

رح نحكي هون انو كيف بموضوع الصيدله نحقق موضوع
sterilization

Sterilization methods

Chapter 19

A hospital- or laboratory-scale steam sterilizer (autoclave)

انا كصيدلاني بدي احافظ /اخلي الابره sterile في طريقتين

Termenal(kill all the
(M.O بالمرحله النهائيه بعد ما
sterilization اغلفه اعمله

Aseptic
كل شيء يكون معقد بكل خطوه
وتحت aseptic condition من الصفر
sterile يكون معقم حتى الهواء لازم يكون



Choice of method for manufacturing a sterile product

- ▶ **Two strategies** are available for manufacturing sterile products:
 - ★ terminal sterilization, in which the product is made, packed in its final container, then sterilized;
 - ★ or aseptic manufacture where the product is made from individual sterile ingredients using aseptic techniques.

Choice of method for manufacturing a sterile product

- ▶ The terminal sterilization methods available include:
 - the use of heat (either as steam or hot air),
 - radiation
 - and microbiocidal gases,

Terminal → heat (autoclave) steam, hot air
.radiation, microbiocidal gas (formaldehyde)

None of them is universally applicable to all types of product, nor does any single technique fulfil all the desirable properties of a sterilization method

ما في طريقه مثاليه كل وحده الها ايجابيات وسلبيات

Desirable properties of a sterilization method

بدي هاي تكون reliable يعني يعتمد عليها لتحقيق المطلوب في التعقيم لحتى اوصل ل 10exponent -6 steril assurance level →

- ▶ reliable in terms of achieving the required sterility assurance level of 10^{-6} ;
- ▶ safe for the operators;
- ▶ safe in terms of inducing no damage to the product or its container, or inducing the formation of toxic residue
- ▶ an easily understood process that can readily be controlled and monitored by physical instruments;
- ▶ short exposure time;
- ▶ low cost

يجب ان تكون امنه يعني هاي الحراره ما تسبب خراب للمركب (لمكوناته او package) او نواتج تحلله تكون toxic

مش معقد يعني بسهولة اتحكم ب parameter كل ما حصلت sterile باقصر وقت يكون امن لل product و اقل مصاري (اخر 3 نقاط)

Choice of method for manufacturing a sterile product

- ▶ Heating methods are preferred by the World Health Organization and the pharmacopoeias,
- ▶ but many products, particularly medical devices containing plastics, cannot be heated, so radiation and ethylene oxide gas are used as alternatives

إذا ما ينفع heat للمستحضر مثل المستلزمات الطبيه (مثل الادوات تبعت القسطره بتكون بلاستيك او بروتين هون استخدم radiation or gas

- ▶ Sterile filtration is a possible approach for heat-sensitive water-soluble drugs,

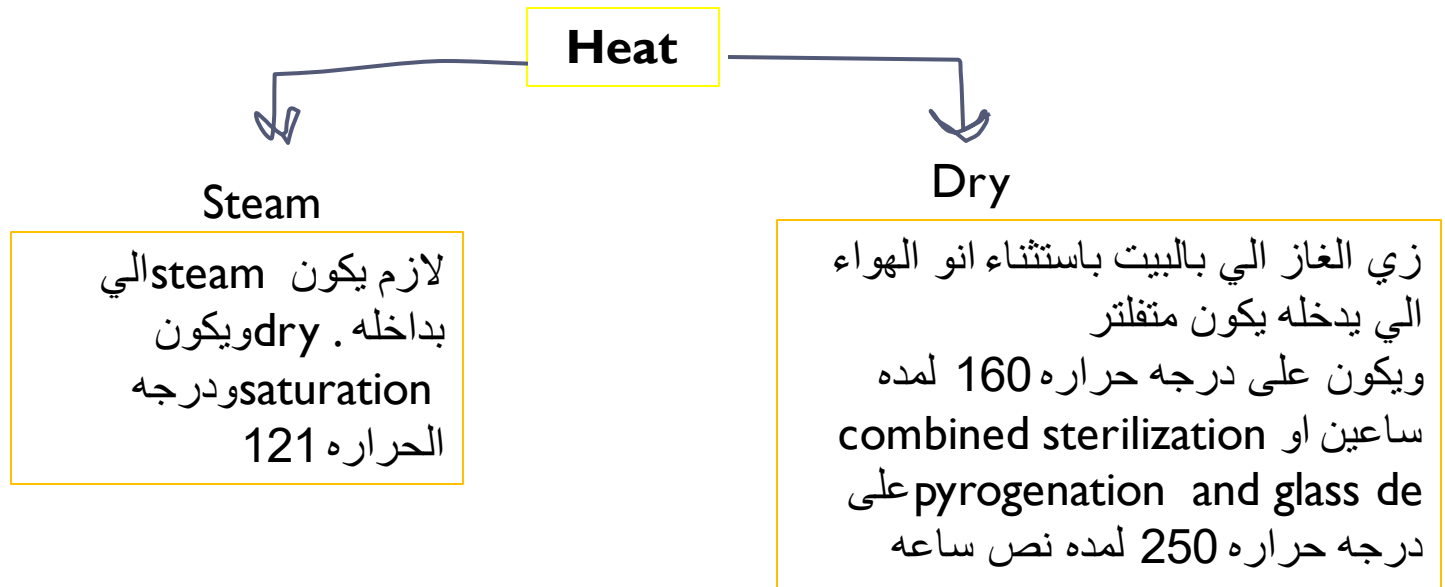
إذا ما ينفع .gas. radiation. heat هون استخدم)fillration وما بقدر احكي انو terminal لانو بس عملت steril solution الي ذائب فيه الدواء

- ▶ for sterile medicines that cannot be filtered, such as ophthalmic creams, aseptic manufacture may be the best option,

إذا ما زبط لا heat
او filtration هون
ابلش استخدم aseptic

Typical operating conditions and applications for common sterilization methods.

