

# FD-Application FD-LS-121

Catchwords: Life Science, Pharma, agents, aqueous, saline solution, aliquot, production for sale, glass-vials

## Aliquot of active pharmaceutical ingredients in salt solutions

### Application:

Aliquot of pharmaceuticals in aqueous salt solutions. Lyophilization for preservation and stabilization in preparation for sale

### Process technology (summary):

• Product designation	Pharmaceutical drug in saline
• Type of solvent, ca. percentage of dry matter	aqueous, proportion of dry matter ca. 1 %
• Type of vessel, number of samples, volume per sample	R 10 ml-glass-vials, V= 0,5-1 ml, 400-2000 samples/run
• Type of machine / configuration	Epsilon 2-25DS (new 2-45 too)
• Freezing (place, range of temperature, freezing point)	Inside
• Process flask-drying /inside /outside /Epsilon*	Epsilon
• Vacuum main-drying (final vacuum or controlled)	0,05 mbar, controlled (depending on product)
• Temperature of shelf, program mode	-40°C, 6 h: 0°C, 18 h: 20 °C (depending on product)
• Time duration of main drying (T <sub>sf</sub> /t)	28 h
• Final-drying? Vacuum?	

### Result and comments:

Special for the pharmaceutical sector: In the PC should have a UPS (emergency power supply) to be present for the process documentation in case of power failure is completely, otherwise it may possibly lead to release problems.

Details of process flow / for programming see next page

#### \*explanation

Process inside	(Freezing and) drying inside the ice condenser chamber
Process outside	Freezing separately (e.g. freezer), drying outside the ice condenser chamber, e.g. with acrylic chamber
EPSILON	Type of machine with rectangular product chamber, front loader

