Sterilization

Sterilization

- Sterilization
- Sterilization in pharmaceutical praxis
- Aseptic preparation
- Disinfection

- destruction/removal of all microorganisms: bakteria (including spores), protozoa, viruses, fungi, prions

Sterilization

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- decrease the amount of microbes 3000 – 6000000 (acceptable level)

Sterilization

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- approach, when during drug preparation microorganism contamination is prevented

Sterilization

- Sterilization
- Sterilization in pharmaceutical praxis
- Aseptic preparation
- Disinfection

- destruction of living pathogenic microorganisms (but no spores are destroyed)
- protective (preventive)
- disinfection in the epidemy center
- cleaning — disinfection — sterilization

History

- Oliver Wendell Holmes 1843
- Ignác Filip Semmelweis 1844
- Louis Pasteur 1860
- Joseph Lister 1867

- essay about possibility of transmitting puerperal sepsis

History

- Oliver Wendell Holmes 1843
- Ignác Filip Semmelweis 1844
- Louis Pasteur 1860
- Joseph Lister 1867

- high mortality on puerperal sepsis (about 15 %)
- worst in hospitals, lower in home deliveries assisted by midwives
- relation between autopsy room and nursing mothers (cadaverous poisoning)
- introduced disinfection (chlorinated lime)
- disagreed with colleagues, his ideas (washing hadns) were ridiculed and rejected, left for Pest, died in mental hospitel soon after admission

History

- Oliver Wendell Holmes 1843
- Ignác Filip Semmelweis 1844
- Louis Pasteur 1860
- Joseph Lister 1867

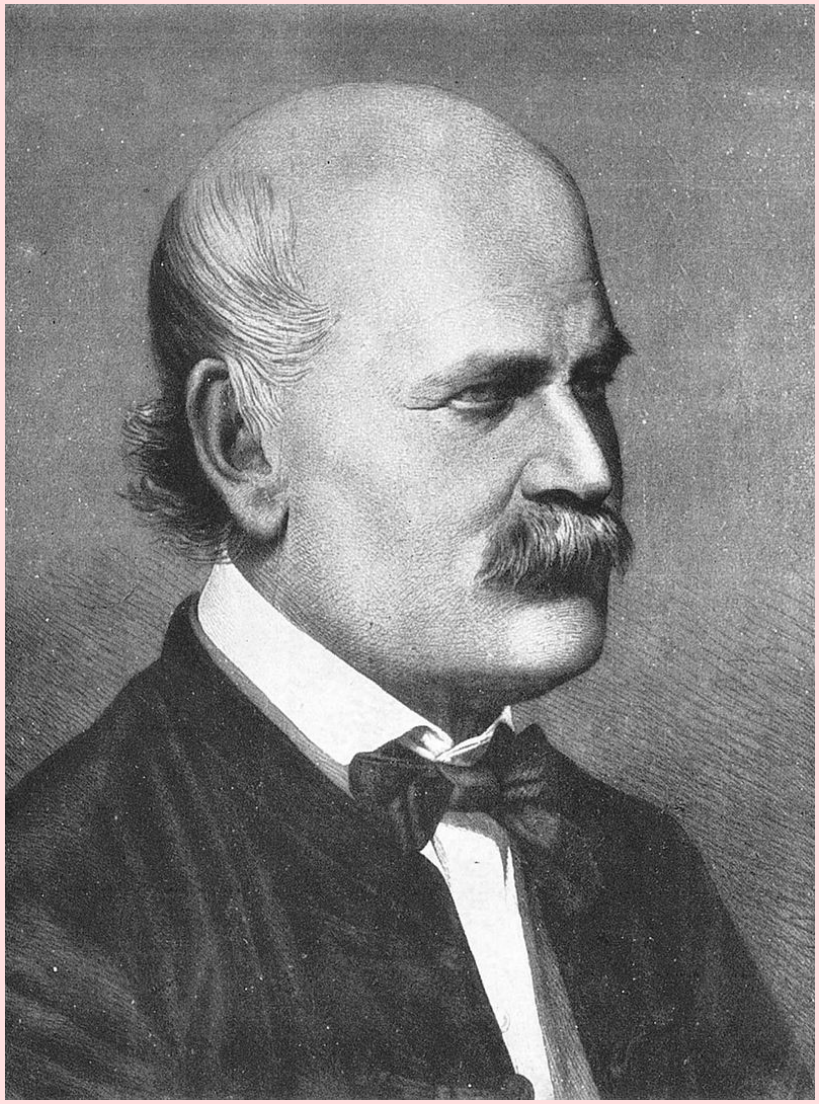
- chemist, microbiologist
- fermentation, vaccination (rabies), pasteurization and other discoveries
- germ theory of disease

