



mRNA therapeutics and vaccines

TheraPure GMP product portfolio

Nucleotides and enzymes for mRNA therapeutics and vaccine development and manufacturing

Count on a partner who knows the way

At Thermo Fisher Scientific, we've proven our ability to help our partners navigate obstacles on their path to developing and commercially manufacturing mRNA therapeutics or vaccines. With the help of the Thermo Scientific™ TheraPure™ GMP* product portfolio of enzymes and nucleotides, you can expect quality, experience, and reliability on your journey to bring transformative therapeutics to the world.

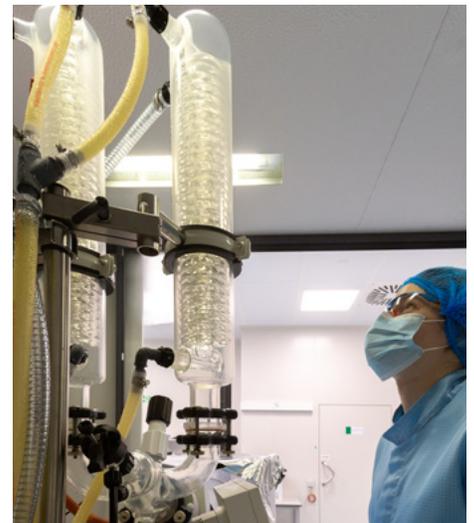


Quality: a commitment to your success

All our raw materials undergo a series of rigorous analytical and performance tests to help ensure that Thermo Scientific™ TheraPure™ GMP products meet your expectations for performance, purity, and animal origin-free (AOF) production. They are manufactured in accordance with relevant GMP principles as outlined in ICH Q7 or equivalent standards and are supported with a comprehensive package of documentation confirming the quality of the products.

Experience a long history of innovation

Thermo Fisher has been manufacturing enzymes and nucleotides for more than four decades. Our deep understanding of enzymology, nucleic acid chemistry, manufacturing sciences, quality control, supply chain management, and logistics encompasses the areas needed to produce and deliver the materials you need.



Reliability: a secure and dependable supply chain



The global scale of our site locations enables our capacity and capability to serve the needs of mRNA therapeutics and vaccine developers around the world, now and in the future. Our mRNA raw material production capabilities give our partners the confidence that they'll have a safe and secure supply chain of materials when they need them.

Sites supporting production of mRNA raw materials



Vilnius, Lithuania
Nucleotides and enzymes



Milwaukee, Wisconsin
Nucleotides and modified nucleotides



Carlsbad, California
Enzymes



Austin, Texas
Nucleotides

The TheraPure GMP product portfolio

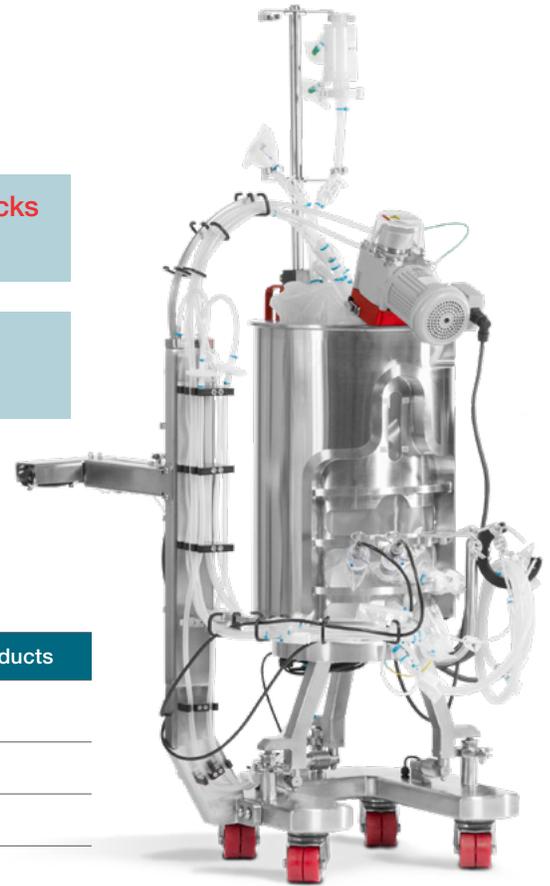
Accelerate your mRNA vaccine and therapeutics development and production with the TheraPure GMP product portfolio of raw materials proven to meet critical process, scale, quality, and regulatory needs.



mRNA building blocks
Nucleotides
Modified nucleotides



In vitro transcription
Restriction enzymes
IVT enzymes
Post IVT enzymes



Product attribute	TheraPure GMP products
Manufacture is in accordance with relevant ICH Q7 GMP principles	✓
Animal origin free (AOF) manufacturing process and raw materials	✓
Validated manufacturing processes and analytical methods	✓
Product-specific stability data	✓
Impurity profile	✓
Verified compendial test methods where applicable	✓
Manufactured in β -lactam free facilities	✓
Quality support documents available (CoA, COO, TSE/BSE, nitrosamine, and melamine statements)	✓
Recommended use	Pre-clinical, clinical and commercial cGMP manufacturing

TheraPure GMP

TheraPure GMP products are designed to support mRNA synthesis for preclinical process development, and clinical and commercial cGMP manufacturing.



mRNA building blocks

Thermo Fisher has long been recognized as a leader in the manufacture and supply of mRNA building blocks—nucleotides and modified nucleotides. Thermo Scientific™ TheraPure™ GMP native and modified nucleotides are specifically intended to be utilized for synthesizing mRNA by IVT during the development and cGMP manufacturing of mRNA vaccines and therapeutics.

Nucleotides	Modified nucleotides
Adenosine triphosphate (ATP) Cytosine triphosphate (CTP) Guanosine triphosphate (GTP) Uridine triphosphate (UTP)	N1-Methylpseudo-UTP

In vitro transcription

Using high-quality, high-performance enzymes is one of the keys to biosynthetically producing large quantities of mRNA for IVT. Our portfolio of Thermo Scientific™ TheraPure™ GMP enzymes and related products for mRNA synthesis is specifically engineered and manufactured to meet tight specifications for purity, lot-to-lot consistency, and functional activity for the development and cGMP manufacture of mRNA vaccines and therapeutics.

Restriction enzyme	IVT enzymes	Post-IVT cleanup enzyme
Eam1104I	T7 RNA polymerase Pyrophosphatase, inorganic RNase inhibitor	DNase I

* TheraPure GMP™ refers to the quality level of the raw, ancillary, or starting materials to be used for further manufacturing. TheraPure GMP products are manufactured in facilities with ISO 9001—certified quality management systems operating in accordance with relevant good manufacturing practice (GMP) principles as outlined in ICH Q7 or equivalent guidance documents or standards.

Connect with us

Partner with us today to help successfully bring your mRNA vaccine or therapeutic to market



Contact us at thermofisher.com/therapure

thermo scientific

For Research Use or Further Manufacturing. Not for diagnostic use or direct administration into humans or animals.

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