

Summary of capabilities

Monza, Italy

Thermo Fisher Scientific's state-of-the-art facility in Monza, Italy, specializes in the manufacturing and fill-finish of prefilled syringes, cartridges, and liquid and lyophilized products. Most recently, we've made investments in sterile injectables and mRNA drug substance manufacturing and development services.

Facility facts		Specialized capabilities
Unique offering:		Prefilled nested syringe and cartridge manufacturing mRNA drug substance development and manufacturing
Regulatory approval:	ANVISA, JP PMDA, US FDA, EMA, MFDS, GCC States, Canada, Russia, Taiwan, Turkey, CFDI, COFEPRIS	<ul style="list-style-type: none"> • RNA drug substance manufacturing, analytical, and development • Lipid nanoparticles (LNP) formulation manufacturing, analytical, and development • Prefilled syringes • Prefilled cartridges • Sterile liquids (SVP and LVP) • Sterile lyophilized products • Biopharmaceuticals: including mAbs, other recombinant proteins • Small molecules • Controlled drugs • Small-scale clinical and commercial filling • Large-scale commercial filling • Secondary packaging (vial)
Potency capability:	Up to cat 3b (3b evaluated case by case)	
Controlled drug schedule registrations:	CD category 1 drug precursors license, narcotics license	
Contact info:	Viale G.B. Stucchi, 110 I-20900 Monza, Italy Tel: +39 039 2047 1 Fax: +39 039 2047 431	

Lifecycle by dosage form

Size / details	Early development			Late development			Commercial supply		
	Formulation development	Analytical development	Phase I	Phase II	Phase III	Commercial scale up	Tech transfer	Regulatory	
RNA & LNP	•	•	•	•	•	•	•	•	
Liquid vials	•	•	•	•	•	•	•	•	
Lyophilized vials	•	•	•	•	•	•	•	•	
Prefilled syringes	•	•	•	•	•	•	•	•	
Prefilled cartridges	•	•	•	•	•	•	•	•	

Summary of capabilities

Monza key equipment list – sterile dose

	Equipment (features/scale)	Prefilled syringes	Cartridges	Liquid vials	Lyophilized vials
Compounding	Jacketed tanks and disposable bag technology (1L-1200L) for all sterile forms	•	•	•	•
Washing	Washing machine for vials (internal and external)			•	•
Depyrogenation	Tunnel (vials)			•	•
Component sterilization and drying	Autoclaves	•**	•**	•	•
	Dry oven (3m ³)			•	•
	E-beam	•	•		
Filling and stoppering	Vial filler			•	•
	PFS filler	•	•		
	Injecta line — multiple lines for flexible filling	•	•	•	
	Bosch Combi FXS line for flexible small-scale filling	•	•	•	
	Smart line — PDS GMP line for liquid and lyo vials (organic solvents handling)	•	•	•	
	VarioSys line — PDS GMP line for liquid, lyo vials, and PFS	•	•	•	
Lyophilization	Lyophilizers (2x37m ² , 2x33m ² , 4x40m ² , 2x20m ² , 2x7m ² , 1x4,7m ²)				•
Capping	Vial capper/crimper			•	•
	External washer				•
	Printer			•	•
Terminal sterilization	Autoclaves	•	•	•	
Inspection and packaging	Automated/semi-automated visual inspection system (up to 18,000 vials/hr, 24,000 PFS/hr)	•	•	•	•
	Fully automatic visual inspection for liquids and lyo + HSA				•
	Manual inspection	•	•	•	•
	Labeling machine			•	•
	Cartoning machine			•	•
	Casing machine			•	•

*Minimum and maximum batch sizes are not necessarily related to scale; batch size requirements are dependent on the project details

** Ready-to-use (RTU) contact parts for prefilled syringes and cartridges

Summary of capabilities

Monza key equipment list – RNA drug substance and LNP formulation

Process step	Equipment (features/scale)	
	GMP	Development
Template DNA linearization	Bioprocess controllers that can control most brands of single-use or autoclavable bioreactors or fermentors that are ≤50L, up to 100g batch scale	All common vessels and plate formats from 5µL-50mL
IVT		Bioprocess controllers that can control most brands of single-use or autoclavable bioreactors or fermentors that are ≤50L (3L max for development scope)
Capping and modifications		
TFF and purification	Single-use fully integrated TFF systems ranging from 2mL->500L	Single-use fully integrated benchtop TFF systems ranging from 2mL-15L
	Compatible with hollow fiber or flat sheet filters	Compatible with hollow fiber or flat sheet filters
	Peristaltic and Quattroflow pumps	Peristaltic and Quattroflow pumps
Encapsulation	Single-use liquid chromatography systems, 3-510 L/h	Single-use liquid chromatography system up to 25mL/min
	T-junction encapsulation technology Up to 500L working volume	Microfluidic technology, up to 50mL diluted T-junction technology, up to 5L diluted Impingement (IJM) technology, 1mL to hundreds of milliliters
	High-pressure pumps Peristaltic and Quattroflow pumps	High-pressure pumps Peristaltic and Quattroflow pumps

For detailed capabilities and capacity information, please contact your Thermo Fisher Scientific representative.



Summary of capabilities

From molecule to medicine: An integrated partner for every step in your drug development journey.

Thermo Fisher Scientific provides industry-leading pharma services for drug development, clinical trial logistics, and commercial manufacturing through our Patheon™ brand. We partner with customers in the pharmaceutical, biotech, and life sciences industries as their trusted CDMO to deliver medicine to patients faster. With more than 60 facilities around the world, we provide end-to-end pharma services across all phases of development and commercial manufacturing, including API, oral solid dose, biologics, cell therapy, mRNA, viral vectors, formulation, clinical trial solutions, logistics services, and packaging. We couple our scientific and technical excellence in these areas with a strategic partnership to provide customers of all sizes access to a global network of facilities and dedicated experts across the Americas, Europe, Asia, and Australia. Through our integrated service offerings, we provide tailored solutions to fit your unique drug development journey, accelerating your time to market.



Discover the power of partnership and our global network.