History

- Oliver Wendell Holmes 1843
- Ignác Filip Semmelweis 1844
- Louis Pasteur 1860
- Joseph Lister 1867

- surgery under carbol shower
- prevented suppuration of surgical wounds
- great appretiation (baron, founder of modern surgery)

Ignác Semmelweiss



Sterilization

- Destroy all microorganism (if possible)
- Never destroy the stuff which is being sterilized
- Economic acceptance
- Time schedule acceptable
- Sterilized items is necessary to protect against another colonization

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- depends of resistance, initial amount, material structure...

Sterilization

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- heat of the flame on the platinum loop
- sterilization of drugs

Sterilization

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- common, widely used methods
- industrial production

Sterilization

- Destroy all microorganism (if possible)
- Never destroy the stuff which is being sterilized
- Economic acceptance
- Time schedule acceptable
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- laboratory, production
- heat: heating, effective time, cooling

Sterilization

- Destroy all microorganism (if possible)
- Never destroy the stuff which is being sterilized
- Economic acceptance
- Time schedule acceptable
- Sterilized items is necessary to protect against another colonization

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- intact envelopes
- time

Disinfection

- Disinfection
- Factors that influence the degree of killing

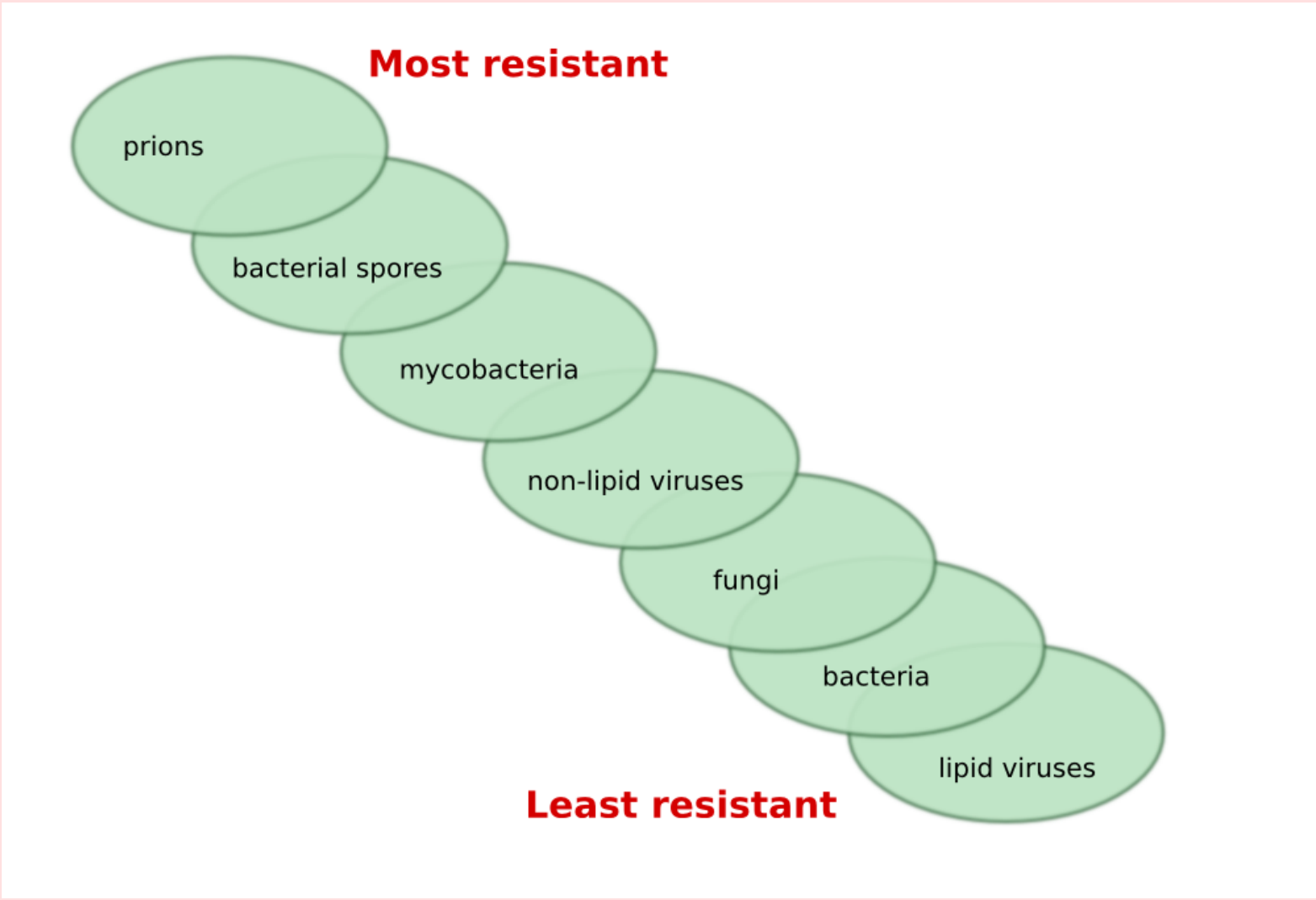
- a process that eliminates a defined scope of microrganisms, except most spores, viruses and prions
- the purpose: prevent transmission of certain microorganisms with objects, hands or skin and prevent spreading the infection
- physical or chemical methods
- most disinfectants are chemical agents applied to inanimate objects

