FD-Application FD-LS-116

Catchwords: Life Science, proteins, aqueous, sample preparation by HPLC, production for sale, glass-vials

Lyophilization of proteins by HPLC purification for sale

Application:

Proteins in aqueous buffer solution should be lyophilized after purification in liquid chromatography, in preparation for sale

Process technology (summary):

• Product designation	Proteins
• Type of solvent, ca. percentage of dry matter	Proportion of dry matter varies, very low
• Type of vessel, number of samples, volume per sample	2ml glass vials with crimp V= 250 µl-1 ml; 1400/run,
• Type of machine / configuration	Epsilon 2-6 D production, Gamma 2-16 for development
• Freezing (place, range of temperature, freezing point)	Inside
• Process flask-drying /inside /outside /Epsilon*	Epsilon
• Vacuum main-drying (final vacuum or controlled)	Several programs depending on the formulation: Standard 0,08 mbar
• Temperature of shelf, program mode?	-42°C up to -48°C
• Time duration of main drying (T_{SF}/t)	27-33h
• Final-drying? Vacuum?	2h at 0,01 mbar

Result and comments:

Temperature of shelf = Temperature of product in the Epsilon-unit

Stability and activity of proteins are dependent on the buffer environment. Some substances (e.g. salts, phosphate) lower the freezing point, cake collapses at already low temperatures. Annealing and slower tempertaure increase can help.

*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