FD-Application FD-LS-119

Catchwords: Life Science, Therapeutica, RNA, clinical specimen, Pharma, gene therapy, Immunotherapy, glass-vials

Preparation of clinical trial / RNA pharmaceuticals for tumor immunotherapy

Application:

Process development for the freeze-drying process in the development of therapeutics itself

Process technology (summary):

• Product designation	RNA-solvents
• Type of solvent, ca. percentage of dry matter	Aqueous, additions of buffer among other ca. >10 %
• Type of vessel, number of samples, volume per sample	10-ml vials (6R 10R), 10-50 samples, V~ 10 ml
• Type of machine / configuration	Epsilon 2-4
• Freezing (place, range of temperature, freezing point)	Inside, T ~ -40°C
• Process flask-drying /inside /outside /Epsilon*	Inside
• Vacuum main-drying (final vacuum or controlled)	Variations
• Temperature of shelf, program mode	Variations
• Time duration of main drying (T_{SF}/t)	~ 24 h
• Final-drying? Vacuum?	

Result and comments:

The development process is integrated into the overall framework of product development. Upon completion of the product development itself, the method for lyophilization is then determined.

*explanation

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