Disinfection

- Disinfection
- Factors that influence the degree of killing

- types of organisms
- number of organisms
- concentration of disinfecting agent
- presence of organic material (e.g., serum, blood)
- nature (composition) of surface to be disinfected
- contact time
- temperature
- pH
- biofilms
- compatibility of disinfectants

Resistance of microorganisms



Materials and their purpose

- Critical materials
- Semicritical materials
- Non critical materials

- will enter tissues or blood system
- will produce infection if contaminated
- require sterilization

Materials and their purpose

- Critical materials
- Semicritical materials
- Non critical materials

- will have contact with mucos membranes
- require high-level disinfection agents

Materials and their purpose

- Critical materials
- Semicritical materials
- Non critical materials

- will have contact with intact skin
- require intermediate-level to low-level disinfection

Progress of sterilization

- Dying of mikroorganisms is exponential
- D-value (DRT)
- Z-value
- F-value
- L-value

- slowly at first, then faster, finally slow again
- the amount of microbes entering the process is necessary to limit as much as possible

Progress of sterilization

- Dying of mikroorganisms is exponential
- D-value (DRT)
- Z-value
- F-value
- L-value

- *decimal reduction time:* time, during which the amount of microorganism decreses to 1/10
- $\frac{\text{heating time}}{\log N_0 - N}$

Progress of sterilization

- Dying of mikroorganisms is exponential
- D-value (DRT)
- Z-value
- F-value
- L-value

- increase of temperature necessary to increase the D-value 10×

Progress of sterilization

- Dying of mikroorganisms is exponential
- D-value (DRT)
- Z-value
- F-value
- L-value