Method	Typical ^a conditions	Common applications
Steam (heating in an autoclave)	Dry, saturated steam at 121°C for 15 minutes	<ul style="list-style-type: none"> • Aqueous solutions in sealed containers (bottled fluids) • Surgical and dental instruments • Dressings (porous loads) • Decontamination of infected materials or laboratory waste
Dry heat (hot air oven)	160°C for two hours, or, in a combined sterilization and glass depyrogenation cycle, 250°C for 30 minutes	<ul style="list-style-type: none"> • Glassware • Oils, fats and waxes, and oily injections
Ionizing radiation	An absorbed dose of 25 kGy	<ul style="list-style-type: none"> • Heat sensitive (thermolabile) raw materials • Medical devices
Ethylene oxide	400–1000 mg/l of ethylene oxide, at 45–65°C and 40–80% relative humidity for 0.5–10 h	<ul style="list-style-type: none"> • Medical devices
Filtration	Passage of liquid through a bacteria-retentive membrane with a pore size of 0.22 µm or less	<ul style="list-style-type: none"> • Solutions of heat-sensitive, water-soluble and oil-soluble materials



على درجات حراره عاليه ووقت اطول Dry

استخدمه لقتل بقايا M.O

درجات حراره اقل ووقت اقل Steam

Steam Sterilization:

- ▶ The autoclaves used for steam sterilization vary in size from benchtop models of the type commonly found in dental surgeries to large floor-standing industrial machines that are loaded with forklift trucks.

اشي ينحط على الطاولة عند دكتور الاسنان
واشي كبير يتثبت بالارض ويتم نقله بشاحنات

A small top-loading laboratory autoclave.



A front-loading laboratory autoclave having approximately four times the capacity of that in Previous figure.

هاد يفتح من قدام زي الثلاجه

Note the thermocouple leads inside to record the temperature at different locations in the load

يتم توزيعهم داخل مختلف المناطق داخل autoclave



Steam Sterilization:

- ▶ Autoclaves can have:
 - ★ circular or rectangular chambers,
 - ★ be top-loading or front-loading
 - ★ and have doors at one end or, less frequently, at both ends of the chamber (to permit transfer of materials from a nonsterile to a sterile area for example).

الاشياء الي بعملهم تعقيم ما
بحطهم بنفس المكان الي ما تم
تعقيمهم

Steam Sterilization

- ▶ The doors of modern autoclaves are fitted with thermal locks which prevent the door being opened until the chamber contents are below a preset temperature → for operator safety

درجه حراره الجهاز بتكون 120 ف اذا بفتح الباب
دغري رح يوصل البخار الحامي لوجهي ويعمل
تشوهات لذلك يكون تصميم autoclave للحفاظ على
الامان انو ما يفتح غير لما يوصل لدرجه حراره امنه

Steam Sterilization

Latent heat is energy released or absorbed, by a body or a thermodynamic system, during a constant-temperature process that is specified in some way

- ▶ Steam is very much better as a sterilizing agent than water at the same temperature,

Steam more efficient than dry

لو حطيت معلقه بماء مغلي على درجه حراره 100 واستخدمت steam على درجه حراره 100 هون رح يكون البخار افضل بالتعقيم من الماء

- ▶ because steam has a high latent heat content which is transferred to the objects being sterilized when the steam condenses on them.
- ▶ Steam kills microorganisms by coagulating and denaturing the cell protein.
- ▶ Consequently, **steam quality is particularly important:**
 1. it should be dry (containing no liquid water droplets)
 2. and saturated (containing the maximum amount of water vapour possible for the given temperature).

يكون كل القطرات على شكل غاز مش سائل

Steam Sterilization

في قطرات ماء وهاد ما

بدنا اياه لانو لازم يكون

داخل outoclave dry

saturated



Saturated Water (0% Dryness)
Temperature: 100 °C [212 °F]



Wet Steam (x% Dryness)
Temperature: 100 °C [212 °F]



Saturated Steam (100% Dryness)
Temperature: 100 °C [212 °F]

تم وضع اكبر
كميه ممكنه داخل
هاد فش ولا قطره
ماء

TYPES OF STEAM

❑ WET STEAM

- Wet steam applies to steam when a portion of its water molecules have given up their energy (latent heat) and condense to form tiny water droplets
- Also known as saturated steam
- Mixture of water in the liquid state (tiny droplets) and gaseous state (steam)



بالوضع الطبيعي انا ما بقدر اشوف الغاز ولكم هون كل ما بعد عم مصدر الحراره رح يتكاثف ويشكل قطرات ماء وهاد الي يصير عشان هيك اشوف يطلع من ابريق الشاي بخار

ما بدى يكون فيه هواء لانه الهواء يمنع saturation
ويمنع وصوله لدرجه الحراره المناسبه ويكون تصميمه
انو يطلع كل الهواء الموجد في الاوتو كيف

Steam Sterilization

- ▶ It is essential that **air is removed** from the autoclave chamber and completely replaced by steam during the operating cycle. Failure to remove all the air results in the temperature being lower than that for pure steam at the same pressure (lower than it should be), so there would be a risk of sterilization failure.

notes

The relevant SI unit of pressure is the kilopascal (kPa), although even modern autoclaves do not necessarily use this scale. Instead, the gauge might display pressure in the units of pounds per square inch (psi) or bar (a unit of pressure equal to 100 kPa)

- ▶ Pure steam at 15 psi (105 kPa) has a temperature of 121°C, and any residual air in the chamber will result in a temperature lower than this (pound per square inch) (psi)