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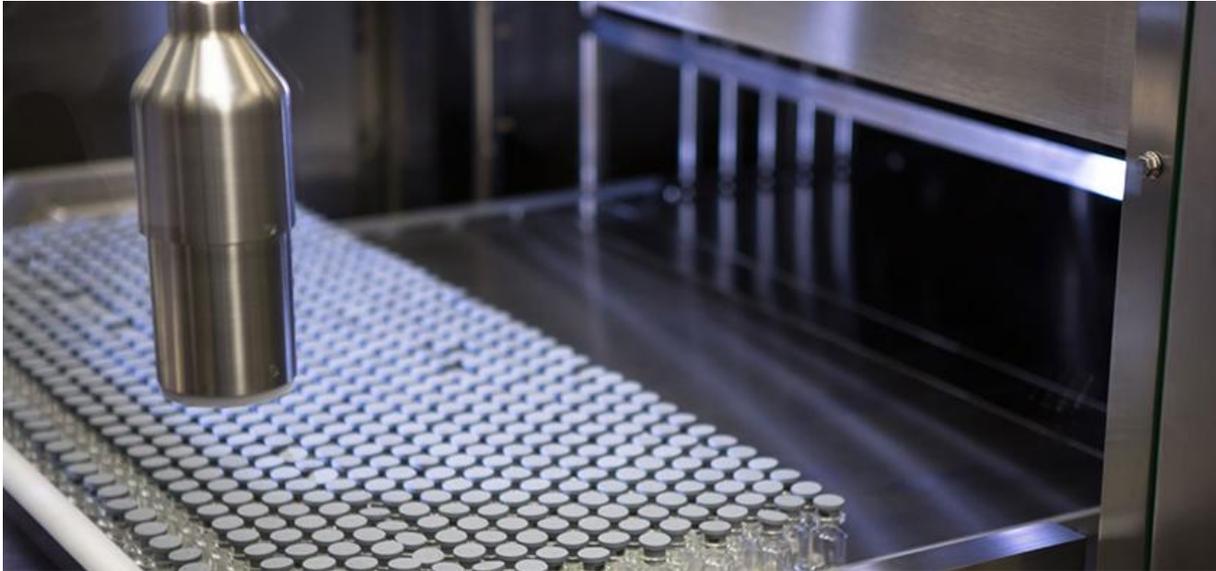
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LyoCoN - Optimisation of freezing for vials

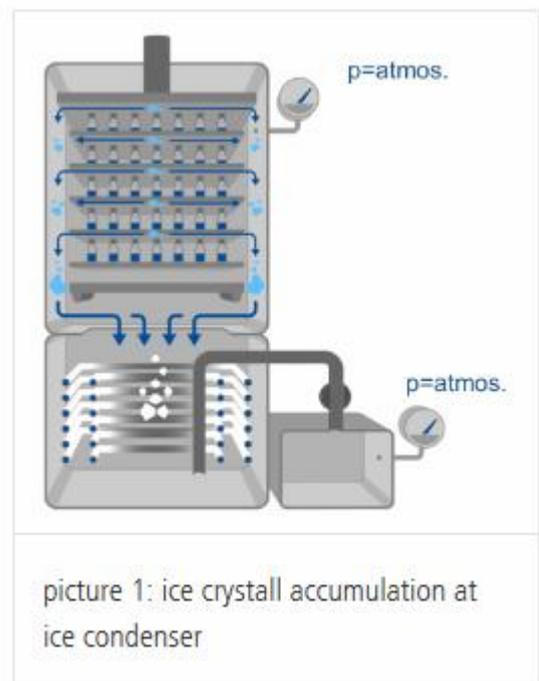


Regarding the freeze-drying of products in vials, it should be avoided, that all samples freeze at different times. It is the aim to gain more process control and more homogenous end product properties.

The introduction of the new accessory LyoCoN by Martin Christ is the answer to this challenge: The vials are initially cooled down and subsequently charged with a fine ice fog. The ice crystals move into the vials and work as freezing nuclei. All vials crystallize within seconds – without the stochastic time lag by supercooling.

Freezing of many vials in a freeze dryer normally works out as a stochastic process. All vials will freeze only within a certain time frame, e.g. 1 hour. Furthermore, this crystallisation happens at different temperatures. Crystal structure and later drying behavior will diverge.

The new developed technology LyoCoN by Christ creates a controlled nucleation of all to be lyophilised vials: After loading of the machine, the cold ice condenser accumulates ice crystals (pict. 1).



Simultaneously the liquid product is cooled down close to the freezing point. In the next step a slight vacuum is established in the freeze-dryer (pict. 2).

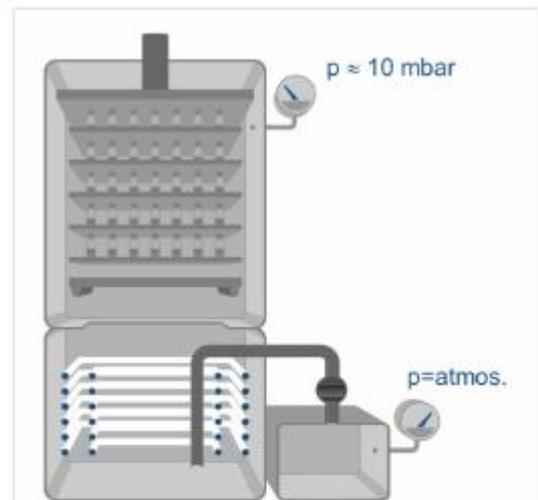
The external recipient is kept under atmospheric pressure. Finally a pressure equilibration between recipient and freeze-dryer is started by opening a valve to the ice condenser. The air/gas from the recipient is injected into the ice condenser. The resulting ice fog infiltrates all vials (pict. 3).

These crystal nuclei immediately start homogenous crystallisation in all vials.

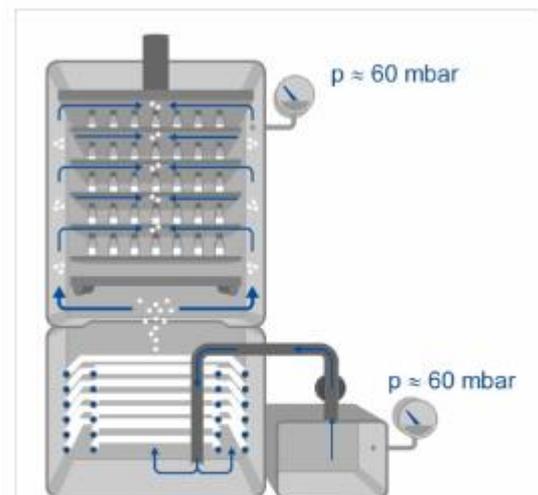
After this, the freeze-dryer is aerated completely to atmospheric pressure. Freezing of all crystallized vials can be continued in a conventional way, e.g. further freezing down, annealing etc.

Martin Christ LyoCoN – facts at a glance:

- formation of the ice fog with moisture out of the product, no external media necessary. GMP-compliant!
- simple basic principle – vacuum available anyhow. No overpressure design of the machine necessary
- therefor also ideal for smaller pilot units + retrofit easy possible
- no external waste media – which might contain drug/product - produced by LyoCoN.



picture 2: formation of a slight vacuum in the freeze dryer



picture 3: injection of an ice fog in the product chamber by pressure compensation between external recipient and ice condenser chamber