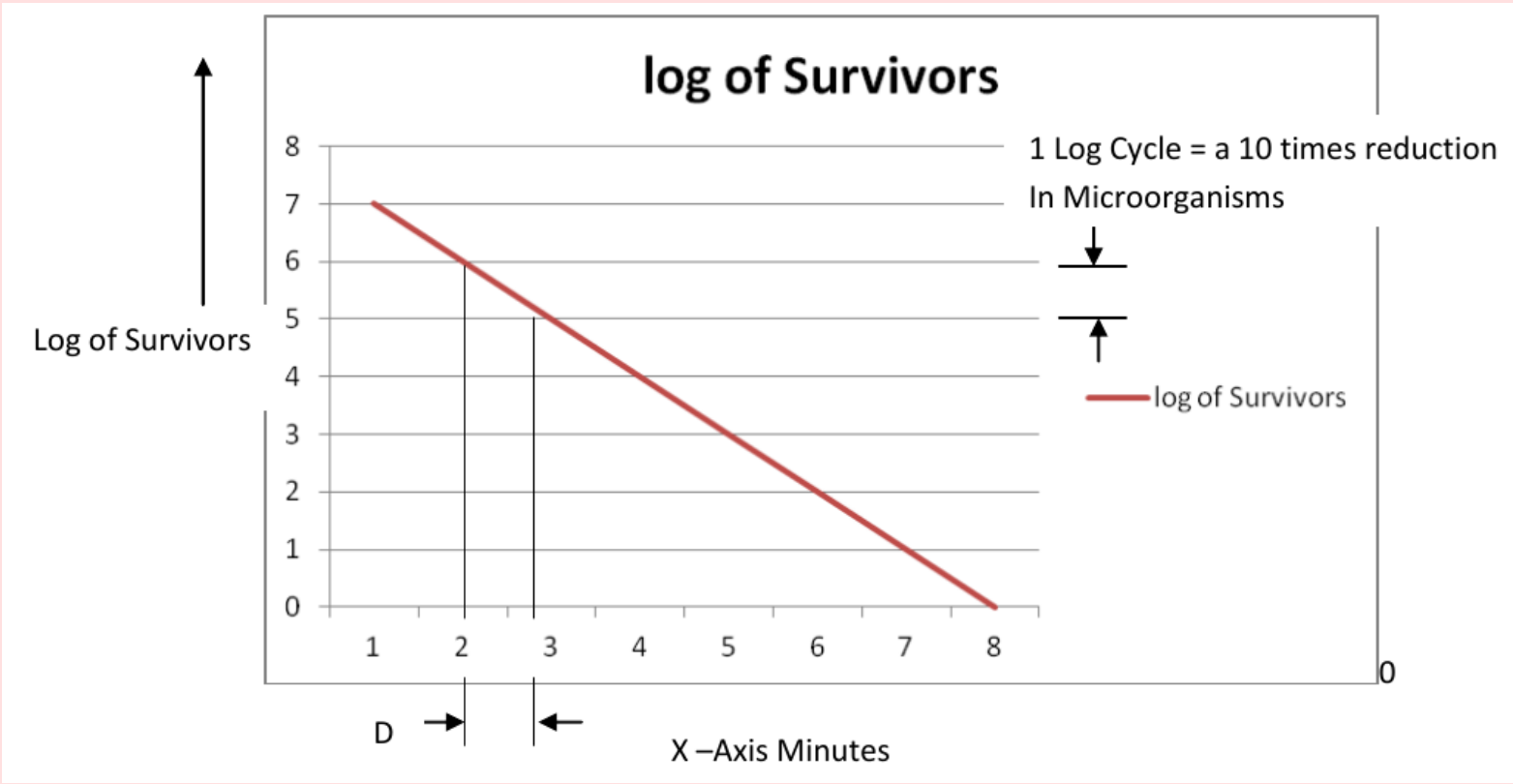
- time in minutes necessary to kill all the microbes under defined conditions

Progress of sterilization

- Dying of mikroorganisms is exponential
- D-value (DRT)
- Z-value
- F-value
- L-value

- lethality factor $(1/F)$, heat efficiency under defined conditions compared with the temperature 121°C

D-value, DRT



Methods of sterilization

- Defined for various sterilized items
- Physical methods
- Chemical methods
- Plasma

- drug production specifications

Methods of sterilization

- Defined for various sterilized items
- Physical methods
- Chemical methods
- Plasma

- heat
- radiation (gamma rays, UV)
- bacterial filters

Methods of sterilization

- Defined for various sterilized items
- Physical methods
- Chemical methods
- Plasma

- baktericid gasses and vapours

Methods of sterilization

- Defined for various sterilized items
- Physical methods
- Chemical methods
- Plasma

- vapourizes sterilizing agent in vacuum; plasma is then generated by microwave generator

Sterilization by heat

- Wet heat
- Dry heat

- boiling in water 100°C 30 minut, 3× in 24 hours
- boiling in water under pressure 300 kPa/134°C for 30 minutes
- heating in running steam 100°C for 45 minutes, 3× in 24 hours
- heating in running steam páře (pressure/temperature):
  - 110°C/150 kPa for 40 minutes
  - 115°C/170 kPa for 30 minutes
  - 120°C/200 kPa for 20 minutes
  - 134°C/300 kPa for 10 minutes
- microwave heating
- tyndalization: repeated heating to low temperature with 24 hours intervals

