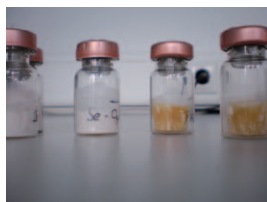


## Bacteria, viruses, fungi, vaccines

### Procedure (Overview)

Freezing	Solidification range, Solidification point	Container for FD	Process A / B / C *	Vacuum primary drying
-50°C and below	-40°C and lower	beaded-rim flasks, vials, ampoules, dishes	A or EPSILON (process C) in the production range	$T_{ICE} = T_{EP} - 10^{\circ}C$ $p_{HT} = f(T_{ICE})$ → ice pressure curve = 0.040 mbar and below

Temp. of the shelves during primary drying ( $T_{SF}/t$ )	Duration of primary drying	Vacuum for secondary drying
-50°C / 5 h, increase every 5 h by 5°C (4 or 5 times), then reduce to time interval to 3 h and 1.5 h, Lyocontrol highly recommended	24–48 h	only in exceptional cases



Various bacteria cultures under vacuum in tightly-sealed injection vials

### Special features

- In laboratories: Disinfection and gas sterilisation possible: Ethylene oxide (highly toxic, outdated), paraformaldehyde,  $H_2O_2$ , (increasingly common)
- Chemically-resistant CHRIST systems can be provided
- Disinfection / decontamination: Liquid cleaning (alcohol, etc.), germs may still be present, special cleaning agents are recommended for plexiglass (e.g. Incidur)
- It is usually necessary to steam-sterilise systems for production purposes
- Sterilisation: with steam  $> 121^{\circ}C$ , complete elimination of germs
- Operating in accordance with GMP (Good Manufacturing Practices) and FDA (Food and Drug Administration) requirements

### Uses of the freeze-dried products

- For human and veterinary vaccination
- Ampoules are sealed under vacuum
- Vials are closed under vacuum or  $N_2$ -atmosphere using special accessories
- (pressure of 800 mbar avoids excessive air diffusion into the closed vial in storage and is enough to keep the sample sterile)