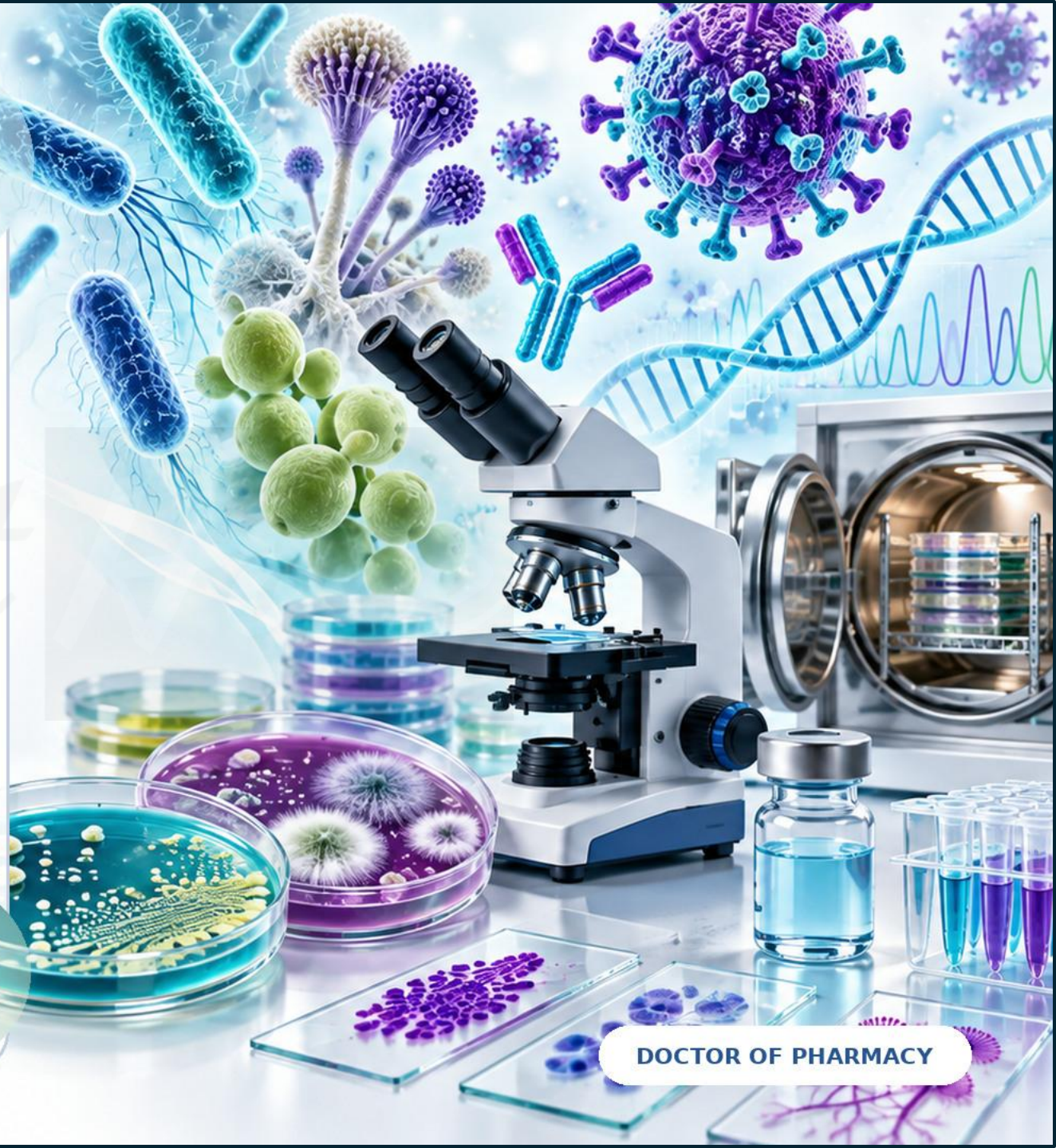
PHARM.D • YEAR 2

Pharmaceutical Microbiology

CHAPTER 5

Methods of Sterilization and Sterility Testing



PPT CHAPTER COVER

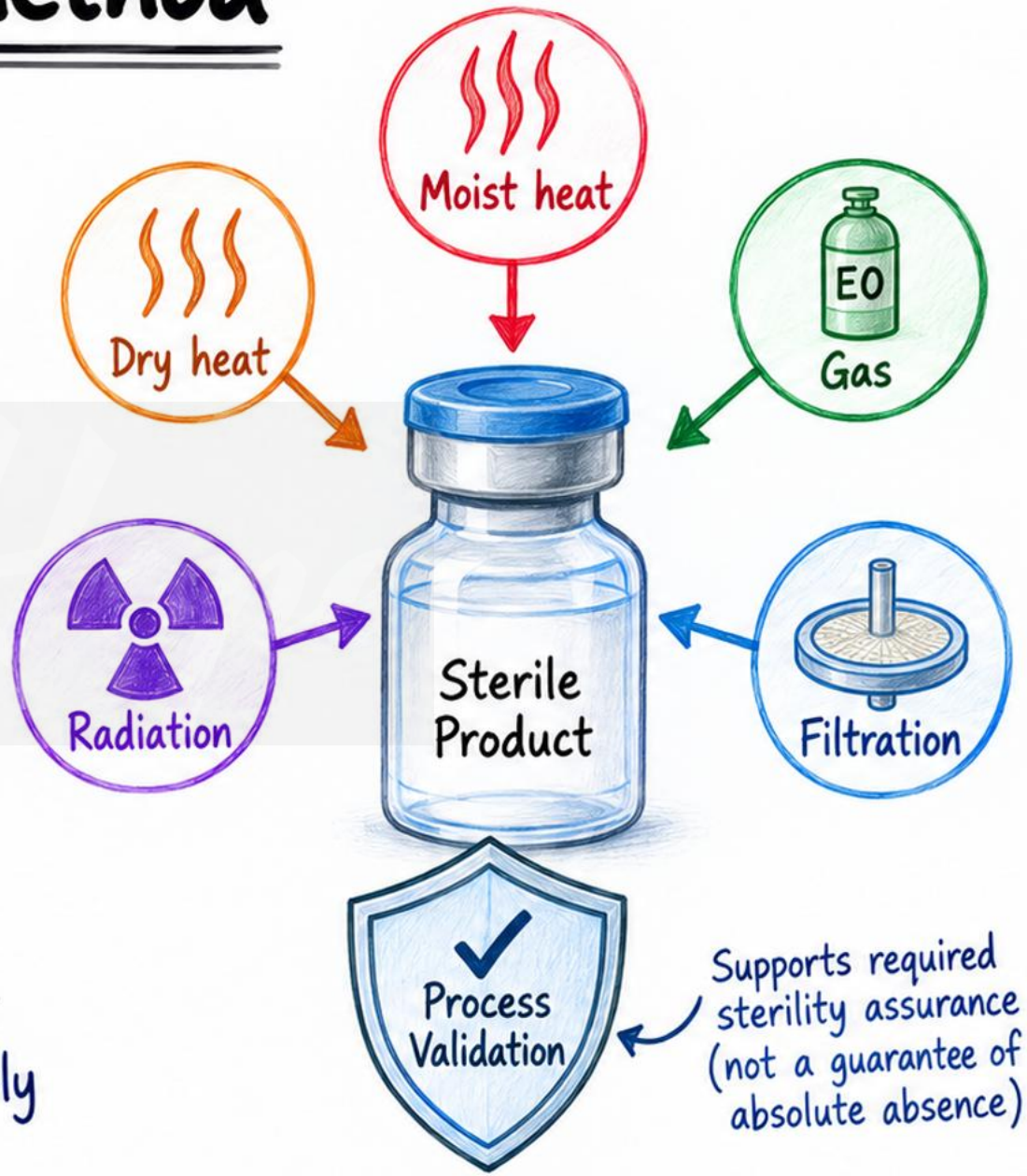
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Sterilization: Choosing a Method

Sterilization aims to eliminate viable microorganisms, including resistant forms, from a defined product or item. Method choice depends on material compatibility, packaging and the required sterility assurance.

