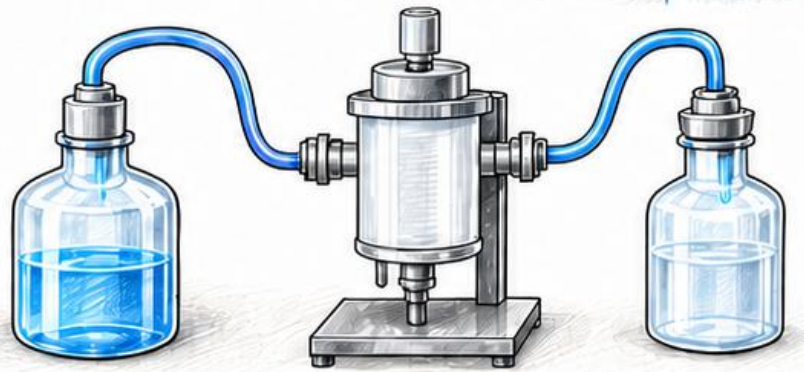
ASEPTIC PROCESSING

- Suitable ingredients, equipment तथा containers separately sterilize करें।
- Recontamination रोककर combine तथा fill करें।
- Terminal sterilization unsuitable हो तो उपयोग होता है।



STERILIZING FILTRATION

- Suitable solutions में validated bacteria-retentive filter उपयोग हो सकता है।
- Filter compatibility तथा integrity महत्वपूर्ण हैं।
- Filtration, suspensions, emulsions या endotoxin removal का universal method नहीं है।

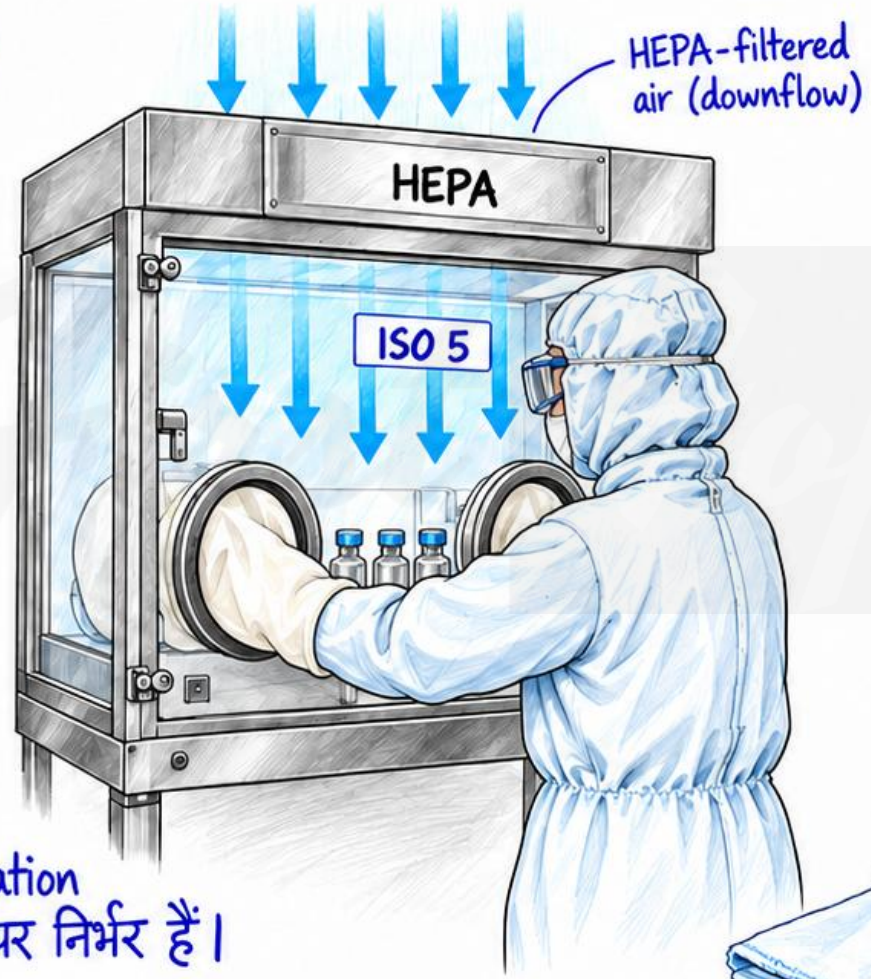


CLEANROOM और CONTAMINATION CONTROL

Critical manufacturing operations में exposed sterile product protect करें।

1. CRITICAL CONTROLS

- Suitable cleanroom design तथा qualified HEPA-filtered air।
- Exposed critical aseptic zones में ISO 5 conditions।
- Controlled personnel तथा material flow।
- Appropriate gowning, hygiene और aseptic technique।



2. SUPPORTING MEASURES

- Cleaning तथा disinfection procedures।
- Environmental और personnel monitoring।
- Equipment qualification तथा process validation।
- Applicable aseptic process simulations।



3. FACILITY DESIGN

- Pressure relationships, contamination control तथा containment needs पर निर्भर हैं।
- Clean-looking room, controlled aseptic environment का evidence नहीं हैं।

First Hope

FREE PREVIEW

Click here to visit our website

PHARMACY PREMIUM NOTES

Complete subject and semesters are available on FirstHope app only.

Scan or click here

Click here to get the app >

Available on Google Play

JOIN THE FIRSTHOPE COMMUNITY

Join our Telegram channel

Click here to join Telegram >

Scan or click here

@FirstHopeNotes

Instagram

@firsthope.official

Click here to follow >

YouTube channel

FirstHope-Pharmacy / Live streams

Click here to watch >

WhatsApp channel

Follow FirstHope on WhatsApp

Click here to join >

FirstHope website

firsthope.co.in

Click here to visit >

B.Pharm / D.Pharm / M.Pharm / Pharm.D

Preview notes. Complete subjects and semesters in the FirstHope app.