Sterilization by heat

- Wet heat
- Dry heat

- annealing, heating to yellow heat (platinum loop)
- circulating hot air, 160°C for 60 minutes
- mineral oil 160°C for 30 minut

Radiation sterilization

- Advantages
- Ionizing irradiation
- UV irradiation
- Checking

- normal temperature
- can run continuously
- sterilized items can be in wrappings

Radiation sterilization

- Advantages
- Ionizing irradiation
- UV irradiation
- Checking

- gama rays, 25 kG
- accelerated electrones

Radiation sterilization

- Advantages
- Ionizing irradiation
- UV irradiation
- Checking

- sterilization of the air
- sterilization of some surfaces (work boxes)

Radiation sterilization

- Advantages
- Ionizing irradiation
- UV irradiation
- Checking

- dozimeters
- bioindicators

Chemical sterilization

- Etylenoxid
- Formaldehyd
- Persteril

- complicated process, special device
- plasts, some drugs

Chemical sterilization

- Etylenoxid
- Formaldehyd
- Persteril

- traditional method
- affects the surface only, easy to remove
- simultaneous wet conditions are necessary
- temperature over 80°C

Chemical sterilization

- Etylenoxid
- Formaldehyd
- Persteril

- aggressive against metals
- unstable
- steam (20 minutes in defined concentration)
- solution 30 – 30 minut in concentration 0.2 – 0.4 %

Chemical disinfection

- Disinfecting agents
- Mechanism

- alcohols (alcohol 70 %)
- aldehydes (formaldehyd)
- halogens (chlorine)
- phenols (added to soaps etc.)
- surfactants (detergents, tensides)
- heavy metals (silver nitrate 1 % eyedrop)
- dyes (crystal violet, brilant green. . . superfically on wounds)
- gases (ethylene oxide, oxidants, eg. hydrogen peroxide)

Chemical disinfection

- Disinfecting agents
- Mechanism

- reaction with components of the cytoplasmic membrane (surfactant compounds, alcohols)
- denaturation of cellular proteins (alcohols, phenols, aldehydes, oxidants)
- reaction with the thiol (-SH) groups of enzymes (heavy metals)
- damage of RNA and DNA (aldehydes, oxidants, dyes)

Sterilization by dry running air

- Sterilized items
- Time of sterilization
- Bioindicators

- glass, metal, machine parts
- sterilizd items must be dry and clean
- must not touch each other
- the air must run

Sterilization by dry running air

- Sterilized items
- Time of sterilization
- Bioindicators

- 160°C 60 minutes, 170°C 30 minutes, 180°C 20 minutes
- + time of heating
- + time of cooling

Sterilization by dry running air

- Sterilized items
- Time of sterilization
- Bioindicators

- Bacillus subtilis

Sterilization by bacterial filters

- Bacterial filter

- pores 0.22 μm or smaller
- must not release its parts to the filtrated substance

Heat resistance of microorganisms

class	temperature	time	microorganism
I.	62 °C	30 minutes	mycobacteria, brucella, streptococcus, polyomavirus
II.	80 °C	30 minutes	most vegetative bacterial forms, yeasts, fungi, most viruses
III.	100 °C	5 – 30 minutes	hepatitis B virus, spores of fungi
IV.	105 °C	5 minutes	anthrax — spores
V.	121 °C	8 – 12 minutes	b. thermophillus — spores, spores of clostridia
VI.	134 °C	6 hours	highly resistant spores

Autoclave

- Device for sterilizing by hot steam
- Method
- Check-up

- efficient sterilization method

Autoclave

- Device for sterilizing by hot steam
- Method
- Check-up

- steam (water heating or steam from other source)
- air removal (evacuation)
- heating
- temperature equalization
- sterilization
- cooling
- letting the air back again

Autoclave

- Device for sterilizing by hot steam
- Method
- Check-up

- heat monitors
- bioindicators

Autoclave

Autoclave

Autoclave

Autoclave