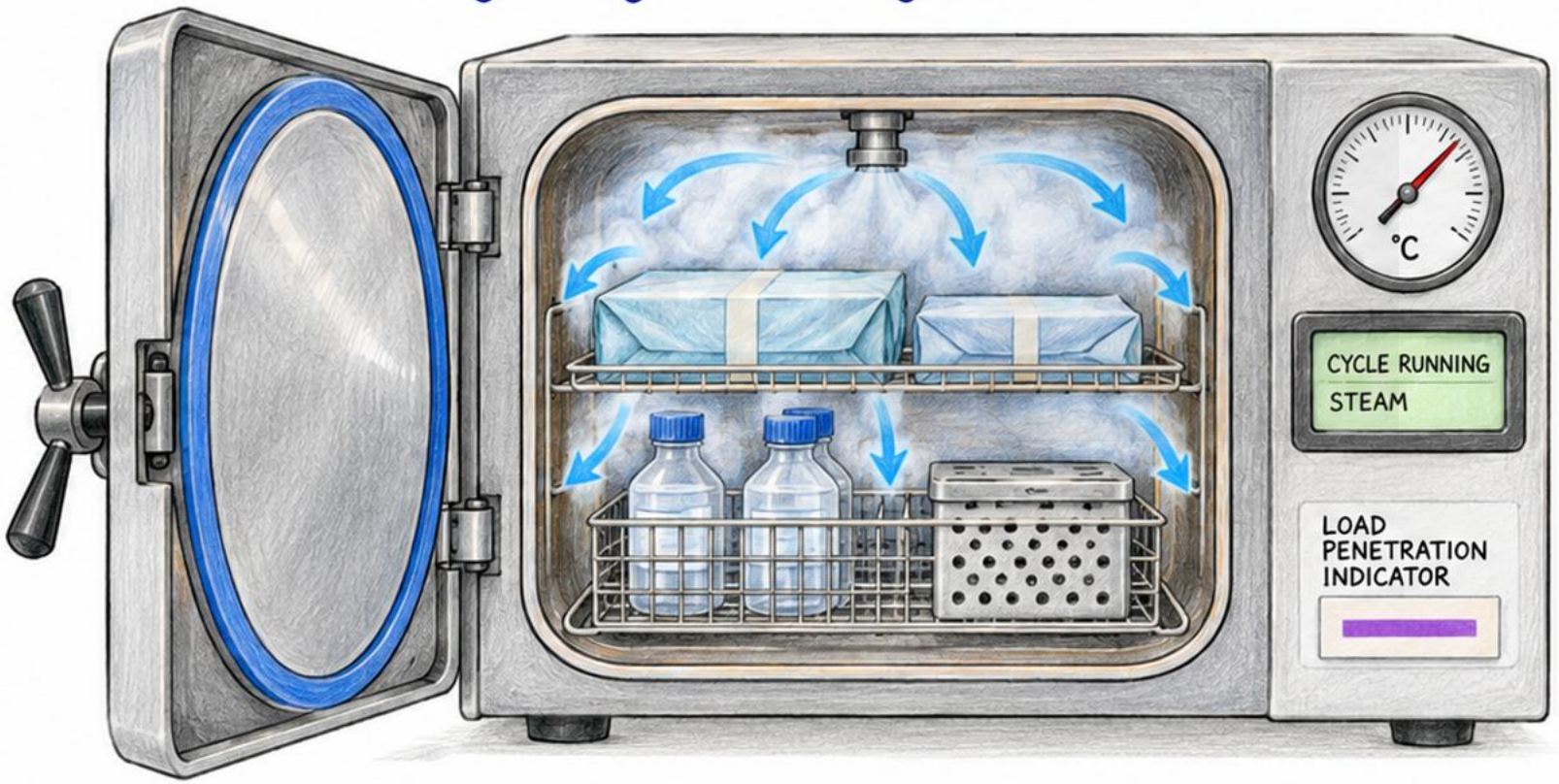
Moist heat, dry heat, gas, radiation and filtration are not interchangeable. Cleaning and process validation are essential; a later negative sterility test cannot rescue an inadequately controlled process.

The key decision is whether the final sealed product tolerates terminal treatment. If not, aseptic assembly requires tighter control of every sterile component.



