



INSULIN

STERILE FORMULATION PROCESS



THE WORLDWIDE CALL FOR INSULIN



More than
450 million adults
(20-79 years) lives
with diabetes.

Designing and building an insulin plant is not a breeze: the plant has to follow cutting-edge technologies and be managed with sophisticated automation systems to implement process phases and to obtain a product to be classified as sterile.

The insulin market is constantly growing and so it does manufacturers' need of production: more than 450 million adults (20-79 years) lives with diabetes; prediction says by 2045 this number will rise to 700 million (International Diabetes Federation).





The synthetic insulin differs just in a short part of its structure

Biosynthetic production of human insulin is mostly done by using bacteria, whose fermentation starts in culture broth.

The lispro insulin produced in this plant with recombinant DNA technology is very much similar to the hormone produced by Beta cells of human pancreas.

The synthetic insulin differs just in a short part of its structure which makes possible a faster absorption and effect.

Lispro insulin can be administered by subcutaneous injection and by continuous subcutaneous infusion through external pump or intravenously too.



PROCESS AND STRUCTURE

Insulin plants
are composed
of specific number
of formulation
stations and
equipment

Manufacturing process usually consist of several steps: dispensing; formulation; sterile filtration; crystallization; final mixture; aseptic filling; sorting and inspection; release testing.

The plant is therefore designed accordingly and following customer's URS.

Insulin plants are composed of specific number of formulation tanks and related formulation stations, filtration lines, sterile and fixed receivers, Temperature Control Modules and C.I.P. skids for cleaning and sterilization of the whole plant.

The plants can be equipped with intermediate portable tanks of different sizes for multiple uses and preparation steps, that can guarantee flexibility of the process.



HIGH STANDARDS

The TECNinox Group can built automated Insulin Plants which are fully compliant with PED, CEI, cGMP, cGEP, FDA, GAMP, GAMP5 regulations; the technical team can design compact systems or large and flexible plant that produces five-digit number batches of insulin cartridge per hour.



**WE LISTEN, WE DESIGN,
WE CREATE WITH PASSION.**

IT IS THE MIND THAT SHAPES THE STEEL

Solutions for the
pharmaceutical and
biotechnological industries



TECNinox S.r.l.

Via Emilia, 89/A

43015 Noceto - Loc. Sanguinaro (PR) - Italy

T. +39 0521.825324 - F. +39 0521.825257

www.tecninox.it - info@tecninox.it



**Find out more
on Process plants**