Load types, Sterilisation Processess and Autoclaves Saturated steam

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Agenda

Introduction Load types, Sterilization processes & Autoclaves

Saturated Steam Autoclave

Generality & cycle description

Counterpressure Autoclaves *Generality & cycle description*





Sterilisation by direct contact

A sterilization process, typically used for **porous/hard goods** where the sterilizing medium is **saturated steam**. PDA TR N. 1, Glossary

Saturated steam is "water vapour in a state of equilibrium between condensation and evaporation"

UNI EN ISO 17665-1

The initial objective for saturated steam sterilization is that the **air** in the sterilizing chamber **must be replaced by saturated steam**.

USP 43 chapter 1229.1

- <u>\i</u>
- Residual air acts as an insulator
- The presence of residual air in the chamber **negates the singular temperature-pressure relationship of saturated steam**





Saturated Steam Autoclave



- Fedegari Horizontal Pharmaceutical is a highly flexible solution for multi-purpose sterilization in biopharma industries.
- From **solids** and **porous** to **liquids** in open or nonhermetically sealed containers.







Saturated Steam Autoclave

The sterilization temperature is controlled according to a **pressure signal**, thanks to the one - to - one correspondence of temperature and pressure for the pure saturated steam.









Process phases



Air removal from the chamber and the product surfaces (e.g., by vacuum)

Heating & Sterilization

Post-sterilization phases (drying and/or cooling)







- **Depressurization plus steam injection**
- <u>Steam/ vacuum pulses</u>

 \rightarrow These methods removes air from the chamber using a mechanical **vacuum pump** or steam eductor.



 <u>Displacement by Gravity (open fluid</u> <u>containers)</u>





Depressurisation plus steam



The vacuum pump extracts both steam/condensate and air from the chamber





Pulsed Air Removal



The vacuum pump extracts both steam/condensate and air from the chamber



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Negative Steam/Vacuum Pulses

Residual air: 0.01% Residual steam: 99.99%









Positive Steam/Vacuum Pulses









Heating & Sterilisation





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Process phases

Drying

• Vacuum and time-controlled/vacuum hold

Cooling

- Indirect cooling
- Direct cooling





Vacuum Drying







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Vacuum Drying



mbara	degC	
1013.3	100	
846.6	96	
700.6	90	
666.6	89	
473.4	80	
311.5	70	
266.6	67	
199.1	60	
133.3	52	
123.3	50	
73 48	40	
42.33	30	>
33.86	27	
30.48	24	
27.09	22	
23.71	21	
20.32	18	







vacuum Drying	mbara	degC	
	1013.3	100	
	846.6	96	
	700.6	90	
	666.6	89	
2.0 bar abs	473.4	80	
A high Δt provides for excellent	311.5	70	
evaporation and therefore load	266.6	67	
drying	199.1	60	
	133.3	52	
1.0 bar abs	123.3	50	
	73.48	40	
	42.33	30	
Load hot = e.g. 120° C	33.86	27	
BPOW @ 42mbar = 30°C	30.48	24	
Δt = 120-30 = 90°C	27.09	22	
0.1 bar abs	23.71	21	
	20.32	18	







Maauum Druina		
		degC
	1013.3	100
	846.6	96
	700.6	90
	666.6	89
2.0 bar abs	473.4	80
The load is cooled during 'vacuum drying' as the	311.5	70
condensate while evaporating, takes energy away from	266.6	67
the hot load in the form of vaporization calories .	199.1	60
	133.3	52
1.0 bar abs	123.3	50
	73.48	40
	42.33	30
Load hot = e.g. 80° C	33.86	27
BPOW @ 42mbar = 30°C	30.48	24
Δt = 80-30 = 50°C	27.09	22
0.1 bar abs	23.71	21
	20.32	18







vacuum Drying		bara de	∋gC
	10	13.3 1	00
	84	46.6 9	96
	71	00.6 🤤	90
	6	66.6 8	39
2 0 har abs	4	73.4 {	30
As the load cools, there will cor	ie a point when no more 3 [.]	11.5	70
evaporation is possible, as the l	pad temperature 20	66.6 6	67
matches the boiling point of wa	ter 1!	99.1 6	60
	1:	33.3 !	52
1.0 bar abs	1:	23.3 ;	50
	7:	3.48 4	40
$\Delta t = 80-30 \Delta t = 60-3$	0 At = 45-30 42	2.33	30
= 50 C = 30°C	$\Delta t = 43-30$ = 15°C $\Delta t = 30-30$ 33	3.86 2	27
19-20	2020 (20°C 3)	0.48 2	24
	2	7.09 2	22
0.1 bar abs	2	3.71 2	21
	21	0.32	18









Vacuum Drying









Vacuum Drying









Hot Air Drying









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Hot Air Drying









Hot Air Drying









Cooling

Indirect cooling

- Water circulation in the jacket
- Air counterpressure

Direct cooling

• Spray of sterile water onto the load





Cooling









Thank you!