Moist Heat

Moist heat in an autoclave transfers heat efficiently and denatures vital microbial components. It is suitable for heat-stable aqueous preparations and equipment when the validated cycle reaches all critical locations. Load arrangement, air removal, exposure and drying affect performance. Heat-sensitive drugs may be damaged, so do not select steam solely because it is familiar.



Steam must contact the load after air removal; a chamber display alone does not prove the coldest item received the validated exposure.

Dry Heat

Dry heat is used for suitable glassware, metal items and certain oils or powders.



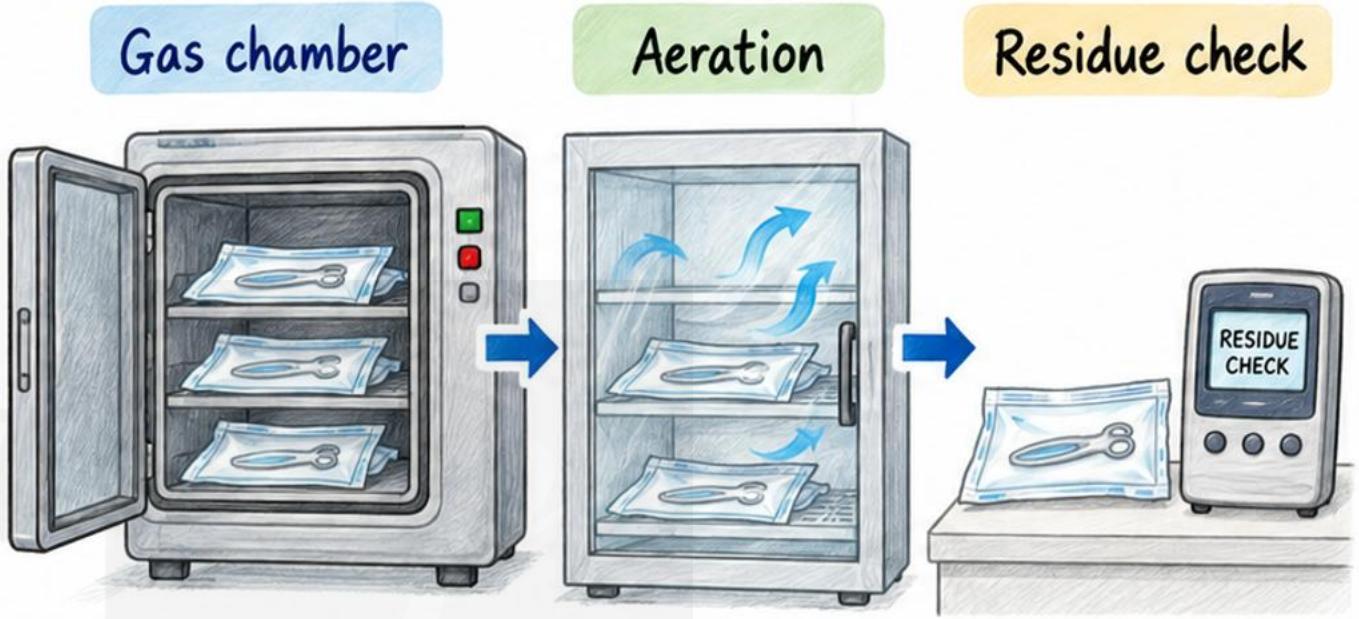
Depyrogenation of suitable glass containers is a separate, validated objective and should not be inferred merely from a dry-heat label.

It acts less efficiently than moist heat, so validated cycles generally require higher temperature or longer exposure. Heat penetration and load pattern must be established.

Distinguish microbial sterilization from endotoxin destruction. Both require their own demonstrated cycle parameters and acceptance criteria for the intended item.

Gas Sterilization

Ethylene oxide can penetrate packaged, heat-sensitive devices, but its cycle must control humidity, exposure and residual gas removal. Formaldehyde methods have narrower, context-specific use and occupational hazards.



Gas compatibility, aeration and residues matter as much as microbial kill. Product-specific validation and worker protection are mandatory.

Residual ethylene oxide may be toxic, so aeration is part of the validated process. Packaging must permit gas entry and subsequent removal.

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